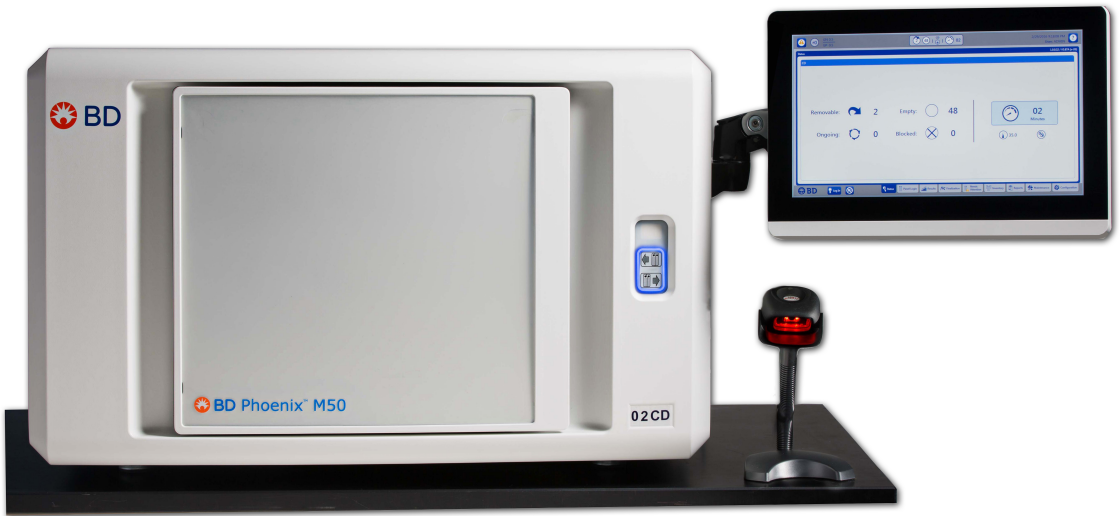
BD Phoenix™ M50
Automated Microbiology System
User's Manual



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Revision	Sections	Change Summary
04	1.3, 1.8, 7.1, 7.4	Added information on detection of BD Phoenix high level Mupirocin resistance (HLMUPH) and the CPO detect test; Updated Bibliography and performance characteristics; Added performance information on new drugs.
05	2.2.1, 2.3.1	Added supported languages and terminology clarification for environmental requirements.
Revision	**Date**	**Change Summary**
06	2018-11	Content flow changed and updated images.

Table of Contents

1 Instructions for Use Guidance

Before operating the BD Phoenix™ M50 system, it is recommended that all users become thoroughly familiar with the contents of the instructions for use.

These instructions for use are a reference tool for personnel who operate and maintain the BD Phoenix M50 system on a regular basis. Every attempt has been made to include all information which would be required during normal use and maintenance. Should a question arise that is not answered in these instructions, please contact your local BD representative.

1.1 Conventions

The following conventions are used in this guide:

Convention	Example
Bold type is used for software button labels.	Select **Save** and select **OK**.
Bold type is used for software options and to indicate a menu option path.	Select **File > Save As**.
Underlined blue type is used for active links to topics.	See User Management.
Italics type is used for names of documents.	For more information, refer to the *BD Phoenix AP Instrument User's Manual*.

1.2 Symbols Used

US Customers only: For symbol glossary, refer to www.bd.com/symbols-glossary.

Meaning	Symbol
	Manufacturer
	Catalog Number
	Authorized Representative in the European Community
	In Vitro Diagnostic Medical Device
	This only applies to US: “Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.”

1.3 Notes, Cautions, and Warnings

Throughout this manual, important information is presented in boxes offset from the regular text, and is labeled as either a NOTE, CAUTION, or WARNING. These messages are formatted as shown below and bear the following significance:

NOTE

Important information about system use worthy of special attention is presented as a NOTE.

CAUTION

Information on an activity which potentially could cause damage to the system is presented as a CAUTION.

WARNING

INFORMATION ON AN ACTIVITY WHICH POTENTIALLY COULD CAUSE INJURY TO THE USER IS PRESENTED AS A WARNING.

2 Introduction

This section provides the following functions:

2.1 Intended Use

The BD Phoenix™ Automated Microbiology System is intended for the rapid identification (ID) and Antimicrobial Susceptibility Testing (AST) of clinically significant bacteria. This system provides rapid results for most aerobic and facultative anaerobic gram-positive bacteria as well as most aerobic and facultative anaerobic gram-negative bacteria of human origin. The BD Phoenix system also facilitates the rapid identification of yeast and yeast-like organisms.

2.2 Scientific Principle

Micromethods for the biochemical identification of microorganisms were reported in 1918.[1] Several publications reported on the use of the reagent-impregnated paper discs and micro-tube methods for differentiating enteric bacteria.[1–9] The interest in miniaturized identification systems led to the introduction of several commercial systems in the late 1960s, and they provided advantages in requiring little storage space, extended shelf life, standardized quality control, and ease of use.

The modern broth microdilution test used today has origins in the tube dilution test used in 1942 by Rammelkamp and Maxon to determine *in vitro* antimicrobial susceptibility testing of bacterial isolates from clinical specimens.[12] The broth dilution technique involves exposing bacteria to decreasing concentrations of antimicrobial agents in liquid media by serial two-fold dilution. The lowest concentration of an antimicrobial agent in which no visible growth occurs is defined as the minimal inhibitory concentration (MIC).

In 1956, the introduction of a microtitrator system (using calibrated precision spiral wire loops and droppers for making accurate dilutions) rapidly allowed Marymont and Wentz to develop a serial dilution AST test.[13] The microtitrator system was accurate and allowed the reduction in volumes of antimicrobial agents. The term microdilution appeared in 1970 to describe the MIC tests performed in volumes of 0.1 mL or less of antimicrobial solution.[14]

2.3 Procedural Principles

The classical micromethods for the biochemical identification of microorganisms have been modified and are now used in BD for fermentation, oxidation, degradation and hydrolysis of various substrates. The BD Phoenix system also utilizes chromogenic and fluorogenic substrates, and single carbon source substrates in the identification of organisms.[10, 11, 26–28]

The BD Phoenix AST is a modified miniaturized version of the micro-broth doubling dilution technique. Susceptibility testing in the BD Phoenix System is performed through determination of bacterial growth in the presence of various concentrations of the antimicrobial agent tested with the aid of the AST indicator in continuously incubated and read micro-wells in the BD Phoenix panels.

2.3.1 Overview of the Phoenix ID/AST System

A maximum of 50 identification and antimicrobial susceptibility tests can be performed in the BD Phoenix M50 instrument at a time, using BD Phoenix combination panels. A sealed and self-inoculating molded polystyrene tray with 136 micro-wells containing dried reagents, serves as the BD Phoenix disposable panel. The combination panel includes an ID side and an AST side.

Figure 1 Example of ID/AST Panel

The BD Phoenix Panel is comprised of a 51 well ID side and an 85 well AST side. The ID side contains 45 wells with dried biochemical substrates and 2 fluorescent control wells for bacterial or yeast identification. The AST side contains up to 84 wells with varying concentrations of antimicrobial agents and 1 growth control well with fluorescent controls. The BD Phoenix system utilizes an optimized colorimetric redox indicator for AST, and a variety of colorimetric and fluorometric indicators for ID. The AST broth is cation-adjusted (e.g., Ca++ and Mg++) to optimize susceptibility testing performance.

Panels are available as Emerge, ID only, AST only, or ID/AST combination. Unused wells are reserved for future use. BD Phoenix panels are inoculated with an organism suspension adjusted to a specific McFarland standard

Once inoculated, panels are placed inside the instrument and continuously incubated at 35 °C. The instrument tests panels every 20 minutes for up to 16 hours if necessary. BD Phoenix panels are read only by the BD Phoenix M50 instrument and the Phoenix 100 instrument. BD Phoenix panels cannot be read manually.

2.3.1.1 Organism Identification

The ID side of the BD Phoenix panel utilizes a series of conventional, chromogenic, and fluorogenic biochemical tests to determine the identification of the organism. Both growth-based and enzymatic substrates are employed to cover the different types of reactivity within the range of taxa. The tests are based on microbial utilization and degradation of specific substrates detected by various indicator systems. Acid production is indicated by a change in indicator color (from red to yellow) when an isolate is able to utilize a carbohydrate substrate. Chromogenic substrates produce a yellow color upon enzymatic hydrolysis of either p-Nitrophenyl or p-Nitroanilide compounds. Enzymatic hydrolysis of fluorogenic substrates results in the release of a fluorescent coumarin derivative. Organisms that utilize a specific carbon source reduce the resazurin-based indicator. In addition, there are other tests that detect the ability of an organism to hydrolyze, degrade, reduce, or otherwise utilize a substrate.

NOTE

A complete list of taxa that comprises the BD Phoenix Database is provided in **Section 9.7 Taxa for ID/AST Determination**. Reactions employed by various substrates and a brief explanation of the principles employed in the BD Phoenix Gram Negative, Gram Positive, Streptococcus, and Yeast ID reactions are described in **Section 9.6 List of Reagents and Principles Employed in the BD Phoenix System**

2.3.1.2 Antimicrobial Susceptibility Testing

The AST method used by the BD Phoenix M50 system is a broth based microdilution test. The system utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent.[15] Continuous measurements of changes to the indicator as well as bacterial turbidity are used in the determination of bacterial growth. Each AST panel configuration contains several antimicrobial agents with a wide range of two-fold doubling dilution concentrations. Organism identification is used in the interpretation of the MIC (Minimum Inhibitory Concentration) values of each antimicrobial agent.

NOTE

A complete list of taxa for which the BD Phoenix panels can provide AST results is shown in **Section 9.7 Taxa for ID/AST Determination**. The list of antimicrobial agents and concentrations available for susceptibility testing in the BD Phoenix system is provided in **Section 9.5 Panel Information**.

Principles of BD Phoenix AST Tests for the Detection of Resistance Markers

The following sections outline the principles of the BD Phoenix AST System in the detection of resistance markers in gram-negative or gram-positive organisms, including:

1. detection of ESBL production among species of *Enterobacteriaceae*;
2. detection of vancomycin resistance in *Enterococcus* species (VRE);
3. detection of high-level aminoglycoside resistance in *Enterococcus* and *Streptococcus* species (HLAR);
4. detection of methicillin-resistance in staphylococci (MRS);
5. detection of β-lactamase production in *Staphylococcus* species (BL);
6. detection of macrolide resistance in *Streptococcus* species (MLSb);
7. detection of *mec*A-mediated Resistance with *S. aureus S. lugdunensis*(*mec*A);
8. detection of Vancomycin Resistant *Staphylococcus aureus* (VRSA);
9. detection of BD Phoenix Inducible Macrolide Resistance (iMLSb) in *Staphylococcus* spp.
10. detection of BD Phoenix high level Mupirocin resistance (HLMUPH);
11. detection of Carbapenemase-Producing Organism (CPO) detect test for *Enterobacteriaceae, Pseudomonas aeruginosa* and *Acinetobacter baumannii*.
12. BD Phoenix Extended Spectrum β-Lactamase (ESBL) Test[16]: The BD Phoenix ESBL test evolved from published data of known ESBL antibiogram patterns in the current literature.[18–21] Selected strains of various species with known β-lactamase genotype/phenotypes in the family *Enterobacteriaceae*, including *Escherichia coli*, *Klebsiella* species (spp.), *Citrobacter* spp., *Enterobacter* spp., *Proteus* spp., and *Serratia* spp., were used to develop the BD Phoenix ESBL test. The BD Phoenix ESBL test is based on the principle of a differential response between the inhibitory effect of selected second or third generation cephalosporins in the presence or absence of a β-lactamase inhibitor, clavulanic acid. The principles of BD Phoenix ESBL test is similar to the CLSI ESBL broth microdilution confirmatory test.[22] The BD Phoenix ESBL test is applied to *E. coli, K. pneumoniae* and *K. oxytoca*. Additionally, at the customer's discretion, it can be applied to other enteric species where production of ESBL has been reported in literature. When a test result of ESBL is positive, the categorical interpretation of all penicillins, cephalosporins (except cephamycins), and aztreonam on the same BD Phoenix panel will be changed to R with BDXpert rule 1529. Carbapenem results will not change for positive ESBL tests. Customers can enable specific rules to report listed drugs as tested.
13. BD Phoenix Vancomycin Resistant Enterococci (VRE) Test: The BD Phoenix VRE test is based on the SIR interpretation of vancomycin. The breakpoint selected in the instrument configuration is used for the categorical interpretation. The BD Phoenix VRE test was developed and optimized to match the CLSI standard broth microdilution test.[22, 23] Selection of a breakpoint other than CLSI may result in less than optimal performance due to differences in categorical interpretations. Only *Enterococcus faecalis* and *E. faecium* with acquired resistance (vanA or vanB) will be reported as positive.[22]

14. BD Phoenix High-Level Aminoglycoside Resistance (HLAR) Tests: The BD Phoenix HLAR tests for *Enterococcus* are based on the growth response in a single well containing either a high-level concentration of gentamicin or streptomycin. These tests were developed and optimized against both the CLSI standard broth microdilution and the CLSI screening agar test.[22]

    The BD Phoenix HLAR tests for Streptococcus are based on the growth response in a single well containing gentamicin, kanamycin, or streptomycin. These tests were developed and optimized using the CLSI recommended standard broth microdilution.

15. BD Phoenix Methicillin-Resistance in Staphylococci (MRS) Test: The BD Phoenix MRS test is based on the SIR interpretation of oxacillin with *Staphylococcus* species. When an MRS test result is positive, several BDXpert rules are designed to handle the reporting and the interpretations of all beta-lactam drugs. A special BDXpert rule is designed to report MRS using cefoxitin results for *Staphylococcus aureus*. The surrogate drug, cefoxitin, has been validated as a better indicator for the presence of mecA in staphylococci.
16. BD Phoenix Gram-Positive β-lactamase (BL) Test[16]: The BL test available in the BD Phoenix AST System is a nitrocefin based β-lactamase test. The nitrocefin based test is a direct detection method located on the ID side of the BD Phoenix panel. The performance of this test was established against the results of testing with BD BBL Cefinase™ Discs (Cat. No. 231650) as the reference method. Currently, only *Staphylococcus* species will be evaluated with these tests. When the result of BL test is positive, the categorical interpretation of all penicillinase labile penicillins on the same Phoenix panels will be changed to resistant.[22]
17. BD Phoenix Macrolide Resistance in Streptococci (MLSb) Test: The BD Phoenix Macrolide Resistance test is based on SIR interpretation of erythromycin and clindamycin. The breakpoint selected in the instrument configuration is used for the categorical interpretation. Erythromycin resistant and clindamycin resistant *Streptococcus* isolates will be reported as macrolide/lincosamide/streptogramin B (MLSb) phenotype.
18. BD Phoenix mecA-mediated Resistance Marker for Staphylococcus aureus (mecA): The BD Phoenix mecA test is used to predict mecA-mediated resistance in *Staphylococcus aureus* and *S. lugdunensis*. The principle is similar to the CLSI-recommended Disk Diffusion test, which uses a cefoxitin (FOX) disk to predict mecA-mediated resistance. The performance of the test was established against multiplex PCR methods[25] as well as the Disk Diffusion test. With the BD Phoenix mecA test, the mecA-specific FOX MICs used for detection of the resistance marker will be configured in the instrument. When the mecA resistance marker is detected, the interpretations for all beta-lactam drugs on the same BD Phoenix panel are changed to resistant,[22] and the BD Phoenix mecA resistance marker is set.

19. BD Phoenix Vancomycin Resistant Staphylococcus aureus (VRSA) Test: The BD Phoenix VRSA detection is based on the SIR interpretation of vancomycin when testing *Staphylococcus aureus*. The breakpoint selected in the instrument configuration is used for the categorical interpretation. The BD Phoenix VRSA test was developed and optimized to match the CLSI standard broth microdilution test, and verified with known VRSA isolates. Selection of a breakpoint other than those found in CLSI M100 may result in less than optimal performance due to differences in categorical interpretations. Only *Staphylococcus aureus* with true resistance (isolates containing resistance marker such as vanA gene) will be reported as VRSA. Strains of S. aureus with vancomycin intermediate results (GISA/VISA) will be identified and reported by separate BDXpert rules. The BD Phoenix Gram Positive AST panel detected vancomycin resistance in the VRSA S. aureus strains available at the time of comparative testing. The ability to detect resistance in other S. aureus strains is unknown due to the limited number of resistant strains available for comparative testing.
20. BD Phoenix Inducible Macrolide Resistance (iMLSb) Test in Staphylococcus species: The BD Phoenix Inducible Macrolide Resistance (iMLSb) Test is used to detect inducible macrolide lincosamide-streptogramin B (iMLSb) resistance in *Staphylococcus* species. iMLSb resistance, usually encoded by ermA or ermC genes, may be either constitutive (always expressed) or inducible after exposure to a macrolide antibiotic (e.g. erythromycin, clarithromycin, etc.). The BD Phoenix Inducible Macrolide Resistance Test is based on the same principle as the CLSI recommended Disk Approximation Test (D-Test) for the detection of inducible clindamycin resistance. When the BD Phoenix Inducible Macrolide Resistance Test result is positive, the categorical interpretation of clindamycin on the same BD Phoenix panel will be reported as resistant and accompanied by a separate BDXpert message. *Staphylococcus* isolates resistant to both erythromycin and clindamycin on initial testing will be reported as constitutive MLSb resistance to distinguish them from isolates that are resistant to macrolides alone by efflux mechanism.
21. BD Phoenix high level Mupirocin resistance (HLMUPH): The BD Phoenix high level Mupirocin resistance test is based on the growth response in a single well containing 256 mcg/mL of the topical antibiotic Mupirocin that is frequently used for eradication of *Staphylococcus* colonization, particularly for nasal carriage of MRSA. The breakpoint selected in the instrument configuration is used for the categorical interpretation of Susceptible (no growth in 256 mcg/mL well) or Resistant (growth in 256 mcg/mL well). High level Mupirocin resistant *Staphylococcus* isolates will be reported as the (HLMUPH) phenotype resistance marker.

22. BD Phoenix™ CPO detect Test: Carbapenem non-susceptibility among *Enterobacteriaceae*, *Pseudomonas aeruginosa* and *Acinetobacter baumannii* can result from two main mechanisms: production of a β-lactamase (carbapenemase) or production of a β-lactamase (cephalosporinase or ESBL) coupled with decreased permeability through porin mutations.[17, 29] World-wide, the most common Ambler classification of carbapenemases with corresponding genes in the *Enterobacteriaceae* are: Class A (*bla*KPC), Class B (*bla*NDM, *bla*VIM, *bla*IMP) and Class D (blaOXA-48).(29) The most common in Pseudomonas aeruginosa are Class B (*bla*VIM and *bla*IMP).(30, 31) The most common in *Acinetobacter baumannii* are Class D (*bla*OXA-23, *bla*OXA-24, *bla*OXA-58).[29, 32]

    The BD Phoenix™ CPO detect test is a qualitative confirmatory growth-based test intended to phenotypically detect carbapenemase enzyme expression in *Enterobacteriaceae, P. aeruginosa* and *A. baumannii*. The test is intended to determine whether an organism is positive or negative for carbapenemase production and, when positive, provide the Ambler classification (i.e., Class A, Class B or Class D). Test performance was established utilizing multiple reference methods.

For more information, refer to the *BDXpert™ System User's Manual*.

2.4 System Overview

Other than the incubation blower and electronics cooling fan, the cylindrical carousel and its drive are the only moving parts within the main instrument incubation bay. The carousel is divided vertically into two tiers, each of which functions as an independent optical source and detection system for panels placed on that tier. Each tier has its own microcontroller to control data acquisition and transmission. The two microcontrollers communicate with the central processor over a serial communications link. The carousel speed, acceleration and deceleration are controlled by the central processor.

Visible illumination in the red, green and blue spectral regions for each tier is provided by a Light Emitting Diode (LED) source board (see **Figure 18 Station Indicators**). The LED source currents are programmable in order to compensate for signal loss at the panel extremes due to parallax and other factors. A source monitor system averages signal from two onboard photodiodes to monitor visible source output. UV (ultraviolet) LEDs provide UV excitation for fluorescent measurements.

For detailed information see **Section 3 System Components**.

2.4.1 Carousel Assembly

The Carousel Assembly is a cage-like structure comprising of aluminum rings and vertical ribs bolted together to form a circular cylinder. The carousel has 52 panel holders in two tiers, where each tier has one normalizer panel and 25 sample panels. The carousel rotates counterclockwise. Following a door closure, an inventory scan is performed to identify panels within the instrument.

Under normal conditions, the carousel is driven at either 1.0 RPM or 2.0 RPM for the current/ongoing operation. During panel location, it can rotate at up to 10.0 RPM. A complete test cycle requires 7 minutes.

2.4.2 Incubation System

The Incubation System maintains the carousel, panel carriers, and panels at a constant nominal temperature of 35 °C. The system is a recirculating forced-air convection design. There is a single filter to remove dust from the electronics bay. The system consists of a cross-flow /incubation blower powered by a brushless DC motor, a resistance style heater bar with automatic over-temperature shut-off, thermoformed inlet and return ductwork, and a user-replaceable polyester fiber air filter.

2.4.3 Panel Status and Internal Barcode Scanner Assembly

Panel Status is indicated by red, green, and amber LEDs mounted on a panel behind the carousel that shine through the light pipes and panels. Eight panel carriers are exposed when the instrument door is open. See **Figure 18 Station Indicators**.

Two barcode scanners, one for each tier, are located inside of the carousel. These scanners read the BD panel sequence barcode located on the back top of the BD Phoenix panel.

2.4.4 External Barcode Scanner

The external barcode scanner can be used to read barcoded accession numbers that have been placed on the panels, as well as the panel's own sequence number barcodes. The accession barcodes can be used to link specimen identification information to specific panels in the instrument.

Figure 2 External Barcode Scanner

NOTE

The placement of customer barcode labels must not interfere with panel reading.

2.4.5 Panel Overview

The BD Phoenix panel is available in four formats: EMERGE, ID only, AST only, and combination ID/AST testing. The pour, serpentine fill motion and seal design is optimized for safety and leak-resistance. Each well in the disposable contains approximately 50 µL of inoculum in an environment that prevents significant evaporation during the course of incubation.

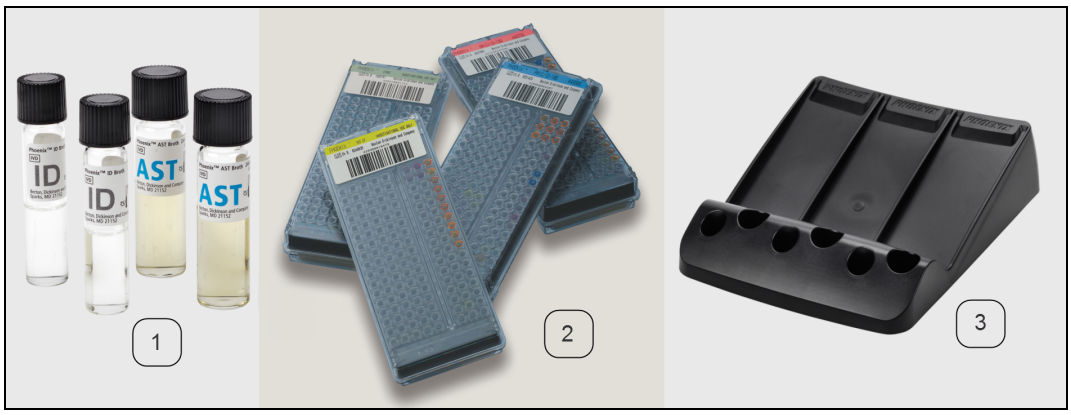


Figure 3 Components Used for Panel Inoculation

Panel Inoculation Components	
Number	Description
1	ID and AST broth tubes
2	Panels
3	Empty Inoculation Station

Table 1 Components Required for Panel Inoculation

A Panel inoculation station holds six tubes of broth (ID, AST) and three panels held at an angle of 24° in order to provide proper gravity-driven inoculum flow through the panel.

Figure 4 Panel Inoculation Station

A Panel Transportation Caddy is a molded plastic tray used to transport filled and sealed BD Phoenix panels from the preparation bench to the BD Phoenix M50 instrument. The caddy capacity is 20 panels. See figure below.

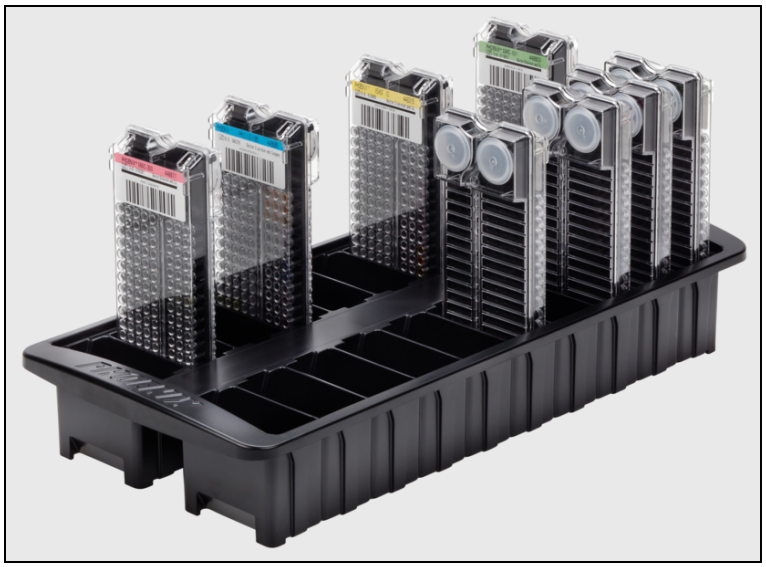


Figure 5 Panel Transportation Caddy

2.4.6 Testing Overview

After the panels are loaded into the carousel, and the door is closed, the instrument reads the panel barcode labels, and performs a scan using the red LEDs. Here, it is determined if panels are actually present in the holders, and well positions are mapped and located. Panel reading occurs immediately after the test cycle begins and readings are taken every 20 minutes for up to 16 hours. The instrument test sequence begins with the system checking that the door is locked and the current time is read. Tiers perform dark readings, then the UV LEDs are turned on and allowed to warm up. UV readings are then taken for one complete revolution. The UV LEDs are turned off. Next the red LEDs are turned on, allowed to warm up, and red LED readings are taken. Then the green LEDs go through the same sequence. Finally, the blue LEDs go through this sequence.

If the test cycle completes successfully, the time is recorded and saved.
A successful test cycle occurs when there are no carousel errors and the user does not preempt the test by initiating any of the following operations:

- Load Panels
- Unload Panels
- Locate Panel

When the user initiates these operations, the current time is compared to the last test cycle's start time. If 30 minutes or more have not elapsed, the requested operation (for example: Load Panels, Unload Panels) is performed.

If more than 30 minutes have elapsed since the last test cycle's start time, the user must allow the test cycle to successfully complete before starting an operation (Load Panels, Unload Panels, or Locate Panel). The Panel In/Out indicator is off and a "cannot get into instrument" tone sounds when a panel operation is requested.

After each test:

- The summary counters on the Status screen are adjusted to indicate current statuses
- Panels/records that require user action have a Needs Attention set
- System alerts are reported in the System Alerts list
- Auto Association occurs

The screen displays the icon below when a panel test is taking place. The number next to the icon indicates the number of minutes remaining in the test cycle.

2.4.7 Normalizers

Normalizers serve as reference panels for adjustment of the instrument's optical detection system and they are used for adjustment of the LEDs (red, green, blue and UV). They expire two years after installation. A system alert will occur before expiration to allow for scheduling replacement.

When the number of days before normalizers are set to expire are less than 60 and more than 30, the alert appears once every week. When only 30 days are left for the normalizers to expire, the message appears every day.

The normalizer panels are always located in station number 0 of each tier. These panels are not presented to the user during normal workflow operations. The normalizer panel is constrained in its carrier to prevent inadvertent removal.

Automatic Adjustment of Light Sources

Automatic light source adjustment attempts to bring normalizer readings within acceptable ranges. It is performed when the instrument is:

- warmed up,
- idle,
- there are no ongoing panels.

UV and RGB light source adjustment process prohibits access to the instrument for activities such as entering panels into unaffected tiers, removing panels, and performing maintenance checks.

Based on the results of the system's Built-In-Test (BIT), as well as time and power cycling factors, the system is capable of detecting if readings from the ultraviolet (UV) and visible light sources (testing LEDs) are out of tolerance. There are two main levels to this condition:

1. The deviation is great enough that panel results are invalidated (panel testing for the tier is aborted), the tier's stations are blocked and an automatic light source adjustment is performed as soon as all panels in the instrument complete testing.
2. The deviation is within limits that do not affect panel results; however available stations are blocked; as soon as all panels on the tier complete testing or are removed, and an automatic light source adjustment is performed.

If any of the above conditions occur, E type error codes, and sub-codes will provide information for each of the tiers.

2.5 Safety and Precautions

For *in vitro* Diagnostic Use.

All patient specimens and microbial cultures are potentially infectious and should be treated with universal precautions. Please refer to CDC manual *Biosafety in Microbiological and Biomedical Laboratories,* 5th Edition, 2009, as well as other recommended literature.

Panels once inoculated should be handled carefully until placed in the instrument.

2.5.1 Summary of Cautions and Warnings

- Protection provided by this equipment may be impaired if the equipment is used in a manner not consistent with the instructions in this manual.
- Due to the size and weight of the BD Phoenix M50 instrument, two people are required to lift the instrument in the absence of mechanical lifting devices.
- All system users should become thoroughly familiar with all controls and indicators before attempting to operate the instrument.
- Observe established precautions against microbiological hazards throughout all procedures. All specimens should be handled according to CDC-NIH recommendations, CLSI guidelines, or local institution guidelines for any potentially infectious human serum, blood, or other body fluids. Prior to discarding, sterilize specimen containers and other contaminated materials by autoclaving.
- In addition to wearing gloves, the use of disposable lab coats or gowns and protective glasses or goggles is recommended when working around the instrument.
- The instrument door is electromagnetically latched and is controlled by the instrument software. Never attempt to defeat the door latching mechanism, or to open the door when the unlocked icon is not displayed. Serious injury can be caused by the rotating carousel manually. If the carousel is not completely stopped when the door is opened, immediately contact BD for service. Never attempt to rotate the carousel manually or serious injury may result.
- When the system displays alerts and errors, immediately respond to the condition.
- All maintenance and repair other than the procedures described in **Section 7 Maintenance** must be performed by qualified service personnel. Non-compliance with this warning may result in personal injury or instrument malfunction.
- All portions of the body that could possibly come into contact with the affected instrument surfaces must be completely covered before beginning the decontamination process.
- If any error sub-codes other than those listed here appear, note the sub-code and contact BD for assistance.
- If the recommended corrective actions do not solve the problem, contact BD.

2.6 Warranty

This warranty details specific legal rights. Additionally, there may be other rights that vary from region to region.

The BD Phoenix M50 Automated Microbiology System is warranted to the original purchaser to be free from defects in materials and workmanship for a period of one year following installation. BD's sole responsibility under this warranty shall be to repair or replace any instrument or its components (except for expendable supplies such as printer cartridges, paper, or filters) which under normal operating conditions, prove to be defective within one year of delivery.

BD will furnish new or re-manufactured components upon its option. All replacements shall meet new part specifications and shall be warranted as above for the remainder of the one year period. Replaced components become the property of BD.

It is understood that the equipment covered by this Agreement has been installed in accordance with the recommendations and instructions in the BD Phoenix M50 System User's Manual.

Any damage to a BD Phoenix M50 instrument resulting from the insertion or removal of cables that connect this instrument to systems other than those approved or supplied by BD, or the failure of the owner to maintain reasonable care and precautions in the operation and maintenance of the system, will void this warranty and terminate the obligations of the manufacturer as stated herein.

This warranty is in lieu of all other warranties, whether express or implied, including but not limited to, warranties of merchantability, or fitness for a particular use. In no event will BD be liable for indirect, incidental, special or consequential damages regardless of whether BD has been advised of such.

2.7 Bibliography

1. Bronfenbrenner, J., and M.J. Schlesginer. 1918. A rapid method for the identification of bacteria fermenting carbohydrates. Am. J. Public. Health. 8:922-923.
2. Arnold, W.M., Jr., and R.H. Weaver. 1948. Quick microtechniques for the identification of cultures. I. Indole production. J. Lab. Clin. Med. 33:195-195.
3. Bachmann, B., and R.H. Weaver. 1951. Rapid microtechniques for identification of cultures. V. Reduction of nitrates. Am. J. Clin. Pathol. 21:195-196.
4. Hannan, J., and R.H. Weaver. 1949. Quick microtechniques for the identification of cultures II. Germentations. J. Lab. Clin. Med. 33:1338-1341.
5. Hartman, P.A. 1968. Miniaturized microbiological methods. Academic Press, New York.
6. Sanders, A.C., J.E. Faber, and T.M. Cook. 1957. A rapid method for the characterization of enteric pathogen using paper discs. Appl. Microbiol. 5:36-40.
7. Snyder, M.L. 1954. Paper discs containing entire culture medium for the differentiation of bacteria. Pathol. Bacteriol. 67:217-226.
8. Soto, O.B. 1949. Fermentation reactions with dried paper discs containing carbohydrate and indicator. Puerto Rican J. Publ. HIth. Trop. Med. 25:96-100.
9. Weaver. R.H. 1954. Quicker bacteriological results. Am. J. Med. Technol. 20:14-26.
10. Kampfer, P., O. Rauhoff, And W. Dott. 1991. Glycosidase profiles of members of the family *Enterobacteriacea*e. J. Clin. Microbiol. 29:2877-2879.

11. Manafi, M., W. Kneifel, and S. Bascomb. 1991. Fluorogenic and chromogenic substrates used in bacterial diagnostics. Microbiol. Rev. 55:335-348.
12. Rammelkamp, C.H., and T. Maxon. 1942. Resistance of *Staphylococcus aureus* to the action of penicillin. Proc. Soc. Biol. And Med. 51:386-389.
13. Marymont, J.H. and R.M. Wentz. 1966. Serial dilution antibiotic sensitivity testing with the microtitrator system. Am. J. Clin. Pathol. 45:548-551.
14. Gavan, R.L., and M.A. Town. 1970. A microdilution method for antibiotic susceptibility testing: an evaluation. Am. J. Clin. Pathol. 53:880-885.
15. Lancaster, M.V. and D. Rebecca. 1996. Antibiotic and cytotoxic drug susceptibility assays using resazurin and poising agents. US Patent #5,501,959.
16. Data on file at Becton, Dickinson and Company.
17. Jorgensen, James H., et al. ed., Manual of Clinical Microbiology, 11th Edition, ASM Press, Washington, D.C., 2015.
18. DM Livermore. 1995. Beta-Lactamases in laboratory and clinical resistance. Clin. Microbiol. Rev. 8: 557-584.
19. K Bush, GA Jacoby, and AA Medeiros. 1995. A functional classification scheme for beta-lactamases and its correlation with molecular structure. Antimicrob. Agents Chemother. 39: 1211-1233.
20. GA Jacoby and P Han. 1996. Detection of extended-spectrum beta-lactamases in clinical isolates of *Klebsiella pneumoniae* and *Escherichia coli*. J. Clin. Microbiol. 34: 908-911.
21. Kenneth S. Thomson, Christine C. Sanders, and Ellen Smith Moland. 1999. Use of Microdilution Panels with and without Beta-Lactamase Inhibitors as a Phenotypic Test for Beta- Lactamase Production among *Escherichia coli*, *Klebsiella* spp., *Enterobacter* spp., *Citrobacter freundii*, and *Serratia marcescens*. Antimicrob. Agents Chemother. 43: 1393-1400.
22. CLSI. M100-S26 Performance Standards for Antimicrobial Susceptibility Testing; Twenty-sixth Informational Supplement. January 2016.
23. CLSI. M07-A10 Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard – Tenth Edition. January 2015.
24. Livermore, D.M., T.G. Winstanley, and K.P. Shannon. 2001. Interpretative reading: recognizing the unusual and inferring resistance mechanisms from resistance phenotypes. J. Antimicrob. Chemother. 48, Suppl. S1, 87-102.
25. Cauwelier, et al. “Evaluation of a disk diffusion method with cefoxitin (30 mcg) for detection of methicillin-resistant *Staphylococcus aureu*s.” Eur J. Clin. Microbiol Infect Dis. May 2004,23(5):389-392.
26. Barnett, J.A., Payne, R.W. and Yarrow, D., Yeasts: Characteristics and Identification, 3rd Edition, Cambridge University Press, Cambridge, U.K. 2000.
27. Larone, D. H., Medically Important Fungi, A Guide to Identification, 5th Edition, ASM Press, Washington, D.C. 2011.
28. de Hoog, G.S., Guarro, J., Gené, J. and Figueras, M.J., Atlas of Clinical Fungi, 4th Edition, Centraalbureau voor Schimmelcultures, Utrecht, the Netherlands/Universita Rovira I Virgili, Reus, Spain, 2014.

29. Djahmi, N., C. Dunyach-Remy, A. Pantel, M. Dekhil, A.Sotto, and J. Lavigne. 2014. Epidemology of Carbapenemase-Producing *Enterobacteriaceae* and *Acinetobacter baumannii* in Mediterranean Countries. BioMed Research International. Article ID 305784, 11 pages.

30. Liakopoulos, A., A. Mavroidi, E.A. Katsifas, A. Theodosiou, A.D. Karagouni, V. Miriagou and E. Petinaki. 2013. Carbapenemase-producing Pseudomonas aeruginosa from central Greece: molecular epidemiology and genetic analysis of class I integrons. BCM Infectious Diseases. 13: 505.

31. Maya, J.J., S.J. Ruiz, V.M. Blanco, E. Gotuzzo, M. Guzman-Blanco, J. Labarca, M. Salles, J.P. Quinn, and M.V. Villegas. 2013. Current Status of Carbapenemaseses in Latin America. Expert Rev Anti Infect Ther. 11(7): 657-667.

32. Naas, T., M. Levy, C. Hirschauer, H. Marchandin and P. Nordmann. 2005. Outbreak of Carbapenem-Resistant Acinetobacter baumannii Producing the carbapenemase OXA-23 in a Tertiary Care Hospital of Papeete, French Polynesia. Journal Clinical Microbiology. 43(9): 4826-4829.

3 System Components

This section describes the following components and functions:

- Section 3.1 BD Phoenix M50 System
- Section 3.2 Navigating Touchscreen Fields
- Section 3.3 Switches, Ports, Buttons, and Panels

3.1 BD Phoenix M50 System

The BD Phoenix M50 system comprises several parts. The figure below describes the system in detail.

Figure 6 BD Phoenix M50 Instrument

The table below lists all the components of the BD Phoenix M50 system.

Item Number	Description
1	AIO PC
2	Phoenix M50 instrument*
3	Barcode Scanner

* The BD Phoenix M50 instrument and the AIO PC together form the BD Phoenix M50 system.

3.1.1 AIO PC

The All-in-one PC (AIO PC) allows you to perform all the tasks in the BDPhoenixM50 system. There are several control icons (see Section 3.3.2 All-in-one (AIO) PC Function Keys) that you can access with the help of the AIO PC.

3.1.2 Printer

For an explanation of controls and indicators on the printer, refer to the manufacturer's operating instructions which is furnished separately. Note that a local printer should be connected to one of the instrument's USB ports. One printer can serve two BD Phoenix M50 instruments connected via one AIO PC.

3.1.3 Barcode Scanners

The external hand-held barcode scanner can be used to read barcoded accession numbers that have been placed on the panels, as well as the panel's own sequence number barcodes. The accession barcodes can be used to link specimen identification information to specific panels in the instrument.

To scan a barcode press the trigger on the bottom side of the scanner. A single beep indicates a successful scan. Press the trigger to scan each additional barcode

3.1.4 Touchscreen Keyboard

A touchscreen keyboard is available on the AIO PC for typing data directly into screen fields. To access the touchscreen keyboard touch the field where data is to be entered. Then touch the keyboard icon that appears to expose a full size touchscreen keyboard. When all data is entered via the touchscreen, touch the return key to close the touchscreen keyboard.

3.2 Navigating Touchscreen Fields

The user cannot enable or disable any field via touch. The fields are enabled/disabled by the actions taken by the user with respect to the panels. If a field is disabled, it appears grayed out as opposed to the active fields that are blue. When the user touches an active (enabled) field, the virtual keypad appears, thus allowing the user to type in data.

To enter data to a field:

1. Touch the field where you intend to enter data. The virtual keypad appears.
2. Type in the data from this keypad.
3. Touch outside the field when you are done and have saved the data.

3.3 Switches, Ports, Buttons, and Panels

The BD Phoenix M50 system has several buttons, ports, controls, indicators, and icons that will be discussed in the following sections.

3.3.1 Power Switch, Inputs / Outputs, and Connector Plate

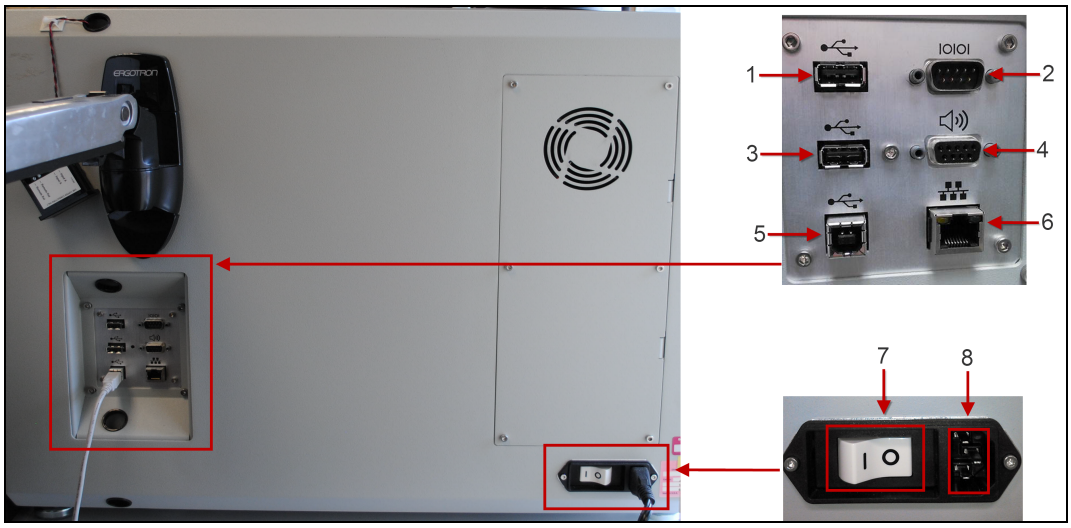


Figure 7 BD Phoenix M50 Connector Plate and Power Switches

Item Number	Description
1	USB Connector
2	Not Used
3	USB Connector
4	Remote Alarm Connector
5	USB Host Connector (to All-in-one Computer)
6	Not Used
7	Power On/Off Switch
8	Power Cord Connector

Table 2 List of BD Phoenix M50 Power Ports and Switches

3.3.2 All-in-one (AIO) PC Function Keys

The AIO icons are located on the lower front portion of the PC. The control buttons can be found directly under each icon on the bottom portion of the AIO PC.

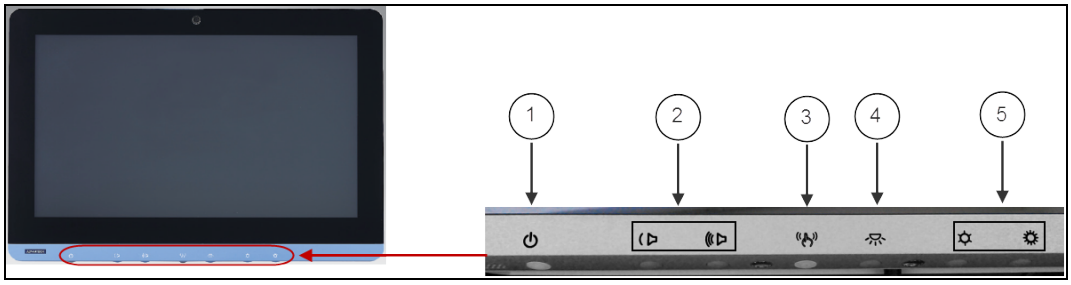


Figure 8 All-in-one Controls

Number	Description
1	Power
2	Decrease/Increase Volume
3	Touchscreen Status Control
4	Light On/Off
5	Decrease/Increase Screen Intensity

Table 3 AIO PC Function Keys

3.3.3 AIO PC I/O Ports

The AIO PC has the following input output ports at the bottom:

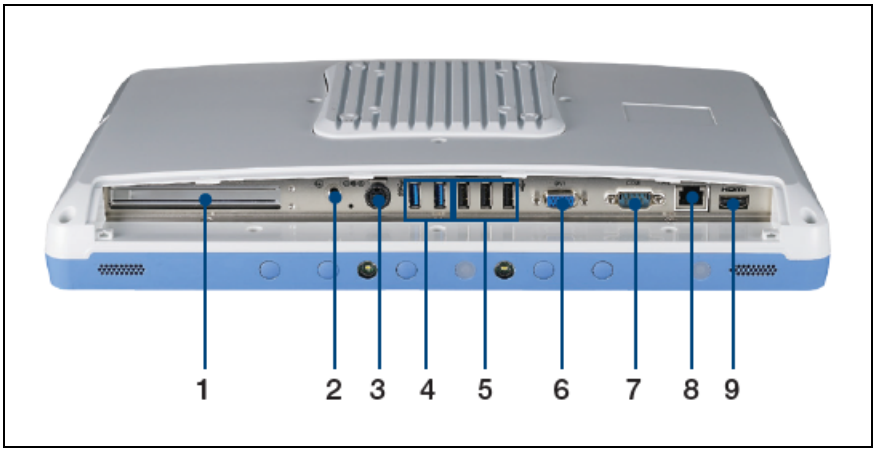


Figure 9 I/O Ports in the AIO PC

Item Number	Description
1	PCIe (x4) card slot
2	Equipotential Terminal Pin
3	Power DC-in
4	2 x USB 3.0 ports
5	3 x USB 2.0 ports
6	VGA port
7	COM port
8	Gigabit Ethernet Interfaces (RJ-45)
9	HDMI-out port

Table 4 Input/Output Ports in the AIO PC

3.3.4 Instrument Indicators

On the right side of the instrument door, there are the following indicators:

Figure 10 Alert Light on BD Phoenix M50 Instrument Door

Item Number	Description	Action
1	Alert Indicator	LED appearance changes
2	Panels In Button	Lights up to indicate Panel operations available or Door Latch status (see Section)
3	Panel Out Button	

Table 5 Light Indicators on BD Phoenix M50 Instrument Door

For more information see Section 4.3.1 Instrument Alert Indicator.

3.3.5 Other Indicators

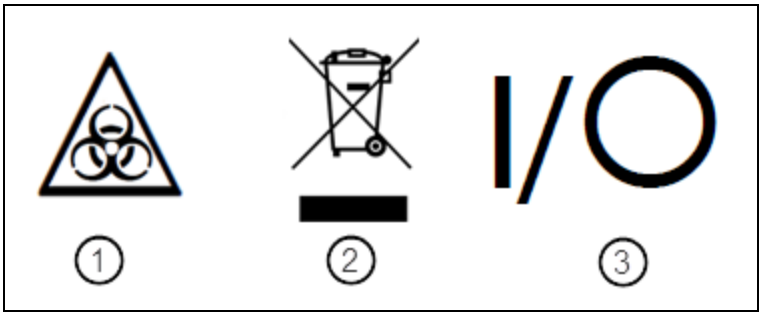


Figure 11 Symbols on Body of BD Phoenix M50 Instrument

Item Number	Description
1	Biohazard
2	Electrical Recycling required
3	On/Off

Table 6 Description of Indicators Used in the BD Phoenix M50 Instrument

4 System Configuration and User Interface

This section describes the following components and functions:

- Section 4.1 User Access Management
- Section 4.2 Software Setup
- Section 4.3 Indicators
- Section 4.4 Isolation Mode
- Section 4.5 BD EpiCenter
- Section 4.7 LIS Operations

4.1 User Access Management

In order to access **User login**, select **Log In** on the Status screen of the BD Phoenix M50 instrument application.

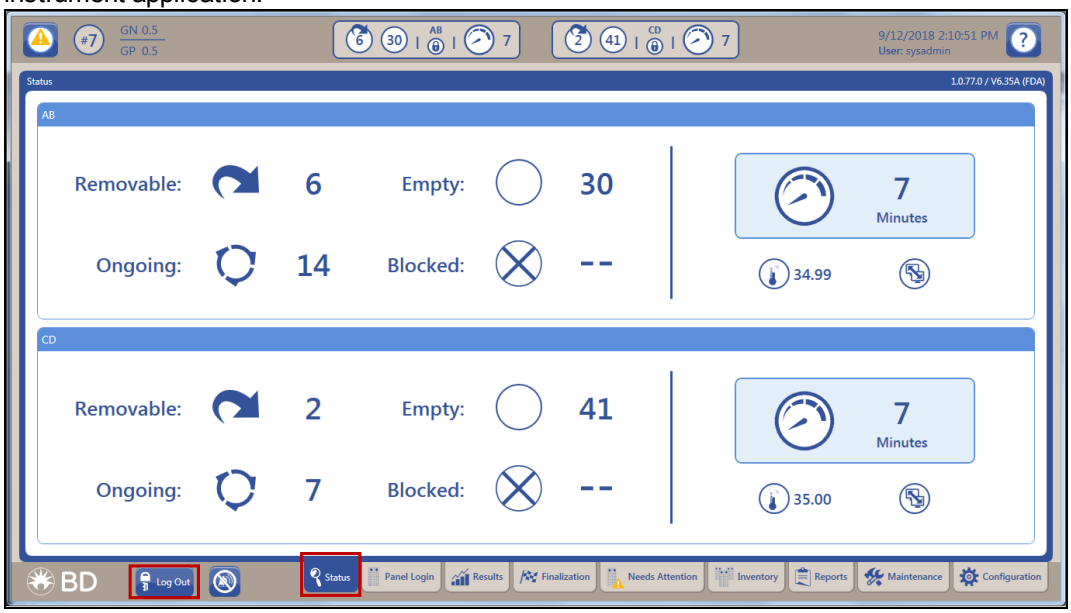


Figure 12 Logging in from Status Screen

When a user is logged in, the text changes to **Log Out**. The current user name is displayed in the upper right corner of application header region.

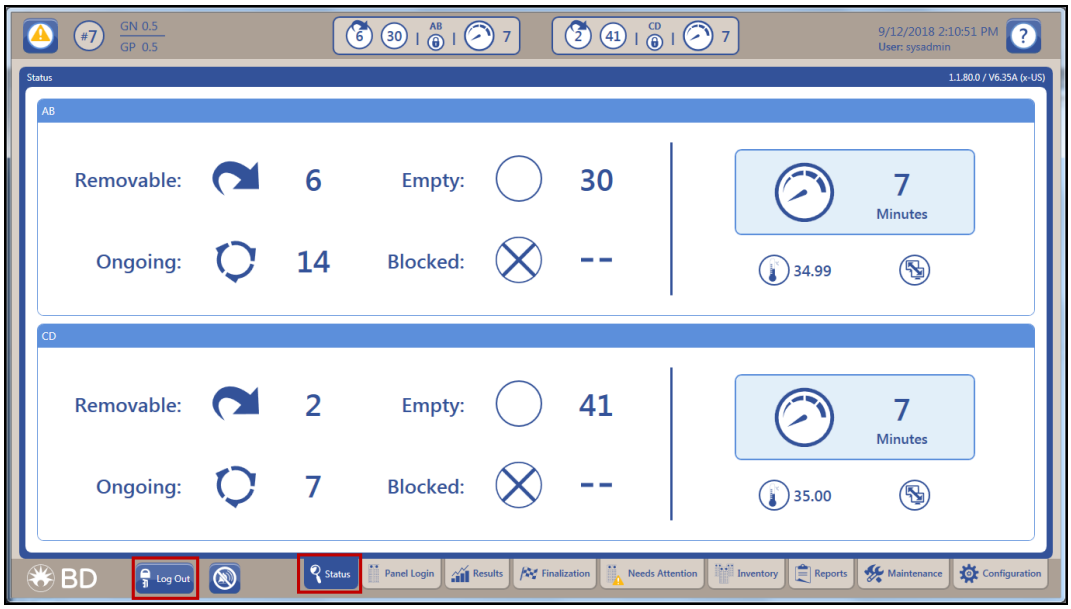


Figure 13 Log In changes to Log Out once logged in

4.1.1 Log On

1. Select **Log In** to access the user log in screen. The user name is the full user name.

WARNING

THE TECH ID WILL NOT BE ACCEPTED AS THE USER NAME FOR LOGGING IN. IF IMPROPER CREDENTIALS ARE SUBMITTED, THE SYSTEM WILL INITIATE AN ALERT AND PROMPT FOR RETRY. AFTER 5 UNSUCCESSFUL LOGIN ATTEMPTS, THE USER ACCOUNT WILL BE LOCKED.

2. Select **Cancel** from the main screen if the user lands at this screen inadvertently or intends to exit without logging in.

NOTE

If the Administrator has logged in, but the screen is idle for 15 minutes, the user will be logged out and any unsaved data will be lost.

For General users (see below) this time is configurable for a span of 15 through 240 minutes in increments of 5 minutes.

4.1.2 User Role Summary

There are two types of user roles that can be assigned:

- Administrator: Lab administrator for lab location. All system functionality is accessible including system configuration. Administrators can create and delete other lab administrators and general lab users.
- General User: All system functionality is accessible except system configuration, which is read only. Users can reset their own password.

4.1.3 User Management

Navigate to the **Configuration** tab to access the user management features. On the Configuration screen, the **Users** tab is the first to appear on the tab list.

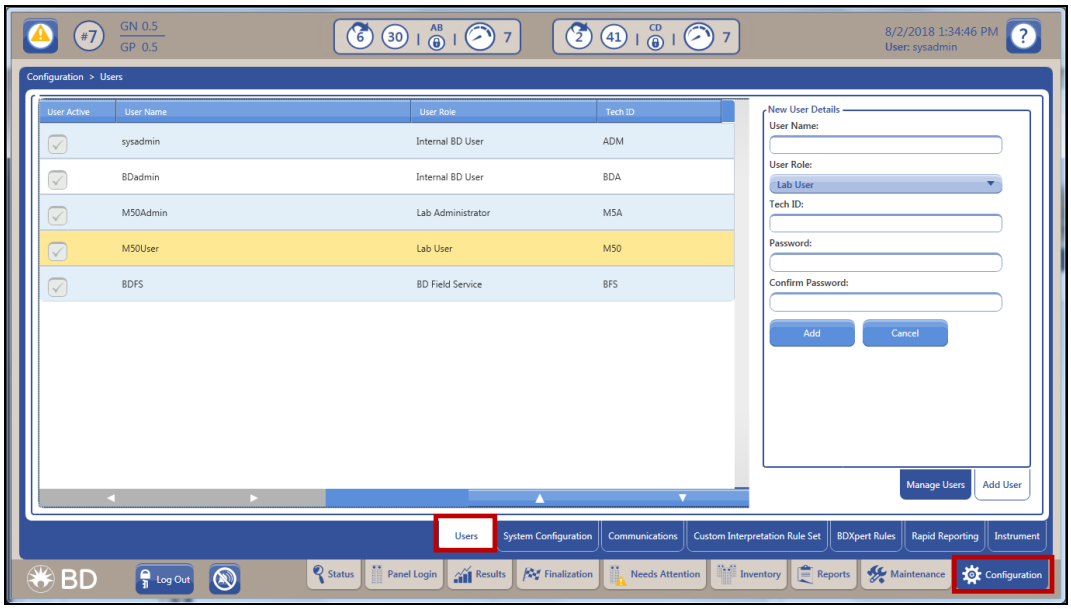


Figure 14 Configuration Tab Selected

4.1.3.1 Lab Administrator Users

Users who are at the Lab Administrator level will be able to access the full set of user management features.

A list of both active and inactive users of the system is displayed for Lab Administrators. User Details show the User ID Role, and Tech ID for the selected user.

Administrators can select a user from the list and perform one of the following actions:

- Reset a user's password.
- Deactivate/disable a user account. Deactivated User accounts still appear in the list.
- Add new users to the system.

4.1.3.2 General Lab Users

The only management feature available to General Lab users is the ability to change their passwords. All users must change their passwords at certain intervals.

4.1.3.3 To change passwords (for Lab Administrators and General Lab Users):

1. Enter the new password and enter it again in the confirm field.
2. Select **Update Password**.

4.1.4 Username Management

While creating a username, the user must make sure that the username:

- contains at least 8 alphanumeric characters
- must not exceed 90 alphanumeric characters
- can have a combination of upper and lower case alphabets and numbers
- can have special characters like dash(-), underscore(_), apostrophe('), period(.)
- must not have any special character not mentioned above or two periods in a row

4.1.5 Password Management

Each account has a password cache of the last 10 passwords used.

To change password:

1. Enter the new password and enter it again in the confirm field.
2. Select **Update Password**; the password has been updated.

4.1.5.1 Password Management Criteria

The password that the user creates must have:

- a minimum of 8 and a maximum of 100 characters appropriate for the selected language
- at least 1 lower case and 1 upper case alphabet
- at least 1 number and
- at least 1 special character [dash(-), underscore(_), apostrophe('), period(.)]

> NOTE
>
> Passwords cannot have two periods in a row.

It must be remembered that:

- The user will not be allowed to reuse the 10 most recent passwords.
- Every 120 days, the password must be changed and the user will receive a notification for the same, each day, for 15 days prior to the due date.
- In case the password has been created by the system administrator, the user must change the password after the first login.

WARNING

USERS MUST CHANGE THE FIRST PASSWORD AFTER THEIR FIRST LOGIN; THIS PASSWORD WILL BE VALID FOR THE NEXT 120 DAYS.

4.1.6 Log Off

1. Select **Log Out** from the Status screen; a confirmation will appear verifying that the user wishes to log out.
2. Select **Cancel** to navigate back to the main application screen to remain logged in.

4.2 Software Setup

The system ships with all setup parameters preset to factory default values. However, before using the instrument for panel testing, review the setup parameters to see if they are suitable for the laboratory. When the BD Phoenix M50 system is connected to BD EpiCenter, features like BDXpert Rules, Custom Interpretation Rule Set and certain functions of Rapid Reporting are not available to the user.

These parameters are grouped in the following categories:

- User Management (**Section 4.1.4 Username Management**)
- System Configuration (**Section 5.9.2 System Configuration Sub-Tab**)
- Communications Configuration (**Section 5.9.3 Communications Sub-Tab**)
- Custom Interpretation Rule Set (**Section 5.9.6 Custom Interpretation Rule Set Sub-Tab**)
- BDXpert Rule Configuration (**Section 5.3.6 BDXpert Rules Sub-Tab**)
- Rapid Reporting Configuration (**Section 5.9.8 Rapid Reporting Sub-Tab**)
- Panel Lot Definition (**Section 5.9.9 Panel Lot Definition Sub-Tab**)

Instrument setup parameters are explained below. The Status screen, which is the default screen when no activity has been initiated, is active immediately after instrument startup, and is shown in **Section Figure 15 Status Screen**. This screen's tabs are explained in detail in **Section 5 Instrument Operations**.

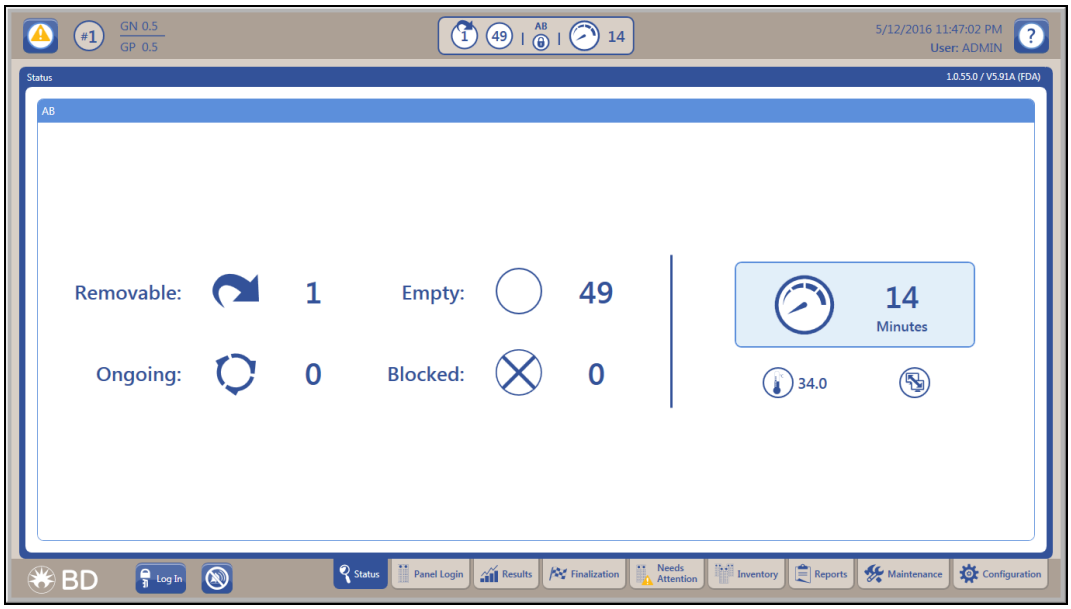


Figure 15 Status Screen

4.2.1 Software Updates

Software updates are user installable. Insert the BD provided USB key in the USB connector on the AIO PC. On the **Maintenance** tab, select Task Category: **Software**, Task: **Upgrade Tap Button: Execute**. The software update will be recorded on the Daily Instrument Report for reference. See **Section 5.8 Maintenance Tab** for step by step instructions.

> NOTE
>
> The local BD services department is responsible for governing the policies that are required to maintain the software of the instrument. Currently, none of the regions allow the end user to update the software in the device.

4.3 Indicators

There are light and sound indicators in the BD Phoenix M50 instrument along with several icons (that appear on the AIO PC) that alert the user of various conditions and status. They are:

- **Section 4.3.1 Instrument Alert Indicator**
- **Section 4.3.2 Instrument Door/Panel Button Status Indicator**
- **Section 4.3.3 Audible Tones and Alarms**
- **Section 4.3.4 System Alerts**
- **Section 4.3.5 Station Indicators**
- **Section 4.3.6 Software Icons**

4.3.1 Instrument Alert Indicator

The instrument alert indicator represents the current alert status.

Figure 16 Instrument Alert indicator

See the table below for status details.

Instrument Alert Indicator		
LED Appearance	State	Meaning
Off	No Alerts / Instrument Communicating	The instrument does not have any outstanding alerts at this time and is connected to the AIO PC.
Blinking	Instrument not connected	The instrument is not connected or it is not communicating with the AIO PC showing the instrument to be in Isolation Mode (see **Section 4.4 Isolation Mode**).
Solid On	Instrument Alert	The instrument has outstanding alerts. Details are available via the alert screen. The instrument is connected to the AIO PC.

Table 7 Instrument Alert Indicator Conditions

4.3.2 Instrument Door/Panel Button Status Indicator

The instrument has an indicator that provides the current panel button and door status to the user.

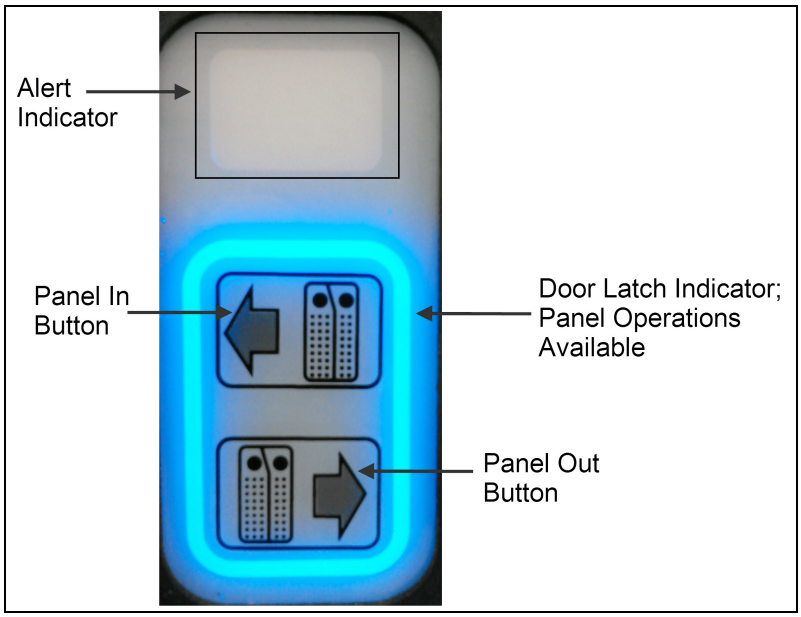


Figure 17 Door Status Indicator

See the table below for status details.

Panel In/Out Indicator		
LED Appearance	State	Meaning
Off	Panels In/Panels Out not available	If the instrument is powered: Panels In/Panels Out are not available at this time. The door is locked and may not be opened by the user. The indicator is off when the instrument is performing an operation that may not be interrupted by a Panels In or Panels Out operation.
Blinking	The door on the instrument is unlocked	The door is unlocked and the user may open the door to access the panels.
Solid On	Panels In/Panels Out active	The Door is locked and may not be opened by the user. The user may press either the Panels In or Panels Out button.

Table 8 Panel Indicator Description

4.3.3 Audible Tones and Alarms

Audible tones and alarms sound to inform the user of various operational states of the instrument. The table below provides a detailed description of such tones and alarms.

Sound	Example	Type
		Informational
Single short high beep	Scanning a barcode	Acknowledge
Three tones progressing from high to low (“Figaro”)	In Configuration mode, the audible alert volume was adjusted	Sample audible alert
Three tones progressing from low to high	The carousel has stopped, the door can be opened	Carousel halted
Two short high beeps	The door has been completely closed and latched	Door closed
Three short high beeps	An operation has been completed	Activity completed
		Alarm
Short high beep then short low beep – sequence repeated four times	Incorrect barcode scanned	Activity error (volume configurable)
Single medium beep – one second on, three seconds off, repeating	Optical failure	System alert (volume configurable)
Short high beep then short low beep	The attempted action cannot be performed	Error tone
Continuous shrill trill	Door has remained open longer than 5 minutes	Door open alarm
Single low beep	A higher priority activity prevents user access to the instrument	Cannot get into instrument
Tone 1 (Medium frequency): Long beep, short beep, long beep, short beep; Tones 2 (low frequency) and 3 (very high frequency): Long beep, short beep, long beep, long beep	Critical Panel: partial results, panel completes, or ID is determined; Resistance Marker: marker has been triggered	Critical Panel/ Resistance Marker notification
High pitched trill	Carousel motion is impeded	Carousel jammed

4.3.4 System Alerts

When the BD Phoenix M50 instrument is in use, and as testing progresses, system alerts and errors may occur. Different types of alerts and errors are flagged by one or more of the following:

- E error codes (see **Section 8.2 System Alerts (E error codes)**)
- W error codes (see **Section 8.3 Workflow Alerts (W error codes)**)
- Audible tones (see **Section 4.3.3 Audible Tones and Alarms**)

When these errors occur, the system Alert icon appears on the LCD screen, or the instrument's System Alert indicator flashes.

The appearance of a System Alert icon in the upper left corner of the screen indicates the presence of a system alert. Touch the icon to display the System Alerts screen. This screen enables the user to review any existing system alerts that may have occurred or that may still exist in the instrument.

The list of system alerts will appear only when the user is logged in.

Touch the >> Error / Alert Messages. Detailed information about the error is provided in this space. All the E type errors are listed under E error codes (see **Section 8.2 System Alerts (E error codes)**). The user will not be able to address or resolve all error sub-codes.

Contact your local BD service representative to resolve the errors.

4.3.5 Station Indicators

Each accessible station has a set of LED indicators that provide the station or panel's status. The station indicators are located in the center of the station (see **Figure 18 Station Indicators**) and their colors vary between green, amber, or red indicating the conditions for a given station. The table below describes the condition indicated by each color.

Figure 18 Station Indicators

Station Status Indicators	
LED Appearance	**Meaning**
Off	Ongoing Panel (if panel is in station) or Available Station (if station is empty)
Green	Removable Panel
Amber	Panel found using locate panel function
Red	Blocked Station (also Temperature Standard Panel)

Table 9 Station Indicators and Status Descriptions

4.3.6 Software Icons

*Icon does not appear when connected to BD EpiCenter™
** Icon does not appear when in standalone mode

GENERAL				
				
Collapsed	Expanded	Enabled	Print	Help

STATUS SCREEN			
			
Log In/ Log Out	Silence Alarm	Status	Panel login
			
Results	*Finalization	Inventory	Reports

ALERTS/NOTIFICATIONS			STATUS STATION	
				
*Cannot Finalize	System Alert	Special Message	Blocked Station	Empty Station

PANELS					NEEDS ATTENTION		
							
Ongoing Panel	Removable Panels, Complete	Final ID Edited, AST Result Edited	*Resistance Marker	Rapid Complete	Active Alert	Not Active Needs Attention	Active Needs Attention

INSTRUMENT STATUS					
					
Door Locked	Door Unlocked	Idle	Processing Data	Warming Up	Temperature
					
Testing	Instrument Number	Light Source Adjustment (RBG, UV)	Inventory Scan	Isolation Recovery (Uploading Data)	**EpiCenter Configured and Connected
					
**EpiCenter Configured but not Connected	*LIS Configured and Connected	*LIS Configured but Disconnected	Instrument Connection Status – Connected (All-in-One PC to Instrument)	Instrument Connection Status – Disconnected (All-in-One PC to Instrument)	

4.4 Isolation Mode

Isolation Mode is the condition that exists when communication between the BD Phoenix M50 instrument and the AIO PC is lost. It is designed to allow the ID/AST system to avoid test cycle gaps when the AIO PC is temporarily disconnected from the instrument. During this time the instrument continues to collect panel test cycle data and incubate the panels.

During isolation mode, the user can log in panels. The system holds data for approximately 5 days when in Isolation Mode. Hence most routine workflows such as unloading and discarding panels (see **Section 5.2.4 Unloading and Discarding Panels**) are stopped. Since panel result analysis occurs at the AIO PC, no panel results are available for completed panels while the system is in Isolation Mode.

The following conditions about Isolation Mode are related to system operation:

- The yellow light will blink when the instrument is in Isolation Mode (see **Section 4.3.1 Instrument Alert Indicator**).
- The AIO PC displays errors when communication is lost with the instrument. On the Status screen, instrument status is not available.

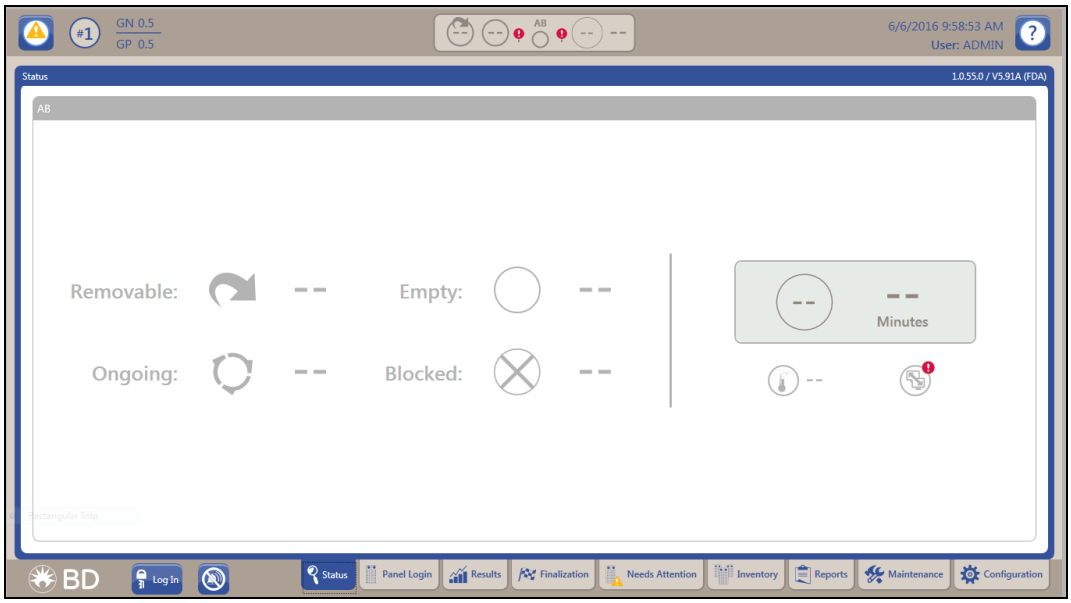


Figure 19 Isolation Mode

- For a stack of BD Phoenix M50 instruments connected to the same AIO PC, each instrument can be in Isolation Mode independent of the other instrument.

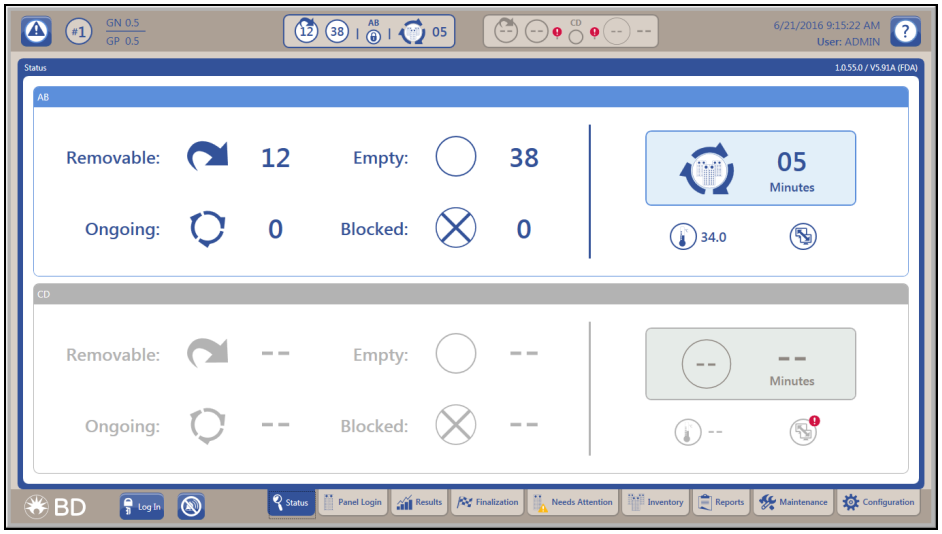


Figure 20 Isolation Mode for One Instrument

- The AIO PC handles the transition of each instrument into and out of Isolation Mode independently.
- In Isolation Mode, when you open the instrument door, no station status indicators are lit. Routine workflow is not supported in Isolation Mode.
- The instrument and the AIO PC both return to normal operations when communication between the two is reestablished. During transition, test cycle data collected by the instrument while in Isolation Mode, is transferred to the AIO PC and processed. Panel results are evaluated at this time for all panels that are still in the instrument when recovering from Isolation Mode.

WARNING

PANELS SHOULD NOT BE REMOVED OR LOADED WHEN THE INSTRUMENT IS IN THE ISOLATION MODE.

4.4.1 Isolation Mode Troubleshooting

Isolation Mode can be caused by the following conditions:

- AIO PC power or communication (USB) cable disconnected
- BD Phoenix M50 instrument application on the AIO PC has stopped working
- AIO PC malfunction

To return to normal operating mode:

1. Check the USB and power cables and reconnect if needed.
2. Reboot the AIO PC and/or instrument if necessary.

If these actions do not correct the problem, contact your local BD representative.

4.5 BD EpiCenter

The BD Phoenix M50 can connect to the BD EpiCenter. BD EpiCenter is BD's single point data management solution. It allows end users to correlate data across multiple platforms. Another major advantage of using BD EpiCenter with the BD Phoenix M50 is longer data retention. The BD Phoenix M50 itself is limited to 31 days of data. The BD EpiCenter can retain data for a much longer time period.

4.6 BDXpert Rules

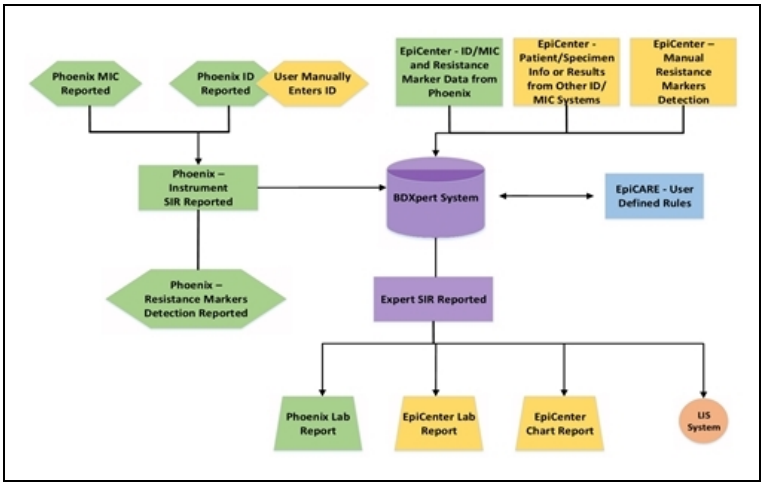
The BDXpert™ System is a rule-based software tool that provides expert advice based on organism ID and AST results obtained by broth micro-dilution in the BD Phoenix System. In addition, ID/AST results obtained from other systems can be expertized via BD EpiCenter. BDXpert rule development is based on published information available through standard organizations and current scientific literature. Reference standards organizations include:

- CLSI (Clinical and Laboratory Standards Institute)
- SFM (Antibiotic Committee of the French Society for Microbiology)
- EUCAST (European Committee on Antimicrobial Susceptibility Testing)

BDXpert rules interpret isolate ID and corresponding Minimum Inhibitory Concentration (MIC) data to the user-selected standard. The resulting instrument report contains necessary and actionable information. Patient management is further enhanced by the application of specimen source and/or patient demographics information contained in the BDEpiCenter database. Distribution of the expertized final report through the Laboratory Information System (LIS) interface facilitates timely communication to assist the clinician in selection of appropriate antimicrobial agent therapy.

Expert analysis takes place in two stages:

1. In the first stage, a susceptible, intermediate, or resistant (SIR) result is determined based on specific standard-driven interpretive breakpoints applicable for the organism ID and MIC.
2. In the final stage of analysis, the BDXpert rule logic is applied to the SIR result. When rule logic criteria are met, the rule is triggered. The outcome is the "BDXpert interpretation" of the AST. Refer to the BDXpert Information Flow diagram (for schematic representation) below:



For more information on BDXpert Rules, refer to the *BDXpert™ System User's Manual.*

4.7 LIS Operations

The Laboratory Information System (LIS) communications feature enables the BD Phoenix M50 instrument to exchange information with a compatible LIS. These communications can be configured to exchange Order records and Results records at a variety of times.

Order records can be downloaded from the LIS to the BD Phoenix M50 instrument. These Order records can include the information listed below. If all this information is sent from the LIS, then the panel is automatically logged in just as if the login were done at the instrument. If the panel sequence number is omitted, the Order record can be associated to a specific panel manually in Panel Login. Order records can also be configured to be uploaded to the LIS.

The LIS Communications function is based on the American Society of Testing and Materials (ASTM) LIS Communications Standards (1381 and 1394), and is compatible with a number of popular LIS systems. For specific information on which LIS systems are compatible, contact your local BD representative. The LIS Vendor Interface Specification (available upon request) provides complete details on the BD Phoenix implementation of LIS Communications.

NOTE

If the BD Phoenix M50 instrument is connected to a LIS, it cannot be connected to the BD EpiCenter system. However, if the BD Phoenix M50 instrument is connected to BD EpiCenter, then a LIS connection can be established via BD EpiCenter.

4.7.1 Results Upload Records

Results records are uploaded from the BD Phoenix M50 instrument to the LIS. These records consist of:

- Header record (Delimiter fields, sender name, version number, message date/time)
- Order record (Accession number, Isolate number, Organism, Test ID, Sequence number, Priority, Report type)
- Comment record (contains Special Messages and/or BDXpert Rules)

4.7.2 Results Record

These records have the following information:

- Panel sequence number
- Instrument number
- Instrument type
- Instrument location (Station)
- Time to result for identification or MIC produced
- Test start time
- Test end time
- Test status (ongoing, complete, partial complete, complete with needs attention reason, complete with all ignored needs attention reasons, complete QC Pass, complete QC Review, pending, or rapid complete)
- Result type
- Antimicrobial code
- MIC value
- S / I / R / No Interp / Error value
- Resistance marker
- ID or Final ID
- Results status (finalized or unfinalized)

4.7.3 Key Concepts About LIS

LIS communication is able to send

- Results records from the instrument to the LIS (upload),
- Order records when panels are placed into the instrument, and
- queries to (and from) the LIS for Order records.

Results upload can be configured to include or exclude Interpretation (SIR) results. The instrument can be set up to upload Results records only when the LIS requests them (solicited upload) or at one of the following unsolicited upload times:

- when panels are finalized;
- when panels complete testing or when complete panel records change;

- when ID or AST results are determined;
- at a fixed time.

QC panels and orphan panels are uploaded only when solicited by the LIS. If the instrument is configured for unsolicited upload, it still responds to requests from the LIS for results (solicitations or queries). If the instrument is configured for unsolicited uploads, the LIS must always be ready to receive data from the instrument.

Organism Configuration and Antimicrobial Configuration enable the user to enter the specific codes required by your LIS for the organisms and antimicrobials uploaded in Results records. (These functions are not available to the user when the BD Phoenix M50 system is connected to BD EpiCenter.) See **Section 5.9.2 System Configuration Sub-Tab** for additional information. LIS configuration settings are independent of critical panel configuration settings (e.g. if LIS configuration is set to send results only when the panel is complete, the results are not uploaded if the panel is critical and rapid reporting configuration is set for notification on ID results or partial results.)

4.7.4 Routine System Operation

The routine operations of the BD Phoenix M50 have very minor differences from the operations of the system when it is connected to an LIS interface. The one difference that should be noted is the ability to enter panel/accession data via the LIS into the system. With LIS communications, patient information can be logged in at the LIS and transferred to the BD Phoenix M50 instrument. Consult your LIS manufacturer's operation manual for complete instructions on data entry and downloading records.

LIS systems operate either in real-time mode, where the system automatically downloads each Order as it is logged in, or in batch mode where multiple Orders in a group are logged in and downloaded by the user. After patient records are logged in, download them to the BD Phoenix M50 instrument. Any data sent to the instrument that does not directly correlate to one of the fields defined as the Order record is ignored by the system. Any information sent from the LIS for a Finalized panel is rejected.

After the Order records have been downloaded, and the panels have been attached to those records, routine system operation does not differ in any way. For example, the user can continue to perform tasks such as: loading the instrument, printing reports, monitoring the system for complete panels, and performing maintenance; however, it is recommended that the user be especially alert and quickly respond to any system or activity alerts that occur.

5 Instrument Operations

The touchscreen presents all of the information needed to:

- monitor instrument status
- log in panels
- configure the instrument
- print reports
- perform routine instrument maintenance

For more information on how to use the touchscreen see **Section 3.2 Navigating Touchscreen Fields**.

Operations are presented in the form of tabs which, when selected, produce functional, interactive screens, as well as icons that graphically represent the information (e.g., a thermometer indicates the current temperature). The screen's application header presents instrument status information that is updated every few seconds. The middle region of the screen initially presents station status information. Display regions are discussed in greater detail in **Section 3.1.1 AIO PC**.

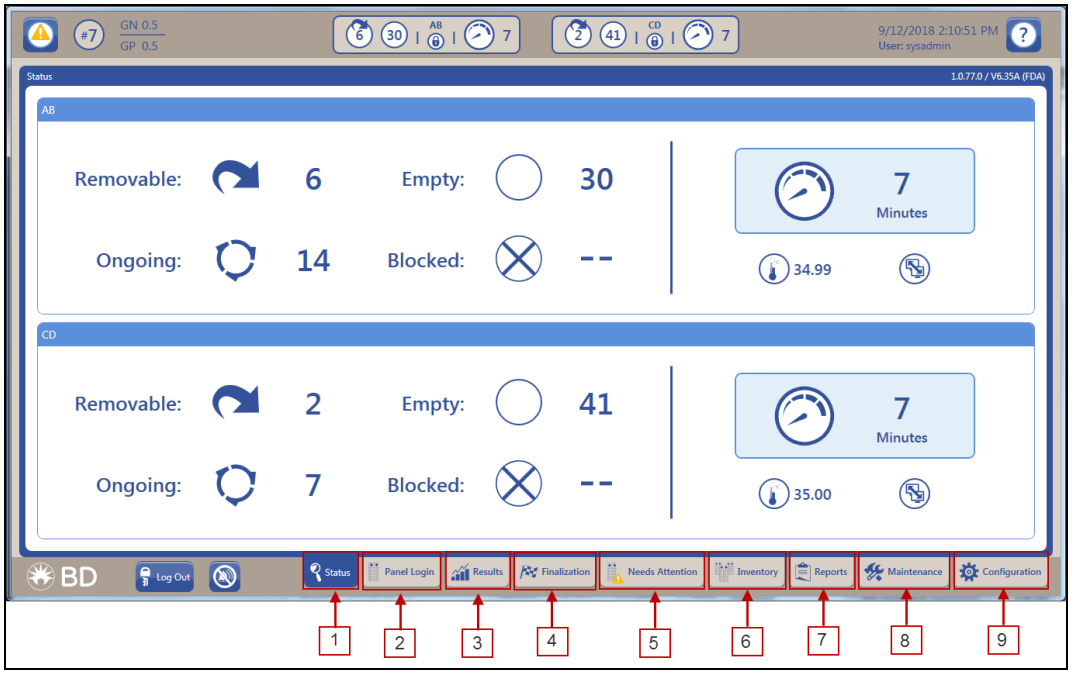


Figure 21 Tabs available for instrument operations

Number	Tab Name
1	Status Tab
2	Panel Login Tab
3	Results Tab

Number	Tab Name
4	Finalization Tab
5	Needs Attention Tab
6	Inventory Tab
7	Reports Tab
8	Maintenance Tab
9	Configuration Tab

Table 10 Tab Identification

This section describes in detail the following:

5.1 Status Tab

The status tab shows the status for each configured instrument and displays the following information:

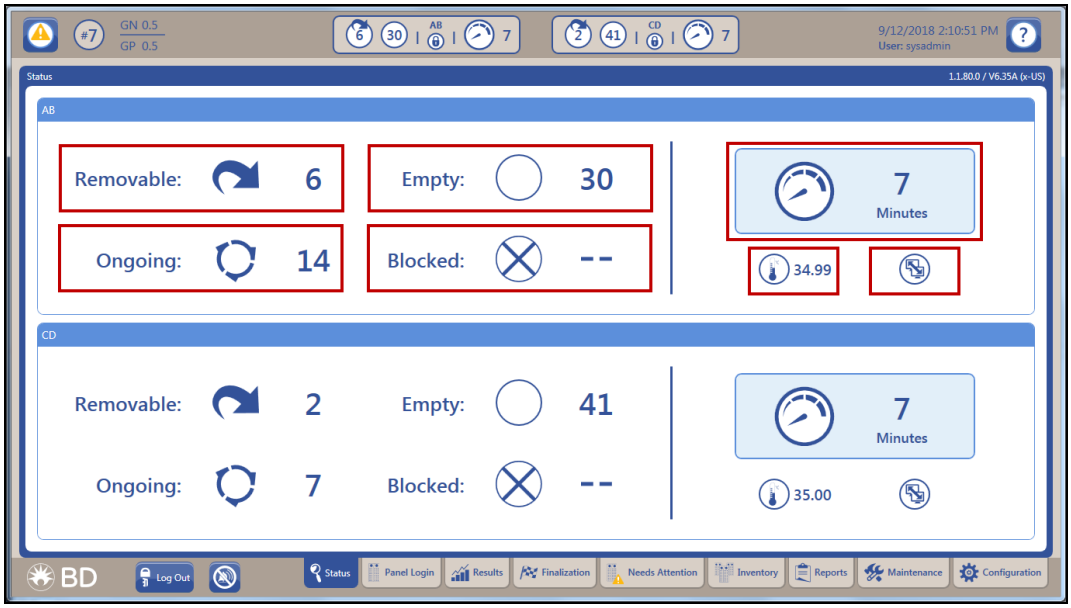


Figure 22 Status Screen Description

Item Number	Name	Description
1	Removable	number of panels ready for removal
2	Ongoing	number of panels in testing progress
3	Empty	number of empty panels
4	Blocked	available stations that cannot be used due to the presence of a temperature panel or due to a system error.
5	Time	time remaining for test cycle time or remaining until the start of the next test cycle
6	Temperature	incubator temperature
7	Connection status	status of AIO connection to instrument

Table 11 Status Screen Description

5.2 Panel Login Tab

The Panel Login tab enables the user to log in panel and demographic information. Depending on the type of panel being used, not all fields listed below may appear on the screen. For information on logging in QC panels, see **Section 5.2.2 Logging in Panels**. More than one of the same panel type may be logged in for an accession number, but the system displays a notification for duplication with an activity error message.

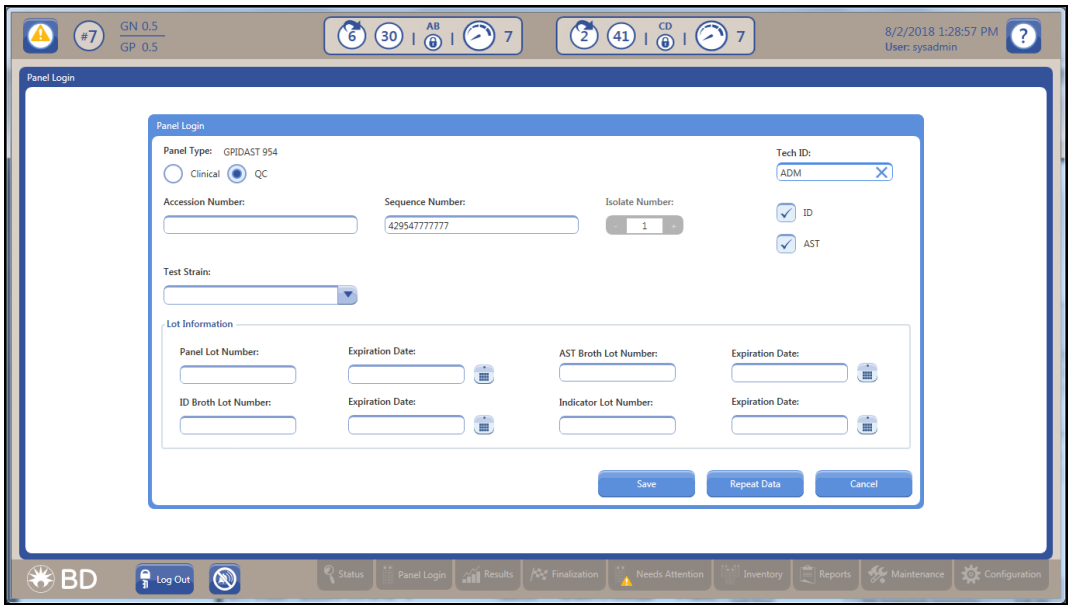


Figure 23 Panel Login Tab

5.2.1 Panel Login Fields

Accession Number

Type in or scan an accession number, up to 20 alphanumeric characters. If the accession barcode was scanned to access Panel Login, the Accession Number is completed automatically. Spaces at the beginning or end of the number are ignored, but spaces within the number are valid. The following characters CANNOT be used in accession numbers: * ? [ ] ! # |.

> NOTE
>
> Characters that are greater than ASCII code 256 (e.g. Japanese, Korean characters) are not accepted and are considered invalid. Users will receive a notice when they enter invalid characters.

Sequence Number

Type in or scan the panel's sequence number. (If the Sequence Number was scanned to access Panel Login, this field is completed automatically.) The sequence number contains digits that identify the panel type. Valid sequence numbers are 12 digits long and must conform to BD panel sequence number specifications. Enter a panel sequence number to save a record. If an existing sequence number is entered, the system displays the Panel Results screen.

Isolate Number

Default isolate number is 1. Valid isolate numbers are 1 to 20. If an accession number has been entered, an isolate number must also be entered. If the isolate number is changed from 1 to another value, an accession number must be entered.

Critical Check Box

By default the Critical check box is disabled. The system can be configured (**Section 5.9.8 Rapid Reporting Sub-Tab**) to provide a notification of critical panel results (ID results obtained, partial panel results, or complete panel results) by sounding an audible alarm and/or printing a Lab Report automatically (or neither).

ID Check Box

By default, the ID check box is enabled if a combination panel sequence number is scanned. This field appears only when a combination panel is used.

AST Check Box

By defaults the AST check box is selected if a combination panel sequence number is scanned. This check box appears only when a combination panel is used.

Organism ID/Test Strain

Use the drop down list to select the organism ID. Organisms are listed in alphabetical order. Enter the first few characters of the organism name to jump to that portion of the list quickly.

This field appears only for AST-only panels or when using the AST side of a Combination panel.

For QC panels, this field is named Test Strain, and lists only the strains of organisms predefined in the database, sorted by strain number (alphanumerically). A test strain must be entered to save a QC panel.

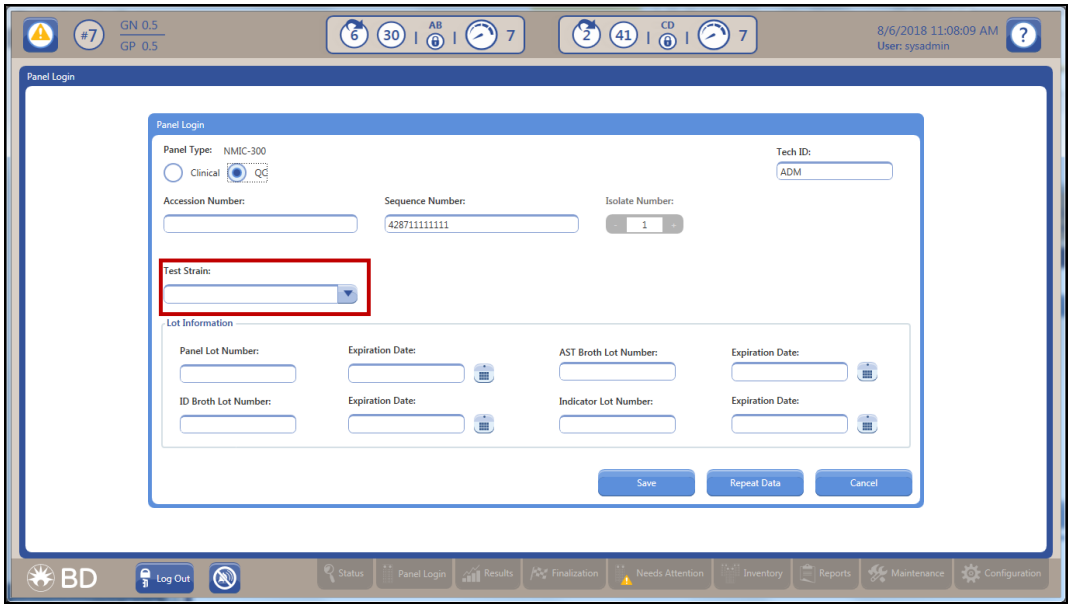


Figure 24 Test Strain ID for QC Panels in Panel Login

Tech ID

This field appears for QC panels. Enter the identification for the technologist performing the QC test. Up to 3 alphanumeric characters are accepted. A tech ID must be entered to save a QC panel.

> NOTE
>
> If the user login has been created with a tech id, this field will be auto-populated with the tech id of the logged in user.

Panel Lot Number

This field appears for QC panels. Type in or scan the panel's lot number. Lot numbers must be 7 digits. A lot number must be entered to save a QC panel. (When the QC Lot Support feature is enabled, this field is completed automatically when the Sequence number barcode is scanned.)

Expiration Date (Panel Lot)

This field appears for QC panels. An expiration date must be entered to save a QC panel. (When the QC Lot Support feature is enabled, this field is completed automatically when the Sequence number barcode is scanned.)

> NOTE
>
> If BD EpiCenter is enabled, the Panel Lot Number and the Expiration Date fields will not be displayed. However, the other lot number fields will be available.

ID Broth Lot Number

This field appears for QC panels. Type in or scan the broth lot number. Lot numbers can be up to 7 characters.

Expiration Date (ID Broth)

This field appears for QC panels. An expiration date must be entered to save a QC panel.

AST Broth Lot Number

This field appears for QC panels. Type in or scan the broth lot number. Lot numbers can be up to 7 characters.

Expiration Date (AST Broth)

This field appears for QC panels. An expiration date must be entered to save a QC panel.

Indicator Lot Number

This field appears for QC panels. Type in or scan the indicator lot number. Lot numbers can be up to 7 characters.

Expiration Date (Indicator Lot)

This field appears for QC panels. An expiration date must be entered to save a QC panel.

5.2.2 Logging in Panels

The inoculum density of the panel is set in Configuration. The density setting cannot be changed during Panel Login. The only way to use a different inoculum density is by blackening well A-17 as described in **Section 6.2 Preparing Panels**.

In order to ensure optimal system performance for Yeast ID panels only, select the correct media type from the drop-down menu or use the default media setting. The media type selection only applies to Yeast ID panels and is not displayed for other panel types. Log the panel into the instrument as follows:

1. Select the **Panel Login** tab.
2. Select **Clinical**.
3. To receive a special notification (audible alarm and/or automatic printing of a Lab Report) when panel results are obtained (ID only, partial, or complete), select **Critical**. More information about critical panels is provided in **Section 5.9.8 Rapid Reporting Sub-Tab**.
4. In the Accession Number field, type in or scan an accession number.
5. In the Sequence Number field, type in or scan the panel's sequence number.

6. In the Isolate Number field the default isolate number is 1. Type in the isolate number, or touch the **+/–** to increase/decrease the number. Valid isolate numbers are 1 to 20. Enter an isolate number if an accession number has been entered.
7. For Yeast ID panels, the user must specify a media type in the Media field. If a media type has not been specified, a workflow error is generated when the user attempts to save the panel. If a Yeast ID panel is not logged in before placing it in the instrument for testing, the panel aborts after the first reading because no media has been specified. A default media type can be configured (see **Section 5.9.2.2 OPTIONS** under **Section 5.9.2 System Configuration Sub-Tab**) which appears when a Yeast ID panel sequence number is scanned during login. Select a different media from the drop down menu, where all media types (abbreviations sorted alphabetically) are listed.
8. If either the ID or AST portion of a combination panel is only being used, disable the part of the panel you are not using.
9. If the user disables ID on a combination panel, or if an AST-only or BD Phoenix Emerge panel is not being used, the Organism ID field appears. If the system is not performing the organism identification, an organism ID for SIR interpretation must be provided. (If an AST panel is being tested and an organism ID is not entered, the panel will go to **Needs Attention** when the instrument completes reading. An organism ID will have to be provided in order for the BDXpert system to interpret MIC results.) Highlight the desired organism from the drop-down box. Organisms are listed in alphabetical order. Enter the first few characters of the organism name to move up to that portion of the list quickly. Select the desired organism. The desired organism can also be scanned from the barcode list of organisms found in the Quick Reference Guide.
10. Select **Save** to save the information.
11. Place the panel in the instrument (see **Section 5.2.3 Inserting Panels in the Instrument**). The user can perform the following functions from Panel Login:

    Save – to save the information displayed

    Repeat Data – enter the last accession number and media types for panels, or media type and lot information for QC panels as follows:

    - if QC Lot Support is disabled (Panel Lot plus Expiration, ID Broth Lot plus Expiration, AST Broth Lot plus Expiration, Indicator Lot plus Expiration),
    - if QC Lot Support is enabled (ID Broth Lot plus Expiration, AST Broth Lot plus Expiration, Indicator Lot plus Expiration)

    Cancel – to clear the displayed record from the screen

5.2.3 Inserting Panels in the Instrument

Insert the panel with the sequence bar code label and reaction wells side facing the interior of the instrument.

1. Select **Panel In**. (see **Section Figure 25 Inserting Panels**).
2. When the blue light is blinking on the door, open the instrument door. An audible tone will sound and the unlock icon will be visible.

WARNING

- **THE INSTRUMENT DOOR IS ELECTROMECHANICALLY LATCHED AND IS CONTROLLED BY THE INSTRUMENT SOFTWARE.**
- **NEVER ATTEMPT TO DEFEAT THE DOOR LATCHING MECHANISM, OR TO OPEN THE DOOR WHEN THE DOOR LOCKED ICON IS DISPLAYED.**
- **IF THE CAROUSEL IS NOT COMPLETELY STOPPED WHEN THE DOOR IS OPENED, IMMEDIATELY CONTACT BD FOR SERVICE. NEVER ATTEMPT TO ROTATE THE CAROUSEL MANUALLY OR SERIOUS INJURY MAY RESULT.**

3. Select a panel holder where there is no panel in place and no LEDs are illuminated. Place the bottom part of the panel in the panel holder.
4. Press downward.
5. Pivot the top of the panel back into the panel holder.
6. Allow the panel and spring clip to move upward into place.
7. Close the instrument door. If more panels need to be inserted than there are available holders in the current section, close the door, and wait for a moment for the carousel to rotate to provide additional available holders and repeat **Steps 2 through 7**.
8. The system performs an inventory scan to locate any newly inserted panels and reads the barcodes of these panels.

NOTE

Do not snap the panel back into the holder. This may result in splashing of the inoculum which may cause inaccurate results.

Do not load panels when the Testing icon is live. 

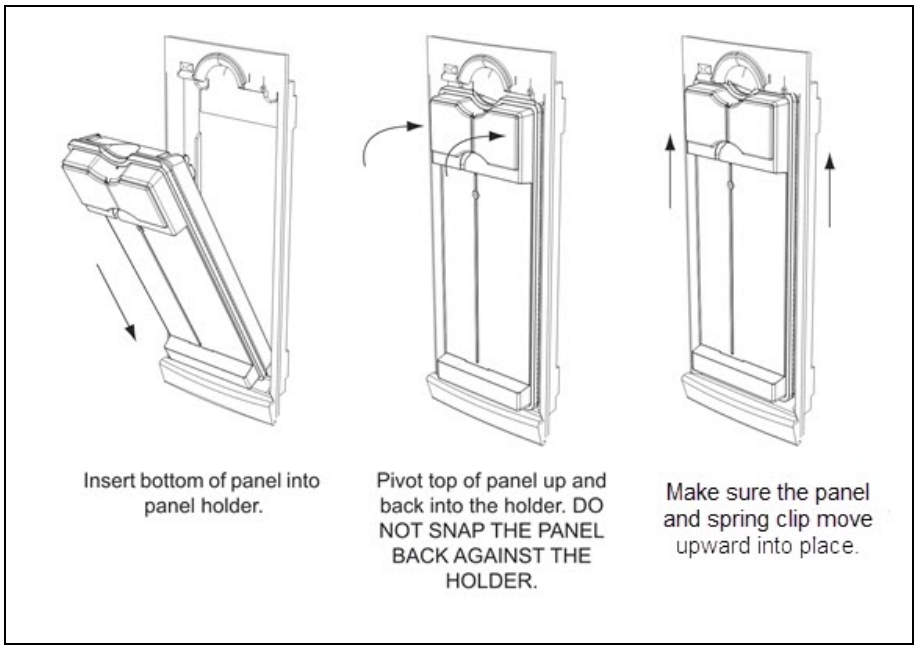


Figure 25 Inserting Panels

NOTE

Check to see if panel closure fits properly before closing the door, as this may lead to jamming of the carousel.

5.2.4 Unloading and Discarding Panels

When panel testing is completed, panels should be removed from the instrument and discarded.

WARNING

- **THE INSTRUMENT DOOR IS ELECTROMECHANICALLY LATCHED AND IS CONTROLLED BY THE INSTRUMENT SOFTWARE.**
- **NEVER ATTEMPT TO DEFEAT THE DOOR LATCHING MECHANISM, OR TO OPEN THE DOOR WHEN THE UNLOCKED ICON IS NOT DISPLAYED. SERIOUS INJURY CAN BE CAUSED BY THE ROTATING CAROUSEL.**
- **IF THE CAROUSEL IS NOT COMPLETELY STOPPED WHEN THE DOOR IS OPENED, IMMEDIATELY CONTACT BD FOR SERVICE. NEVER ATTEMPT TO ROTATE THE CAROUSEL MANUALLY OR SERIOUS INJURY MAY RESULT.**

To remove panels:

1. Press the **PANELS OUT** button on the instrument door.
2. When the blue Panel In/Out indicator blinks, open the instrument door.
3. All panels that are ready to be removed are indicated by a solid green LED indicator.
4. Remove the panels by pushing the panel down, pivoting the top of the panel outward, and pulling the panel out of the panel holder.
5. If there are completed panels that are not in the accessible stations, close the door and allow the instrument to reposition the carousel to provide access to those panels. Open the door and continue removing completed panels.
6. Discard the panels in a biohazard container.

5.3 Results Tab

The Results tab enables the review and modification of panel test results. Results can be used for the following functions:

- to display a panel whose data is stored in the BD Phoenix database
- to modify the information for a panel in the BD Phoenix database 
- to mark a panel as critical 
- to print a Lab Report on any panel that can be recalled or displayed on the screen 
- to locate a panel resident in the instrument
- to delete panel information from the BD Phoenix database

- to answer or display any triggered BDXpert Rules
- to display any special messages
- to finalize a panel
- to view Needs Attention items (they can also be resolved from the Results tab)

Results can be accessed in several ways:

- Scan a known panel sequence number or accession number with the external scanner while the Status screen is displayed.
- Select **Results** from the Status screen (see **Figure 26 Results Screen**).
- Scan or enter a known panel sequence number while the Panel Login screen is displayed.
- Select **Results** from Inventory (see **Section 5.6 Inventory Tab**).

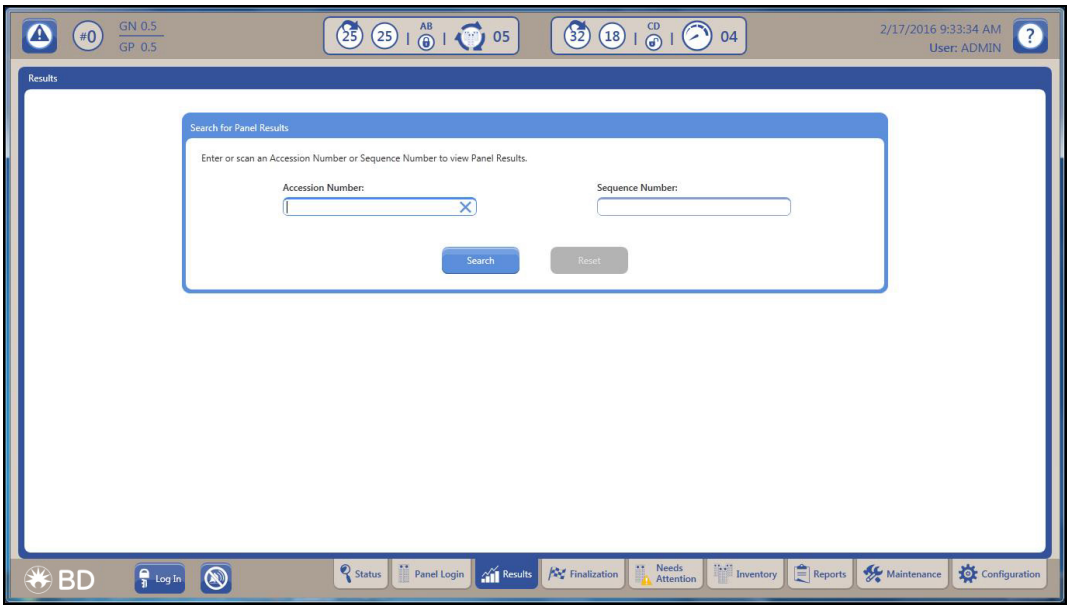


Figure 26 Results Screen

Typical Panel Results are shown in the figure below (**Figure 27 Panel Results Screen**).

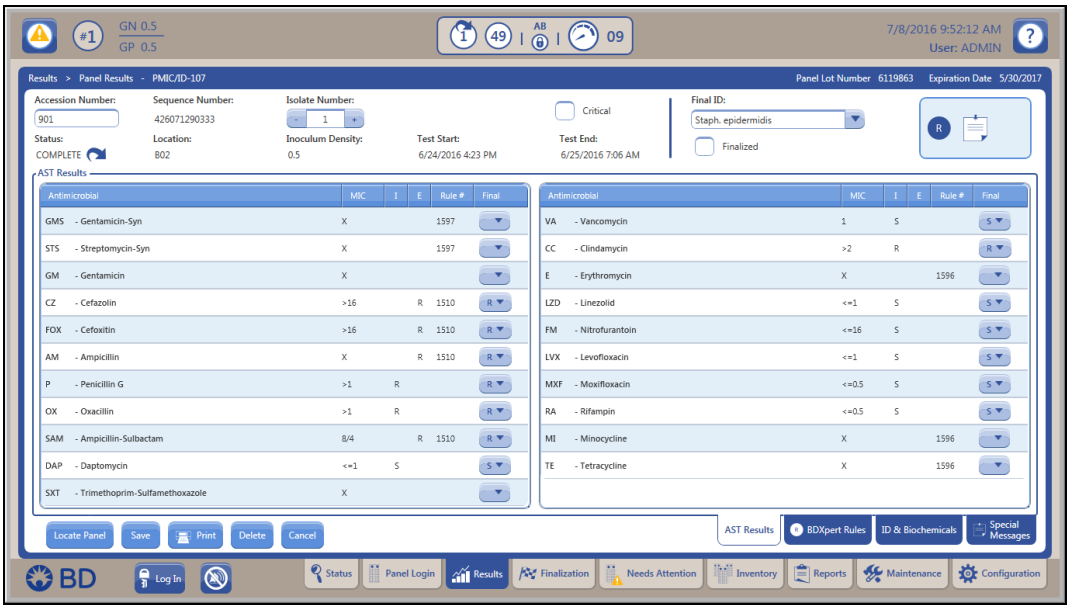


Figure 27 Panel Results Screen

Actions available from all sub-tabs are:

Locate Panel – causes the instrument to locate, unlock the door, and indicate the current panel

Save – saves any changes

Print – prints a copy of the Lab Report for the current panel

Delete – deletes the panel results

Cancel – returns user to initial Search for Panel Results screen or whichever the last screen the user was in

Panel Results (clinical panels) are retained for 31 days (possibly longer depending on number of QC panels tested). QC panel results are retained for at least six months.

The type of panel is shown in the title area of the screen. The inoculum density used for the identification (if applicable) is shown on the Results screen.

The user will be able to see different sub-tabs, depending on the type of panel that the instrument reads or the type that the user has logged in. For example, the BDXpert Rules sub-tab appears only when the BDXpert functionality is enabled. The Special Messages and the Needs Attention sub-tabs appear only when these are messages that need user intervention.

5.3.1 Adding/Modifying ID Results

ID Results can be added and modified directly from the Results tab and this option is available to the user no matter which sub-tab is selected.

The user can manually enter an organism ID to the system, or in case the instrument an identifies an organism, it can be overridden. In some cases, the system is not able to make a single identification determination based on panel results. In these cases, two or three organisms may appear in the Instrument ID field. When more than one organism appears as the Instrument ID, the system does NOT automatically populate an identification in the Final ID field. Select the desired organism at that time. The actual organism may be determined either through supplemental tests, which are recommended in the Instrument ID window and/or the Special Messages screen (accessible via **Special Messages**), or through other tests performed.

To add/modify the Final ID

1. Select **Final ID** field in the Results header
2. Highlight the desired organism.
3. Select **Save**; the following icon appears:

5.3.2 AST Results Sub-Tab

This sub-tab displays read-only fields like:

Antimicrobial

This Read-only field shows the abbreviation and name for the antimicrobial.

MIC

The Minimum Inhibitory Concentration value determined by the instrument. The following values may also appear in this field:

Value	Meaning
>	growth occurred for all concentrations of the antimicrobial
≤	no growth occurred in all of the concentrations of the antimicrobial
?	MIC determination is pending (SIR values remain blank)
X	MIC value cannot be produced; or Final ID is not claimed in the Taxa listing (see **Section 9.7 Taxa for ID/AST Determination** for AST testing; or the panel's drug dilution series does not cover the BD Phoenix reportable MIC range, or for additional causes, (see **Table 12 MIC/SIR Values and Causes**). Check the Special Messages displayed on the screen (see **Section 5.3.8 Special Messages Sub-Tab**) for an explanation.
C	Rapid Complete (MIC is pending, BDXpert SIR is based on ID and completed drug and/or resistance marker results). These values are replaced by actual MIC values as they are determined.

For QC Panels, the following values may appear in this field:

Actual MIC Value	Expected MIC Range	Status
number,?, or X for error	Appears, if defined	P (the actual MIC value is within the expected MIC range)
		F (the actual MIC value is not within the expected MIC range)
		R (repeat: the actual MIC value is X)
		blank (no range is defined for the antimicrobial/organism combination)

I(nstrument SIR)

This field is the instrument interpretation for the MIC based on the breakpoints currently running in the system (selected in the System Configuration Sub-Tab). See **Section 5.9.2 System Configuration Sub-Tab** for more information.

The SIR value is blank for antimicrobials that require an ID to perform the SIR interpretation. In this case, the *BDXpert SIR* field (if present) and the *Final SIR* field are also blank.

The following represent the interpretation values:

Value	Interpretation
S	Susceptible
I	Intermediate (does not appear if the BD EpiCenter system is attached and communicating. If communications with the BD EpiCenter system is lost, the field automatically appears.)
R	Resistant
N	Not Susceptible*
X	Cannot produce interpretation
Blank	No SIR (missing or invalid Final ID; MIC = ?, C, or X; unclaimed organism for Final ID)

* N indicates that the antimicrobial/organism does not have an upper breakpoint. When there is no upper breakpoint there are no criteria for calling an organism intermediate or resistant. This often occurs when there is an absence or rare occurrence of resistant strains of an organism. In this case, if the MIC is below the lower breakpoint the SIR results can be reported as susceptible but if the MIC is above the lower breakpoint the only result that can be reported is N or not susceptible.

(BD)E(Xpert SIR)

Possible field values are: Blank, S, I, R, N, and X.

The BDXpert SIR field is not shown when the BDXpert System is disabled. The BDXpert SIR field is not displayed when the BD Phoenix M50 system is connected to the EpiCenter. It is also not shown for QC, ID, or ID/AST panels with AST disabled. This field contains the results calculated by the BDXpert System based on the execution of all enabled BDXpert Rules. Values appear in this field only if a BDXpert rule triggered and caused the BDXpert SIR value to differ from the instrument interpretation.

Rule

This Read-only field shows the numeric designation of the highlighted rule. It may not display when the BD Phoenix M50 system is connected to the EpiCenter.

F(inal SIR)

Field values are the same as I(nstrument SIR) above. The Final SIR can be one of the following (from highest to lowest priority): a user-entered SIR value; the BDXpert SIR value; the instrument SIR value; or blank.

Final SIR values are produced when a MIC value or error is determined, AND there are no pending manual BDXpert rules (if the BDXpert System is enabled).

When the BD EpiCenter System is not connected and the BDXpert System is disabled, the Final SIR field is not displayed for an antimicrobial until the MIC value is something other than ?.

The following table provides explanations of different combinations of blank and X results. Detailed explanations for actual results are provided as Special Messages (see **Section 5.3.8 Special Messages Sub-Tab**).

Antimicrobial	MIC	Instrument SIR	BDXpert SIR	Final SIR	Possible Cause Examples
Any Drug	?	[Blank]	[Blank]	[Blank]	Results pending.
Any Drug	BD Phoenix MIC Result	S, I, R	[Blank]	S, I, R	Instrument SIR = Final SIR (No BDXpert rule SIR).
Any Drug	BD Phoenix MIC Result	S or I	R	R	Final SIR = BDXpert SIR if rule accepted.
Any Drug	BD Phoenix MIC Result	[Blank]	[Blank]	[Blank]	No breakpoints for this drug/organism combination within the chosen standard (CLSI, SFM, EUCAST, Custom).
Any Drug	BD Phoenix MIC Result	X	[Blank]	X	MIC value is outside the breakpoints for the selected standard. Example: Panel drug range = 1–16 µg/mL, susceptible breakpoint = 0.5 µg/mL
Any Drug	BD Phoenix MIC	X	[Blank]	X	SIR is suppressed by a BDXpert rule.

Antimicrobial	MIC	Instrument SIR	BDXpert SIR	Final SIR	Possible Cause Examples
	Result				User must provide Final SIR based on manual interpretation or additional testing.
Any Drug	X	[Blank]	[Blank]	[Blank]	The MIC for this drug and organism combination is not reported by the BD Phoenix system. An alternative method should be used.
All Drugs	X	[Blank]	[Blank]	[Blank]	This species is not included in the BD Phoenix AST taxonomy; perform an alternative method.An excessive amount of indicator was detected in the panel. The AST portion of the panel has been terminated and the isolate should be retested.
Any Drug	X	[Blank]	[Blank] or R	[Blank] or R	The MIC for this antibiotic is not reported (see Special Message). Interpretation based on BDXpert Rule.
Any Drug	C	[Blank]	R	R	Rapid Completion SIR (BDXpert SIR based on ID and/or another completed drug and/or resistance marker result).

Table 12 MIC/SIR Values and Causes

5.3.2.1 Modifying AST Results

There may be times when the Final SIR results for a panel need modification.

> NOTE
>
> The user cannot modify Final SIR results if there are manual BDXpert rules pending. First accept or reject the pending rules, which allows the system to perform its final results processing. After the final processing is complete, the SIR results can be modified manually.

To modify the Final SIR results:

1. Select **AST Results** from the Results tab.
2. Select **FINAL SIR** for the desired antimicrobial. The following selections are available:

- S(usceptible)
- I(ntermediate)
- R(esistant)
- X = Invalid, cannot interpret (see in Section)
- N(not Susceptible)*
- Blank (indicates ID is required)

* N indicates that the antimicrobial/organism does not have an upper breakpoint. When there is no upper breakpoint there are no criteria for calling an organism intermediate or resistant. This often occurs when there are no known resistant strains of an organism. In this case, if the MIC is below the lower breakpoint the SIR results can be reported as susceptible but if the MIC is above the lower breakpoint the only result that can be reported is N or not susceptible.

5.3.3 ID and Biochemicals Sub Tab

This sub-tab displays the organisms (up to 3 organisms) identified by the instrument based on biochemical results in an ID or ID/AST panel. In some cases the system will not be able to make a single identification determination based on panel results. In these cases, two or three organisms may appear in this field. The user must select the desired organism to enter into the Final ID field.

Confidence

The Confidence value computed by the system is based on the actual biochemical results versus the expected results. The Confidence value is a percentage from 0 to 99.

Supplemental Tests

Supplemental Tests are displayed in the Instrument Organism ID field and/or on the Special Messages screen if there is more than one Organism listed there. Once these tests have been performed, the results of the tests will help to distinguish which organism ID to associate to the AST results. At this point, a single organism ID can be selected from the Final ID field.

Biochemical

This Read-only field shows the abbreviation for the biochemical used to determine the ID.

Actual

This Read-only field shows the observed biochemical result at the time when the organism ID was determined:

Result	Meaning
+	positive
-	negative
?	the biochemical result is pending or that the test was aborted prior to ID results being determined
X	error

Expected

This Read-only field shows the expected biochemical result according to the Instrument Organism ID:

+ or – for the organism.

The letter V indicates that the result can be variable. This field is blank when the actual results are ? (for non-QC panels), or until an Organism ID has been determined, or when more than one organism is listed in the Instrument Organism ID field.

Resistance Marker Field

Resistance markers are shown in the order in which they trigger. The following information is shown when a Resistance Marker is detected and is displayed on the BDXpert Rules tab:

- The BDXpert rule number that triggered the Resistance Marker
- The Resistance Marker code (abbreviation)
- The Resistance Marker Name
- The BDXpert Rule Description

When ID and Biochemicals is selected, the following appears:

- Instrument Organism ID which may consist of Instrument Organism ID, Confidence Value, and Up to 5 Supplemental Tests if the panel was set up using low inoculum. See **Figure 30 Lot Information Sub-Tab Screen** for more details.
- Biochemical Results which consist of: Biochemical Abbreviation, Actual Result (+, -,?, or X) or Expected Result (+, -, V, or blank) shown in **Figure 28 ID and Biochemical Results**.
- Special Messages 
- Needs Attention 

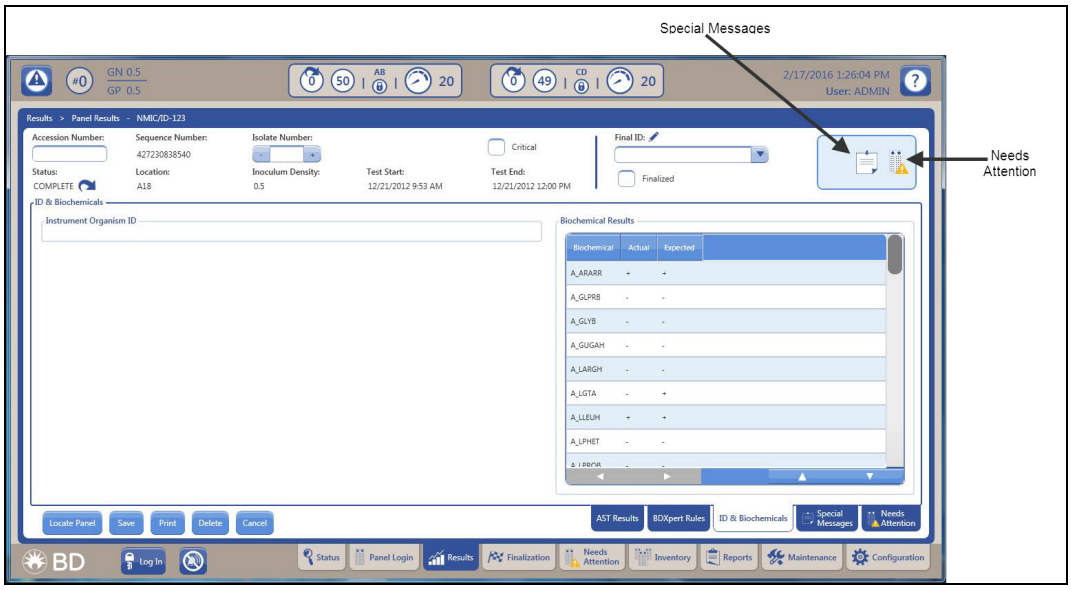


Figure 28 ID and Biochemical Results

- If a Needs Attention (see **Section 5.3.9 Needs Attention Sub-Tab**) exists for the panel, it appears in the results header area.
- If a Special Message (see **Section 5.3.8 Special Messages Sub-Tab**) exists for the panel, an icon displays in the results header area.
- If a Resistance Marker has triggered for the panel, the Resistance Marker icon (see **Section 6.4.7 Resistance Markers**) is shown in the results header area.
- If a panel is recalled by accession number only, and there is more than one panel attached to the accession, the Results List screen appears. From this screen, select the specific panel to review/modify.

> NOTE
>
> Depending on the type of panel being used, as well as other circumstances, not all fields listed below may appear on the screen.

AST or Combination panel types (with at least the AST side enabled) each contain a set of antimicrobials. The instrument reports a result for each antimicrobial on the panel. Each antimicrobial reports an individual MIC value. Once an antimicrobial has a MIC value, the instrument calculates an Instrument susceptibility (SIR) value for each MIC value that has been determined. (The instrument requires the panel to have an Organism ID defined to interpret MIC values into Instrument SIR values.

NOTE

SIR values are not calculated by the instrument if it is attached to a BD EpiCenter Data Management System.

If Rapid Completion is enabled, the instrument provides BDXpert AST results (SIR) before determining actual MIC values. The instrument MIC values are provided as soon as they can be accurately determined. Within a test panel, some MIC values may be available earlier than others. The Rapid Completion feature can be used to predict resistance for uncompleted antibiotics using the ID alone (intrinsic resistance), or ID with completed MICs of related antibiotics, or resistance marker tests (BL, ESBL). The BDXpert system is used to make these predictions. This can be useful in situations where, for example, the results for drugs that have not yet received MICs would be of no clinical value based on the other results that are already available. Antimicrobials with Rapid Complete BDXpert interpretations are indicated by a C in the MIC column on Results screens and Lab reports.

When both a MIC value and Instrument SIR value have been determined for an antimicrobial, the instrument executes the BDXpert Rules (providing the BDXpert System is enabled). The instrument reports a value in the BDXpert SIR field if an enabled BDXpert Rule triggered and the reported BDXpert SIR value is different from the value in the Instrument SIR field.

Different results appear depending on which tab is selected. The header information remains the same no matter which tab is selected.

5.3.4 Panel Results Fields

NOTE

Modifying the Accession Number or Isolate Number may invoke Auto Association which can change results.

Accession Number

Type in or scan the accession number to recall. If only an accession number is entered, and there is more than one panel attached to the accession, the Results List screen appears.

This field can be modified for unfinalized panels. Enter up to 20 alphanumeric characters for the accession, excluding * ? [ ] ! # |. Modifying an accession number does not affect the accession number of any related panels.

Sequence Number

This field cannot be edited.

Isolate Number

Valid isolate numbers are 1 to 20. This field can be modified for unfinalized panels, however an existing isolate number cannot be changed to a blank number.

Media

This field is editable only before the first test cycle completes.

Shows the media type selected during Panel Login for Yeast ID panels only. The following values can appear in this field: blank for Unspecified Media Type; INVLD (Invalid Media Type); SABDX (Sabouraud Dextrose Agar); TSASB (BD Trypticase™ Soy Agar w/5% SB); COLSB (Columbia Agar w/5% SB); CHOC (Chocolate II Agar); SABEM (Sabouraud Dextrose Emmons); SABHI (Sab Brain Heart Inf Ag Deep).

Critical

Select and enable this field to mark the panel as critical. The user can configure an audible alarm and/or an automatically printed Lab Report (or neither) as notification (See **Section 5.9.8 Rapid Reporting Sub-Tab**) for critical panel results (ID results have been obtained, partial panel results, or complete panel results).

Previously marked critical panels can be disabled.

This field does not appear for QC panels.

Status

This Read-only field shows the panel's testing status:

- Pending
- Ongoing
- Complete
- Rapid Complete (if enabled).

Rapid Complete panels have not finished testing and show BDXpert results. If a Rapid Complete panel is removed from the instrument, it then becomes Complete. If it is left in the instrument, Rapid Complete MICs are replaced by actual MIC results as they are determined.

Location

This Read-only field shows the location of the panel, in the form Tst, where "T" is the Tier, and "st" is the station number.

Inoculum Density

This field cannot be edited.

Test Start

This Read-only field shows the date and time that panel testing was started.

Test End

This Read-only field shows the date and time that panel testing was completed.

Final ID

The user can automatically complete the Final ID on the system from a single instrument-based ID or by selecting among 1, 2 or 3 tie instrument-based IDs.

NOTE

If the Modify Related Panels check box is selected, the ID in the database of all related panels (those with the same accession and isolate number) is set with the same organism ID through the Auto Association function (see **Section 6.4 Automatic Association of Panels**).

Organisms are listed alphabetically. Enter the first few characters of the organism name to find that portion of the list quickly.

When the field is modified, the system re-evaluates each antimicrobial's instrument SIR value, as well as re-evaluating BDXpert information. The field cannot be modified if the panel is finalized.

For QC panels, this field is named *Test Strain*, and lists only the ATCC strains of organisms predefined in the database, sorted by strain number.

Finalized

Select the check box to finalize the panel. The *Finalized* field is displayed as a read-only field when the BD Phoenix system is connected and communicating with the BD EpiCenter Data Management Center. In this case, all Finalization is done at the BD EpiCenter system. *Finalized* is not displayed for QC panels.

The panel cannot be finalized if there are any outstanding Needs Attention messages.

If a panel with Rapid Complete status is finalized, MIC results processing stops, and the panel status becomes Complete. Any drugs that did not complete testing maintain their current MIC value (e.g., C in MIC column remains C, X remains X, etc.).

Modify Final ID of Related Panels

This check box appears when the Final ID field has been modified irrespective of whether there are related panels or not. This option is not available if the BDEpiCenter is connected to the BD Phoenix M50 system.

Special Messages icon

There are several conditions that can generate a Special Message and then the icon appears. The user must select the **Special Messages Sub-Tab** (see **Section 5.3.8 Special Messages Sub-Tab**) to see what the message is.

Needs Attention icon

There are several conditions that can generate a Needs Attention alert and then the icon appears. The user must select the **Needs Attention Sub-Tab** (see **Section 5.3.9 Needs Attention Sub-Tab**) to see what the message is. For details on these conditions, see **Section 5.5 Needs Attention Tab**.

Panel Lot Number

This Read-only field displays the panel lot number and this field is active only when the QC Lot Support feature is enabled.

Expiration Date

This Read-only field shows the date and time when the panel lot expires. This field is active only for QC panels and only when the QC Lot Support feature is enabled.

Modify Final ID of Related Panels Check Box

This field appears when the Final ID field is modified. Check defaults when the Final ID is modified. If the ID for unfinalized related panels is NOT to be modified when the currently displayed panel is modified, disable this field as it has no effect on related QC panels. This field does not appear if the BDEpiCenter system is attached and communicating.

QC Status

This field shows the status of a QC panel. The field is blank until the panel status becomes Complete. Statuses are initially PASS or REVIEW. Review indicates that the panel has not passed. Check any panels with Review status and determine why the panel did not pass.

The status is REVIEW if any of the following conditions occur:

- QC strain was identified incorrectly
- The test on a QC panel is aborted
- At least one of the antimicrobial results fail

From a status of REVIEW, the final status may be set to REPEAT if it is determined that the panel failed due to error in preparation or handling of the panel. If it is not determined that a panel preparation/handling error was made, the final status should be set to FAIL. Select REPEAT or FAIL to clear the Review QC Results Needs Attention condition.

5.3.5 Modify Panel Usage Sub-Tab

The Results tab will display the Modify Panel Usage sub-tab when the currently recalled panel:

- is an ID/AST Combination panel type and both sides of the panel are enabled
- status is not complete
- has no instrument organisms determined for the panel
- does not have any AST Complete set on its AST side

The user can disable the ID or the AST side of the panel when no other changes have been made to the panel on the Results screen. When the user disables the ID or AST side of the panel, no other tab will be accessible. If the user attempts to leave the tab, a message will be displayed instructing the user to save or cancel the panel usage change.

To modify panel usage:

1. Select **Results**.
2. Enter or scan the panel barcode sequence number of the panel whose usage you wish to modify. The system automatically completes the Accession # and Isolate # fields, which are read-only.
3. Select **Modify Panel Usage**.

4. The following screen appears:

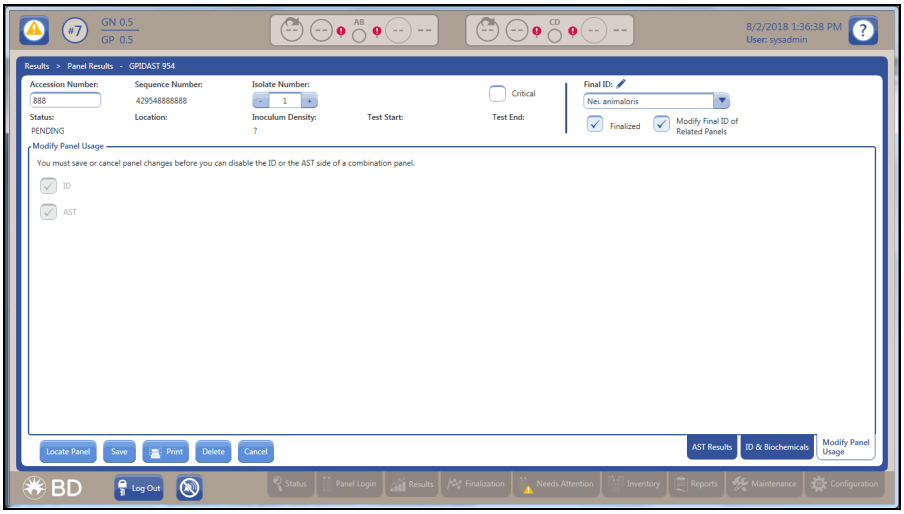


Figure 29 Modify Panel Usage Screen

5. Select **ID or AST** for the side of the panel to be disabled. If both are selected then workflow alert code W305 will be displayed. The screen data will be maintained and the save attempt will be stopped.
6. Select **Save** to save the panel modification.

NOTE

The following conditions are applicable for panel usage modification:

- No information for related panels is modified when panel usage is changed.
- If there is no user-entered Final ID and the ID side is disabled, the Instrument ID, Biochemical Results, Confidence Values, SIR Values, and ID Special Messages are removed from the record.
- If there IS a user-entered Final ID and the ID side is disabled, this ID is retained, as are SIR Values. However, Instrument ID, Biochemical Results, Confidence Values, and ID Special Messages are removed from the record.

5.3.6 BDXpert Rules Sub-Tab

When the user selects the BDXpert Rule sub-tab, the following are displayed:

- Rule Number
- Status
- Resistance Marker
- Name
- Rule Description

> NOTE
>
> All fields may not be displayed depending on the type of panel and whether or not the instrument is connected to a BD EpiCenter system.

The BDXpert Triggered Rules screen provides a view of the BDXpert system rules that have been triggered for a panel (the panel currently selected in the Results tab). Other views available are:

- a listing of rules that have been triggered,
- the text of those rules,
- the effect that the rules have on Final SIR values, and
- the ability to accept or reject pending (manual) rules.

Additionally, all rules can be re-run. After all rules have been reviewed and Accepted/Rejected, save any change made.

If the BD EpiCenter system is attached and communicating with the BD Phoenix M50 instrument, the BDXpert Rules tab does not appear. However, if communication with the BD EpiCenter system is lost, and the BDXpert system is reactivated in Configuration (see **Section 5.9 Configuration Tab**), the tab reappears and the screen can be accessed.

When communication with the BD EpiCenter system is restored, BDXpert rules interpretations are once again performed at the BD EpiCenter system.

Rules Field

Rule #

This Read-only field shows the numeric designation of the highlighted rule.

Status

Shows the status of the rule. The initial status of **Automatic** (a rule that executes automatically without user intervention) or **Manual** (a rule that must be manually accepted or rejected) is set in the BDXpert Rule

Configuration screen (**Section 5.9.7 BDXpert Rules Sub-Tab**). Statuses are:

Status	Meaning
Automatic	rule is enabled and set to Automatic
Pending	rule is enabled and set to Manual; Manual rules must be Accepted or Rejected; only the first Manual rule shows as Pending
Accepted	rule is enabled and set to Manual and has been Accepted by the user
Rejected	rule is enabled and set to Manual and has been Rejected by the user

Pending rules can be accepted or rejected via **Accept** or **Cancel**. Once a rule is accepted or rejected, the status can only be changed by re-running the rules.

5.3.7 Lot Information Sub-Tab

This sub-tab provides a listing of disposables used in the setup of QC panels. It is not available to the user when the system is connected to the BD EpiCenter.

To access this sub-tab:

1. Enable QC Lot Support (see **Section 5.9.2 System Configuration Sub-Tab**).
2. Go to Panel Lot Definition (see **Section 5.9.9 Panel Lot Definition Sub-Tab**) and scan in the barcodes.
3. Go to Results and enter an Accession Number.
4. Select Search; Lot Information Sub-tab appears (see **Figure 30 Lot Information Sub-Tab Screen**).

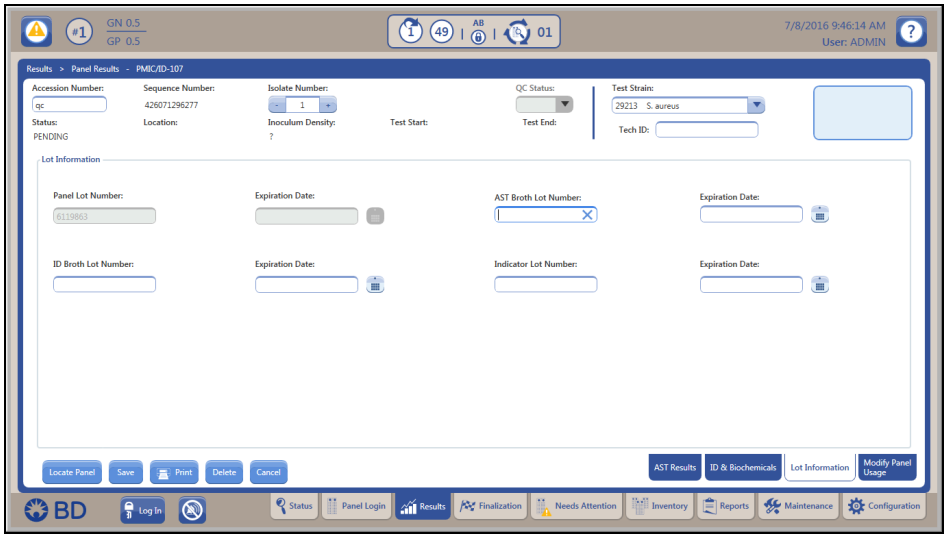


Figure 30 Lot Information Sub-Tab Screen

NOTE

For a QC panel, the Panel Lot Number and the Panel Expiration Date are displayed on a separate tab. However, for a Clinical panel, they are displayed at the top right side of the Results screen.

5.3.8 Special Messages Sub-Tab

The user can access information about certain panel ID and AST results, as well as some panel readings from Special Messages. These special messages are triggered and are available for viewing regardless of whether the BDXpert System is enabled or disabled. If a recalled panel has an associated **Special Message**, an icon is displayed in the header area of the results screen.

Special Messages on a recalled panel are shown according to hierarchy on the Special Messages window.

The Special Messages screen reflects messages that exist at the time the screen is accessed. It is not updated dynamically with messages that are triggered after the screen has been accessed. To view newly triggered messages, recall the panel again, and select **Special Messages** again.

5.3.9 Needs Attention Sub-Tab

Needs Attention provides a list of all Needs Attention reasons, listed in priority order as shown in **Table 13 Needs Attention Resolutions**. When any of these conditions occur, the panel will have a Needs Attention reason code set and the Panel with a Needs Attention reason will be displayed on the Needs Attention screen. To ignore a Needs Attention reason, select the corresponding field next to the condition.

On the Needs Attention panel list, the system provides the opportunity to resolve or ignore the condition that has caused the panel to be placed in the list.

- If the panel was placed in the list due to missing or unresolved information (e.g., a tie), the instrument provides the ability to add or edit the information to resolve the condition.
- If the panel was placed in the list due to a software, panel, or hardware error, the instrument provides the ability to delete the panel to resolve the error condition. Deleting a panel that is still testing causes that panel's protocol to be aborted. Only panels whose Needs Attention reason has not been ignored are shown in the screen.

Condition	Active Operations
Test Aborted	• ignore • locate panel • delete panel
Cannot Identify Barcode	• ignore • locate panel
Cannot Read Panel Wells	• locate panel • delete panel

Condition	Active Operations
Panel Lot Expired	• ignore • Ignore All
Invalid AST Results	• ignore
Panel Missing	• ignore • delete panel
No Growth on Panel	• ignore • locate panel • delete panel
Panel Lot Undefined	• none to address condition
Review QC results	• ignore • locate panel • delete panel • panel results
Missing Accession Number	• locate panel • panel results
Missing Organism ID	• panel results
Cannot Determine Organism ID	• ignore • panel results
Invalid Organism ID	• ignore • panel results
Organism ID Conflict	• panel results
BDXpert Rule Flagged (if enabled and manual)	• panel results
Pending Too Long	• ignore

Table 13 Needs Attention Resolutions

Needs Attention resolution options

Ignore Check Box – Select the check box to ignore the Needs Attention condition. Ignoring it does not correct the Needs Attention reason code, but it informs the system that the problem has been acknowledged by the user.

Save – Saves any selections that are made.

Print – Prints the accession reports for the displayed panels and enables the printing of a Needs Attention List report.

Delete – deletes all panel results.

Cancel – removes any selections that have been made.

These options are designed to enable the correction of (whenever possible) the condition causing the panel to need attention. Where it is not possible, other solutions are provided. AST Results displays the Panel Results screen, where the Needs Attention condition may be able to be corrected by adding information to the panel record.

To resolve panels that need attention

1. Access the Needs Attention screen.
2. Refer to the chart below for detailed information on the particular Needs Attention reason.
3. Go to the AST Results tab to access Results (to add or modify information). Select **Delete** to delete the panel, and select the Ignore or Locate Panel check box to find the panel in the instrument.

Condition	Meaning	Possible Cause(s)	Resolution(s)
Test aborted	A condition occurred which caused the panel to be invalid	Ongoing panel not tested for more than 1 hour Instrument turned off for more than 1 hour Instrument door open more than 1 hour Panel moved to a different tier/instrument Incubator temperature too high or too low System software did not execute testing algorithms for more than 1 hour Media type not specified for Yeast ID panel	Delete the panel Repeat testing
Cannot identify barcode	Internal barcode scanner could not read a panel barcode in a station where the instrument could determine that a panel was present	Barcode label obscured or missing Unknown panel type was placed into the instrument	Locate the panel in the instrument and examine the barcode If the barcode is obscured, the panel must be discarded and another inoculated If the barcode appears to be intact, replace the panel and close the door. After the next inventory, check the Panel Needs Attention screen. If the panel does not appear, the internal scanner can now read the panel
Cannot read panel wells	Internal barcode scanner has read a	Panel not seated properly	Locate panel, remove it and replace it, as above

Condition	Meaning	Possible Cause(s)	Resolution(s)
	sequence number in a station but the instrument does not detect that a panel is present in that station		
Panel lot expired	A panel was logged in (or has a test start date) with a panel lot number that has already expired	Panel being logged in or placed in the instrument is from an expired lot	Discard panel, reinoculate isolate using unexpired panel lot
Invalid AST results	At least one MIC cannot be interpreted. (Excludes QC panels.)	See **Table 12 MIC/SIR Values and Causes**	Repeat testing of the antibiotic that cannot be interpreted
Panel missing	Internal barcode scanner read a sequence number on an Ongoing panel, but the panel is missing	Panel removed before the test was completed Internal scanner failure and the sequence number can no longer be read	If the panel is replaced on the same tier within 1 hour after removal, testing will resume. If the panel is not replaced, testing will abort
No growth on panel	No growth in growth control well. (Excludes ID only and QC panels.)	Instrument did not detect growth in the growth control well of the panel	Subculture the organism (to insure that it is viable) and inoculate a new panel. Panel has been aborted From the Needs Attention screen delete or ignore the panel
Panel lot undefined	A panel has been entered whose lot number is undefined (non QC panel)	Panel is from an undefined lot	Define panel lot or ignore
Review QC results	Status of a completed QC panel is “Review”	QC panel which yielded an incorrect ID or incorrect AST result for at least one antibiotic, or has no growth in growth control well	Repeat QC organisms. Check: culture purity, inoculum density
Missing accession number	Panel is missing accession or isolate information. (Orphan panel.)	Failure to enter accession or isolate information	Press the “panel results” key. Add the accession number using the barcode

Condition	Meaning	Possible Cause(s)	Resolution(s)
			reader or by typing it in
Missing organism ID	Panel has no organism ID. (ID required to determine SIR results. Excludes QC panels.)	• For AST only panel, no ID has been entered • The panel has an unresolved tie or triplet instrument ID and has no related panel with an ID	Select the organism ID. Any BDXpert rules triggered by the given ID will automatically be presented at this point. Select or ignore the rules and save. When completed, exit to see complete test results.
Cannot determine organism ID	Panel has an Instrument ID of “No identification” or has a related panel with “No identification” as a final ID	Panel has been in test for 12 hours and the instrument cannot determine the identification	Repeat testing. Check the following: Culture purity Inoculum density Correct panel used? Organism may not be in the BD Phoenix database
Invalid organism ID	Organism ID is not in BD Phoenix database	Panel received download information of an organism ID that is not in the BD Phoenix database	Use alternate method
Organism ID conflict	Panel completes testing and has at least one related unfinalized panel that contains a different Final ID. Excludes QC panels.	Completed panel has at least one related panel that contains a different ID	Select Results and choose an organism. Selecting the organism may trigger BDXpert rules. If the rules are configured as manual, BDXpert appears
BDXpert Rule flagged	Panel triggered at least one BDXpert rule and the rule is manually enabled in Configuration.	A BDXpert rule needs to be invoked in order to determine AST results. A panel is flagged if BDXpert rules are configured as enabled/manual. (Rules that are configured as enabled/automatic will automatically “trigger” and the panel will not be displayed in Needs Attention.	Each Expert rule is displayed individually in sequence. To accept the rule, select Accept. To reject the rule, select Reject. Use ReRun to delete BDXpert system decisions and start over. When all rules have been displayed and dispositioned, complete AST results

Condition	Meaning	Possible Cause(s)	Resolution(s)
			show. After all rules have been invoked, select Special Messages (if present) to view Special messages about characteristics of the organism.
Pending too long	Panel has not been scanned (during an inventory count) within 30 minutes of logging in Panel Login.	Panel was logged into the instrument but was not placed in the instrument within 2 reading cycles (approximately 30 minutes).	Repeat testing. Delete the panel

For additional information on Needs Attention see **Section 5.5 Needs Attention Tab**.

5.3.10 Lab Report

Lab Report can be printed from the Results or Finalization screens. It contains all information for a panel sequence number that exists in the BD Phoenix database, including all information in the Results screen, any special messages, BDXpert Rules that triggered, or Needs Attention reasons if they exist.

Regular and QC Clinical panel reports can be printed from the Reports tab. As the reports are printed based on accession numbers, one or more panels will be printed. The QC Lab Report is accessible from the Reports menu and Results screen. It provides similar information to the Lab Report, but prints when a QC panel is being displayed and a report is requested.

On the Results screen only the currently displayed panel report is be printed. If the user changes information and does not save it then the unsaved information is printed and the following message appears at the bottom of the report:

"Report contains information as displayed on the Results screen".

The report provides the following information:

Header: Report Title, Preliminary indication (if Status is Ongoing, Pending, or Partial Complete; and/or if there are unignored Needs Attention conditions or a Needs Attention condition of Cannot Identify Barcode; and/or if the panel is not eligible for finalization), Laboratory Information (if configured), and Date and Time Printed, Software version/PUD version.

Body of Report: Top Region: Accession Number, Isolate Number, Sequence Number, Panel Type, Status (Ongoing, Complete), Critical panel indication, Test Start with time, Test End with time, Instr #/Station (location), Finalized status, Panel Lot # (if QC Lot Support is enabled), and Inoculum Density. The Lab Report is sorted by Accession # then by Isolate # within accessions.

Below this information the organism Final ID is listed. An asterisk next to the Final ID indicates that the ID was changed by the user. Below this, the Media Type (for Yeast ID panels only) appears.

Next any instrument ID results are listed, along with the Confidence Value for the result. In the lower region of the report, for ID tests, the Biochemical, Instr(ument) Result, and Expected Result are provided. For AST tests, the Antimicrobial, Instr(ument) MIC, Instr(ument) SIR,

BDXpert SIR, Final SIR, and Rule # are printed. If any panels have Resistance Markers, BDXpert Rules, Needs Attention, or Special Messages, these are printed at the bottom of the report. ID and AST sections of combination panels print on separate pages of the report.

For QC panels, in addition to the information listed above, the following information is included: Panel Lot # and Expiration Date, Tech ID, ID Broth Lot # and Expiration Date, AST Broth Lot # and Expiration Date, Indicator Lot # and Expiration Date, and Test Strain. The QC Status of PASS, REVIEW, ERROR, or FAIL is indicated.

The system can be configured (see **Section 5.9.2 System Configuration Sub-Tab**) to print an abbreviated lab report. The abbreviated report does not contain the individual biochemical results for ID or ID/AST panels. Press the **Print** button to print a report.

5.4 Finalization Tab

Finalization enables the user to select a panel and view the results from the Results screen. When the instrument is connected to the BD EpiCenter Data Management System, the Finalization screen is not available.

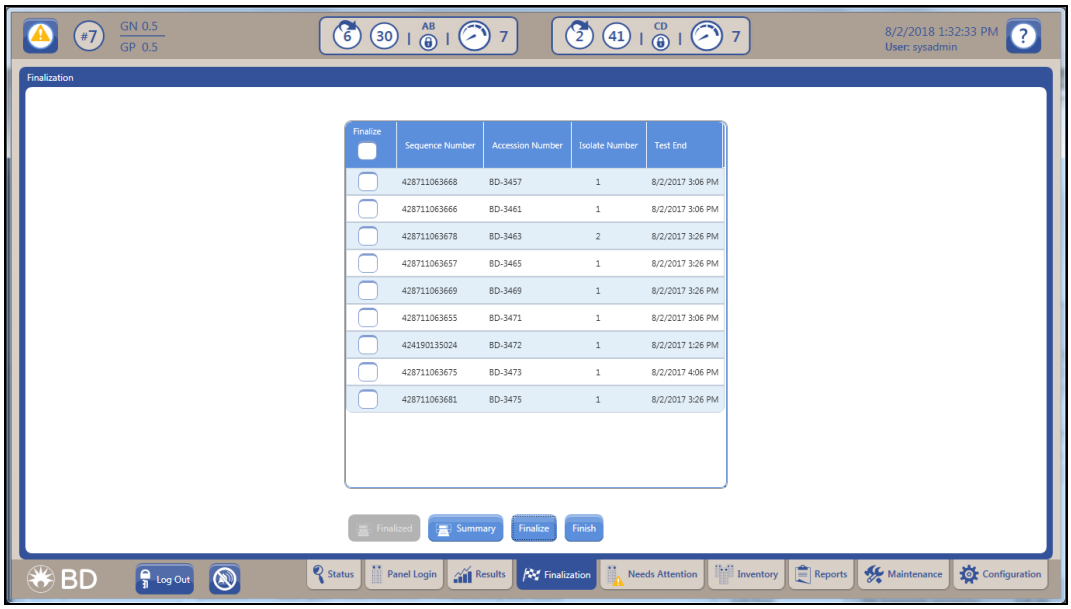


Figure 31 Finalization Tab

When the **Finalization** tab is selected, the instrument finds the records that are eligible for finalization. To be eligible, a panel must have a status of Removable, not be a QC panel, and have no unignored Needs Attention reasons. Eligible panels are sorted first by accession number and then by isolate number.

A maximum of 200 panels may be finalized in a given finalization session.

To finalize/batch finalize panels:

1. If there are no panels to be finalized, no data appears on the Finalization screen. If there ARE panels to finalize, the following options appear:
   a. To finalize ALL eligible panels, select **Finalize**.
   b. To finalize panels one at a time, select the box next to the panel, then select **Finalize**.
   c. To print a summary report of all panels eligible for finalization, select **Finalized**. This report shows the Accession Number (primary sort), Isolate Number (secondary sort), Test End date and time, Sequence Number, Instrument Number/Station, and Finalized status (* if finalized, blank if not). Select the panel row to go to the **Results** tab.
   d. If the user accesses **Results** to add or modify information before finalizing a panel, be sure to save the modifications, and return to the **Finalization** screen.
   e. Once an individual (or batch of) panel(s) has been finalized, the **Finalized** button appears on the Finalization screen. This action enables the printing of Lab Reports for all panels that have been finalized during this session (up to 200 maximum).
   f. Continue to review panel records and finalize until no additional panel records are displayed.

The user can print two types of report:

- Standard Lab Report(s)
- Finalization Summary Report.

The Lab Report can only be printed after one or more panels have been finalized. The Summary report may be printed any time.

Finalization fields:

Sequence Number

This Read-only field shows the panel's sequence number.

Accession Number

This Read-only field shows the panel's accession number.

Isolate Number

This Read-only field shows the panel's isolate number.

Test End

This Read-only field shows the panel's end of testing date and time.

5.5 Needs Attention Tab

The Needs Attention tab displays a list of panels in the instrument's database that have encountered a condition that requires operator attention. These conditions generally represent problems with the panels themselves, or with the information related to the panels. If the user is unable to see the **Ignore** check box alongside the Needs Attention Reason, then the user must correct that condition.

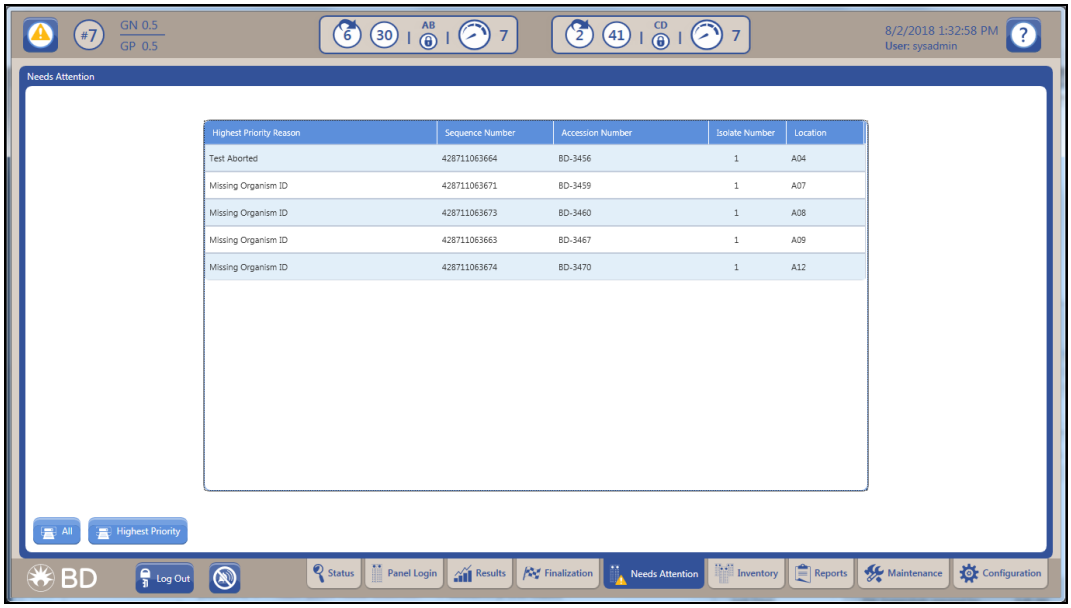


Figure 32 Needs Attention Tab

The Needs Attention screen lists the highest priority reason (see Table below). Select a panel to open the results screen in the Needs Attention tab. It lists additional reasons if they exist. Two reports are available for printing:

- all Needs Attention reasons
- highest priority Needs Attention reasons

The user can access the first 200 panels with the highest priority Needs Attention message from this tab. When the user selects the Needs Attention icon, the messages are displayed on the Needs Attention Sub-tab. Any action performed by the user with regards to the Needs Attention messages will be executed from the Results Tab that houses the Needs Attention Sub-Tab (see **Section 5.3.9 Needs Attention Sub-Tab**).

Condition	Active Operations
Test Aborted	• ignore • locate panel • delete panel
Cannot Identify Barcode	• ignore • locate panel
Cannot Read Panel Wells	• locate panel • delete panel

Condition	Active Operations
Panel Lot Expired	• ignore • Ignore All
Invalid AST Results	• ignore
Panel Missing	• ignore • delete panel
No Growth on Panel	• ignore • locate panel • delete panel
Panel Lot Undefined	• none to address condition
Review QC results	• ignore • locate panel • delete panel • panel results
Missing Accession Number	• locate panel • panel results
Missing Organism ID	• panel results
Cannot Determine Organism ID	• ignore • panel results
Invalid Organism ID	• ignore • panel results
Organism ID Conflict	• panel results
BDXpert Rule Flagged (if enabled and manual)	• panel results
Pending Too Long	• ignore

Table 14 Needs Attention Resolutions

The Needs Attention screen lists the first 100 panels with a Needs Attention status, sorted by reason code (in the same order as the list above) and then by accession number within each reason code. Panels without an accession number are listed first within each Needs Attention reason code. Even after panels have been removed from the Needs Attention list, the highest priority reason code in the Panel Results screen can still be viewed.

Needs Attention resolution options

Reason – The highest priority reason appears here. To view all the reasons with the Needs Attention status see **Section 5.3.9 Needs Attention Sub-Tab**.

Locate panel – This field is available only if the instrument cannot read the bar code. It causes the carousel to rotate to the panel's location and lights the station where the panel resides.

Print – The user can all the panels and all the reasons with the Needs Attention status.

Highest Priority – Displays the highest priority reason of a panel.

Condition	Meaning	Possible Cause(s)	Resolution(s)
Cannot identify barcode	Internal barcode scanner could not read a panel barcode in a station where the instrument could determine that a panel was present	• Barcode label obscured or missing • Unknown panel type was placed into the instrument	Locate the panel in the instrument and examine the barcode • If the barcode is obscured, the panel must be discarded and another inoculated • If the barcode appears to be intact, replace the panel and close the door. After the next inventory, check the Panel Needs Attention screen. If the panel does not appear, the internal scanner can now read the panel

5.6 Inventory Tab

The Inventory tab provides a list of all panels in the instrument (except temperature reference panels). This list can be sorted in ascending or descending order by the following fields:

- sequence number
- accession number
- results
- needs attention reason

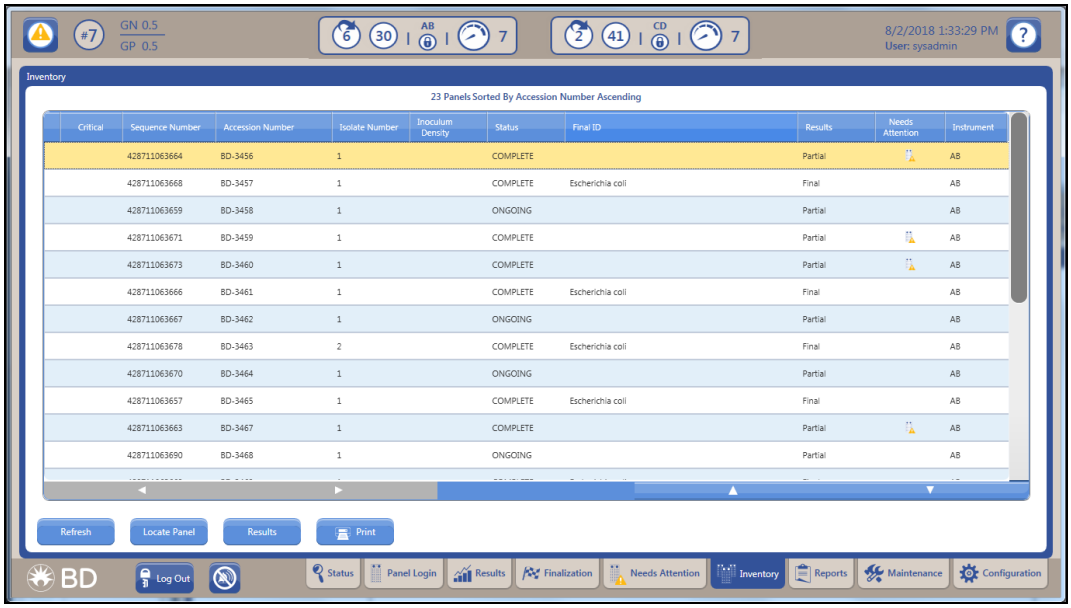


Figure 33 Inventory Tab

The initial default sort order is by accession/isolate number in ascending order. Subsequently, the list defaults to the last sort criteria and screen configuration (primary/secondary) used. If there are no panels in the instrument **No Data Available** appears on the screen.

The top of the Panel Inventory screen shows (see **Figure 33 Inventory Tab**):

1. the number of panels in the list (if there is more than one panel)
2. the sort field, and
3. whether the sort field is ascending or descending.

The following fields are shown on the Panel Inventory screen (if the information is known) (see **Figure 33 Inventory Tab**):

- A **!** (exclamation mark) at the beginning of the row indicates that a critical panel or a panel with a resistance marker has not been acknowledged
- Critical - This check box is selected if panel has been marked as Critical at login
- Sequence Number (of the panel)
- Accession Number (panels without accession numbers are listed first)
- Isolate Number
- Inoculum Density (blank for AST panels; ? for ID panels until first test completes)
- Status (ongoing; complete; rapid if Rapid Completion is enabled and has been triggered for a panel)
- Final (Organism) ID
- Results
  - (**final** if panel is complete and there are no active Needs Attention conditions) [all MIC results are determined for an AST panel, or all MIC values *and* the organism ID are determined for a Combination panel, or the organism ID is determined for an ID panel];
  - **partial** if a panel is ongoing or complete but has an active (unignored) Needs Attention condition [at least one MIC value is determined for an AST or Combination panel, or the organism ID is determined for a Combination panel];
  - **none,** if no MIC values or organism ID is determined for any type of panel.
- Needs Attention - the active Needs Attention icon appears if an unresolved Needs Attention reason exists; it is **blank** when no Needs Attention reasons exist or they have all been ignored).
- Instrument - the instrument in which the panel is located.

After the list appears, highlight a panel and access the Results screen to:

- view or edit panel information
- perform an instrument locate panel operation
- to print a Lab Report for panels with final or partial results

5.7 Reports Tab

The following instrument reports are available for printing from the Reports tab:

- **Section 5.7.3 Accession Lab Report**
- **Section 5.7.12 Antimicrobial Code Report**
- **Section 5.7.10 BDXpert Rule Set Database Report**
- **Section 5.7.2 Completed Lab Report**
- **Section 5.7.7 Cumulative QC Report**
- **Section 5.7.8 Daily Instrument Report**
- **Section 5.7.9 Custom Interpretation Rule Set Report**
- **Section 5.7.4 Needs Attention List Report**
- **Section 5.7.11 Organism ID Code List Report**

- Section 5.7.18 Panel Lot Report
- Section 5.7.19 Panel Lot Database Report
- Section 5.7.6 QC Lab Report
- Section 5.7.5 Resident Panel Report
- Section 5.7.13 Lab Report/QC Lab Report
- Section 5.7.14 Finalization Summary Report
- Section 5.7.13 Lab Report/QC Lab Report
- Section 5.7.15 Custom Breakpoint Difference Report
- Section 5.7.16 Current QC Panel Lot Report
- Section 5.7.17 Historical QC Panel Lot Report

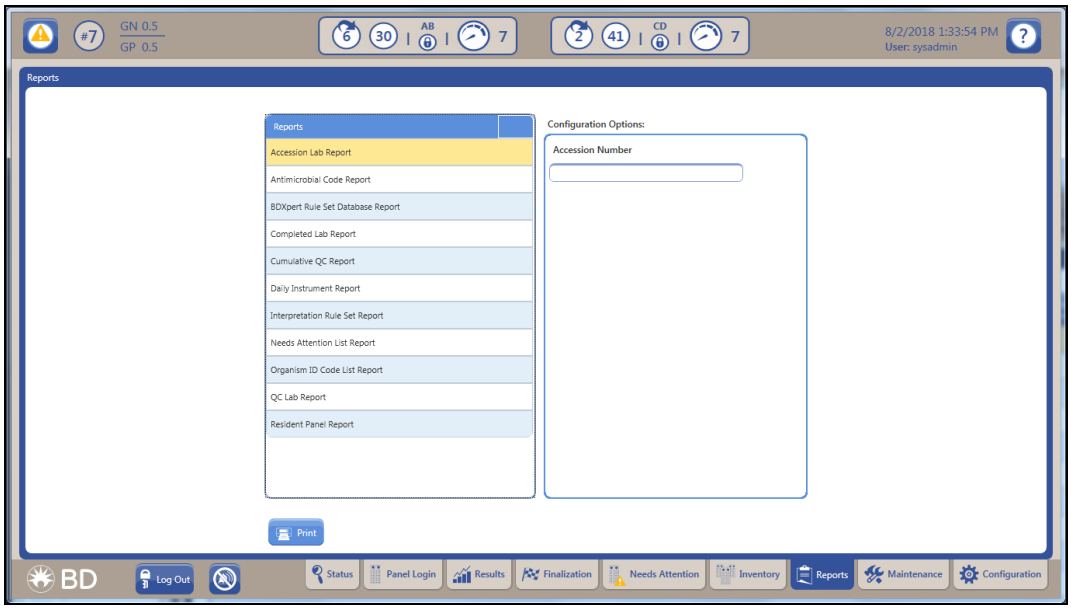


Figure 34 Reports Tab

5.7.1 How to Print Reports

To print a report:

1. Select the **Reports** tab.
2. Highlight the desired report.
3. Complete any additional fields (such as an Accession Number for the Accession Lab Report) and select **Print Reports**.

Several reports can also be printed from the screens that relate to them (e.g., Needs Attention List Report).

Each of the reports is discussed in greater detail in the sections that follow.

5.7.2 Completed Lab Report

This report contains information for **all panels** whose status became **Complete** during the time period selected (up to the past 48 hours). The report provides the following information:

Header: Report Title, Preliminary indication (if Status is Ongoing, Pending, or Partial Complete; and/or if there are unignored Needs Attention conditions or a Needs Attention condition of Cannot Identify Barcode; and/or if the panel is not eligible for finalization), Laboratory Information (if configured), and Date and Time Printed, Software version / PUD version.

Body of Report: On top, the Accession #, Isolate #, Sequence #, Panel Type, Status (Ongoing, Complete), Critical panel indication, Test Start with time, Test End with time, Instr #/Station (location), Finalized status, Panel Lot # (if QC Lot Support is enabled), and Inoculum Density are displayed. The Completed Lab Report is sorted by Accession # then by Isolate # within accessions.

For QC panels, the following information is included (in addition to the information listed above):

- Panel Lot # and Expiration Date,
- Tech ID,
- ID Broth Lot # and Expiration Date,
- AST Broth Lot # and Expiration Date,
- Indicator Lot # and Expiration Date, and
- Test Strain.

The QC Status of PASS, REVIEW, ERROR, or FAIL is indicated.

Below this information, the organism Final ID is listed. An asterisk next to the Final ID indicates that the ID was changed by the user. Below this, the Media Type (for Yeast ID panels only) appears.

Next, Instrument ID results are listed, along with the Confidence Value for the result. In the lower region of the report, the following are provided:

For ID tests: the Biochemical, Instr(ument) Result, and Expected Result are provided.

For AST tests: the Antimicrobial, Instr(ument) MIC, Instr(ument) SIR, BDXpert SIR, Final SIR, and Rule # are printed.

If any panels have Resistance Markers, BDXpert Rules, Needs Attention, or Special Messages, these are printed at the bottom of the report. Any SIR values and Rule # are not reported for QC panels.

ID and AST sections of combination panels print on separate pages of the report.

5.7.3 Accession Lab Report

This report is a collection of lab reports for a specified accession number. It provides information for the specified accession number. Such information includes, as applicable:

- organism ID results, including specific biochemical reactions
- AST results including SIR interpretation and MIC

- QC pass/fail results
- any BDXpert Rules that were triggered

The report provides the following information:

Header: The header displays Report Title, Preliminary indication (if Status is Ongoing, Pending, or Partial Complete; and/or if there are unignored Needs Attention conditions or a Needs Attention condition of Cannot Identify Barcode; and/or if the panel is not eligible for finalization), Laboratory Information (if configured), Date and Time Printed, Software version / PUD version.

Body of Report: On top, the Accession #, Isolate #, Sequence #, Panel Type, Status (Ongoing, Complete), Critical panel indication, Test Start with time, Test End with time, Instr #/Station (location), Finalized status, Panel Lot # (if QC Lot Support is enabled), and Inoculum Density are displayed. The Completed Lab Report is sorted by Accession # then by Isolate # within accessions.

Below this information the organism Final ID is listed. An asterisk next to the Final ID indicates that the ID was changed by the user. Below this, the Media Type (for Yeast ID panels only) appears.

Next, any Instrument ID results are listed, along with the Confidence Value for the result. In the lower region of the report the following are provided:

- For ID tests: the Biochemical, Instr(ument) Result, and Expected Result are provided.
- For AST tests: the Antimicrobial, Instr(ument) MIC, Instr(ument) SIR, BDXpert SIR, Final SIR, and Rule # are printed.

If any panels have Resistance Markers, BDXpert Rules, Needs Attention, or Special Messages, these are printed at the bottom of the report. Any SIR values and Rule # are not reported for QC panels.

ID and AST sections of combination panels print on separate pages of the report.

For QC panels, in addition to the information listed above, the following information is included:

- Panel Lot # and Expiration Date
- Tech ID, ID Broth Lot # and Expiration Date
- AST Broth Lot # and Expiration Date
- Indicator Lot # and Expiration Date
- Test Strain

The QC Status of PASS, REVIEW, ERROR, or FAIL is indicated.

5.7.4 Needs Attention List Report

This report lists all the panels in the instrument's database that have an unignored Needs Attention. This report can also be printed from the Needs Attention screen. The user is able to filter the reports on the highest priority reason by selecting the Filtered check box. If the check box is not selected, the report shows all reasons. The report provides the following information:

Header: The header displays Report Title, Filtered report notification (if selected), Laboratory Information (if configured), and Date and Time Printed.

Body of Report: The report displays Needs Attention Reason, Sequence #, Accession #, Isolate #, Instr #/Station (location), and Status (Ongoing, Complete). If the report is filtered (default selection), an asterisk appears to the left of the Reason for panels with multiple Needs Attention

conditions. The report is sorted by the priority of the Needs Attention Reasons (**Figure 35 Needs Attention List Report**), and by Accession within each Reason type.

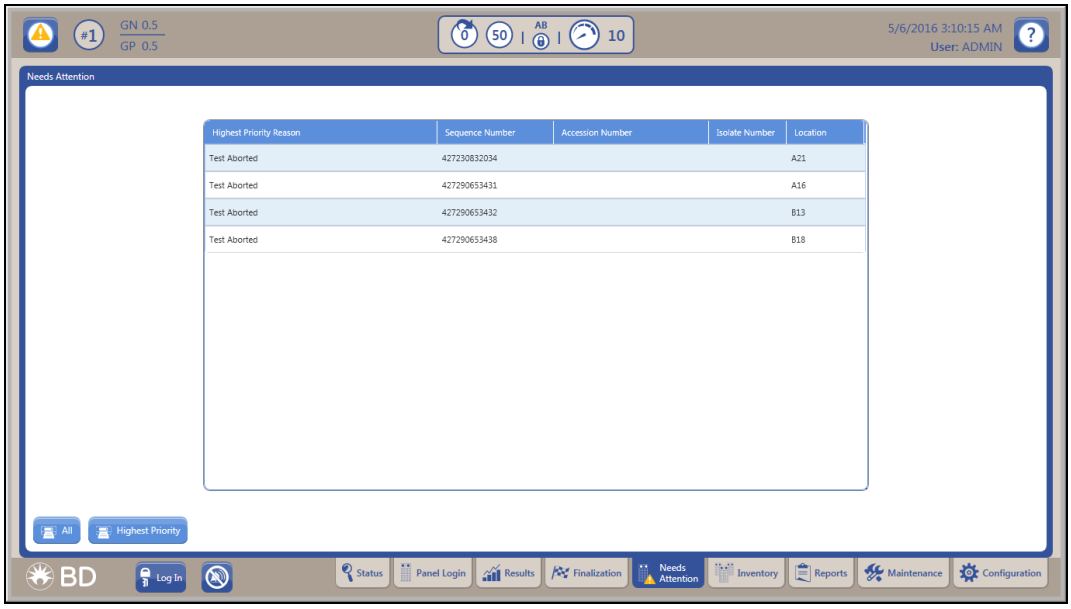


Figure 35 Needs Attention List Report

5.7.5 Resident Panel Report

This report lists the panels contained in stations 1–25 for each tier detected during the last inventory scan. The report provides the following information:

Header: The header displays Report Title, Laboratory Information (if configured), Date and Time Printed, and Instrument #.

Body of Report: The report contains the Accession #, Isolate #, Sequence #, QC (if panel is QC), Test Start with time, Inoculum Density, Panel Type, Status (Ongoing, Complete), and the highest priority Needs Attention Reason if one exists. The report is sorted by Accession # and then by Isolate # within each Accession.

5.7.6 QC Lab Report

This report lists all QC panels from the Test Start date entered to the current date. It lists all Test Strain Organisms that have completed testing and all biochemical and/or antimicrobial MIC results (for a specified panel lot number) that exist in the BD Phoenix database. The report provides the following information:

Header: The header displays the Report Title, Laboratory Information (if configured), and Date and Time Printed, Software version / PUD version.

Body of Report: The report contains the Panel Lot # and Expiration Date, Test Start and time, Test End and time, Panel Type, Instr #/Station (location), Status (Ongoing, Complete), Tech ID, ID Broth Lot # and Expiration Date, AST Broth Lot # and Expiration Date, Indicator Lot # and Expiration Date, Sequence #, Accession #, Isolate #, Test Strain, Inoculum Density, Media Type (Yeast ID panels only), Instrument ID(s), and QC Status of PASS/FAIL/REPEAT/REVIEW. At the bottom of the report, any Needs Attention reasons or Special Messages are printed. Each Biochemical, along with Instr(ument) Result, and Expected Result are provided, as well as Antimicrobials, Instr(ument) MICs, Expected MICs, and Pass/Fail status.

This report is only available when BD EpiCenter is disabled.

5.7.7 Cumulative QC Report

This report provides information on completed quality control testing of all panel types. It provides the following information:

Header: The header displays the Report Title, Laboratory Information (if configured), Date and Time Printed, and Instrument #.

Body of Report: The report contains the Selection Criteria: Panel Lot #, Panel Type, and Test Strains selected.

Below this, the panel Sequence # (sort order), QC Status (PASS, FAIL, REVIEW, ERROR), Test Strain, Test Start and Time, Panel Lot #, ID Broth Lot #, AST Broth Lot #, Indicator Lot #, and Tech ID are listed for each panel.

This report is only available when BD EpiCenter is disabled.

5.7.8 Daily Instrument Report

This report lists the status of the instrument at the time the report is generated, and provides areas to record maintenance activities. The Daily Instrument Report can be set to print automatically at a specified time.

The report provides the following information:

Header: The header displays Report Title, Laboratory Information (if configured), Date and Time Printed, and Software version/PUD version.

Body of Report: The report contains the Instrument #, Serial #, Instrument Temperature Pass/Fail status, Carousel Rotational Test Pass/Fail status, Power Supply Check Pass/Fail status, Normalizer Panels Sequence #, Pass/Fail status, and Expiration Status (date if expiration is more than 60 days; “expires on date” if expiration is between 60 and 0 days; and “EXPIRED” if the panel is expired) for each tier, and blanks to record the reading, Pass/Fail status, and Tech ID for each of the following maintenance checks: Daily: Instrument Temperature (Status screen), Standard Panel Temperature, Printer Paper Supply: Weekly: Internal Green LEDs, Internal Red LEDs, Internal Amber LEDs, Alert Indicator, and Instrument Audible Alarm. An area is provided for comments at the bottom.

The instrument temperature is considered to have passed when there are no outstanding E01 temperature alerts.

5.7.9 Custom Interpretation Rule Set Report

This report lists the antimicrobial breakpoints of the currently selected Interpretation Rule Set (defined as the default Rule Set in the Instrument Configuration screen). The report provides the

following information:

Header: The header displays the Report Title, Laboratory Information (if configured), and Date and Time Printed.

Body of Report: The report contains the Rule Set, Rule Version, and columns for Antimicrobial (sort order), Test Group, Organism Group, Organism Name, S(usceptible) value, and R (esistance) value. Each antimicrobial breakpoint is listed in a separate row of the report.

This sub-tab is not available if BD EpiCenter is connected to the BD Phoenix M50 system.

The Interpretation Rule Set is a large report. Spooling and printing the report can consume system resources such that other reports cannot be printed until the current one completes.

To print reports of ALL the rule sets in the instrument:

1. Select a rule set in **System Configuration** (see **Section 5.9.2 System Configuration Sub-Tab**), and then select **Reports.**
2. Select Interpretation Rule Set Report. The currently selected rule set prints.
3. When printing is complete, return to **System Configuration**, and select the next rule set.
4. Access **Reports** again and print the current Interpretation Rule Set.
5. Continue selecting rule sets and printing until all rule set selections are printed. Remember to return to System Configuration and select the desired rule set to use for interpretations when all printing is complete.

> NOTE
>
> Do not modify the interpretation Rule Set while there are ongoing panels. This could lead to inaccurate interpretations.

Interpretation Codes (some examples):

CLSI or EUCAST

Interpretation Code	Interpretation Name
ACIN_IC	*Acinetobacter* spp.
AERM_IC	*Aeromonas* spp.
BURCEP_IC	*Burkholderia cepacia* complex
ENTC_IC	*Enterococcus* spp.
ENTERIC_IC	*Enterobacteriaceae*
NFGNROTH_IC	Nonfermentative GNR, other than ACIN_IC, BURCEP_IC, PSEAER_IC, STEMAL_IC, ACTBACT_IC, CARHOM_IC, EIKCOR_IC
PSEAER_IC	*Pseudomonas aeruginosa*
STAAUE_IC	*Staphylococcus aureus*
STAOTH_IC	*Staphylococcus* spp., other than STAAUE_IC

Interpretation Code	Interpretation Name
STEMAL_IC	*Stenotrophomonas maltophilia*
STRBET_IC	*Streptococcus* beta-hemolytic
STROTH_IC	Streptococcus spp., other thanSTRBET_IC, STRPNE_IC, STRVIR_IC
STRPNE_IC	*Streptococcus pneumoniae*
STRVIR_IC	*Streptococcus viridans* group

5.7.10 BDXpert Rule Set Database Report

This report lists each BDXpert rule number and the text describing the rule, whether each rule is enabled/disabled and whether each rule shall trigger automatically/manually in the system. The report provides the following information:

Header: Report Title, Laboratory Information (if configured), Date and Time Printed, Rule Set (CLSI, SFM, EUCAST, or Custom), and Based On (CLSI, SFM, or EUCAST if Rule Set is Custom).

Body of Report: Rule #, text of the rule, Enabled/Disabled status, and Automatic/Manual status.

The BDXpert Rule Set Database is a large report. Spooling and printing the report can consume system resources such that other reports cannot be printed until the current one completes.

5.7.11 Organism ID Code List Report

This report prints all Organism Names and Abbreviations for all Organism Names that exist in the BD Phoenix database. It provides the following information:

Header: The header displays the Report Title, Laboratory Information (if configured), and Date and Time Printed.

Body of Report: The report contains the Organism name (sort order), BD Code (abbreviation), and LIS Code (if enabled).

The Organism ID Code List is a large report. Spooling and printing the report can consume system resources such that other reports cannot be printed until the current one completes.

5.7.12 Antimicrobial Code Report

This report prints all antimicrobials and abbreviations for all antimicrobials that exist in the BD Phoenix database from all panel configurations. The report provides the following information:

Header: Report Title, Laboratory Information (if configured), and Date and Time Printed.

Body of Report: Antimicrobial name (sort order), BD Code (abbreviation), and LIS Code (if enabled).

The Antimicrobial Code is a large report. Spooling and printing the report can consume system resources such that other reports cannot be printed until the current one completes.

5.7.13 Lab Report/QC Lab Report

This report (see **Section 5.3.10 Lab Report**) contains all information for a panel sequence number that exists in the BD Phoenix database, including all information in the Panel Results screen, any special messages, BDXpert Rules that triggered, or Needs Attention Reasons if they exist.

> NOTE
>
> The Lab Report is not accessible from Reports. It can only be printed from Results or Finalization.

Panel Inventory Lab Report

These reports print the same information for all panels listed in the Panel Inventory screen (i.e., resident in the instrument and with final or partial results).

The QC Lab Report (see **Section 5.7.6 QC Lab Report**) is also accessible from the Results Tab (see **Section 5.3 Results Tab**). It provides similar information to the Lab Report, but for QC panels.

5.7.14 Finalization Summary Report

This report contains a list of all the panels eligible for finalization at the time the report was requested, as well as finalization status. The Finalization Summary Report is not accessible from Reports; it can only be printed from Finalization. See **Section 5.4 Finalization Tab** for more information.

5.7.15 Custom Breakpoint Difference Report

This report contains a list of differences between old breakpoints and new ones after a BD Phoenix Update Data or install/upgrade operation. The Custom Breakpoint Difference Report is not accessible from Reports. It can only be printed from the Custom Interpretation Rule Set (Configuration) tab by selecting the **Difference Report** button located at the bottom of the screen. Breakpoints that have been customized will not be overwritten with updates from the PUD. The Custom Breakpoint Difference Report will provide the appropriate data to determine if customized breakpoints need to be manually updated to reflect the currently installed PUD. See **Table 15 Rules Updates** for details on how breakpoints are updated.

5.7.16 Current QC Panel Lot Report

This report contains information on the most recent QC test for each of the required strains for a panel lot, up to a maximum of 20 strains. The report includes information for any instruments whose data has been restored to the current instrument. The Current QC Panel Lot Report cannot be printed from Reports. It can only be printed from Panel Lot Definition. See Section **Section 5.9.9 Panel Lot Definition Sub-Tab**.

This report is only available when BD EpiCenter is disabled and QC Lot Support is enabled.

5.7.17 Historical QC Panel Lot Report

This report contains information on all tests for a strain for the current instrument (only), up to 200 tests. The Historical QC Panel Lot Report cannot be printed from Reports. It can only be printed from Panel Lot Definition. See **Section 5.9.9 Panel Lot Definition Sub-Tab**.

This report is only available when BD EpiCenter is disabled and QC Lot Support is enabled.

5.7.18 Panel Lot Report

This report lists all the panel records for any panel lot number in the current instrument. The report first lists clinical panels, then QC panels. Within each of those groups, the report is sorted by Accession # then Isolate #.

The report provides the following information:

Header: The header displays the Report Title, Laboratory Information (if configured), Date and Time Printed, Instrument where printed.

Body of Report: The report contains the Panel Lot # and Panel Type; Accession #, Isolate #, Sequence #, QC (if panel is QC), Test Date, and Status (Pending, Ongoing, Complete) for each panel tested that belongs to the lot.

This report is only available when BD EpiCenter is disabled and QC Lot Support is enabled.

5.7.19 Panel Lot Database Report

This report lists all the defined panel lots in the current instrument, and provides statistical and reference information on those lots.

The report provides the following information:

Header: The header displays the Report Title, Laboratory Information (if configured), Date and Time Printed, Instrument where printed.

Body of Report: The report contains the Panel Lot # (sort order, descending); Panel Type; Expiration Date; Extension Date (if Expiration date was extended); Start and End Sequence #s (Range); Definition Date; First and Last Date Used; and number of Panels Used.

This report is only available when BD EpiCenter is disabled and QC Lot Support is enabled.

5.8 Maintenance Tab

The Maintenance tab (see **Figure 36 Maintenance Screen**) provides several tasks for performing instrument maintenance. There are user tasks for weekly and as needed maintenance. There are other tasks for BD use only.

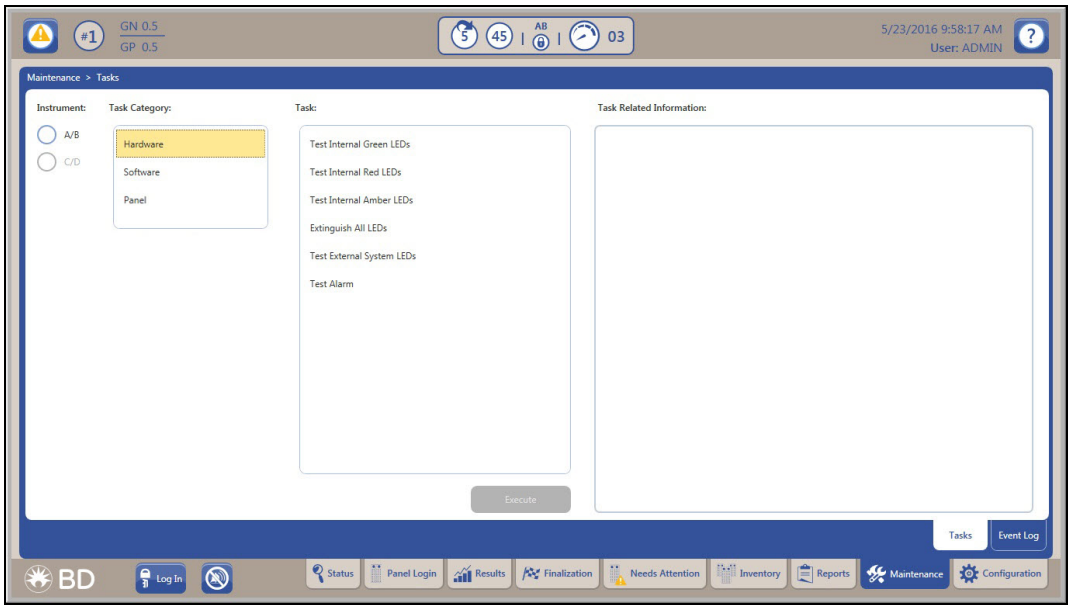


Figure 36 Maintenance Screen

Under Task Category, select the category of maintenance to be performed:

- Hardware
- Software
- LIS (will appear only if LIS is enabled)
- Panel

5.8.1 Maintenance Hardware Functions

For detailed information, see **Section 7.1 Routine Maintenance**.

To make sure that the instrument is functioning correctly, test the system indicators and the alarms (see **Table 17 Routine Maintenance: Time-frame and Procedure**).

5.8.2 Maintenance Software Functions

Each of the software functions is described in detail below. Unless otherwise specified, perform the following steps to save data after accessing each software function via the Maintenance tab.

1. Insert the USB key, BD part number 443866, into the AIO PC.
2. Select the Maintenance screen tab.
3. On the Maintenance screen select Software under the Task Category.
4. From the Task list select the function to be performed.
5. Select **Execute**; the **Are You Sure?** message is displayed.
6. Select **OK**.

Save System Data Task

Under certain circumstances, BD may advise that system data be saved to a USB key. These circumstances include some error conditions and system malfunctions. The Save System Data function is NOT a backup and cannot be restored by the user.

Save Event Log Task

Save Event Log to Network should only be used when advised by a local BD representative. This option appears only when the instrument is connected to a BD EpiCenter system. It enables the event log to be saved to a BD EpiCenter system.

Under certain circumstances, a BD representative may advise that the Event Log be saved to the BD EpiCenter system or to a USB key. These circumstances include some error conditions and system malfunctions. The Save Event Log function copies the system event log, which contains logged system messages about various system, instrument, and communications events. The instrument door must be closed, and the instrument must be idle to save the Event Log.

Upgrade Task

Upgrade enables field service experts to upgrade the instrument and the AIO PC. The software update will be recorded on the Daily Instrument Report for reference. If the system is not connected to BD EpiCenter, customers can upgrade the system. For more information, contact the local BD representative.

To perform this operation, the instrument:

- door must be closed
- must be idle
- should not be taking readings
- must not run algorithms

Once the upgrade is complete, the system will reboot and the newly installed version of the application on the AIO PC will synchronize with the instrument. If the upgrade includes new software for internal components of the instrument, these updates will take place immediately and the use of the application will be temporarily blocked. Once the instrument software has been successfully updated, the application will be available for use.

If custom breakpoints are in place, print the Custom Breakpoint Difference Report (see **Section 5.9.6 Custom Interpretation Rule Set Sub-Tab**).

> NOTE
>
> When the software is updated, or when the PUD install is performed, if any of the standard interpretation rule sets have changed, new rule sets are installed into the system database. Since custom rule sets are based on standard rule sets, a custom interpretation rule set will be merged with new standard rules. If custom breakpoints are used, be sure to print out the Custom Breakpoint Difference Report (**Section 5.9.6 Custom Interpretation Rule Set Sub-Tab**) after each system update or PUD install.

Save User Data Task

Save User Data allows the back up of Configuration parameters to a USB key. This includes Custom Interpretation Rule Set Configuration and BDXpert Rules Configuration. The information

that is saved is for the current instrument only. However, information saved at one instrument can be restored on another instrument. It is recommended that Configuration parameters be stored on a USB key in the event of a system failure.

Restore User Data Task

Restore User Data enables the restoration of the saved configuration parameters. This data includes: Custom Interpretation Rule Set Configuration, and BDXpert Rules Configuration. To restore, the instrument door must be closed.

BD Phoenix Update Data (PUD)

A BD Phoenix Update Data may be provided from time to time to update BD Phoenix M50 instrument databases and support files. These updates do not affect or change the basic instrument application software. For this reason, the Status screen shows both the software version and the PUD version near the top of the screen.

BD Phoenix Update Data (PUD) enables the update of numerous data files in the instrument, such as antimicrobial breakpoints and rules, QC data, drugs, organisms, etc.

> NOTE
>
> After a PUD upgrade, a Custom Breakpoint Difference Report should be printed and reviewed to determine if manual updates are required for custom breakpoints. See **Section 5.9.6 Custom Interpretation Rule Set Sub-Tab** for additional information on this report. The report is available only is the BD Phoenix M50 system is not connected to BD EpiCenter.
>
> See **Section 5.9.6 Custom Interpretation Rule Set Sub-Tab**l information on how custom interpretation rules are updated with a PUD upgrade.

Backup SQL Database Task

This feature provides data to BD Service for instrument troubleshooting purposes.

5.8.3 Maintenance of LIS Functions

Each of these functions is described in detail below. Unless otherwise specified, perform the following steps to save data after accessing each software function via the Maintenance tab.

1. Insert the USB key, BD catalog number 443866 into the AIO PC.
2. Select the Maintenance screen tab.
3. On the Maintenance screen select LIS under the Task Category.
4. From the Task list select the function to be performed.
5. Select **Execute**; the **Are You Sure?** message is displayed.
6. Select **OK**.

Save LIS Codes Task

Save LIS Codes enables all the Organism and Antimicrobial LIS codes you have defined to be saved. This produces a text file that can be edited on a PC, which might be quicker for some users who have many edits to perform. Then, the edited codes can be restored back to the BD Phoenix M50 instrument. The function also enables codes to be copied from one instrument to another. Save LIS Codes appears on the Maintenance tab only if LIS Communications is enabled.

Entries in the text field consist of:

- Identifier (ORG, QC_ORG, DRUG)
- BD Code
- Short Name/Drug
- LIS Code

Codes cannot be added or deleted, and only the LIS Code portion can be modified. If another field is changed, the instrument will not restore the codes.

Restore LIS Codes Task

Restore LIS Codes enables the restoration of the Organism and/or Antimicrobial codes that were previously saved. The restore operation completely overwrites the existing Organism/Antimicrobial LIS Code database Codes will not be restored if any field other than LIS Code was modified, or if LIS Code was entered in an incorrect format. If this happens, an error log is written, and the file can be reviewed to see what caused the error. Restore LIS Codes appears on the Maintenance menu only if LIS Communications is enabled.

5.8.4 Maintenance Panel Functions

Each of these functions is described in detail below. Unless otherwise specified, perform the following steps to save data after accessing each software function via the Maintenance tab.

1. Insert the USB key into the AIO PC.
2. Select the Maintenance screen tab.
3. On the Maintenance screen select Panel under the Task Category.
4. From the Task list select the function to be performed.
5. Select **Execute**; the **Are You Sure?** message is displayed.
6. Select **OK**.

Save Panel Lot Definitions Task (Panel lot definition is enabled and system is not connected to BD EpiCenter)

This enables the transfer of lot definitions (and QC panel results) to other instruments so that the records can be viewed/used there. Save Panel Lot Definitions saves the defined panel and related data (Sequence #s, Expiration Dates, etc.), and QC results for any strains tested in those. Save Panel Lot Definitions only applies when QC Lot Support is enabled.

Restore Panel Lot Definitions Task (Panel lot definition is enabled and system is not connected to BD EpiCenter)

This makes Panel Lot definitions and QC panel results transferable in labs that use multiple instruments, so that a lot only has to be defined once using the box (carton) label. Restore Panel Lot Definitions only applies when QC Lot Support is enabled.

Save Panel Configuration Task

Save Panel Configuration enables the backup of the instrument's panel configuration. The information saved is for the current instrument only. However, information saved at one instrument can be installed at another instrument. This enables the presence of consistent panel configurations among all the instruments.

Install Panel Configuration Task

Install Panel Configuration enables the update of the instrument's panel configurations. To perform this operation, the instrument door must be closed.

> NOTE
>
> This operation should not be performed while there are ongoing panels.

5.8.5 Maintenance Field Service Functions

For Field Service use only.

5.8.6 Maintenance Internal BD Use Functions

For internal BD use only.

5.8.7 Maintenance Event Log Tab (confirm if active)

The Event Log provides a list of messages generated by LIS communications. Note that the screen (see **Figure 37 Event Log Screen**) will not contain messages if the BD EpiCenter system is connected. The messages represent status messages that have occurred during LIS communications such as:

- query messages,
- log entries,
- interface messages.

The Event Log list of LIS messages may be filtered based on date range. There is also a Find function to search for specific message content.

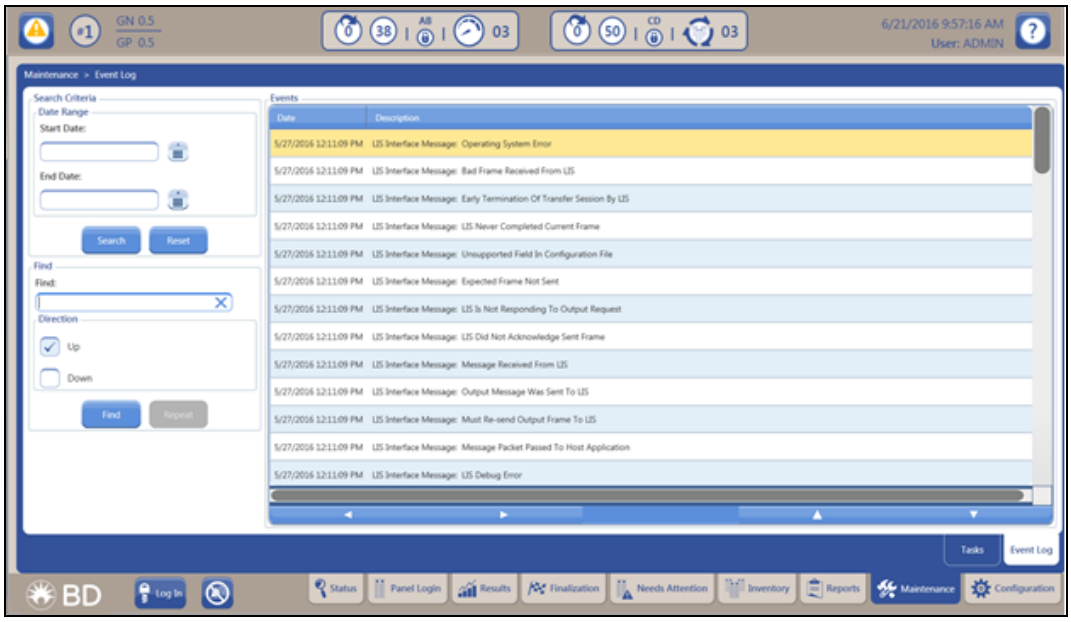


Figure 37 Event Log Screen

5.9 Configuration Tab

To access the configuration functions, select the **Configuration** tab. The configuration screen then appears with the following sub-tabs for each specific configuration:

- Section 5.9.1 Users Sub-Tab
- Section 5.9.2 System Configuration Sub-Tab
- Section 5.9.3 Communications Sub-Tab
- Section 5.9.4 Organism Configuration Sub-Tab
- Section 5.9.5 Antimicrobial Configuration Sub-Tab
- Section 5.9.6 Custom Interpretation Rule Set Sub-Tab,
- Section 5.9.7 BDXpert Rules Sub-Tab
- Section 5.9.8 Rapid Reporting Sub-Tab
- Section 5.9.9 Panel Lot Definition Sub-Tab
- Section 5.9.10 Instrument Sub-Tab

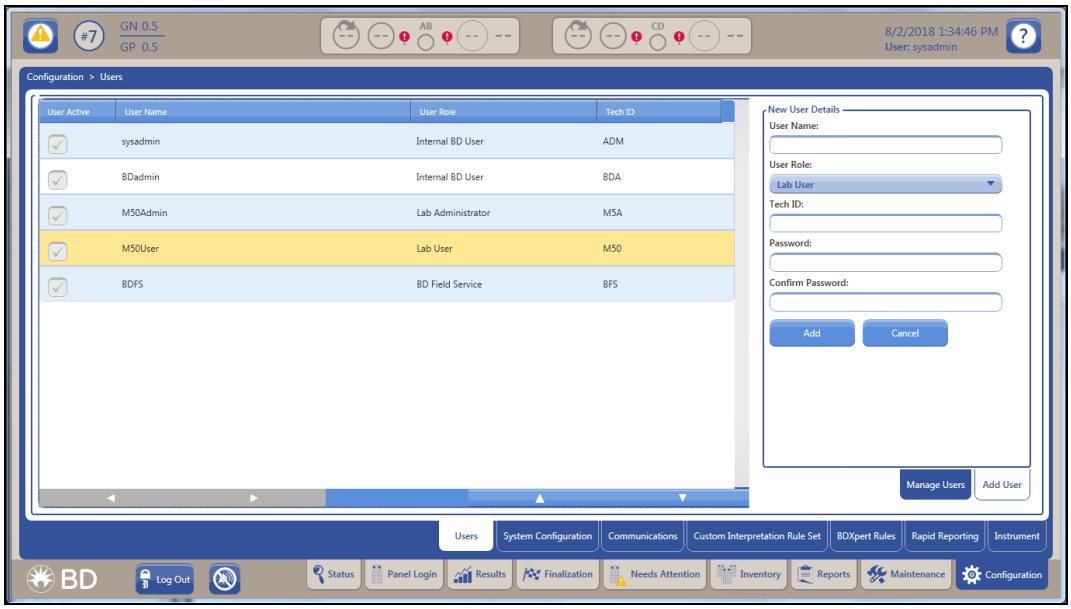


Figure 38 Configuration Tab

When the desired configuration parameters have been entered or modified, select **Save** to make the changes permanent.

> NOTE
>
> The Custom Interpretation Rule Set and BDXpert Rules Configuration tabs do not appear if the BD Phoenix M50 instrument is connected to and communicating with a BD EpiCenter system.

5.9.1 Users Sub-Tab

See **Section 4.1 User Access Management** for details.

5.9.2 System Configuration Sub-Tab

It is not available to the user when the system is connected to the BD EpiCenter. The following parameters can be set in System Configuration (see **Figure 39 Systems Configuration Screen**).

5.9.2.1 GENERAL System Settings

System Number

Select the system identification number. The default setting is 1. Choose a number from 1 to 99. If there is only one instrument, leave this value set at 1.

Rule Set

Select the rule set that the interpretation engine is to use. Only one rule set can be used. Choose from the following selections:

CLSI (Clinical and Laboratory Standards Institute)

EUCAST (European Committee on Antimicrobial Susceptibility Testing)

SFM (Société Française de Microbiologie)

Custom (defined in **Section 5.9.6 Custom Interpretation Rule Set Sub-Tab**)

Rule Version

This read-only field shows the current version of the rule set selected in the previous field.

Alarm (audible) Volume

Select the volume of the instrument's audible alarm. The default setting is 5. Select from 0 (audible alarm off) to 10 (loudest). Only the volume of Alert and Activity alarms (see **Section 4.3.3 Audible Tones and Alarms**) is affected by this setting.

Resistance Marker Notification

This field appears only when the BD Phoenix M50 instrument is connected to a BD EpiCenter system but is not communicating with it. Enable the instrument to operate in a standalone mode when communications with BD EpiCenter is interrupted. When this field is enabled, the BDXpertSystem Active field appears.

BDXpert System Active

This field activates the entire BDXpert System rules which includes CLSI, EUCAST, SFM, or Custom Interpretation Rules.

This field does not appear if the BD EpiCenter system is attached and communicating. However, if communication with the BD EpiCenter system is lost, the field reappears. This enables the activation of BDXpert rules interpretations in the standalone BD Phoenix M50 instrument. When communications with the BD EpiCenter system is restored, BDXpert rules interpretations are once again performed at the BD EpiCenter system, and this field is removed from the screen.

> NOTE
>
> Disabling all BDXpert rules also disables detection of Resistance Markers (e.g., ESBL), except those triggered by 1500-series rules.

Rapid Completion

This field enables the instrument to provide BDXpert AST results (SIR) before determining actual MIC values. The instrument MIC values are provided as soon as they can be accurately determined. Within a test panel, some MIC values may be available earlier than others. The rapid completion feature can be used to predict resistance for uncompleted antibiotics using the ID alone (intrinsic resistance), or ID with completed MICs of related antibiotics, or resistance marker tests (BL, ESBL). The BDXpert system is used to make these predictions. This can be useful in situations where, for example, the results for drugs that have not yet received MICs would be of no clinical value based on the other results that are already available. Antimicrobials with Rapid Complete BDXpert interpretations are indicated by a **C** in the MIC column on Results screens and Lab reports.

If Rapid Completion is selected at the BD Phoenix M50 instrument and the instrument is connected to BD EpiCenter, then it must also be enabled (checked) at the BD EpiCenter.

5.9.2.2 OPTIONS

Abbreviated Lab Report

Enabling this field causes the system to print a shortened version of the Lab Report. The shortened version does not contain results for the biochemical (ID) reactions. Disable this field to print the standard full-length Lab Report. The default is disabled (full length). Note that QC Reports always print standard full-length Lab Reports.

QC Lot Support

This field enables the QC Lot feature, which can be used to facilitate panel lot QC testing and tracking (see **Section 5.3.7 Lot Information Sub-Tab**).

Daily Instrument Report Printing

These reports can be printed at regular intervals or a specific report can be printed based on the time it was generated. See**Section System Check Box and EpiCenter Check Box**.

System Check Box and EpiCenter Check Box

The user can select either of the check boxes and the Daily Print Hour and Daily Print Minute fields to appear. The user can then set the time to tell the instrument to print a Daily Instrument Report automatically at the time specified in these fields. If automatic printing is disabled, the report can still be printed at any time from Reports.

> NOTE
>
> If the BD EpiCenter is not connected to the BD Phoenix M50 system, then the user will not be able to see the BD EpiCenter check box.

The following fields appear and must be completed before printing the reports. They have to be filled in just once and that information is retained for future prints.

Laboratory Information

Information entered in the Laboratory Information window prints in the header of system reports.

Name

Enter the laboratory name, up to 40 characters.

Address

Enter the address, up to 40 characters.

City

Enter the city (as well as state and zip code, if desired), up to 40 characters.

Director

Enter the name of the laboratory director, up to 40 characters.

NOTE

Laboratory Information, Name, Address, City and Director can contain only the first 256 ASCII characters.

Inoculum Density

Inoculum Density enables the default McFarland concentration for inoculum to be set. Select 0.25 (acceptable density of 0.20–0.30) or 0.5 (acceptable density of 0.50–0.60) for Gram Positive and Gram Negative panels (Strep panels use only 0.5). The default density is 0.5 for Gram Negative and Gram Positive panel types. The density for Yeast ID panels is fixed at 2.0 McFarland (acceptable density of 2.00–2.40). Inoculum density is applicable only to panels that have an ID side.

Default Media Type

Yeast – This field enables the selection of a default media type that appears during Panel Login when a Yeast ID panel sequence number is scanned or typed in. From the drop down box, highlight the desired media and select save to store the configuration setting. A default media type does not have to be specified, but a media type must be selected when logging in Yeast ID panels.

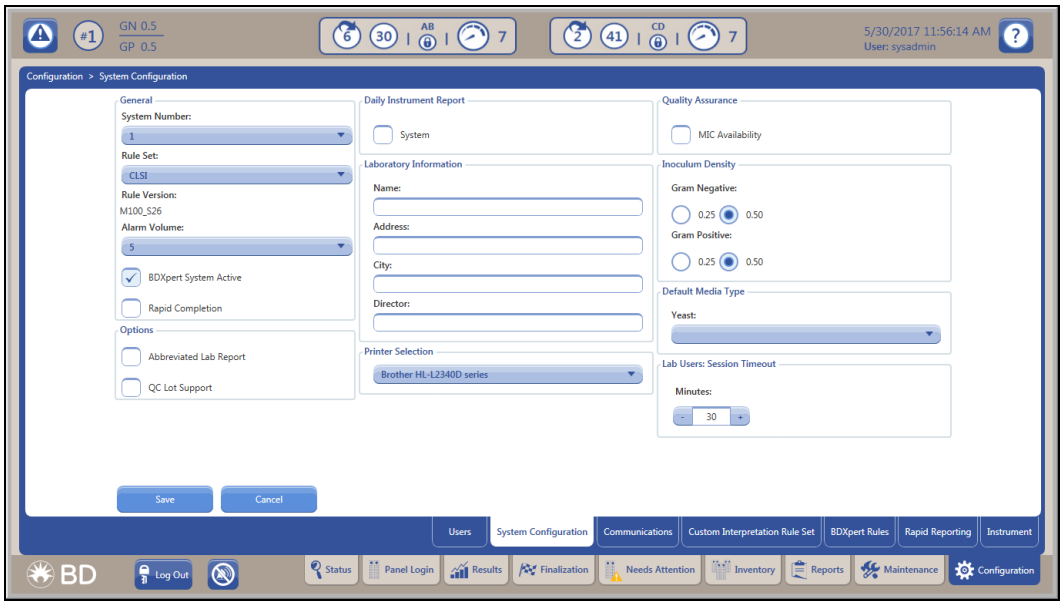


Figure 39 Systems Configuration Screen

Lab Users: Session Timeout

Minutes – This field enables the user to configure when the session will be timed out. It ranges from 15 through 240 minutes.

5.9.3 Communications Sub-Tab

The Communications Configuration screen (see **Figure 40 Communications Configuration Screen**) enables/disables and configures communications for the BD Phoenix M50 instrument

with a compatible LIS (Laboratory Information System). It also enables BD representatives to enable/ disable/adjust communications with the BD EpiCenter advanced data management system. Only LIS or BD EpiCenter communications can be enabled. If there is a BD EpiCenter system connected and communications with a LIS system is required, BD EpiCenter can be configured to communicate with the LIS.

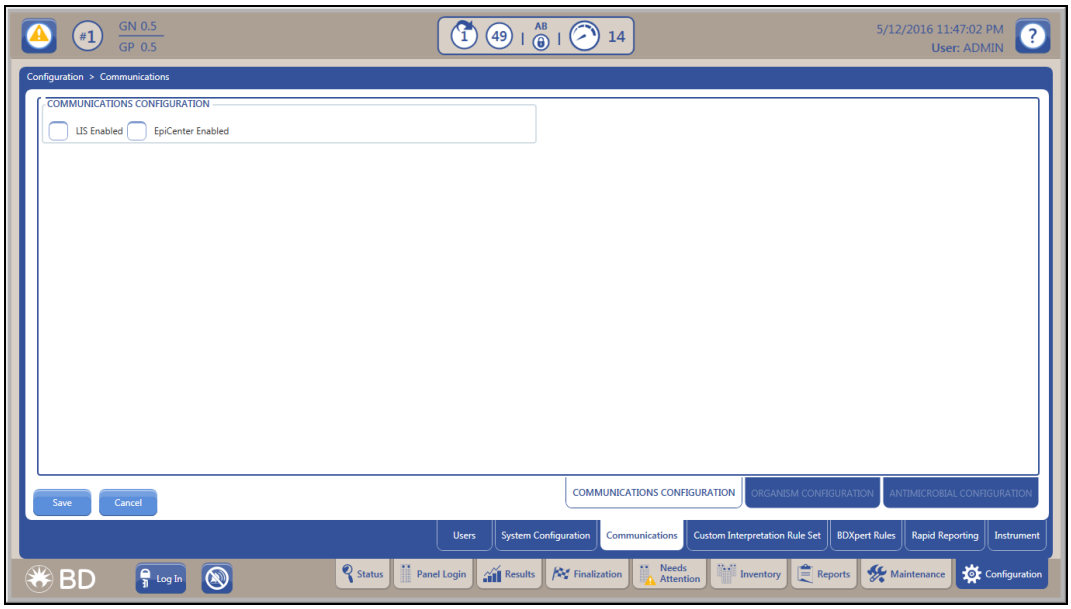


Figure 40 Communications Configuration Screen

The AIO PC displays the LIS connection status icon the upper left side of status screen. (See **Section 4.7 LIS Operations** for details.)

LIS Enabled

Touch the **LIS Enabled** field to establish a connection. When LIS Enabled is checked, the following fields appear: Network Configuration, Options, and Results Upload Options.

Network Configuration

Baud

Available choices are: 2400, 4800, 9600 (default), 14400, 19200, 38400, 57600, 115200.

Data Bits

Available choices are: 7, 8 (default).

Parity

Available choices are: None (default), odd, even.

Stop Bits

Available choices are: 1 (default), 2.

Packed Frames

Select whether packed frames can be used for serial communications with the LIS system. Enable this field to allow the BD Phoenix M50 instrument to send multiple records per frame. A disabled field indicates that one record per frame is uploaded to the LIS.

Options

Send Interpretation Results

Enabling this option causes the final SIR values for antimicrobials to be included in the Results record uploaded to the LIS. Its default value is enabled.

Unsolicited Queries

Enabling this option causes the BD Phoenix M50 instrument to request panel information from the LIS if the panel is placed into the instrument lacking an organism ID for AST panels or Combination panels with only the AST portion of the panel enabled.

This field's default value is disabled, which means the BD Phoenix M50 instrument will NOT request missing information from the LIS.

Send When Placed in Instrument

Enabling this option causes the BD Phoenix M50 instrument to send a Results upload to the LIS when the panel is placed into the instrument. This field's default value is enabled.

ASTM Byte Mode Comments

This field only appears when Japanese is selected for the language and causes the ASTM standard to be followed (when enabled) or not followed (when disabled). When the ASTM standard is not followed, escape sequence characters that are usually rejected are instead accepted.

This field's default value is enabled.

Results Upload Options

Only one option from the list below can be selected.

Solicited

Enabling this option causes the BD Phoenix M50 instrument to upload Results records only when the LIS requests the information. Its default value is disabled.

QC panels and orphan panels are uploaded only when solicited by the LIS.

Send on Finalization

Enabling this option causes the BD Phoenix M50 instrument to upload Results records only when the panel is finalized. Its default value is disabled.

Send on Completion

Enabling this option causes the BD Phoenix M50 instrument to upload Results records only when the panel status becomes complete or when a change is made to a complete panel. Its default value is enabled.

Send as Available

Enabling this option causes the BD Phoenix M50 instrument to upload Results records at the following times: when an ID is determined; when an AST result is determined; when there is a change to a panel record that already has at least partial results. Its default value is disabled.

Send at Fixed Time

Enabling this option causes the BD Phoenix M50 instrument to upload Results records for a panel with partial results at a fixed, specified time. The default value is disabled.

NOTE

Send as Available and Send at Fixed Time results should be considered PRELIMINARY until the panel is complete.

Results records are uploaded from the BD Phoenix M50 instrument to the LIS system. These records are covered in detail in **Section 4.7.1 Results Upload Records**.

5.9.4 Organism Configuration Sub-Tab

NOTE

This sub-tab is unavailable when the instrument is connected to BD EpiCenter.

The Organism Configuration screen enables the user to edit the LIS codes for the organisms in the BD Phoenix M50 instrument database. LIS codes for organisms must be unique.

The Organism Configuration screen enables the selection of the organism (or Test Strain for QC organisms) to be edited.

To edit an organism LIS code:

1. In the Organism Configuration screen, select the name in the list and type in the new LIS Code in the Modify Organism ID LIS Code area at the bottom of the screen.
2. Select **Save LIS Code** to save the changes.
3. When all modifications to the LIS codes have been completed, save and exit the Communications Configuration screen.

5.9.5 Antimicrobial Configuration Sub-Tab

NOTE

This sub-tab is unavailable when the instrument is connected to BD EpiCenter.

The Antimicrobial Configuration screen enables the user to edit the LIS codes for the antimicrobials in the BD Phoenix M50 instrument database. LIS codes for antimicrobials must be unique.

This screen also enables the selection of the antimicrobial to be edited. Antimicrobials are presented alphabetically by antimicrobial name.

To edit an antimicrobial LIS code:

1. In the Antimicrobial Configuration screen, select the antimicrobial.
2. In the Modify LIS Code window at the bottom of the list, type in the new LIS code.
3. Select **Save LIS Code** to save the modifications.
4. When all modifications to the LIS codes are complete, save and exit the Communications Configuration screen.

5.9.6 Custom Interpretation Rule Set Sub-Tab

Custom Interpretation Rule Set Configuration enables interpretation rules to be tailored to the specific needs or requirements of your laboratory. The current rule set (whether default or already customized) is used as the basis for custom rules. The current interpretation rule set from Reports can be printed (see **Section 5.7 Reports Tab**). Note that this configuration function is not available if the BD Phoenix M50 instrument is connected to and communicating with a BDEpiCenter system. A Custom Breakpoint Difference report is generated only if the BD Phoenix M50 system is not connected to BD EpiCenter.

Periodically, a software update or BD Phoenix Update Data (PUD) operation may install new breakpoints. When a software or PUD update has been performed, print a Custom Breakpoint Difference Report by selecting the Difference Report button at the bottom of the screen. Breakpoints that have been customized will not be overwritten with updates from the PUD. The Custom Breakpoint Difference Report will provide the appropriate data to determine if customized breakpoints need to be manually updated to reflect the currently installed PUD. See for details on how breakpoints are updated. See **Section 5.7.15 Custom Breakpoint Difference Report** for additional details on this report.

Rules (Standards) Updates

The chart below depicts the logic of updates to Rules Sets. The top of the chart shows the effect of rules changes when a customized rule set is present. The bottom of the chart shows the rest of the cases for rules updates.

In the chart, the letters A, B, and C represent the entirety of a rule set (standard). For example, CLSI Rule Version M100_S27 might be indicated by value A. An update, delivered via PUD, might install CLSI Rule Version M100_S28, which might be indicated by the value B. The customization of A might be represented by C. Therefore, by following the chart below, the effect of the update is that value C (the customized rules based on Version M100_S25) would be retained.

	Old Standard	New Standard	Old Custom		Result after PUD (New Custom)
Custom rules are present	A	A	B		B
	A	B	C		C
	–	–	A		A
	–	A	A		A
	–	A	B		A
	A	–	B		B

	Old Standard	New Standard	Old Custom		Result after PUD (New Custom)
No custom rules	A	A	A		A
	A	B	A		B
	–	A	–		A
	A	A	–		A
	A	B	–		B
	A	–	A		–

Table 15 Rules Updates

> NOTE
>
> An interpretation rule is considered custom if any of the following are modified: Susceptible Breakpoint, Resistant Breakpoint, DTG.

> NOTE
>
> To use the custom rule set for interpretation, see **Section 5.9.2 System Configuration Sub-Tab** and select **Custom** from the Rule Set drop down menu.

Custom Interpretation Rule Set – Based On

The Based On drop down list selects the standard rule upon which the custom rules are to be based. The standard rule sets are: CLSI, EUCAST, and SFM.

> NOTE
>
> If a rule set other than the current rule set is selected, the currently defined custom interpretation rules are deleted.

Custom Rule Set Table

The main window on this screen shows the current rules in the rule set. The following values are shown from left to right (items are explained below under To modify a rule):

Check box next to a rule (indicates the rule is marked for deletion)

Antimicrobial

DTG (Drug Test Group - see information below)

Org (anism) Group

Organism

S (usceptible Value)

R (esistant Value)

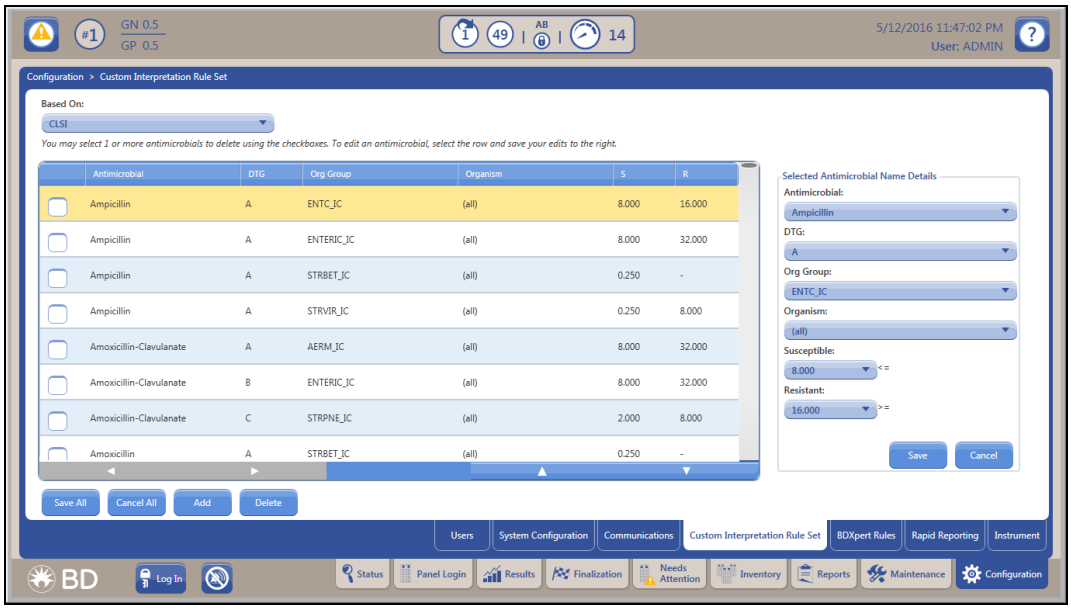


Figure 41 Custom Interpretation Rule Set Screen

To add a rule

1. Select **Add**. A new rule is added to the end of the list and selected for modification.
2. Modify the rule attributes in the Selected Antimicrobial Name Details window and then save.
3. Once all new rules have been added select **Save All** to save the new rules and exit the custom interpretation rule set configuration screen.

To modify a rule

1. Select the row containing the rule to be modified. The row will be highlighted and the rule attributes will be populated in Selected Antimicrobial Name Details.

> NOTE
>
> Do not check the field next to the rule. This is used to delete rules.

2. Modify the rules attributes and save when all modifications are complete.

DTGs are derived from the AST Standards and are used to categorize antibiotics into distinct groups. For each drug, the groups are specific to the organism group and the recommended utilization for that drug.

DTGs have no significance in the BD Phoenix system alone. They are used in conjunction with the BDXpert rules and are necessary for interface with the BD EpiCenter system.

Generally, these are divided into seven groups shown below. Only the A, B, C and U codes may be reported on the Lab report(s). B and C groups are only reported when they are promoted to A by the BDXpert system.

Code	Details
A	Always tested and always reported
B	Usually tested, but not always reported
C	Sometimes tested and not always reported
U	Urinary tract specific drug; tested and reported for source urinary tract.
O	Other drugs that may be tested; will not be reported unless changed by user
I	Investigational drugs; drugs not approved for clinical use are never reported
N	Not grouped by standard; will not be reported unless changed by user

These drug testing codes are used for two purposes in the BD Phoenix M50 instrument. First, drug testing codes can be altered to more closely match the antibiotic formulary and drug utilization guidelines within an institution. The initial codes will be determined by the AST interpretive standard that have been selected. Allowable changes are shown below.

Starting Code	Allowable (Recommended) Changes
A	B, C, U, O
B	A, C, U, O
C	A, B, U, O
U	A, B, C, O
O	A, B, C, U
I	None
N	A, B, C, U

The second application of the drug testing codes is for the promotion or suppression of drug results for the chartable report. This application is driven by the rules in the BDXpert system. If the rules alter the drug testing codes, these will be reflected on the Lab Report generated by the BD Phoenix M50 instrument. The promotion and suppression actions are shown below. At the BDEpiCenter level, the drug testing codes will be used to determine which drug results actually appear on the chartable report.

Starting Code	Promotion	Suppression
A	Not applicable	C
B	A	C
C	A	Not applicable
U	Not applicable	C
O	Not allowed	Not allowed
I	Not allowed	Not allowed

When the desired rules have been modified, select Save All to save modifications to the rule set and exit Custom Interpretation Rule Set Configuration.

To delete a rule:

1. Check the field next to the rule to be deleted.
2. Select **Delete**.
3. Select **OK** in the Are you sure message box.
4. Select **Save All** to save the modifications and exit the Custom interpretation rule set screen.

5.9.7 BDXpert Rules Sub-Tab

BDXpert Rule Configuration allows individual BDXpert rules to be enabled or disabled, or triggered automatically or manually according to the specific needs or requirements of each laboratory. The existing BDXpert rule set can be printed by selecting BDXpert Rule Set Database Report from the Reports Tab (see **Section 5.7 Reports Tab**). For more information refer to the *BDXpert™ System User's Manual*.

> NOTE
>
> This configuration function is not available if the BD Phoenix M50 instrument is connected to, and communicating with a BD EpiCenter system. See **Figure 42 BDXpert Rule Configuration Screen**.

BDXpert Rule Set fields:

Rule Set

The rule set currently being displayed is shown in this field. Values are CLSI, SFM, EUCAST, or Custom. Only rules in the selected set appear in the Rule Set field.

Based On

If the rule set is Custom, the rule set on which custom values are based is shown in this field.

Rule Description

The Rule Description field shows the text of the rule selected.

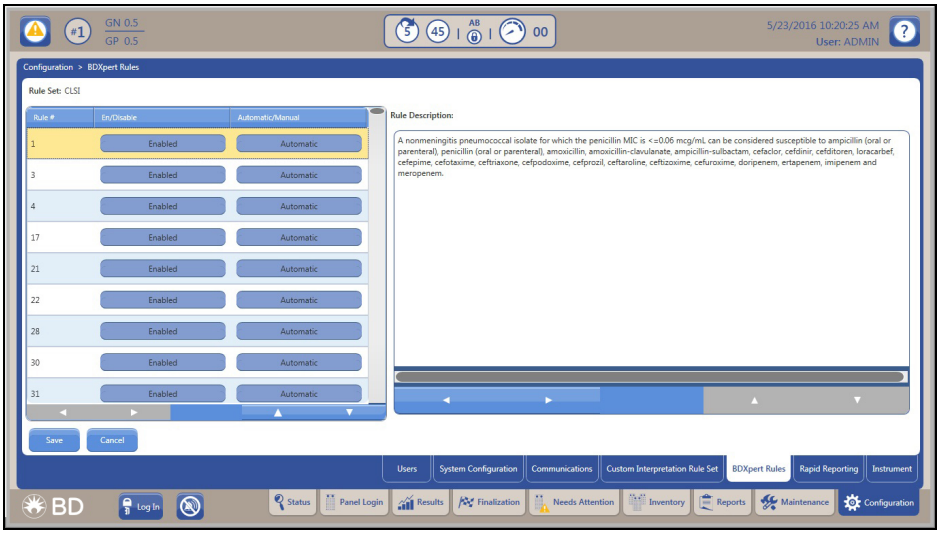


Figure 42 BDXpert Rule Configuration Screen

Rule Set

This screen presents a summary of the status of each of the BDXpert rules and enables users to select rules for modification.

To enable or disable a rule, Select **Enable/Disable** to toggle the status. When disabled, a rule is not available for use in the system.

To set the rule to automatic or manual trigger, select Automatic/Manual to toggle the status. When set to Automatic, a rule will be triggered automatically by the system. When set to manual, the rule must be accepted by the user before it is applied to results.

While 1500 series rules can be selected for viewing, they are fixed as enabled and automatic. These settings cannot be changed. When all parameters have been modified, select **Save**.

5.9.8 Rapid Reporting Sub-Tab

The Rapid Reporting configuration specifies the criteria for notification of critical panels and resistance markers. Notifications for critical panels can originate from:

- an automatic Lab Report printing
- an audible alarm
- an upload to the LIS when certain types of results are obtained in non-QC panels.

The types of results, which are selected, are ID only, partial results, and complete results. For Resistance Markers, designate the type of notification desired when resistance markers (that are enabled) are triggered. For both, disabling both printing and audible alarms can be chosen. In this case, the only notification is that the panel is shown in red text on the Panel Inventory screen.

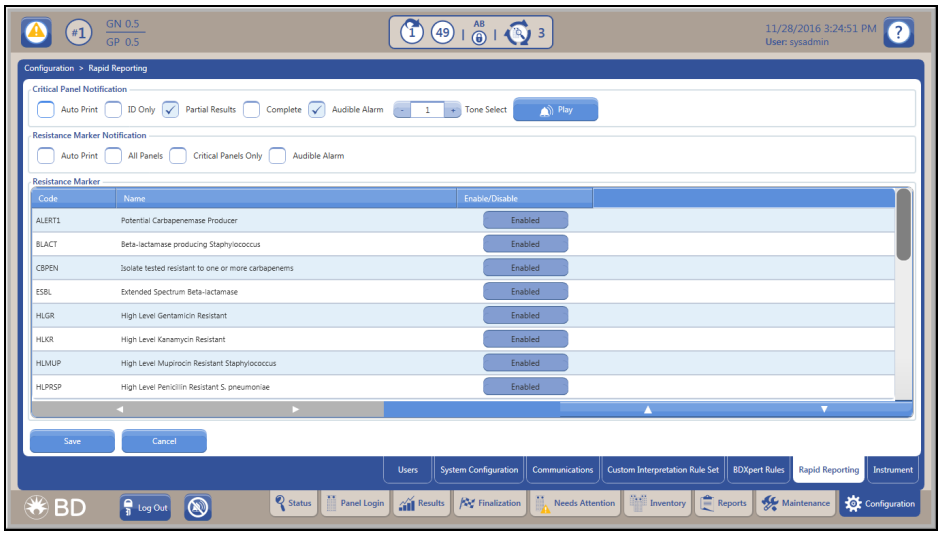


Figure 43 Rapid Reporting Configuration Screen

Rapid reporting alarms exist in two states: unacknowledged and acknowledged. Unacknowledged alarm panels continue to display a red ! (exclamation mark) on the Inventory screen. Acknowledgment is achieved when an automatic Lab Report for the panel prints or when the panel is viewed in Results. Audible alarms continue to sound for unacknowledged alarms until the Silence Alarm button is pressed.

Critical Panel Notification

The Critical Panel Notification field allows the user to set parameters for notification on critical panels. Any panel where special notification occurs when results become available is called a Critical Panel. Notification can be audible and/or by immediate printing of a Lab Report (or neither). Panels can be marked as critical when they are logged in via Panel Login, or subsequently on the Results screen.

Auto Print

When enabled, the system prints a Lab Report whenever the selected results parameters occur (ID Only, Partial, or Complete – see below). This field is disabled by default (auto print off). Both Auto Print and Audible Alarm may be enabled simultaneously.

Upload to LIS

This only appears if LIS Communications is enabled. The default value is disabled. When enabled, the system uploads results records whenever the selected results parameters occur (ID Only, Partial, or Complete – see below). This field overrides the results upload values set in Communications Configuration.

Audible Alarm

When enabled, the system sounds an audible alarm whenever the selected results parameters occur (ID Only, Partial, or Complete – see below). This field is enabled by default (audible alarm on). Both Auto Print and Audible Alarm may be enabled simultaneously.

Tone Select

This field allows the selection of the tones sounded by the critical panel audible alarm. It appears only if Audible Alarm is checked (enabled). This field is set to Tone 1 by default. The system sounds a sample tone each time the field is selected or its contents are changed.

> NOTE
>
> Enable one of the following three fields in order to receive any critical panel notifications.

ID Only

When enabled, critical panel notification is performed only when an organism ID is detected on a panel. This field is set to disabled by default (alarm/report on partial results). If this field is enabled, Partial Results and Complete cannot be enabled.

Partial Results

When enabled, critical panel notification is performed when partial panel results are obtained. This field is set to enabled by default (alarm/report on partial results). If this field is enabled, ID Only and Complete cannot be enabled.

Complete

When enabled, critical panel notification is performed only when complete panel results are obtained. This field is set to disabled by default (alarm/report on partial results). If this field is enabled, ID Only and Partial Results cannot be enabled.

Resistance Marker Notification

This field does not appear if the BD EpiCenter system is connected.

Auto Print

When enabled, the system prints a Lab Report whenever a resistance marker is triggered. This field is set to disabled by default.

Upload to LIS

This appears only if LIS Communications is enabled. The default value is disabled. When enabled, the system uploads results records whenever the selected results parameters occur (ID Only, Partial, or Complete – see above).

This field overrides the results upload values set in Communications Configuration (**Section 5.9.3 Communications Sub-Tab**).

> NOTE
>
> Enable one of the following two fields in order to receive any resistance marker notifications.

All Panels

When enabled, resistance marker alarms are generated for all panels in which markers occur. This field is disabled by default. If this field is enabled, Critical Panels Only cannot be enabled.

Critical Panels Only

When enabled, resistance marker alarms are generated only for critical panels in which markers occur. This field is enabled by default. If this field is enabled, All panels cannot be enabled.

Resistance Marker

This field enables or disables the notification of individual resistance markers. The field shows the abbreviation and text of the Marker, as well as whether it is currently enabled or disabled. By default, all resistance markers are enabled. Resistance marker alarm notification occurs only for enabled markers.

5.9.9 Panel Lot Definition Sub-Tab

Panel Lot Definition enables the definition of panel lots to facilitate QC testing and tracking. Panel lot definition saves the lot number, beginning and ending panel sequence numbers, definition date, and first and last used dates for a lot. Current and historical QC results can be viewed and printed. Note that this configuration function is not available if the BD Phoenix M50 instrument is connected to and communicating with a BD EpiCenter system. It is not available to the user when the system is connected to the BD EpiCenter.

This tab's activities are:

- Define new panel lots
- Recall existing panel lots
- Review current and historical QC results for panel lots
- Print Panel Lot (current, historical) reports

When a panel lot definition is saved, any Test Strain recommendations that exist are displayed in the Current QC Results window. There is a toggle feature between Current and Historical QC Results windows. Current results show a summary of the most recent test for each strain for all instruments, up to 20 entries. Historical results show all tests for a strain for the current instrument only, up to 200 entries. In order to display results from other instruments, Panel Lots must be saved at those instruments and restored to the current instrument (see **Restore Panel Lot Definitions Task (Panel lot definition is enabled and system is not connected to BD EpiCenter)** in **Section 5.8.4 Maintenance Panel Functions**).

Field contents of these windows are explained below.

Panel Lot Number

This field shows the lot number for the panel. To enter a new panel lot number, scan the lot number barcode (next to the L symbol) on the box. The panel lot number is encoded in the barcode. The lot number cannot be typed in this field when defining new panel lots.

To recall a panel lot definition, select a panel lot from the drop down list, or type the first few numbers of the panel lot number to jump to that portion of the list, or scan the panel lot barcode.

Expiration Date

This field shows the lot's expiration date. This information is encoded in the panel lot barcode and is filled in automatically when the panel lot barcode is scanned. The expiration date cannot be typed in when defining new panel lots. This date can only be changed by scanning a new panel lot barcode provided by the BD Quality department (only if an administrator is logged in).

Start Sequence Number

This field shows the starting barcode sequence number for the panel lot. To enter a new Start Sequence number, scan the lowest sequence number in the lot (next to the symbol on the box). This field can only be completed by scanning the panel sequence barcode; the sequence number cannot be typed in this field.

End Sequence Number

This field shows the ending barcode sequence number for the panel lot. To enter a new End Sequence number, scan the highest sequence number in the lot (next to the symbol on the box). This field can only be completed by scanning the panel sequence barcode; the sequence number cannot be typed in this field.

Definition Date

This field shows the date on which the panel lot was defined. It is completed automatically when the panel lot definition is saved. This is a read-only field that cannot be changed by the user.

First Used Date

This field shows the first date on which a panel from this lot was used. It is completed automatically when the panel is placed in the instrument. This is a read-only field that cannot be changed by the user.

Last Used Date

This field shows the last date on which a panel from this lot was used. It is completed automatically when the panel is placed in the instrument. This is a read-only field that cannot be changed by the user.

Where Defined

This field appears only if the panel lot was defined at a different number instrument than the current one. It shows the instrument number where the panel lot was defined. Panel lot definitions can be saved at one instrument and restored to another instrument through the Save/Restore Panel Lot Definitions functions found on the **Section 5.8 Maintenance Tab**.

Current QC Results

This window appears only after a panel lot is saved. When a panel lot definition is saved, any QC Test Strain recommendations that exist are displayed in the Current QC Results window. Only the most recent QC test is shown for each test strain, up to a maximum of 20 tests. Results for other instruments can be shown in this window by saving those results at that instrument and restoring them at the current one (see **Save Panel Configuration Task** and **Restore Panel Lot Definitions Task (Panel lot definition is enabled and system is not connected to BD EpiCenter)** in **Section 5.8 Maintenance Tab**).

The following read-only fields are shown in the Current Results window: Test Strain (sort order by name); Test Date; Sequence Number; (Test) Type (ID, AST, or ID/AST); QC Status (None for uncompleted test; Pass, Fail, Review, or Error for completed tests).

A Current QC Panel Lot Report is available by exiting the Panel Lot Definition tab and selecting the Reports tab. In addition to the fields listed above, the report includes standard report header information (Report Title, Laboratory Information (if configured), Date and Time Printed, and Instrument number where the report was printed); Panel Lot number; Panel Type; Expiration Date; Instrument number for each strain tested (blank if instrument is the same); and Tech ID.

Historical QC Results

This appears only after a panel lot is saved. Historical results show all tests for a strain for the current instrument only, up to 200 entries. When the desired panel is highlighted, move to the QC Panel Results screen, or print a Historical QC Panel Lot Report.

The following read-only fields are shown in the Historical Results window: Test Strain (drop down selection box); Test Date (sort order); Sequence #; (Test) Type (ID, AST, or ID/AST); QC Status (None, Pass, Fail, Review, Error); Tech ID.

A Historical QC Panel Lot Report is available by exiting the Panel Lot Definition tab and selecting the Reports tab. In addition to the fields listed above, the report includes standard report header information (Report Title, Laboratory Information (if configured), Date and Time Printed, and Instrument number where the report was printed); Panel Lot number; Panel Type; and Expiration Date.

5.9.10 Instrument Sub-Tab

BD field service only.

6 Routine Panel Operation

This section describes the following routine panel operations:

- **Section 6.1 Storage and Handling** of the panels
- **Section 6.2 Preparing Panels**
- **Section 6.3 Quality Control**
- **Section 6.4 Automatic Association of Panels**

For more information, refer to the *BD Phoenix AP Instrument User's Manual*.

6.1 Storage and Handling

BD Phoenix Panels

Panels are individually pouched and packaged in a box of 25. They must be stored unopened at room temperature (15–25 °C). Visually inspect the packaging for holes or cracks in the foil package.

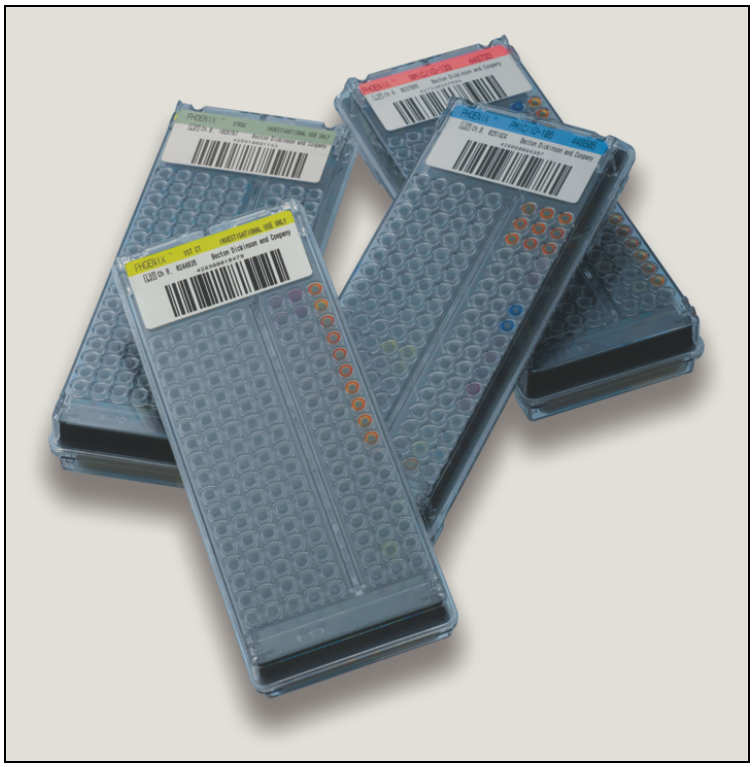


Figure 44 BD Phoenix Panels

CAUTION

Do Not:

- **refrigerate or freeze.**
- **use if the packaging appears to be damaged.**
- **use the panel if there is no desiccant or if the desiccant pouch is torn.**

If stored as recommended, the panels will retain expected reactivity until the date of expiration.

BD Phoenix ID Broth

Figure 45 ID and AST Broth and BD Phoenix AST Indicator Solution

Tubes are packaged as 100 tube packs. Visually inspect the tubes for cracks, leaks, etc.

CAUTION

Do not use if there appears to be a leak, tube or cap damage or visual evidence of contamination (i.e., haziness, turbidity).

Store BD Phoenix ID Broth tubes at 2–25 °C and keep them away from direct light. Expiration dating is shown on the tube label.

BD Phoenix AST Broth and BD Phoenix AST-S Broth

Tubes are packaged as 100 tube packs. Visually inspect the tubes for cracks, leaks, etc.

CAUTION

Do not use if there appears to be a leak, tube or cap damage or visual evidence of contamination (i.e., haziness, turbidity).

Store BD Phoenix AST Broth tubes at 2–25 °C. Expiration dating is shown on the tube label.

BD Phoenix AST Indicator Solution and BD Phoenix AST-S Indicator Solution

The indicator solution is individually pouched and packaged as a pack of 10 dropper bottles. Visually inspect the bottle for cracks and/or leaks.

CAUTION

Do not use if there appears to be a leak, bottle or cap damage, or any change from a dark blue color.

Store the BD Phoenix AST Indicator Solution at 2–8 °C. Each bottle contains enough solution to test up to 100 panels. Expiration date is shown on the box, pouch, and bottle label and is applicable for unopened bottles. An opened bottle will be stable for up to 14 days if stored at 2–8 °C. Be sure the bottle is held vertically when dispensing the AST Indicator Solution.

6.2 Preparing Panels

The BD Phoenix system is not used directly with clinical specimens. Only pure culture isolates of aerobic and/or facultatively anaerobic gram-negative, gram-positive, and yeast organisms are acceptable for testing. Make sure the test isolate is a pure culture. Cultures must be 18–24 hours old for gram-negative and gram-positive organisms and 18 to 48 hours old for yeast organisms.

For AST testing in the BD Phoenix system, isolates must be recovered from non-selective media. Media containing antibiotics should not be used for organisms to be tested in the BD Phoenix system except those specifically claimed in the table below. Selective media may inhibit some strains of bacteria and yeast, therefore use caution when selecting isolated colonies from these media. Use isolates from a blood agar plate such as BD Trypticase Soy Agar with 5% Sheep Blood. The Media selected during login of Yeast ID panels refers to the media on which the organism was grown.

Other recommended media are included in the table below:

Recommended Media	Approved Use			
	ID	AST	Strep	Yeast ID
BD BBL™ CHROMagar™ Orientation	Yes	Yes[1]	X	X
Bromthymol Blue (BTB) Lactose Agar	Yes[4]	Yes	X	X
Chocolate Agar	Yes	Yes	Yes[2]	Yes
Columbia Agar with 5% Horse Blood	Yes	Yes	Yes[3]	X
Columbia Agar with 5% Sheep Blood	Yes	Yes	Yes	Yes
Columbia CNA Agar with 5% Sheep Blood (Gram Positives)	Yes	X	Yes	X
Cystine-Lactose-Electrolyte-Deficient (CLED) Agar	Yes[5]	Yes	X	X
Dey/Engley (D/E) Neutralizing Agar (Gram Negatives)	Yes	X	X	X
Eosin Methylene Blue (Gram Negatives)	Yes	Yes	X	X
Hektoen Enteric Agar (Gram Negatives)	Yes	X	X	X
MacConkey Agar (Gram Negatives)	Yes	Yes	X	X
Phenylethyl Alcohol Agar (Gram Positives)	Yes	X	Yes	X
Sabouraud Brain Heart Infusion Agar - SAB HI (Yeast)	X	X	X	Yes
Sabouraud Dextrose Agar	X	X	X	Yes

Recommended Media	Approved Use			
	ID	AST	Strep	Yeast ID
(Yeast)				
Sabouraud Dextrose Agar-Emmons (Yeast)	X	X	X	Yes
BD Trypticase Soy Agar with 5% Sheep Blood	Yes	Yes	Yes	Yes
BD Trypticase Soy Agar with Lecithin and Tween 80	Yes	X	X	X
BD Trypticase Soy Agar without Blood	Yes	X	X	X
Xylose Lysine Desoxycholate Agar (Gram Negatives)	Yes	X	X	X

The use of CHROMagar Orientation may produce false susceptibility results when testing erythromycin with Gram positive organisms. Antimicrobial susceptibility test results should be confirmed using BD Trypticase Soy Agar with 5% Sheep Blood.

This media type should not be used for Streptococcal identification with SMIC/ID panels. Chocolate Agar may be used for Streptococcal susceptibility testing only.

The use of Columbia Agar with 5% Horse Blood may produce significantly higher MIC for SXT with Streptococcus species, which may result in false resistance. Antimicrobial susceptibility test results should be confirmed using BD Trypticase Soy Agar with 5% Sheep Blood.

The use of Bromthymol Blue Lactose Agar with Gram Positive organisms should be restricted to Staphylococci for both the 0.5 and 0.25 GP systems.

The use of Cystine-Lactose-Electrolyte-Deficient Agar with Gram Positive organisms should be restricted to Staphylococci for the 0.25 GP system.

Table 16 Recommended Media

The applicator swabs should be sterile cotton swabs; polyester swabs are not recommended. The quality of applicator swabs may vary from vendor to vendor and on occasion, loose fibers may dislodge from the swab affecting McFarland readings.

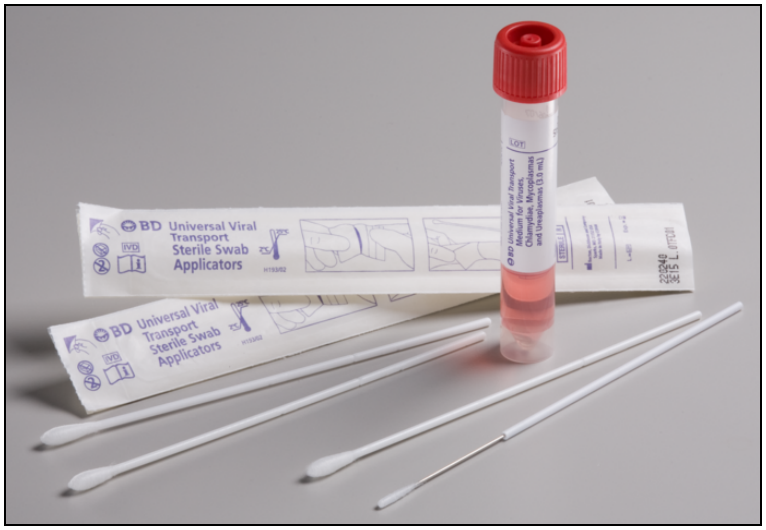


Figure 46 Cotton Swabs

The usefulness of the BD Phoenix system or any other diagnostic procedure performed on clinical specimens is directly influenced by the quality of the specimens themselves. Laboratories must employ methods discussed in the Manual of Clinical Microbiology 17 for specimen collection, transport, and placement on primary isolation media.

Due to variations in inoculum concentrations prepared with McFarland standards, use the BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument for adjusting the test inoculum prior to using them in the BD Phoenix system.

Instructions for an optional purity check are provided at the end of this subsection.

WARNING

- **OBSERVE ESTABLISHED PRECAUTIONS AGAINST MICROBIOLOGICAL HAZARDS THROUGHOUT ALL PROCEDURES.**
- **ALL SPECIMENS SHOULD BE HANDLED ACCORDING TO CDC-NIH RECOMMENDATIONS, CLSI GUIDELINES, OR LOCAL INSTITUTION GUIDELINES FOR ANY POTENTIALLY INFECTIOUS HUMAN SERUM, BLOOD, OR OTHER BODY FLUIDS.**
- **PRIOR TO DISCARDING SPECIMEN CONTAINERS AND OTHER CONTAMINATED MATERIALS BY AUTOCLAVING, STERILIZE THEM.**
- **IN ADDITION TO WEARING GLOVES, USE DISPOSABLE LAB COATS OR GOWNS AND PROTECTIVE GLASSES OR GOGGLES WHEN WORKING AROUND THE INSTRUMENT.**

6.2.1 Materials Required

- BD Phoenix Panels
- BD Phoenix ID Broth or BD Phoenix Inoculum Broth
- BD Phoenix AST and/or BD Phoenix AST-S Broth
- BD Phoenix AST Indicator Solution and/or BD PhoenixAST-S Indicator Solution
- BD Phoenix Panel closures
- BD Phoenix Inoculation Station
- BD Phoenix Transport Caddy
- BD BBL CrystalSpec Nephelometer, the BD PhoenixSpec Nephelometer, or the BD Phoenix AP instrument
- 25 µL pipettor and tips

6.2.2 Materials Required but Not Provided

- Gram Stain Reagents
- Sterile Cotton Swabs, Inoculation Loops or Needles
- Nonselective Culture Plated Media (see **Section 6.2 Preparing Panels**)
- Incubators
- Biohazard Disposable Container
- Markers, etc.
- Vortex mixer

NOTE

- Exercise care in handling BD Phoenix panels. Handle panels by the sides only to avoid marking, smudging, or obscuring the bottom or top of the panel in any way.
- Accession bar code labels affixed to a BD Phoenix panel must not be of fluorescent material, should not cover any BD Phoenix panel reaction wells, and should not cover the BD Phoenix sequence number (panel) barcode.
- The procedure that follows describes all the steps in preparing a combination panel for both identification and susceptibility testing. If a combination panel is being used for only ID or only AST testing, note that certain steps are not applicable in the procedure.

6.2.3 Preparing General Panels

If the BD Phoenix AP instrument is being used, refer to the *BD Phoenix AP Instrument User's Manual* for panel preparation.

BD Phoenix Strep panels, BD Phoenix Yeast ID panels, BD Phoenix Emerge panels, BD Phoenix Inoculum Broth, and BD Phoenix MIC panels have separate instructions that appear after Step 19 of these instructions.

NOTE

Before proceeding with the inoculum preparation for use in the BD Phoenix M50 instrument, confirm the Gram stain reaction of the isolate.

1. Once the Gram stain reaction is confirmed, select the appropriate BD Phoenix panel for inoculation. Do not use the panel if the pouch is punctured or opened.

2. Remove the panel from the pouch. Discard the desiccant. Do not use the panel if there is no desiccant or if the desiccant pouch is torn.

NOTE (See NOTE above)

- AST-S Broth and AST-S Indicator Solution are for use with the BD Phoenix Strep panels (SMIC/ID, SMIC) only. These reagents are not interchangeable with the AST Broth and AST Indicator Solution used with BD Phoenix Gram Positive and Gram Negative panels.
- Allow AST-S Indicator Solution to warm to room temperature before dispensing into AST-S broth.
- Make sure the unused portion of the indicator return to 2–8 °C as soon as possible. Do not store at room temperature for more than two hours. After 14 days from opening, discard the bottles.
- If volume other than one drop is added inadvertently, discard the tube and use a fresh tube of AST-S broth.
- After the addition of the Indicator to AST-S broth, the mixed solution can be stored in the dark, at room temperature, for as long as 8 hours.
- After the addition of AST-S Indicator Solution, if the tubes are exposed to light, they must be used within two hours.

3. Place the panel on the Inoculation Station so that the inoculation ports are on top, and the pad is at the bottom.
4. Label a BD Phoenix ID broth tube with the patient's specimen number.
5. Using aseptic technique, pick colonies of the same morphology with the tip of a sterile cotton swab (do not use a polyester swab) or a wooden applicator stick from one of the recommended media.
6. Suspend the colonies in the BD Phoenix ID broth (4.5 mL).
7. Cap the tube and vortex for five seconds.
8. Allow approximately ten seconds for air bubbles to surface. Tap the tube gently to aid in eliminating bubbles.
9. Insert the tube into the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer. Make sure the tube is inserted as far as it will go. (Refer to the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer product insert for correct usage instructions).

10. If the inoculum density is set to 0.5 McFarland for the panel type being run, then a range of 0.50–0.60 is acceptable. If the inoculum density is set to 0.25 McFarland for the panel type being run, then a range of 0.20–0.30 is acceptable.

    If the density of organisms is low, colonies can be added from the isolate. Re-vortex the sample and reread to confirm that the correct McFarland has been achieved. If the density of organisms exceeds 0.6 McFarland, follow the steps below to dilute the broth. It is very important to accurately indicate the level of the liquid in the tube since this volume is needed to adequately fill the wells in the panel.

    a. Using a marker, mark the broth level in the over-inoculated BD Phoenix ID Broth tube.
    b. Using a sterile pipette, aseptically add fresh BD Phoenix ID Broth to the inoculum. Only BD Phoenix ID Broth may be used to dilute the inoculum.
    c. Vortex the tube and allow to sit for 10 seconds.
    d. Place the tube in the nephelometer and remeasure the turbidity of the suspension.
       - If the reading is greater than 0.6, repeat Steps b–d.
       - If the reading is 0.5–0.6, go to Step e.
    e. Using a sterile pipette, aseptically remove excess broth to the original level indicated by the mark on the tube created in Step a.

       Remove excess broth to avoid overfilling the panel. Also, do not remove too much broth, as there may be insufficient broth to adequately fill the panel.
    f. Broth may now be used to inoculate the BD Phoenix AST Broth and/or the BD Phoenix Panel.

    NOTE

    - Yeast ID panels must be inoculated using a 2.00–2.40 McFarland inoculum density.
    - Confirm current instrument settings for inoculum density before inoculating panels.
    - See instructions below, ID Inoculum Density Flexibility, for information on using alternate densities.
    - Only the BD PhoenixSpec Nephelometer and BD Phoenix AP instrument can be used to make inoculum densities of 0.25 McFarland
    - Standardized bacterial suspension in ID Broth or Inoculum Broth must be used within 60 minutes of preparation.

11. If the test is for identification only, proceed to Step 15 and continue the procedure. If a BD Phoenix Emerge Panel is being inoculated, see **Section 6.2.7 Preparing BD Phoenix Emerge Panels**.

12. Label a BD Phoenix AST broth tube (8.0 mL) with the patient's specimen number. Add one free falling drop of AST Indicator solution to the AST broth tube. Invert to mix. DO NOT VORTEX.

> NOTE
>
> - Allow AST Indicator Solution to warm to room temperature before dispensing into AST broth.
> - Return the unused portion of the indicator to 2–8 °C as soon as possible. Do not store at room temperature for more than 2 hours. Discard opened bottles after 14 days from initial opening.
> - If volume other than one drop is added inadvertently, discard the tube and use a fresh tube of AST broth.
> - After adding the Indicator to AST broth, store the mixed solution in the dark, at room temperature, for as long as 8 hours.
> - After adding AST Indicator Solution, if it is exposed to light, use the tubes within 2 hours.

13. If an inoculum density of 0.50–0.60 was used, transfer 25 µL of the bacterial suspension from the ID tube into the AST broth tube. If an inoculum density of 0.20–0.30 was used, transfer 50 µL (use 2 shots if utilizing a 25 µL pipettor) of the bacterial suspension from the ID tube into the AST broth tube.

> NOTE
>
> Inoculate panels within 30 minutes of the time that the AST broth inoculum is prepared.

14. Cap the AST tube and invert several times to mix.
15. Wait a few seconds for air bubbles to surface. Tap the tube gently to aid in eliminating bubbles.
16. Pour the ID tube inoculum into the fill port on ID side of the panel (51-well side). Allow the fluid to traverse down the tracks before moving the panel. If an AST (only) panel is being used, DO NOT inoculate the ID side of the panel. Retain the ID tube for an optional purity check (see below).
17. Pour the AST broth inoculum into the fill port on AST side of the panel (85-well side). Allow the fluid to traverse down the tracks before moving the panel.
18. Before placing panel closures check for residual droplets of inoculum on the edge of the fill ports. If a droplet is present remove the droplet with absorbent material. The used absorbent material must be decontaminated before discarding.

19. Snap on the panel closures. Make sure that the closures are fully seated. Use 2 closures regardless of panel type.
20. Visually inspect panels to be sure each of the wells is full. Look at both sides of the panel. Make certain that the wells are not overfilled. If any of the wells are unfilled or overfilled, inoculate a new panel.

NOTE

See NOTE above

- Panels must be loaded into the instrument within 30 minutes of inoculation.
- Panels must be kept in the inoculation station after inoculation until the excess fluid has been completely absorbed by the pad.
- Panels should stay vertical in the caddy until loaded.
- Inoculated panels should be handled with care. Avoid knocking or jarring the panel.

NOTE

OPTIONAL PURITY CHECK

It is highly recommended that the purity of both ID and AST inocula be checked by preparing a purity plate.

To perform a purity check, using a sterile loop, recover a small drop from the inoculum fluid tube either before or after inoculating the panel and inoculate an agar plate (any appropriate medium) for purity check. Discard inoculum fluid tube and cap in a biohazard disposal container. Incubate the plate for 24–48 h at 35 °C under appropriate conditions.

6.2.4 Preparing BD Phoenix Strep Panels

BD Phoenix Strep panels are for the identification and antimicrobial susceptibility testing of most Streptococcus species. Although Streptococcus species may be identified in the gram positive panels, antimicrobial susceptibility cannot be reported when using these panels. The BD Phoenix Strep panels, which must be used with BD Phoenix AST-S Broth and BD Phoenix AST-S Indicator Solution, provide the conditions required for rapid AST testing of most Streptococcus species.

1. Follow Steps 1–9 from Section **Section 6.2.3 Preparing General Panels** to prepare the suspension of bacteria.
2. Add one drop of the BD Phoenix AST-S Indicator to each AST-S broth tube. Invert to mix. DO NOT VORTEX.

NOTE

(See NOTE above.)

- AST-S Broth and AST-S Indicator Solution are for use with the BD Phoenix Strep panels (SMIC/ID, SMIC) only. These reagents are not interchangeable with the AST Broth and AST Indicator Solution used with BD Phoenix Gram Positive and Gram Negative panels.
- Allow AST-S Indicator Solution to warm to room temperature before dispensing into AST-S broth.
- Make sure the unused portion of the indicator return to 2–8 °C as soon as possible. Do not store at room temperature for more than two hours. After 14 days from opening, discard the bottles.
- If volume other than one drop is added inadvertently, discard the tube and use a fresh tube of AST-S broth.
- After the addition of the Indicator to AST-S broth, the mixed solution can be stored in the dark, at room temperature, for as long as 8 hours.
- After the addition of AST-S Indicator Solution, if the tubes are exposed to light, they must be used within two hours.

3. Using a pipettor, transfer 25 µL of the standardized bacterial suspension from the ID tube into the AST-S broth tube.

NOTE

Panels must be inoculated within 30 minutes of the time that the AST-S broth inoculum is prepared.

4. Cap the AST-S tube and invert several times to mix.
5. Wait a few seconds for air bubbles to surface. Tap the tube gently to aid in eliminating bubbles.
6. Pour the ID tube inoculum into the fill port on ID side of the panel (51-well side). Allow the fluid to traverse down the tracks before moving the panel. If a BD Phoenix Strep MIC only panel is being used, DO NOT inoculate the ID side of the panel. Retain the ID tube for an optional purity check (see below).
7. Pour the AST-S broth inoculum into the fill port on AST side of the panel (85-well side). Allow the fluid to traverse down the tracks before moving the panel.
8. Before placing panel closures, check for residual droplets of inoculum on the edge of the fill ports. If a droplet is present, remove the droplet with absorbent material. The used absorbent material must be discarded with biohazard waste.
9. Snap on the panel closures. Make sure that the closures are fully seated.

10. Visually inspect panels to be sure each of the wells is full. Look at both sides of the panel. Make certain that the wells are not overfilled. If any of the wells are unfilled or overfilled, inoculate a new panel.

NOTE

- Panels must be loaded into the instrument within 30 minutes of inoculation.
- Panels must be kept in the inoculation station after inoculation until the excess fluid has been completely absorbed by the pad.
- Panels should stay vertical in the caddy until loaded.
- Inoculated panels should be handled with care. Avoid knocking or jarring the panel.

NOTE

OPTIONAL PURITY CHECK

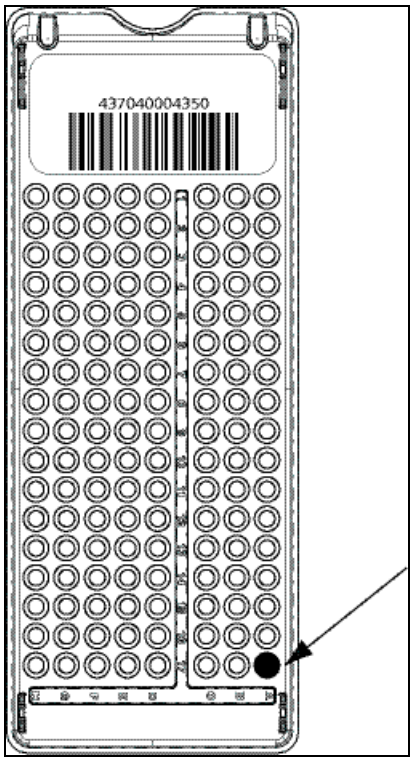
It is highly recommended that the purity of both ID and AST-S inocula be checked by preparing a purity plate.

To perform a purity check, using a sterile loop, recover a small drop from the inoculum fluid tube either before or after inoculating the panel and inoculate an agar plate (any appropriate medium) for purity check. Discard inoculum fluid tube and cap in a biohazard disposal container. Incubate the plate for 24–48 h at 35 °C under appropriate conditions.

6.2.5 ID Inoculum Density Flexibility

An ID portion of a panel may be run in the opposite mode from what is configured by darkening well A-17 on the back of a panel before placing the panel in the instrument. This allows a panel to be run at an inoculum density of 0.20–0.30 even if a density of 0.5 is configured for that particular panel type. Likewise, a panel can be run at an inoculum density of 0.50–0.60 if a density of 0.25 is configured.

There is no way to alter the density setting during Panel Login. To use a panel in the opposite density mode, using a black permanent marker blacken the entire A-17 well as shown in the figure below.



Inoculum densities sent from the BD Phoenix AP instrument (via the BD EpiCenter system) cannot be changed by darkening well A-17. Inoculum densities sent from the BD Phoenix AP instrument are invalid if they are received after the completion of the first test cycle, or if the ID portion of the panel is disabled, or if the panel type does not support the inoculum density. If the instrument receives an invalid inoculum density for an ID panel that differs from the panel's determined inoculum density, the ID side of the panel fails, a Needs Attention code is triggered (Cannot Determine Organism ID), and a Special Message is triggered.

The following table outlines how to run the opposite mode from the density for which the instrument is configured.

Current Instrument Inoculum Density Configuration	Inoculum Concentration Desired for Test Panel	Amount of ID Inoculum to Add to AST Broth**	Well A-17
0.50	0.25	50 µL	Blackened
0.25	0.50	25 µL	Blackened
** If also running AST			

6.2.6 Preparing BD Phoenix Yeast ID Panels

BD Phoenix Yeast ID panels are for the identification of most clinically relevant yeast and yeast-like species.

1. Follow Steps 1–8 (**Section 6.2.3 Preparing General Panels**) to prepare the suspension of yeast.
2. The inoculum density is set to 2.0 McFarland for Yeast ID panels, with a range of 2.00–2.40 as acceptable. If the density of organism is low or the density of organisms exceeds 2.40 McFarland, follow the steps discussed in Step 9 of **Section 6.2.3 Preparing General Panels** to obtain the correct McFarland density.
3. Pour the ID tube inoculum into the fill port on the ID side of the panel (51-well side). Allow the fluid to traverse down the tracks before moving the panel.
4. Before placing panel closures, check for residual droplets of inoculum on the edge of the fill ports. If a droplet is present remove the droplet with absorbent material. The used absorbent material must be discarded with biohazard waste.
5. Snap on the panel closures. Make sure that the closures are fully seated. Use 2 closures regardless of panel type.
6. Visually inspect panels to be sure each of the wells is full. If any of the wells are unfilled or overfilled, inoculate a new panel.

NOTE

Yeast ID panels must be inoculated using a 2.00–2.40 McFarland inoculum density.

Standardized bacterial suspension in ID Broth or Inoculum Broth must be used within 60 minutes of preparation.

NOTE

Load panels into the instrument within 30 minutes of inoculation.

Keep panels in the inoculation station after inoculation until the excess fluid has been completely absorbed by the pad.

Panels should stay vertical in the caddy until loaded.

Handle inoculated panels with care. Avoid knocking or jarring the panel.

NOTE

OPTIONAL PURITY CHECK

It is highly recommended that the purity of ID inoculum be checked by preparing a purity plate.

To perform a purity check, using a sterile loop, recover a small drop from the inoculum fluid tube either before or after inoculating the panel and inoculate an agar plate (any appropriate medium) for purity check. Discard inoculum fluid tube and cap in a biohazard disposal container. Incubate the plate for 24–48 h at 35 °C under appropriate conditions.

6.2.7 Preparing BD Phoenix Emerge Panels

BD Phoenix Emerge panels are designed to perform susceptibility testing on an expanded number of antimicrobial agents. To accomplish these susceptibilities, antimicrobial agents are present on both sides of the BD Phoenix panel. These panels do not have the ability to perform bacterial identification. Because of the design, the inoculation technique is unique and is outlined below. Two tubes of AST broth will be required.

1. Follow Steps 1–9 (see **Section 6.2.3 Preparing General Panels**) to prepare the suspension of bacteria.
2. Add one drop of the BD Phoenix AST Indicator to each AST broth tube.
3. Transfer 25 µL (50 µL if low inoculum option is used) of the suspension to two BD Phoenix AST broth tubes. Cap and gently invert.
4. Using sterile technique, remove 3.5 mL of broth from one of the inoculated BD Phoenix AST broth tubes and discard in an appropriate container.
5. Pour the remaining 4.5 mL into the left side of the BD Phoenix Emerge panel. Pour the other BD Phoenix AST broth tube into the right side of the BD Phoenix Emerge panel.
6. Cap the panel and follow the normal panel login procedure.

6.2.8 Using BD Phoenix Inoculum Broth

BD Phoenix Inoculum Broth can be used to make the initial McFarland suspension of microorganisms when utilizing BD Phoenix MIC only panels (PMIC, NMIC, SMIC). The BD Phoenix Inoculum Broth is filled with 2.2 mL of BD Phoenix ID Broth and will reach the correct inoculum density by using fewer bacterial colonies.

1. Follow Steps 1–9 (described in **Section 6.2.3 Preparing General Panels**) to prepare the suspension of bacteria using the BD Phoenix Inoculum Broth rather than the BD Phoenix ID Broth.
2. For NMIC and PMIC panels, add one drop of the BD Phoenix AST Indicator to the BD Phoenix AST broth tube.
3. For SMIC panels, add on drop of the BD Phoenix AST-S Indicator to the BD Phoenix AST-S broth tube.

4. Transfer 25 µL (50 µL if low inoculum option is used) of the BD Phoenix Inoculum Broth suspension to the BD Phoenix AST or AST-S tube(s).
5. Follow Steps 16–19 (described in **Section 6.2.3 Preparing General Panels**). Follow the normal panel login procedure.

BD Phoenix MIC (NMIC, PMIC, SMIC) Panels

Inoculum can be prepared using either BD Phoenix ID Broth or BD Phoenix Inoculum (Step 4, described in **Section 6.2.3 Preparing General Panels**)

1. Follow Steps 1–9 (**Section 6.2.3 Preparing General Panels**) to prepare the suspension of bacteria.
2. For NMIC and PMIC panels, add one drop of the BD Phoenix AST Indicator to the BD Phoenix AST broth tube.

   For SMIC panels, add one drop of the BD Phoenix AST-S Indicator to the BD Phoenix AST-S broth tube.
3. Transfer 25 µL (50 µL if low inoculum option is used with NMIC or PMIC panels) of the BD Phoenix ID Broth to the BD Phoenix AST or AST-S tube. Cap and gently invert. Retain the ID tube or Inoculum tube for an optional purity check (see above).
4. Follow Steps 16–19 (**Section 6.2.3 Preparing General Panels**). Follow the normal panel login procedure.

6.3 Quality Control

Refer to the panel package insert for information on ID/AST Quality Control. QC panels cannot be marked as critical.

Quality Control testing is recommended for each lot of panels. The QC Lot Support feature can facilitate QC panel tracking and testing. If the QC Lot Support feature is enabled, then the panel lot number must be defined prior to logging in QC panels.Inoculate a panel with one of the organisms listed in the package insert.

1. Log the panel in as a QC panel as follows:

> NOTE
>
> All microbial cultures, including QC organisms, are potentially infectious and should be treated with universal precautions. QC organisms are prepared for panel inoculation as specified in **Section 6.2 Preparing Panels**.

2. Log the panel in as a QC panel.

NOTE

For most reliable results, it is recommended that the QC organisms be subcultured at least twice on two consecutive days onto TSA with 5% Sheep Blood agar before use in the BD Phoenix M50 instrument. Use only well-isolated colonies.

For Yeast ID QC, the use of Sabouraud Dextrose Agar as the subculture media is also acceptable.

3. Do the following:
   a. Select Panel Login and then select QC.
   b. Enter Tech ID. By default, the entry is the same as the logged in user's assigned tech id. The user can edit the value.
   c. In the Accession Number field, type in or scan an accession number (optional).
   d. In the Sequence Number field, type in or scan the panel's sequence number. If an invalid Sequence Number is entered, message W100 appears. For information on Invalid Panel Sequence Number (see Figure 4-1).
   e. The Isolate Number field defaults to isolate number 1. Type in the isolate number, or select the + or the – to increase or decrease the number. Valid isolate numbers are 1 to 20.
   f. For Yeast ID panels, the Media field appears to the right of the isolate number field. If a media type is not specified, a workflow error is generated when the panel is attempted to be saved. If a Yeast ID panel is not logged in before placing it in the instrument for testing, the panel aborts after the first reading because no media has been specified. A default media type can be configured (see **Section 5.9.2 System Configuration Sub-Tab**), which appears when a Yeast ID panel sequence number is scanned during login.
   g. To select a different media, select a media type from the drop down box. When the media type is selected, the full name appears at the top right of the screen. Highlight the desired media. Select Save.
   h. In the Test Strain field, select QC organism from the drop down menu. Only the predefined, required test strains appear (if available), otherwise all of the test strains appear. If a Sequence number has not been entered, No Data Available is displayed. Highlight and select the desired QC organism.
   i. In the Panel Lot Number field, type in or scan the panel's lot number. Lot numbers must be seven numeric digits. Press Tab to advance to the next field. (If the QC Lot Support feature is enabled, this field is completed automatically when the Sequence Number barcode is scanned.)
   j. In the Expiration Date field, select the calendar icon to enter the expiration month, day, or year. (If the QC Lot Support feature is enabled, then once the lot number barcode is scanned, both the serial number and the expiration date are automatically populated.)
   k. In the ID Broth Lot Number field, type in or scan the broth lot number (optional). Lot numbers must be seven numeric digits.

l. In the Expiration Date field, press the calendar icon to select the expiration month, day, or year (Optional).

m. In the AST Broth Lot Number field, type in or scan the broth lot number (optional). Lot numbers must be seven numeric digits.

n. In the Expiration Date field, press the calendar to select the expiration month, month, or year (optional).

o. In the Indicator Lot Number field, type in or scan the broth lot number (optional). Lot numbers must be seven numeric digits.

p. In the first Expiration Date field, press the calendar to select the expiration month, day, or year (optional).

q. Select Save to save the information.

r. Place the panel in the instrument (see **Section 5.2.3 Inserting Panels in the Instrument**).

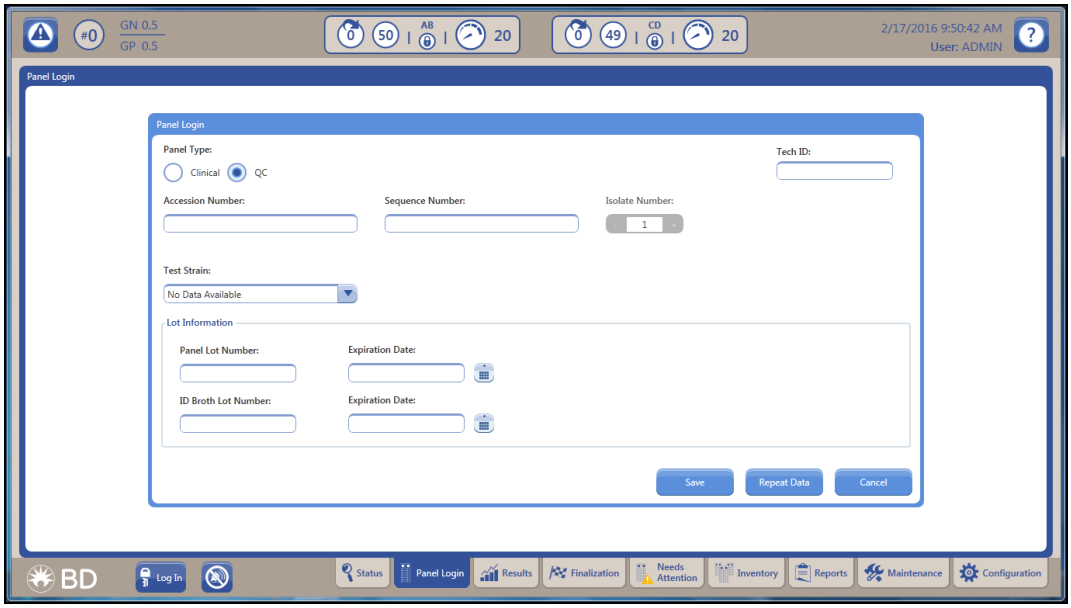


Figure 47 QC Panel Login Screen

The Panel Lot Number field does not display when BD EpiCenter communications is enabled. The user can enter information in all the other fields when BD EpiCenter is configured.

6.4 Automatic Association of Panels

The purpose of Automatic Association of Panels is to associate ID results from one panel (an ID or Combination panel) to the AST panels that are related to it and that lack an ID. Panels are related by virtue of having the same accession and isolate number. Thus panels with the same accession number and different isolate numbers are NOT related, and Auto Association does not occur between such panels.

Auto Association often involves the initial stage of Organism ID Conflict Checking. Conflict Checking is the process where the system verifies that the panel which has triggered the process does not have a related panel with a Final ID that is different from its own. If there is a conflict, Auto Association does not occur between related panels. The circumstances where Conflict Checking occurs are described below.

Auto Association can help eliminate unnecessary work such as the need to manually enter an organism ID for related panels. In addition, the Conflict Checking function helps to ensure that the same organism ID is made for all the panels related to a patient specimen. Auto Association does not set the critical panel attribute for related panels.

6.4.1 Panel Types

The panel types whose ID information is associated to related panels are:

- ID panels
- Combination panels (with both ID and AST sides enabled)
- Combination panels with only the ID side enabled

Auto Association uses the Final ID.

The related panels whose IDs are set by Auto Association are:

- AST panels
- Combination panels with only the AST side enabled

6.4.2 When Auto Association Is Not Performed

Auto Association is NOT performed under the following circumstances:

- When an organism ID conflict exists within an accession/isolate
- To a related AST panel that has been finalized or deleted, or that already has a Final ID
- Between related ID-type panels
- Between related AST-type panels
- Between QC and regular panels
- Between related QC panels

If the Instrument ID field contains a tie/triplet, this information is not associated to any related AST panels, however the Final ID information IS auto associated

6.4.3 Organism ID Conflict Checking

Organism ID Conflict checking is performed using the Final ID for panels within the same accession/ isolate (i.e., related panels) that are not finalized (and are not QC panels). If both panels have a Final ID (both are not blank) and they do not match exactly, an Organism ID Conflict is considered to exist. When an Organism ID Conflict exists, no Auto Association is performed. All the panels involved in the conflict have a Needs Attention set indicating that there is an organism conflict. Once the conflict is resolved (and provided that all other conditions for Auto Association are met), then Auto Association does occur.

Organism ID Conflict checking is not performed on QC panels.

6.4.4 Auto Association and Related Actions

The trigger events that invoke Auto Association are:

- an ID or Combination panel status transitioning to Removable
- accession/isolate information being modified

If there are no unresolved tie/ triplet conditions and no Organism ID Conflicts exist:

1. The instrument searches for the first unfinalized related ID or Combination panel with a Final ID. If a panel with these criteria is found, the instrument performs Auto Association.
2. If a panel with the above criteria is not found, the instrument then searches for the first finalized related ID or Combination panel. If a finalized panel is found, the instrument performs Auto Association.
3. If there are related ID panels with no Final ID when an AST panel invokes Auto Association (and no Organism ID Conflict condition exists), the instrument sets a Missing Organism ID Needs Attention reason for the AST panel if its status is Removable.
4. Auto Association is performed for any related AST panels that do not have information in their Final ID fields if the AST panel's status is either ongoing or Removable (Auto Association is not performed on AST panels with a status of Pending).
5. Auto Association is the action of modifying an AST panel's Final ID field (when this field is blank) to contain the same information as a related ID panel's information.
6. The instrument ID information is only associated provided it is a single Organism ID and not a Tie/Triplet condition.
7. A Combination panel with both sides enabled uses its ID result to perform interpretations on the AST side of the panel.
8. When Auto Association is performed successfully, any existing Missing Organism ID Needs Attention reasons are automatically cleared from the AST panels.

6.4.5 Typical Auto Association Examples

Instrument ID Is Associated

ID and AST panels are logged with the same Accession/Isolate number. (The AST panel is not logged in with an Organism ID.) They are both placed into the instrument at the same time. The ID panel finishes testing. The panels look like the following:

Panel	Instrument ID	Final ID
ID	Org A	Org A
AST		

When the ID panel has completed testing, it looks for related panels. It sees the AST panel with no Final ID. The ID panel checks for Organism ID Conflicts. There is no Organism ID Conflict condition, so the ID panel associates its Instrument ID to the AST panel record's Instrument ID field (regardless of the AST panel's status).

The panels look like the following:

Panel	Instrument ID	Final ID
ID	Org A	Org A
AST	Org A	Org A

Instrument ID and Final ID Are Associated

The ID panel is logged in with an Accession/Isolate number. It is placed into the instrument to test. It completes testing and looks like the following:

Panel	Instrument ID	Final ID
ID	Org A	Org A

The user changes the Final ID for this panel. It now looks like the following:

Panel	Instrument ID	Final ID
ID	Org A	Org B

The user then logs in an AST panel with the same Accession/Isolate number as the ID panel. (The AST panel is not logged in with an Organism ID.) The AST panel completes testing and looks for related panels. It sees the ID panel and checks to make sure that there is no Organism ID Conflict within the Isolate. There is no Organism ID Conflict, so the AST panel associates the ID panel's ID to itself. The panels now look like the following:

Panel	Instrument ID	Final ID
ID	Org A	Org B
AST	Org A	Org B

Final ID Is Associated

An ID panel is logged in with an Accession/Isolate number. The panel is placed in the instrument to test. The ID panel finishes testing first with a tie /triplet condition. When this situation occurs, the panel looks like the following:

Panel	Instrument ID	Final ID
ID	Org A	
	Org B	
	Org C	

When the tie/triplet is resolved (by the user selecting one of the organisms listed or another organism), the ID panel will look like the following:

Panel	Instrument ID	Final ID
ID	Org A	
	Org B	
	Org C	Org A

The user then logs in an AST panel with the same Accession/Isolate number as the ID panel. (The AST panel is not logged in with an Organism ID.) The AST panel completes testing and looks for related panels. It sees the ID panel and checks to make sure that there is no Organism ID Conflict within the Isolate. There is no Organism ID Conflict, so the AST panel associates the ID panel's Final ID to itself. The panels now look like the following:

Panel	Instrument ID	Final ID
ID	Org A	
	Org B	
	Org C	Org A
AST		Org A

6.4.6 BDXpert Triggered Rules Screen

By default, the BDXpert Rules are enabled and set to trigger automatically when test results are processed. However, there is an option in the BDXpert Rule Configuration to disable some rules (which means they would not be applied to results) or to set BDXpert rules to trigger manually. Any rules set to trigger manually must be accepted or rejected by the user before any additional rule processing or Final SIR determination occurs.

To access BDXpert Triggered Rules:

1. Select **BDXpert Rules** from the Results screen.
2. The first pending rule is highlighted.
3. The effect of the rule is displayed on Final SIR values in the AST Results screen.
4. Select one of the following:
   - **Accept** to accept the pending rule
   - **Reject** to reject the rule
   - **Re-Run** to cause all interpretation rules to be reapplied to the raw data

6.4.7 Resistance Markers

If Resistance Markers have triggered on a particular panel, they are listed with the BDXpert rules.

The following information is displayed:

- The BDXpert rule number that triggered the Resistance Marker
- The Resistance Marker code (abbreviation)
- The Resistance Marker Name
- The BDXpert rule Description: Accept, Reject, Re-execute or Exit

7 Maintenance

The BD Phoenix M50 instrument requires little maintenance from the user to provide reliable performance. Daily activities include checking the instrument temperature and printer paper supply. On a weekly basis check the operation of the station status indicators (LEDs), the audible alarm, and the alert indicator. Routine preventive maintenance consists of a monthly check of the ambient air filter. All other procedures are on an as needed basis. Any maintenance or repair not described in this section should be performed by BD personnel only.

WARNING

ALL MAINTENANCE AND REPAIR OTHER THAN THE PROCEDURES DESCRIBED IN SECTION Section 7.1 Routine Maintenance AND SECTION Section 7.2 Module Replacement, MUST BE PERFORMED BY QUALIFIED SERVICE PERSONNEL. NON-COMPLIANCE WITH THIS WARNING MAY RESULT IN PERSONAL INJURY OR INSTRUMENT MALFUNCTION.

No yearly preventative maintenance is required to be performed by BD authorized service personnel.

This section describes the following functions:

- **Section 7.1 Routine Maintenance**
- **Section 7.2 Module Replacement**
- **Section 7.3 Software Update**

7.1 Routine Maintenance

Time Frame	Procedure
The results of maintenance checks can be recorded on the Daily Instrument Report.	• Check paper supply. • Record temperature from the Status screen. The temperature should be from 35 °C ± 1.5 °C. Record temperature standard panel. The temperature standard panel can be brought into view by selecting one of the instrument LED check functions on the Maintenance tab. The temperature should be 35 °C ± 1.5 °C. • Perform Daily Verification on BD PhoenixSpec. See Nephelometer Calibration in the BD PhoenixSpec package Insert.
Weekly	• Test Internal Green LEDs • Test Internal Red LEDs • Test Internal Amber LEDs • Extinguish all LEDs • Test External System LED

Time Frame	Procedure
	• Test Alarm • Perform the tasks listed under the Maintenance Hardware category. See below for task description.
Every 3 Months	• Perform calibration of BD PhoenixSpec. See Nephelometer Calibration in BD PhoenixSpec package Insert.
As Needed	Clean panel stations if they become contaminated by a leaking panel. The priority in this situation is to first limit the extent of the contamination and then to decontaminate the panel location(s) and other accessible instrument areas receiving the spill. • The contamination procedure applies only to accessible areas. If the spill extends into regions of the carousel that are not accessible, contact your local BD Service representative. • The solution recommended to clean the affected surfaces should be at least a 10% household bleach solution. All surfaces must be thoroughly washed with the freshly prepared bleach solution, so that the surfaces are glistening wet. If the extent of the contamination is uncertain, thoroughly wash the exposed portions of the carousel and cabinet with the freshly prepared bleach solution. See **Section 7.1.5 Cleaning / Decontamination** for a detailed cleaning procedure. Replacing the Barcode Scanner 1. Locate the cable connecting the barcode scanner to the instrument. 2. Unplug the cable. 3. Plug in the new scanner cable. 4. Verify the proper operation of the new scanner by scanning a panel sequence number at the Login screen. 5. Check to see if the sequence number is correct. 6. Select **Cancel** to exit the screen without saving the panel.

Table 17 Routine Maintenance: Time-frame and Procedure

7.1.1 Cleaning and Checking the Air Filter

Check the filter monthly and clean/replace if needed (see **Section 7.1.3 Cleaning the Air Filter**).

If the instrument's environment is especially dusty, check the air intake filter more frequently and clean or replace if needed. The filter must remain clean and unobstructed; restricted airflow from a dirty filter may cause the instrument interior to reach excessive temperatures, which can affect results and possibly cause hardware malfunctions or failures. The filter can be cleaned and reused.

The instrument’s filter is located inside the panel accesses area on the lower right. The filter can be removed without tools.

7.1.2 Removing the Air Filter

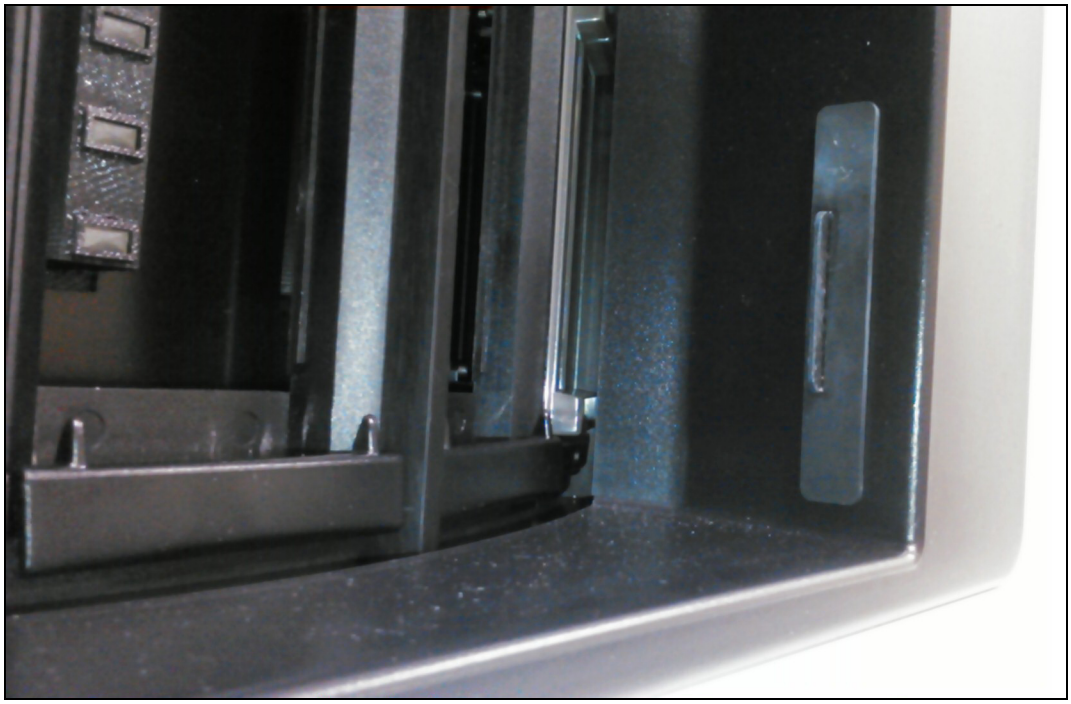


Figure 48 Air Filter Location

1. Press the Panels in or Panels out button to access panel entry area. The filter is located on the lower right side of the opening.
2. Grasp the black tab and slide towards the left side of the panel access area to remove the filter.
3. Remove the old filter, and clean and dry it before replacing it back into the instrument, or place a new filter in the housing while the old one is cleaned and dried.
4. To insert a clean filter, grasp the black tab on the side of the filter and slide to the right until filter flange is flush with right side of instrument access area.
5. Close the instrument door.

7.1.3 Cleaning the Air Filter

1. Wash the dirty filter in a bactericidal disinfectant.
2. Place the filter on a paper towel and dry it thoroughly (if it is going to be reused immediately).
3. To save time, replace the dirty filter with a spare clean filter. Wash, dry, and set aside the removed dirty filter for the next filter replacement.

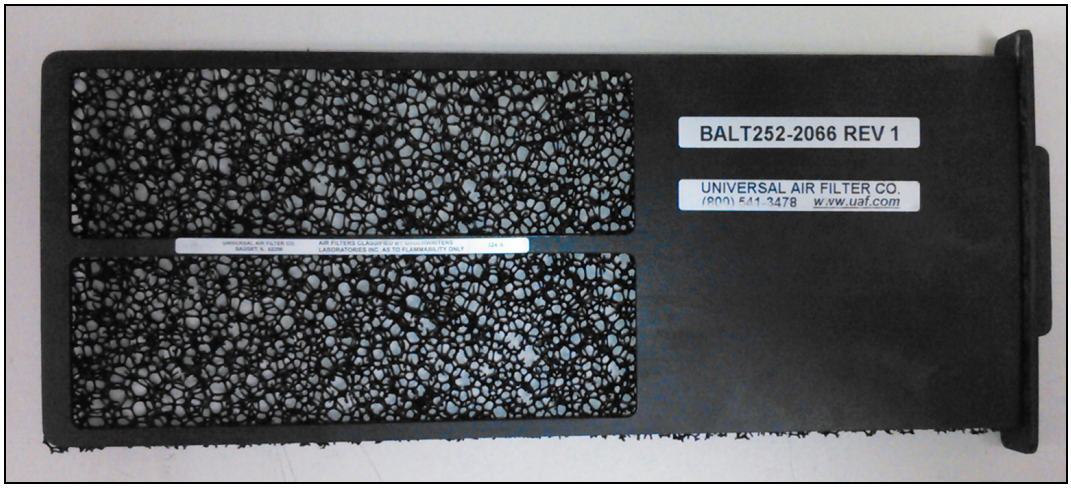


Figure 49 Air Filter

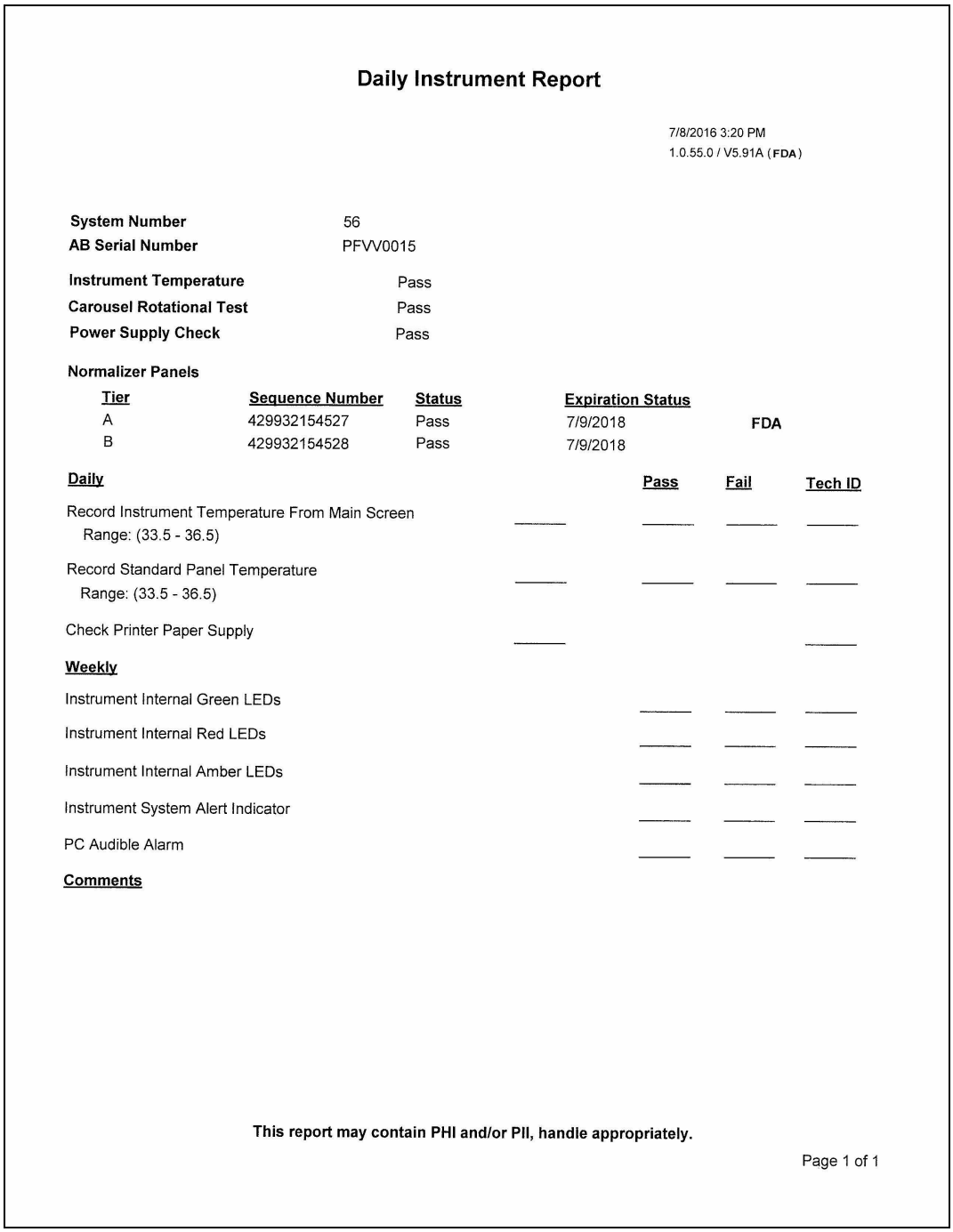
7.1.4 Daily Instrument Report

The Daily Instrument Report can automatically print at a user defined time or it can be printed upon request (see **Figure 50 Daily Instrument Report**).

For instructions on configuring the report to automatically print at a certain time, see the Instrument Configuration section of this manual.

The Daily Instrument Report has three sections:

Section	Description
Top	Lists information that was configured when the system was set-up: • Facility name and address • Date and Time the report was printed • Instrument Number • Serial Number
Middle	Lists information about the internal operation of the Phoenix as well as the Normalizer Panels. • This section should be reviewed on a daily basis to make sure that these operations have passed testing.
Bottom	Lists the maintenance items that need to be checked and recorded on a Daily and Weekly basis.



Daily Instrument Report

7/8/2016 3:20 PM
1.0.55.0 / V5.91A (FDA)

System Number 56
AB Serial Number PFVV0015

Instrument Temperature Pass
Carousel Rotational Test Pass
Power Supply Check Pass

Normalizer Panels

Tier	Sequence Number	Status	Expiration Status	
A	429932154527	Pass	7/9/2018	FDA
B	429932154528	Pass	7/9/2018	

Daily		Pass	Fail	Tech ID
Record Instrument Temperature From Main Screen Range: (33.5 - 36.5)	_____	_____	_____	_____
Record Standard Panel Temperature Range: (33.5 - 36.5)	_____	_____	_____	_____
Check Printer Paper Supply	_____			_____
Weekly				
Instrument Internal Green LEDs		_____	_____	_____
Instrument Internal Red LEDs		_____	_____	_____
Instrument Internal Amber LEDs		_____	_____	_____
Instrument System Alert Indicator		_____	_____	_____
PC Audible Alarm		_____	_____	_____

Comments

This report may contain PHI and/or PII, handle appropriately.

Page 1 of 1

Figure 50 Daily Instrument Report

7.1.5 Cleaning / Decontamination

A situation requiring biological decontamination of one or more panel locations can occur if a panel should leak while in the instrument. The priority in this situation is to first limit the extent of the contamination and then to decontaminate the panel location(s) and other accessible instrument areas receiving the spill. If the spill extends into regions of the carousel not accessible for topical decontamination, contact your local BD representative for further instructions.

Decontaminating Carousel Panel Locations

The solution recommended to clean the affected surfaces should be at least a 10% household bleach solution. All surfaces must be thoroughly washed with the freshly prepared bleach solution, so that the surfaces are glistening wet. If the extent of the contamination is uncertain, thoroughly wash the exposed portions of the carousel and cabinet with the freshly prepared bleach solution.

Required Materials

- 10% bleach solution
- Personal protection equipment, including gloves, gown, eye protection (e.g., face shield, goggles, etc.)
- Gauze pads or paper towels
- Tap water

Cleaning Procedures

1. Wear gloves and a gown, completely covering any body surfaces that could possibly come into contact with the affected instrument surfaces.
2. Turn off power to the instrument. Unplug the instrument power cord before proceeding.
3. Completely absorb the contaminated spill (gauze pads are most effective).
4. Apply the bleach solution to the affected surfaces, so that the surfaces are glistening wet. Let stand for approximately 15 minutes.
5. Absorb the applied solution with gauze pads or paper towels.
6. Dampen a clean cloth with water. Wipe down the decontaminated surfaces.
7. Thoroughly dry all wet surfaces.
8. Discard all cleanup materials as biohazardous waste.

WARNING

ALL PORTIONS OF THE BODY THAT COULD POSSIBLY COME INTO CONTACT WITH THE AFFECTED INSTRUMENT SURFACES MUST BE COMPLETELY COVERED BEFORE BEGINNING THE DECONTAMINATION PROCESS.

To Clean Monitors

During normal use, the AIO PC may become dirty and should be cleaned regularly. The solution recommended for cleaning the monitor is 70% alcohol.

Required Materials

- 70% alcohol

Cleaning Procedures

1. Prepare a cleaning agent per manufacturer's instruction or hospital protocol.
2. Prepare a clean cloth that has been moistened in a cleaning solution.
3. Wipe the AIO PC thoroughly with a clean wipe.

CAUTION

Do not:

- **immerse or rinse a POC terminal or its peripherals**
- **spray cleaning agents on the chassis**
- **use disinfectants containing phenol**

7.2 Module Replacement

The BD Phoenix M50 instrument has been designed and tested for trouble-free performance. In the event of malfunction, contact BD for service under existing contract terms or warranty. Only the external barcode scanner is user-replaceable.

Replacement modules may be exchanged. Only replacement parts supplied by BD should be used in the procedures described in this section.

7.2.1 Thermometer Removal

If the fluid in the thermometer of the temperature standard panel has separated, follow the procedure below to remove the thermometer and replace it.

To Remove/Replace the Thermometer

1. Remove the temperature standard panel from the BD Phoenix M50 instrument.
2. Using the small access hole at the bottom of the panel, gently push the thermometer upward through the large slotted opening at the top of the temperature panel.
3. Manually pull the thermometer completely out of the temperature standard panel through the slotted opening at the top of the temperature panel.
4. Reunite the separated fluid column per the instructions below.
5. Install the thermometer in the reverse order described above.

7.2.2 Reuniting Separated Liquid in the Thermometer

If the fluid in the thermometer of the temperature standard panel has separated, follow the procedure below to reunite the liquid.

To Reunite Separated Liquid

1. Should there be a separation in the capillary or in the expansion chamber at the top of the thermometer, heat the bulb of the thermometer in a hot liquid which exceeds the range of the thermometer until the separation and main liquid column enter the expansion chamber and unite with each other.
2. Quickly remove the thermometer from the liquid, so that the liquid does not completely fill the expansion chamber which could possibly harm the thermometer.
3. Check the thermometer against a certified, traceable thermometer or an ice bath to assure the thermometer is reading correctly.

7.3 Software Update

The user will receive the system with setup parameters that are preset to factory default values. But it is necessary to test and review these settings to see if they are compatible with the laboratory where the instrument will be housed.

Software updates are user installable. Insert the BD provided USB key in the USB connector on the AIO PC.

On the Maintenance tab select **Software** (as Task Category), and **Upgrade Execute** (as Task).

The software update should be recorded on the Daily Instrument Report for reference. See **Table 17 Routine Maintenance: Time-frame and Procedure** for details.

Each software function is accessed via the Maintenance tab. BD recommends thats the users save the system data to a USB key in case some error occurs or the system malfunctions. For more information on maintenance of software functions, see **Section 5.8.2 Maintenance Software Functions**.

For more information of software setup, see **Section 4.2 Software Setup**.

8 System Alert Messages

This section describes the following functions:

8.1 Error / Alert Messages

CAUTION

When the system displays alerts and errors, immediately respond to the condition.

When the system encounters an alert or error condition, the error code (EXX or WXXX, where XX or XXX is a number) is either displayed on the screen or written into the system alert list. The error code is an abbreviation for the conditions described in the listing below.

Different types of alerts and errors behave in different ways. There are three basic types of alert conditions:

- Self-Clearing – these alerts are removed from the System Alert Screen after they have been displayed and the screen has been exited. No other intervention is required.
- Persistent – these alerts remain in the System Alert Screen (even after displaying the alert code) until the instrument determines that the error causing the alert has been corrected. Correction can be accomplished with or without user intervention, depending on the alert.
- Auto Clear – these alerts are removed from the System Alert Screen as soon as the condition causing the error has been cleared. There is no requirement to display the alert code on the System Alerts List Screen. If the alert is still present when reviewing the Alert list, it will be displayed.

Each error code called out in this chapter will contain one of these three types of alerts and errors.

W error codes are displayed on the screen when they occur. (They also cause the Workflow Error tone to sound [sequence of short high beep and short low beep repeated four times].) These are activity (or workflow) types of errors. In most cases, this means that some action that was performed was not what the system expected, but the correct action can usually be performed, as recommended below, without exiting the current operation. These activity errors are flagged by a Workflow Error (see Figure 51 Workflow Error).

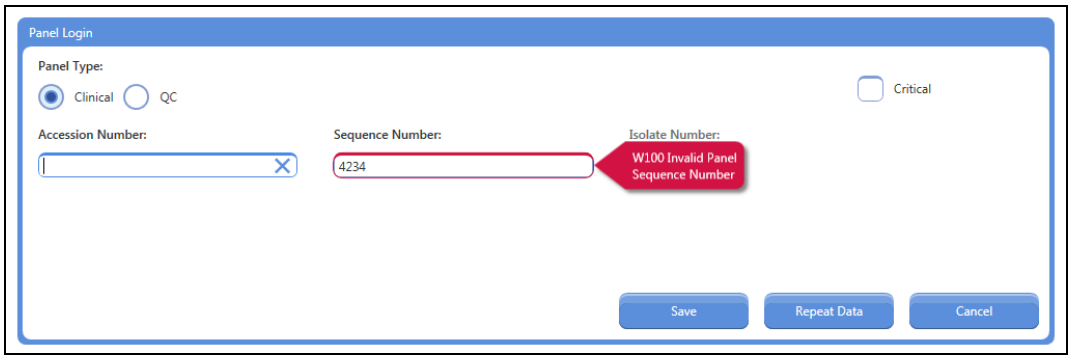


Figure 51 Workflow Error

W error codes are grouped as follows and full descriptions can be found in **Section 8.3 Workflow Alerts (W error codes)**:

W1XX Problem with the Sequence Number

W2XX Problem with the Accession, Isolate Number, or Media type

W3XX Problem with a QC panel only

W4XX Action to get into the instrument is not allowed

W5XX Configuration/Maintenance screen activity not allowed (as long as it is not an instrument action)

W6XX Screen activity is not allowed

W7XX LIS errors

W8XX QC Lot Support errors

8.2 System Alerts (E error codes)

System alerts (each shown in separate tables below), comprise of all **E** type error codes and are reported in the system alert list. These errors cause the Alert tone (medium beep on for one second, off for 3 seconds, repeating) to sound (if it is enabled). Also the System Alert icon appears on the Status screen and the Alert indicator is illuminated. The errors must be reviewed to clear the system alert condition. The system alert list can be viewed from the Status screen by touching the alert icon on the upper left corner of the display.

The **E** error codes are listed in numerical order. Error sub-codes are 8-digit numeric codes that appear below the EXX readout in the system alert list. The sub-codes indicate specific conditions detected and many are listed in the associated alert tables below.

CAUTION

If any error sub-codes other than those listed here appear, note the sub-code and contact BD for assistance. If the recommended corrective actions do not solve the problem, contact BD.

E01 Incubator Temperature			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Persistent	Average temperature too high (> 36.5 °C)	For all sub-codes, causes include: room temperature is not within recommended range, or other environmental specification is not being met (such as instrument sitting in direct sunlight or too close to HVAC air register). Make sure environmental specifications are met (see **Section 11.4 Instrument Specification Charts**). Clean and/or repair air filters to permit fresh air intake.
00000002		Average temperature too low (< 33.5 °C)	
00000004		Communication with the incubator temperature sensor is lost	
00000010		Average temperature too high for more than one hour (> 36.5 °C)	
00000020		Average temperature too low for more than one hour (< 33.5 °C)	
00000040		Absolute high temperature (> 38.5 °C)	
00000080		Control and QC temperatures disagree	
00000100		QC temperature is out of range	

Temperature readings are taken every 5 seconds for 10 minutes and these readings are averaged. Note that if the instrument temperature reaches 38.5 °C, the instrument disables the heater.

E05 Carousel Alert			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
0000000100000080	Persistent	Carousel RPM is below specification.Carousel is jammed (no panel flags detected, drum not moving)	The instrument reports these alerts if something is impeding the motion of the carousel. This can be attributed to one of the following: the reported RPM is below spec, certain flag readings are incorrect, or the carousel is jammed or stalled. It is detected during any carousel rotation. Any inventory scan or panel test in progress is aborted and the instrument ignores any data received from the test or scan.Open the door, look for and remove any obstructions such as a panel that is ajar or a panel closure that is not seated. Do not manually rotate the carousel. Close the door. If message reoccurs, contact your local BD representative.

E06 Tier Alert*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001 00000002 00000004 00000008 00000010 00000040 00000080 00000100 00000200	Persistent	This is the general alert condition for problems related to specific tiers including: incorrect flag readings, optical errors, timeout conditions, and normalizer problems.	Tier alerts are detected during a test cycle or inventory scan. The instrument ignores any data received from the test or scan for the tier that has sustained the error. Data received from good tiers is retained. All locations in the bad tier are automatically blocked. Some conditions reported for the E05 alert are also detected by the tier micro and reported with the E06 alert. They include missing/extra panel flags, home flag, etc. Follow screen instructions to correct the alert.

E06 Tier Alert*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000400 00004000 00020000 00040000 00080000 00100000 00200000 00400000			

* The first line of the error represents Tier A, the second line represents Tier B, the third line represents Tier C, and the fourth line represents Tier D. A code of 00000000 indicates that there is no error condition for that tier.

E09 Test Aborted Sub-code			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
20000000	Self-clearing	Panel testing has not occurred for more than one hour because the instrument was off, the door was open for more than an hour, the system clock was set ahead one hour or more or the test cycle had not occurred in more than an hour.	All ongoing panels are set to Needs Attention, and their status is set to Removable. Some results may be incomplete, and all affected panel results should be reviewed.

E10 System Database Corruption			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000002	Self-clearing	System Parameters Database Corrupted	Check your settings in the Configuration screens (see **Section 5.9.2 System Configuration Sub-Tab** and reset them to your preferences. Save data to a USB key and contact your local BD representative.
00000008		BDXpert Rules Database Corrupted	Check your settings for BDXpert Rule Configuration (see **Section 5.9.7 BDXpert Rules Sub-Tab**) and reset them to your preferences. Save data to a USB key and contact your local BD representative.
00000020		Custom Breakpoint Database Corrupted	Check your breakpoint settings for Custom Interpretation Rule Set

E10 System Database Corruption			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
			Configuration and reset them to your preferences. Save data to a USB key and contact your local BD representative.
00000040		User Codes Database Corrupted	Check your settings in the Organism and Antimicrobial Configuration screens see **Section 5.9.4 Organism Configuration Sub-Tab** and **Section 5.9.5 Antimicrobial Configuration Sub-Tab**) and reset them to your preferences. Save data to a USB key and contact your local BD representative.
00000001 00000010 00000080 00001000 00002000 00004000 00008000 00010000 00020000 00040000 00080000 00100000 00200000 00400000		Database corruption: Panel, Panel Lot, Alert / Eventlog. Corruption of instrument configuration record, instrument history, system parameters, light source, etc.	Save data to a USB key and contact your local BD representative.

E11 Printer Error			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
20000000	Self-clearing	Paper jam or power condition	Check printer paper (jammed our out), cable connection, power on, and/or online indicator.

E13 Power Failure			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
0x20000000	Self-clearing	Power removed from instrument	Message is informational. If multiple power failures have occurred, only the latest one is reported in the alert list. Note the power failure and restore times in your instrument log. Note that power fail events are not recognized until the instrument user interface has successfully loaded.

E14 CCD Underrun*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000000	Persistent	Scanning of a panel stopped prematurely during a test cycle	The instrument ignores any data received from the test for the panel/station that has sustained the error. Data received from good panels is retained, unless the station sustaining the error was the normalizer station. All error stations are automatically blocked. If the normalizer has this error, the whole tier is blocked.To clear, re-boot the instrument.

*The first line of the error represents stations with errors in Tier A, the second line represents stations with errors in Tier B, the third line represents stations with errors in Tier C, and the fourth line represents stations with errors in Tier D. A code of 00000000 indicates that there is no error condition for that tier

E18 Normalizer Row Averages*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001 00000002 00000004 00000008 00000010 00000020 00000040 00000080	Self-clearing	The tier had a problem with normalizer panel data averages	A source adjustment can only be performed when all panels in an instrument are no longer ongoing.Normalizer errors are detected during a test cycle. Test data received may be discarded or retained depending on the error sub-code. All available stations in the bad tier are automatically blocked; ongoing stations become blocked as testing completes or panels are removed. Do not enter any new panels or move an ongoing panels into any tier reporting this error. The instrument may be able to correct this error via the light source adjustment process.

* The first line of the error represents Tier A, the second line represents Tier B, the third line represents Tier C, and the fourth line represents Tier D. A code of 00000000 indicates that there is no error condition for that tier.

E20 Barcode Scanner Not Communicating			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001 00000002 00000004 00000008 00000010	Self-clearing	Tier barcode scanner (or handheld scanner) is not communicating and all the tier stations are automatically blocked	Reboot the instrument.

E21 Level 2 Rotor Step Warning*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000000	Persistent	The instrument has sensed that rotor rotation was not ideal but still acceptable	Check for a panel protruding from its carrier, an improperly seated closure, or user applied label peeling off. If no obvious visible cause for the error exists, contact your local BD representative.

* The first line of the error represents stations with errors in Tier A, the second line represents stations with errors in Tier B, the third line represents stations with errors in Tier C, and the fourth line represents stations with errors in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

E22 Level 3 Rotor Step Error*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000000	Persistent	The instrument has sensed that rotor rotation was out of specification	The instrument ignores any data received from the test for the panel/station that has sustained the error. Data received from good panels is retained, unless the station sustaining the error was the normalizer station. All error stations are automatically blocked. If the normalizer has this error, the whole tier is blocked.Check for a panel protruding from its carrier, an improperly seated closure, or user applied label peeling off. If no obvious visible cause for the error exists, contact your local BD representative.

* The first line of the error represents stations with errors in Tier A, the second line represents stations with errors in Tier B, the third line represents stations with errors in Tier C, and the fourth line represents stations with errors in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

E30 Normalizer Expiration Alert*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Self-clearing	The tier's normalizer panel expiration date is between 60 and 30 days away	The instrument issues a weekly alert beginning when Normalizer panel expiration is 60 days away, which progresses to a daily alert when expiration is 30 days away. Schedule Normalizer panel replacement for the affected tiers before they expire (expiration date is shown on Daily Instrument report.) Contact your local BD representative.
00000002		The tier's normalizer panel expiration date is less than 30 days away but has not expired	

*The first line of the error represents Normalizers in Tier A, the second line represents Normalizers in Tier B, the third line represents Normalizers in Tier C, and the fourth line represents Normalizers in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

E31 Normalizer Expired*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Persistent	Normalizer panel expiration date has passed. Stations	Schedule normalizer replacement immediately to

E31 Normalizer Expired*			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
		in all affected tiers are blocked	resume testing.

* The first line of the error represents Normalizers in Tier A, the second line represents Normalizers in Tier B, the third line represents Normalizers in Tier C, and the fourth line represents Normalizers in Tier D. A code of 00000000 indicates that there is no error condition for that tier.

E44 LIS Fatal Operating System Error			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Persistent	The instrument is not able to send data to the LIS due to a fatal software exception that occurs within the LIS library at the instrument	Start LIS system. Look for obvious source of problem such as disconnected cable. If no obvious source exists, contact your local BD representative.
00000008		A fatal operating error was detected by the LIS_IM	Contact your local BD representative.

E50 Internal Software Error			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Self-clearing	System encountered a software general protection error.	Save data to USB key (see **Section 5.8.1 Maintenance Hardware Functions**) and contact your local BD representative.
00000002		Internal software error	

E51 Duplicate Panel Barcode Detected			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000000	Self-clearing	Duplicate barcodes have been detected.	Carefully examine the reported stations for duplicate barcodes. All panels with duplicate barcodes have been aborted. If duplicates are found, then remove the panels from your system and contact your local BD representative

E51 Duplicate Panel Barcode Detected			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
			immediately.If no duplicates are found, then the alert may be a result of moving an existing panel between instruments. Avoid moving panels across instruments as they will be aborted.If the alert reoccurs, contact your local BD representative.

E52 Instrument Communications Application Layer (ICAL) Alert			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Self-clearing	Instrument is not registered	Configure the instrument in the system.
00000002		Instrument history purged because instrument was in isolation mode too long.	Reconnect the instrument and Tablet PC or contact your local BD representative.
00000004		Extra Device Alert: three or more instruments are plugged into the application.	Remove the instrument(s) that are not configured in the system.

E98 PC Alert			
Sub-code	**Alert Type**	**Possible Causes**	**Corrective Actions**
00000001	Persistent	The IDS layer timed out	If the condition reoccurs, contact your local BD representative.
00000002		The IDS system received an invalid parameter	Contact your local BD representative.
00000004		The IDS system rejected a message	
00000008		An invalid alert sub-code was detected	

8.3 Workflow Alerts (W error codes)

Field level alerts are displayed when data, entered into a specific field, is invalid. These errors (such as attempting to enter an invalid Sequence Number in the Panel Login screen) cause workflow error messages to appear on the displayed screen. They do not put the system into an alert condition. These errors can frequently be cleared by simply performing the activity correctly (such as entering a valid Sequence Number). When the error is corrected, the field level alert is removed from the display. All other workflow alerts are displayed in a dialog with two or more buttons.

W100 Invalid Panel Sequence Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	The panel sequence number typed or scanned does not meet the required number format.	Panel sequence number barcode is located at the top of the reaction side of the panel. Scan or type in the correct panel sequence number. Check panel carton for panel update barcodes if they are present.

W101 Missing Panel Sequence Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	Panel sequence number field empty when save is pressed.	Type in or scan the correct panel sequence number before attempting the operation again.

W102 Unknown Panel Sequence Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save or select a panel sequence number that is not in the BD Phoenix database.	Verify that the correct panel sequence number was entered. If error reoccurs, the panel may need to be logged in if it is a new panel. Older, completed, finalized panels eventually age out of the database.

W103 Invalid Panel Type for Region		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to log in a panel barcode that is not valid for the region.	Verify that the correct panel barcode was entered.

W200 Invalid Accession Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made save, find, or print information for an invalid accession number.	Enter a valid accession number, up to 20 characters excluding : * ? [ ] ! #

W201 Missing Accession Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An operation (find, save, print) was attempted and the value in the Accession Number field was invalid or blank. This can include: a record with a valid panel Sequence Number and an Isolate Number greater than 1 with no Accession Number; an orphan panel with just an Isolate Number, or trying to change a saved record to a blank Accession Number.	Type in or scan the correct accession number before attempting the operation again.

W202 Unknown Accession Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	At attempt was made to find data or print a report for an accession number that is not located in the BD Phoenix database.	Verify that the correct accession number was entered. If error recurs, the record may need to be logged in if it is new. Older, completed, finalized records eventually age out of the database.

W203 Missing Isolate Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a record when an accession number is present without an isolate number.	To save a record, if you enter an accession number, you must also enter an isolate number

W204 Missing Media Type		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a Yeast	To save a record, if you enter a Yeast ID

W204 Missing Media Type		
Message Type	**Alert Cause**	**Alert Corrective Action**
	ID panel during Panel Login and no Media is specified.	panel sequence number, you must select a media type.

W205 Panel Not Found		
Message Type	**Alert Cause**	**Alert Corrective Action**
OKPrint Screen	An attempt was made to find a Sequence and Accession combination that is not in the BD Phoenix database.	The Sequence and Accession combination does not exist in the database.

W300 Missing Test Strain for a QC Panel		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt was made to save a QC panel without an organism ID (Test Strain).	You must select an organism (Test Strain) to save a QC panel. Advance to the Test Strain field to drop down a box listing the available test strains. Highlight the desired organism. **Select** the highlighted organism.

W301 Missing Tech ID for a QC Panel		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a QC panel without a Tech ID.	You must enter a Tech ID to save a QC panel. Advance to the Tech ID field and enter a Tech ID, up to 3 alphanumeric characters excluding: * ? [ ] ! # |.

W302 Invalid Tech ID for a QC Panel		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a QC panel with an invalid Tech ID.	Enter up to 3 alphanumeric characters excluding: * ? [ ] ! # | for the Tech ID.

W303 Invalid Lot Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a record or print a report for an invalid panel lot number, ID broth lot number, AST broth lot number, or indicator lot number.	Enter the correct lot number. Lot numbers can be up to 7 characters. The lot number is shown on the item carton.

W304 Missing Lot Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save or print a report for a QC panel without a panel lot number, or an expiration date has been entered for one of the optional lot number fields (ID Broth, AST Broth, Indicator) with no corresponding lot number.	You must enter a panel lot number to save a QC panel. Advance to the Panel Lot # field and enter a lot number, up to 7 digits. The lot number is shown on the panel carton.

W305 ID or AST Must be Enabled		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt was made to save a panel or QC panel, and both the ID and AST fields are enabled.	The ID/AST fields are enabled or disabled based on the type of panel, according to the panel sequence number. At least one field must be enabled for the panel record to be saved and for testing to occur.

W400 Door Already Open		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	A request was made to perform a task that requires the door to be opened when the door is already open.	Select **OK**.

W401 Cannot Perform Panel Locate		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	The panel you are trying to locate is not in the instrument, or you cannot access the instrument using the Normalizer Panel Replacement function (e.g.,	Verify that the correct panel sequence number is entered or that the instrument can be accessed (for Normalizer Panel Replacement

W401 Cannot Perform Panel Locate		
Message Type	**Alert Cause**	**Alert Corrective Action**
	because there are ongoing panels).	activity, ongoing panels render the instrument inaccessible for this activity).

W500 Upgrade Error		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	The USB key does not contain a readable, same, or newer version of instrument software. Causes include: older version of instrument software; USB key was removed before the update completed, or the USB key contains a corrupted or missing file.	Attempt the update operation again. If error reoccurs, contact your local BD representative.

W502 Removable Media Error		
Message Type	**Alert Cause**	**Alert Corrective Action**
Retry Cancel Print Screen	The USB key is not in the drive, full, write protected or it was removed before completion of the task.	Attempt the update operation again. If error reoccurs, contact your local BD representative.

W503 Duplicate Rule		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	The data contained in the Antimicrobial, Org(anism) Group, and Organism fields is the same for the rule being saved as a different rule already defined in the Rule Set.	One of the parameters (Antimicrobial, Organism Group, or Organism) must be unique for the record to be saved.

W506 Instrument Not Idle		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK	An attempt to execute an upgrade failed because the instrument was not	Wait until instrument is idle (or correct carousel jam) before performing this

W506 Instrument Not Idle		
Message Type	**Alert Cause**	**Alert Corrective Action**
Print Screen	idle.	activity.

W507 Invalid Password		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An invalid (or no) password was entered to access a Configuration screen.	Enter the correct password and perform the action again.

W511 Battery Mode		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt to install or restore data while the tablet is unplugged and working in battery mode.	Retry the install or restore data when battery mode is not in progress.

W600 Panel Cannot Be Deleted		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt was made to delete a panel that is still physically in the instrument or a non-pending QC panel that is not physically in the instrument (if QC Lot Support is enabled).	Remove the panel from the instrument. You can use the find panel tab to make the carousel present the panel when the door is opened. If you know you have already removed the panel, then close the instrument door and allow the instrument to complete an inventory scan before attempting to delete the panel.

W601 Cannot Finalize		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to finalize a panel either whose status is not Removable or that has an unignored Needs Attention set.	If panel is Ongoing, wait until it becomes Removable before attempting to finalize it. If panel has a Needs Attention set, resolve the reason before attempting to finalize the panel.

W602 Invalid Date		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a record containing, or to print a report specifying, an invalid date. Or, a panel lot barcode containing an invalid expiration date was scanned.	Enter a valid date.

W604 Panel Still Testing		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a Final ID to an ID or Combination panel that has not reported an Instrument organism ID.	A Final ID cannot be selected and saved until the instrument ID results are obtained. Wait until the instrument calculates an ID before attempting to select a Final ID.

W606 Cannot Modify Date for a Finalized Panel		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt was made to save a panel without a panel lot number expiration date or without expiration dates for other lot number fields IF panel lot numbers have been entered.	If information for a finalized panel must be modified, recall the panel and un-finalize it by disabling the Finalize field. Make the required changes and save the information.

W607 Missing Date		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to save a panel without a panel lot number expiration date or without expiration dates for other lot number fields IF panel lot numbers have been entered.	A valid panel lot number expiration date must be entered for panels. If other lot number fields are completed, their corresponding expiration dates must be entered.

W608 Improper Barcode Scan		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK	The barcode number scanned is too long for the current active	Verify which field is currently active and check what type of barcode you are trying to scan.

W608 Improper Barcode Scan		
Message Type	**Alert Cause**	**Alert Corrective Action**
Print Screen	field, or is not the correct type of barcode for the field (e.g., scanning a lot number in a non-lot number field).	

W609 Database Full		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt was made to log in a new panel and 50 panels exist in the instrument database with a pending record status, with no panels eligible for deletion.	Pending panels should be placed in the instrument and allowed to complete an inventory scan before you attempt to log in any new panels.

W700 Invalid LIS Code		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An invalid LIS code was entered in the Organism Configuration or Antimicrobial Configuration screen.	LIS Codes can be up to 20 alphanumeric characters.

W701 Duplicate LIS Code		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	A duplicate LIS code was entered in the Organism Configuration or Antimicrobial Configuration screen.	LIS Codes must be unique in the system.

W800 Panel Lot Undefined		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	An attempt was made to log in a QC panel but the panel sequence number is not within the range of a defined/saved Panel Lot.	When QC Lot Support is enabled in Configuration, all QC panels must belong to a defined/ saved panel lot. Clinical panels may be from an undefined panel lot and still be logged in, though such panels generate a Panel Lot Undefined Needs Attention

W800 Panel Lot Undefined		
Message Type	**Alert Cause**	**Alert Corrective Action**
		condition.

W801 Panel Lot Range Incomplete		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	During Panel Lot Definition, an attempt was made to save a panel lot but one or both panel sequence number fields were blank.	Both a starting sequence number (lowest) and ending sequence number (highest) must be scanned for any panel lot to be saved. The sequence numbers can be scanned in any order, but both must be scanned. You cannot type in a sequence number on the Panel Lot Definition screen.

W802 Panel Lot Range Invalid		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	During Panel Lot Definition, an attempt was made to save a panel lot but the two panels scanned were different panel types.	Both panels must be the same type for any panel lot to be saved.

W803 Panel Lot Range Conflict		
Message Type	**Alert Cause**	**Alert Corrective Action**
Field Level	During Panel Lot Definition, an attempt was made to save a panel lot but one or both panel sequence numbers conflicted with an existing panel lot definition.	A panel sequence number can only belong to one defined/saved panel lot. Contact your local BD representative.

W806 Panel Lot Expired		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	A panel lot number barcode is scanned containing an expired expiration date.	Enter an unexpired panel log number barcode.

W900 Commission Duplicate Serial Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	There is an instrument with the same serial number already commissioned.	Enter a unique serial number.

W901 Commission Duplicate Instrument Identifier		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	There is an instrument with the same designation already commissioned.	Check for instrument designation duplication.

W904 Commission Invalid Serial Number		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	The serial number must be a minimum of six characters.	The serial number must be six characters.

W905 Decommission of Connected Instrument		
Message Type	**Alert Cause**	**Alert Corrective Action**
OK Print Screen	An attempt is being made to decommission an instrument.	Disconnect the instrument prior to decommissioning.

8.4 Event Log Messages

8.4.1 LIS Related Messages

The Event Log tab, located on the bottom right of the Maintenance screen enables the user to see messages that the instrument writes to the Event Log. The messages are in the following format:

date time message type: message text

where *date* represents the day, month, and year in the format you have chosen

time represents the time in the format you have chosen

message type is one of the following:

- LIS Interface Message
- LIS Unsolicited Message
- LIS Order Cancelled
- LIS Query Assembly
- LIS Receiving Query
- LIS Configuration Change

message text is the actual text message that appears

Below is a list of the messages, along with a description of the message and any actions that may be performed to correct the problem. These messages are grouped by the message type listed above.

LIS Interface Messages

LIS Interface Messages are library messages generated by the LIS manager. They are listed below in alphabetical order.

Bad Frame Received From LIS
DESCRIPTION – This error is generated when the LIS downloads a frame that has not been properly formatted. The error type is listed as LIS_NON_FATAL.
CORRECTIVE ACTION(S) – The solution to this problem is to review the information that is being sent to the instrument via a communications line monitor. Compare the information captured with the specifications found in the BD – LIS Vendor Interface Document. Any discrepancies observed should be corrected and then the transmission should be attempted again

Detailed Download Message Attached to Notification
DESCRIPTION – These notifications are generated whenever a complete message is sent or received across the port. The error types are LIS_NOTIFY. The detailed description is not displayed.
CORRECTIVE ACTION(S) – Message is informational – no action required.

Detailed Upload Message Attached to Notification
DESCRIPTION – These notifications are generated whenever a complete message is sent or received across the port. The error types are LIS_NOTIFY. The detailed description is not displayed.
CORRECTIVE ACTION(S) – Message is informational – no action required.

Detailed Upload Message Attached to Notification
DESCRIPTION – These notifications are generated whenever a complete message is sent or received across the port. This provides the Host Application with the complete ASTM message string that was exchanged. The error types are LIS_NOTIFY and the detailed descriptions contain the ASTM message string.
CORRECTIVE ACTION(S) – Message is informational – no action required.

Disallowed Characters Contained in Field
DESCRIPTION – This error is generated when an upload field contains characters that are not allowed in an upload message. These characters differ based on logical protocol and will be stripped from the upload field. This error type is LIS_NON_FATAL. The detailed description is not displayed.
CORRECTIVE ACTION(S) – If this error is reported the problem should be reported to your local BD representative for further investigation.

Download Field Was Concatenated
DESCRIPTION – This notification is generated when a download field is larger than the maximum size set by the Host Application. The field will be concatenated to the maximum size. This error type is listed as LIS_LOG. The detailed description is not displayed.
CORRECTIVE ACTION(S) – In this case the content that is being assembled needs to be reviewed. Review the BD – Vendor Interface Specification for limitations on field lengths in the message. Then the LIS code should be updated so that the information sent to the instrument remains within the defined limits.

Download Message Has a Bad or Missing Header Record
DESCRIPTION – This error is generated when a download message does not have a properly formatted header record. The LIS IM cannot continue processing the message and it will be deleted. This error type is listed as LIS_NON_FATAL, and the detailed description holds the ASTM message received from the LIS.
CORRECTIVE ACTION(S) – Check the header line for errors. Correct the header error and resend the message.

Download Physical Communication with LIS Has Begun
DESCRIPTION – This notification is generated when the download thread in the physical layer is actively downloading a message.
CORRECTIVE ACTION(S) – Message is informational – no action required.

Download Physical Communication with LIS Has Completed
DESCRIPTION – This notification is generated when the download thread in the logical layer has completed processing a download message.
CORRECTIVE ACTION(S) – Message is informational – no action required.

Download Record is Out Of Sequence Or Has Bad Sequence Number
DESCRIPTION – This error is generated when a download record contains records with a bad sequence number, or violates the record hierarchy for the logical level protocol. This will cause the message to be deleted from the download queue. This error type is listed as LIS_NON_ FATAL.
CORRECTIVE ACTION(S) – Appropriate updates should be made to the application generating the logical message so the structure conforms to the ASTM specifications for the interface. Most questions concerning the message content can be addressed by referencing the BD – Vendor Interface Specifications and the ASTM specifications for the interface.

Early Termination of Transfer Session By LIS
DESCRIPTION – This error is generated when there is an error in LIS communication. The control character to end a transfer session was received before the appropriate number of characters for the frame were received.
CORRECTIVE ACTION(S) – Review the frames being exchanged between the instrument and the LIS to assure that the proper number of characters are contained within the packets that are being exchanged. If the correct number of characters is not in the packet, update the code so that the correct number of characters is included in each frame.

Expected Frame Not Sent
DESCRIPTION – This error is generated when there is an error in LIS communication. The LIS initiated a transfer session but did not send any data before a time-out occurred. This error type is listed as LIS_NON_ FATAL.
CORRECTIVE ACTION(S) – Connect a communications line monitor and restart the transmission. Observe the transmission to determine if the complete transmission occurs or if the transmission is interrupted early. If the transmission appears to be complete or the LIS appears to be attempting to send the transmission contact your local BD representative for assistance. If the transmission appears to be incomplete from the LIS side of the transmission then the LIS code should be investigated for problems that could terminate the transmission early.

Internal Assert Condition Found in LIS Library
DESCRIPTION – This message indicates that the Instrument has encountered an error that should not occur. This error will result in the instrument rebooting.
CORRECTIVE ACTION(S) – Contact your local BD representative. At the time the problem occurs the application writes data to the log file that indicates the nature of the Assert. The BD representative should instruct you on the appropriate procedure to collect the data for the condition.

LIS Debug Error
DESCRIPTION – This error is generated when there has been a problem internally to the instrument physical layer. This error may be triggered for an index out of bounds, or unsupported memory area IDs, etc. This error type is listed as LIS_FATAL.
CORRECTIVE ACTION(S) – This error is a Fatal Error. If this error appears in the log file, contact your local BD representative. The sequence of events that produced this message should be documented so that BD representatives can reproduce the error and then provide an appropriate course of action to address the problem.

LIS Did Not Acknowledge Sent Frame
DESCRIPTION – This error is generated when the instrument has sent a frame to the LIS but has not received an acknowledgment before a time-out occurred. This error type is listed as LIS_ NON_FATAL.
CORRECTIVE ACTION(S) – This message should not occur during normal operation of the instrument interface. If this error is being encountered during development of the interface then the LIS development group should connect a data communication monitor to the serial interface cable and review the information that is being exchanged between the two devices. It is likely that the LIS is not generating the appropriate response to the message that the instrument has sent.

LIS Is Not Responding To Output Request
DESCRIPTION – This error is generated when the instrument is trying to establish a transfer session but the LIS is not responding. When this error is sent, the instrument is assuming the LIS connection is broken or the LIS is down. This error type is listed as LIS_NON_FATAL.
CORRECTIVE ACTION(S) – Check to assure that the LIS interface is active and ready to receive messages from the instrument. If the LIS is operating correctly, connect a communications line monitor and review the information that has been captured. If the instrument is attempting to establish communications with the LIS, it would be appropriate to review the code that has been written to interface with the instrument and assure that the code is appropriate to receive the information sent by the instrument.

LIS Never Completed Current Frame
DESCRIPTION – This error is generated when there is an error in LIS communication. The control characters expected to end a transmitted frame were never received.
CORRECTIVE ACTION(S) – Review the frames being exchanged between the instrument and the LIS via line monitor. Be sure to review all frames included in the transmission. If any frames do not contain the appropriate termination characters make appropriate changes to the interface code to correct the problem.

Logical Processing of LIS Data Has Begun
DESCRIPTION/CORRECTIVE ACTION(S) – Message is informational – no action required.

Logical Processing of LIS Data Has Completed
DESCRIPTION/CORRECTIVE ACTION(S) – Message is informational – no action required.

Message Packet Passed to Host Application
DESCRIPTION – This notification is generated when the LIS IM has successfully passed a message on to the Host Application. This notification exists mostly as a debug message. This error type is listed as LIS_ LOG.
CORRECTIVE ACTION(S) – No action required by user. Information is included to help LIS manufacturers debug and implement their interface.

Message Received By LIS
DESCRIPTION – This notification is generated after the LIS has received and acknowledged a message from the instrument.
CORRECTIVE ACTION(S) – Message is informational – no action required.

Message Received From LIS
DESCRIPTION – This notification is generated when a download message has been properly received by the Physical Interface from the LIS. This error type is listed as LIS_LOG.
CORRECTIVE ACTION(S) – This message is an informational message and requires no action to be taken. The transmission was successful. This message will be generated even if the message contained content errors.

Must Re-send Output Frame to LIS
DESCRIPTION – This notification is generated when a frame sent by the LIS IM was not properly received by the LIS. The message frame will be resent, according to low level protocol specifications. This error type is listed as LIS_LOG.
CORRECTIVE ACTION(S) – If this message appears infrequently and the messages that are being exchanged are completed correctly, it is likely that no action is required. If the message above is encountered frequently, there is likely a problem in the interface. The LIS manufacturer and BD representative should be contacted to diagnose the interface to assure that it is operating properly. When the link is operating optimally this message should not appear in the log.

No Queue Memory for Download Messages
DESCRIPTION – The BD Phoenix M50 Instrument is designed to operate in a limited amount of memory (as defined in the configuration structure). When these memory resources are full with download or upload messages, this notification will be generated. The notification may be common if the LIS tries to download too much information at once. The BD Phoenix M50 Instrument will NAK data for which it cannot allocate memory, and the LIS will have to resend the data.
CORRECTIVE ACTION(S) – Resend the messages that were rejected by the instrument.

No Queue Memory for Upload Messages
DESCRIPTION – The BD Phoenix M50 Instrument is designed to operate in a limited amount of memory (as defined in the configuration structure). When these memory resources are full with download or upload messages, this notification will be generated. This message should not be encountered when using the instrument LIS interface.
CORRECTIVE ACTION(S) – If this message is encountered, the problem should be reported to the BD representative. It will be helpful if the process that generated the problem is documented.

No Response Received From Previous LIS Request Message
DESCRIPTION – This notification is generated when the LIS IM has uploaded a query but no response is received. This notification indicates that the original query was cancelled. This notification should occur some time after the query, as determined by the value in the configuration structure. The error type is listed as LIS_LOG. The detailed description is not displayed in the current version.
CORRECTIVE ACTION(S) – Validate that the LIS system is correctly connected to the instrument and that the LIS interface has been activated.

Operating System Error
DESCRIPTION – This error is generated when the operating system class encounters an error in one of its routines. This could be caused by a number of OS errors, including not properly initializing a port or not properly creating an event handle, and others. These errors should not occur under normal conditions and the LIS IM cannot recover from them. The error type is listed as LIS_FATAL.
CORRECTIVE ACTION(S) – If this error is reported the problem should be reported to your local BD representative for further investigation.

Output Message Was Sent To LIS
DESCRIPTION – This notification is generated when an upload message has been successfully transmitted to the LIS. This error type is listed as LIS_NOTIFY. Notification sent when the instrument begins sending a message to the LIS. Receiving this notification does not signify the message was accepted by the LIS.
CORRECTIVE ACTION(S) – Message is informational – no action required.

Queue Memory for Download Messages Free
DESCRIPTION – This notification is used in pairs with the No Queue Memory For Download Messages above. When memory has previously been determined to be full, and now has been released, this notification will be generated.
CORRECTIVE ACTION(S) – This is an indication to a user of a batch-oriented interface that the instrument is capable of receiving the next group of messages.

Queue Memory for Upload Messages Free
DESCRIPTION – This notification is used in pairs with the No Queue Memory For Upload Messages above. When memory has previously been determined to be full, and now has been released, this notification will be generated.
CORRECTIVE ACTION(S) – This message should not appear in the log during operation of the interface. If this message appears in the log, contact your local BD representative.

Response Message Received
DESCRIPTION – This notification is generated when the LIS has downloaded a response to a BD generated query. This is also an indication that the LIS IM can upload another query to the LIS. The error type is LIS_NOTIFY. The detailed description is not displayed in the current version.
CORRECTIVE ACTION(S) – Message is informational – no action required.

Unsupported Field in Configuration File
DESCRIPTION – This error is generated during startup when a field in the configuration structure does not match one of the supported configurations of the LIS IM. This error type is listed as LIS_FATAL.
CORRECTIVE ACTION(S) – If this error is reported the problem should be reported to your local BD representative for further investigation.

Upload Physical Communication With LIS Has Begun
DESCRIPTION – This notification is generated when the upload thread in the physical layer is actively uploading a message.
CORRECTIVE ACTION(S) – Message is informational – no action required.

Upload Physical Communication With LIS Has Completed
DESCRIPTION – This notification is generated when the upload thread in the physical layer has completed sending a message to the LIS.
CORRECTIVE ACTION(S) – Message is informational – no action required. LIS Unsolicited Message The following sections contain the possible messages associated with Event Log entries in response to unsolicited download requests. They are listed below in alphabetical order.

LIS Response Error
DESCRIPTION – This message is set after the LIS sends an incorrectly formatted query message to the instrument. We will respond by sending a response error message to the LIS.
CORRECTIVE ACTION(S) – If the interface is operating correctly, this message should not be present in the log. If this message is found in the log during validation or development of the interface, the code responsible for generating the queries should be reviewed and adjusted so that the query is assembled without the invalid field. The invalid field will be the last “LIS Query Assembly” message listed before this message in the log file.

LIS Sent Query Before Previous Query Completed
DESCRIPTION – This message is set if the LIS initiates a query and while the instrument is busy with this query, the LIS cancels the first query and immediately starts another.
CORRECTIVE ACTION(S) – If the interface is operating correctly this message should not be present in the log. If this message is found in the log during validation or development of the interface, the code responsible for generating the queries should be reviewed and adjusted so that it will not send another query while it is waiting for an outstanding query to be canceled.

LIS Order Canceled Messages

(Message consists of a field name shown below at * and invalid field contents.)	
DESCRIPTION –	The validation for the noted field failed.
	*Invalid Sequence Number Field
	Missing Accession Number Field
	Invalid Accession Number Field [cannot be 12 digits and begin with 42 or 50–59; see **Section 5.2 Panel Login Tab** for other requirements.
	Missing Isolate Field
	Invalid Isolate Field
	Invalid Panel Usage
	Invalid Test ID Field
	Invalid Test Strain for this QC Panel Type
	Mismatch Sequence Number and Test ID
	Missing Test ID Field
	Invalid Organism ID Field
	Invalid Priority Field
	Problem Storing Record to Database

When an error is detected, the message for that error is logged and the remainder of the message checking is terminated. There could be other errors in the order that were not reported. The error checking priority depends upon whether the order contains a sequence number or not.

CORRECTIVE ACTION(S) – In an operational interface it is possible to encounter these errors if the LIS implementation allows entry of data into the fields that violate the Instrument field rules. In this case the user of the LIS should limit the characters entered into the fields sent to the instrument to those characters noted in the System User's Manual as valid for the field. Once the information has been updated to conform with the instrument's rules the order should be sent to the instrument again.

If the interface is under development the developer of the interface should limit the data being sent to the instrument to those characters that are appropriate for the fields.

LIS Query Assembly Messages

All of the following messages are written to the log file regardless of whether they are invalid or valid. They are placed in the log so that they can be used in conjunction with the messages that follow them. If an error is found in one of the fields, the contents of the field in error will be logged.

(Message consists of a field name shown below at **.)	
DESCRIPTION –	The message is logged when the instrument uploads a query to the LIS.
	**Accession Number
	Sequence Number
	Test ID
	Test Status
	Result Qualifier
	Time Qualifier
	Start Date/Time
	End Date/Time
CORRECTIVE ACTION(S) – If the query is valid, the message is informational – no action required. If the query is invalid, then review the field in error, correct, and resend the query.	

(Message consists of a field name and value shown below at ***.)
DESCRIPTION – This message is logged when the instrument uploads a query to the LIS. *** Sequence Number and the value
CORRECTIVE ACTION(S) – Message is informational – no action required. LIS Configuration Change Messages

(Message consists of a configuration value shown below at ** with old and new values.)	
DESCRIPTION –	The message is logged when the LIS configuration is changed.
	**LIS Enabled Value Changed
	Send Interpretation Results Option Changed
	Unsolicited Queries Option Changed
	Send When Placed In Instrument Option Changed
	Results Upload Options Changed
	Baud Value Changed
	Data Bits Value Changed

(Message consists of a configuration value shown below at ** with old and new values.)	
	Parity Value Changed
	Stop Bits Value Changed
	Packed Frames Value Changed
CORRECTIVE ACTION(S) – Message is informational – no action required.	

9 Performance, Limitations, Organism Codes, and Panel Information

This section describes the following:

9.1 Supplemental ID Test Abbreviations

Test	Description	Test	Description
10C	Growth at 10 °C	CAT	Catalase
42C	Growth at 42 °C	CEL	Cellobiose
45C	Growth at 45 °C	CIT	Citrate
50C	Growth at 50 °C	COA	Coagulase
ACE	MBM + Acetate	DNA	Dnase
ALC	a-Lactose	ESC	Esculin
ANR	Anaerobic growth	FRU	Fructose
ARA	Arabinose	GAS	Gas from Glucose
ARG	Arginine	GEL	Gelatin
BE	Bile esculin	GLC	Beta glucuronidase
BSO	Bile solubility	GLU	Glucose
CAM	CAMP with *Staphylococcusaureus*	H^2S	Hydrogen Sulfide
HGN	Hemolysis - Gram Negative	OPS	Optochin susceptibility
HGP	Hemolysis - Gram Positive	ORN	Ornithine
HIP	Hippurate	OX	Oxidase
IND	Indole	PXR	Polymyxin Resistance
KCN	Growth in KCN	PXS	Polymyxin Susceptibility
LAC	Lactose	PYR	Pyrrolidonyl arylamidase
LYS	Lysine	RAF	Raffinose
MAC	Growth in MacConkey	SBT	Sorbitol
MAL	Maltose	SLT	Growth in 6.5% NaCl
MEL	Melibiose	SOR	Sorbose

Test	Description	Test	Description
MNS	Mannose	SUC	Sucrose
MNT	Mannitol	TRE	Trehalose
MOR	Morphology	URE	Urea
MOT	Motility	VAN	Vancomycin
MR	Methyl Red	VP	Voges Proskauer
NIT	Nitrate	XYL	Xylose
NVR	Novobiocin Resistance	YEL	Yellow/orange pigment

9.2 Performance Characteristics

Definitions:

Essential Agreement (EA): Essential agreement occurs when the MIC of the BD Phoenix system and the CLSI Reference Broth Microdilution are identical or within ± 1 dilution of each other.

Category Agreement (CA): Category agreement occurs when the BD Phoenix system results are within ± 1 dilution from the CLSI Reference Broth Microdilution with respect to the CLSI categorical interpretative criteria.

9.2.1 Gram Negative Performance

Gram Negative Identification

In two internal studies, the performance of the BD Phoenix Gram Negative Identification was evaluated. The 0.5 inoculum density configuration and the 0.25 inoculum density configuration were tested with 721 strains (0.5) and 784 strains (0.25) respectively. Enteric and non-enteric isolate results were evaluated against commercial and noncommercial methods.

The BD Phoenix Gram Negative Identification performance is outlined below:

	Inoculum Density (McFarland)	Agreement	No Agreement	No ID
Genus Level	0.5	97.3%	2.1%	0.6%
	0.25	98.5%	1.0%	0.5%
Species Level	0.5	95.6%	3.6%	0.8%
	0.25	98.1%	1.4%	0.5%

Gram Negative Susceptibility

BD Phoenix™ Confirmatory CPO Detect Test

The BD Phoenix CPO detect test uses the principles of Ambler-class specific beta-lactamase inhibition and Ambler-class specific antibiotic resistance to detect the presence of a carbapenemase and to derive the Ambler class of the carbapenemase. In some isolates, the presence of complicated or multiple resistance mechanisms, including more than one carbapenemase, may result in a “CPO Positive” test result with no Ambler classification. The frequency of these isolates may vary regionally.

To determine the accuracy of the CPO detect test with *Enterobacteriaceae*, *P. aeruginosa*, and *A. baumannii*, testing was performed at multiple sites using Clinical and Challenge isolates. For clinical isolates a composite reference method was used, which included, but was not limited to, the modified Carbapenem Inactivation Method (mCIM), MIC Screen (utilizing carbapenem threshold values) and multiplex PCR testing. Multiplex PCR testing for *Enterobacteriaceae* included *bla*KPC, *bla*NDM, *bla*IMP, *bla*VIM, and OXA-48-like genes. Multiplex PCR testing for *P. aeruginosa* and *A. baumannii* included *bla*KPC, *bla*NDM, *bla*IMP, *bla*VIM, OXA-23-like, OXA-24-like, OXA-48-like, and OXA-58-like genes. Challenge isolates were compared to previously established results.

Positive/Negative Detection:

Positive Percent Agreement = 465/473 = 98.3%
Negative Percent Agreement = 538/562 = 95.7%
Overall Percent Agreement = 1003/1035 = 96.9%

Ambler Classification (A,B,D):

Overall Accuracy = 914/944 =96.8%

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Amikacin	AN	974	94.3	974	99.2
Amoxicillin	AMX	725	95.9	839	96.9
Amoxicillin-Clavulanate	AMC	636	97.8	749	97.1
Amoxicillin-Clavulanate (f)	AXC	364	96.4	411	97.6
Ampicillin	AM	639	97.5	753	98.0
Ampicillin-Sulbactam	SAM	848	96.8	962	96.9
Ampicillin-Sulbactam (f)	SXA	1682	92.3	1682	94.5
Arbekacin	ARB	2083	94.1	2083	99.2
Aztreonam	ATM	1488	97.8	1431	98.5
Cefazolin	CZ	634	97.0	752	97.1
Cefdinir	CDR	633	92.7	747	94.5
Cefditoren	CDN	1270	97.2	1270	98.4
Cefepime	FEP	1463	97.8	1463	98.6
Cefetamet	CAT	629	96.0	746	97.7
Cefixime	CFM	1454	96.7	1454	98.1
Cefmetazole	CMZ	608	94.7	718	96.4
Cefoperazone	CFP	854	95.1	972	97.7
Cefoperazone-Sulbactam	SCP	1921	93.1	1921	96.0
Cefotaxime	CTX	849	96.9	970	97.2
Cefotetan	CTT	627	96.2	748	96.4
Cefotiam	CFT	1428	94.9	1428	97.6
Cefoxitin	FOX	628	96.7	748	97.6

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Cefpirome	CPO	846	96.2	964	97.0
Cefpodoxime	CPD	616	94.5	737	97.0
Cefsulodin	CFS	55	98.2	56	98.2
Ceftazidime	CAZ	2388	96.6	2388	94.7
Ceftazidime-Avibactam	CZA	1528	96.8	1413	99.2
Ceftibuten	CTB	590	90.5	708	95.9
Ceftizoxime	ZOX	854	97.3	971	97.2
Ceftriaxone	CRO	2416	96.1	2416	91.6
Cefuroxime	CXM	623	97.0	744	98.5
Cephalexin	CN	319	97.8	366	96.5
Cephalothin	CF	613	98.0	731	98.5
Chloramphenicol	C	978	97.7	978	98.7
Ciprofloxacin	CIP	977	99.4	977	99.7
Colistin	CL	467	97.9	467	98.7
Ertapenem*	ETP	1632	97.7	1265	99.4
Fosfomycin	FF	446	93.0	446	96.9
Garenoxacin	GRN	1977	98.1	1977	99.4
Gatifloxacin	GAT	752	99.5	752	99.6
Gemifloxacin	GEM	2096	98.6	2096	99.0
Gentamicin	GM	973	95.8	973	99.8
Imipenem	IPM	1549	94.8	1487	99.0
Isepamicin	ISP	468	93.8	468	99.4
Kanamycin	K	735	95.8	735	99.9
Levofloxacin	LVX	972	99.6	972	100.0
Lomefloxacin	LOM	976	99.1	976	99.6
Mecillinam	MEC	345	95.7	345	94.8
Meropenem	MEM	1451	96.3	1395	98.3
Minocycline	MI	2094	93.8	2094	98.3
Moxalactam	MOX	2063	96.9	2063	98.3
Moxifloxacin	MXF	746	98.5	747	99.7
Nalidixic Acid	NA	750	94.0	750	99.1
Netilmicin	NET	974	96.7	974	99.3
Nitrofurantoin	FM	744	98.4	744	98.8
Norfloxacin	NOR	976	98.9	976	99.6

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Ofloxacin	OFX	971	99.3	971	99.7
Pefloxacin	PEF	469	98.5	469	99.4
Piperacillin	PIP	860	94.7	973	97.1
Piperacillin-Tazobactam	TZP	856	92.9	970	96.2
Temocillin	TEM	1410	96.1	1410	98.9
Tetracycline	TE	975	95.6	975	98.5
Ticarcillin	TIC	859	94.8	973	97.8
Ticarcillin-Clavulanate	TIM	534	92.7	589	94.6
Tigecycline	TGC	1428	97.1	1110	96.7
Tobramycin	NN	977	94.2	977	99.4
Trimethoprim	TMP	752	96.0	752	99.6
Trimeth-Sulfa (DIN)	STG	463	97.8	463	97.8
Trimethoprim-Sulfamethoxazole	SXT	976	95.5	976	97.3

* Ability to Detect Resistance Unknown

9.2.2 Gram Positive Performance

Gram Positive Identification

In two internal studies, the performance of the BD Phoenix Gram Positive Identification was evaluated. The 0.5 inoculum density configuration and the 0.25 inoculum density configuration were tested with 696 strains (0.5) and 755 strains (0.25) respectively. Results were evaluated against commercial and non-commercial methods.

The BD Phoenix Gram Positive Identification performance is outlined below:

	Inoculum Density (McFarland)	Agreement	No Agreement	No ID
Genus Level	0.5	99.1%	0.3%	0.6%
	0.25	99.6%	0.0%	0.4%
Species Level	0.5	95.4%	3.9%	0.7%
	0.25	98.0%	1.6%	0.4%

Gram Positive Susceptibility

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Amikacin	AN	487	95.7	487	95.7
Amoxicillin	AMX	395	90.6	659	97.1
Amoxicillin-Clavulanate	AMC	180	97.8	446	97.5

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Amoxicillin-Clavulanate (f)	AXC	397	96.7	664	97.6
Ampicillin	AM	402	94.0	667	98.7
Ampicillin-Sulbactam	SAM	179	96.7	445	97.1
Ampicillin-Sulbactam (f)	SXA	1449	94.6	1449	95.2
Arbekacin	ARB	973	96.2	973	99.9
Azithromycin	AZM	702	95.7	702	97.7
Cefaclor	CEC	182	91.8	449	95.6
Cefazolin	CZ	180	97.2	441	97.5
Cefdinir	CDR	182	94.5	434	96.8
Cefditoren	CDN	944	96.2	944	97.8
Cefepime	FEP	181	97.2	446	97.5
Cefmetazole	CMZ	174	96.6	430	97.2
Cefoperazone	CFP	184	95.7	447	97.8
Cefotaxime	CTX	185	96.2	446	97.8
Cefotetan	CTT	183	94.5	439	96.6
Cefotiam	CFT	965	91.5	965	94.0
Cefoxitin	FOX	184	96.2	445	97.5
Cefozopran	CFZ	1130	89.8	1130	89.6
Cefpirome	CPO	183	100.0	446	97.5
Cefpodoxime	CPD	185	91.4	451	95.6
Ceftaroline*	CPT	1313	94.5	866	99.7
Ceftazidime	CAZ	183	95.1	448	97.1
Ceftizoxime	ZOX	184	93.5	447	96.2
Ceftriaxone	CRO	184	95.1	447	97.3
Cefuroxime	CXM	184	94.6	447	98.2
Cephalexin	CN	185	90.3	452	97.4
Cephalothin	CF	182	97.8	441	97.3
Chloramphenicol	C	705	92.8	705	95.3
Ciprofloxacin	CIP	686	96.4	686	97.4
Clarithromycin	CLR	485	96.3	485	98.1
Clindamycin	CC	703	98.2	703	98.3
Daptomycin*	DAP	1361	97.6	1361	99.8
Doxycycline	D	1211	96.5	1211	99.8
Ertapenem	ETP	670	91.6	670	95.4

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Erythromycin	E	474	95.4	474	95.8
Fosfomycin	FF	472	97.0	472	98.3
Fusidic Acid	FA	477	96.7	477	99.0
Garenoxacin	GRN	1212	97.1	1212	99.0
Gatifloxacin	GAT	481	98.8	481	100.0
Gemifloxacin	GEM	1400	96.2	1400	97.4
Gentamicin	GM	487	98.4	487	99.2
Gentamicin-Syn	GMS	NA	NA	198	97.5
Gentamicin-Syn (SFM)	GMF	NA	NA	87	100.0
Imipenem	IPM	185	100.0	448	97.5
Inducible Macrolide Resistance (iMLSb) Test	ECC	NA	NA	295	97.6
Kanamycin	K	463	92.2	464	97.4
Kanamycin Synergy	KS	501	100.0	501	96.6
Levofloxacin	LVX	698	96.9	698	98.6
Lincomycin	L	696	98.3	696	98.7
Linezolid	LZD	474	99.4	474	100.0
Lomefloxacin	LOM	486	97.7	486	99.2
Meropenem	MEM	185	98.4	447	97.5
Minocycline	MI	1448	98.5	1448	99.2
Moxalactam	MOX	935	95.9	935	96.0
Moxifloxacin	MXF	486	99.0	486	99.6
Mupirocin	MUP	938	96.6	938	99.7
Mupirocin High Level	MUH	968	100.0	968	99.9
Netilmicin	NET	488	93.9	488	96.3
Nitrofurantoin	FM	707	98.3	707	98.3
Norfloxacin	NOR	674	96.0	674	97.8
Ofloxacin	OFX	487	99.2	488	99.8
Oxacillin	OX	449	95.8	449	97.8
Pefloxacin	PEF	706	97.9	706	98.0
Penicillin	P	401	96.0	662	98.0
Piperacillin	PIP	382	81.7	639	98.0
Piperacillin-Tazobactam	TZP	386	100.0	649	98.3
Pristinamycin	PR	695	93.2	695	95.5
Quinupristin-Dalfopristin	SYN	704	97.2	704	97.6

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Rifampin	RA	700	84.0	700	88.3
Streptomycin-Syn	STS	NA	NA	198	99.0
Streptomycin-Syn (SFM)	STF	NA	NA	87	98.8
Teicoplanin	TEC	671	97.6	671	99.4
Telithromycin	TEL	898	97.3	898	98.9
Tetracycline	TE	707	96.3	707	98.6
Ticarcillin	TIC	395	95.4	659	98.2
Ticarcillin-Clavulanate	TIM	396	97.5	656	97.9
Tigecycline*	TGC	1356	96.8	1044	100
Tobramycin	NN	473	97.0	473	97.3
Trimethoprim	TMP	479	95.4	479	97.9
Trimeth-Sulfa (DIN)	STG	645	91.0	646	92.7
Trimethoprim-Sulfamethoxazole	SXT	654	89.5	654	93.0
Vancomycin	VA	702	99.3	702	99.9

* Ability to Detect Resistance Unknown

9.2.3 Streptococci Performance (with BD Phoenix SMIC/ID, SMIC Panels)

Streptococci Identification (SMIC/ID only)

In an internal study, the performance of the BD Phoenix Streptococci Identification was evaluated. Results from 655 isolates were evaluated against commercial and noncommercial methods.

The BD Phoenix Streptococci Identification performance is outlined below:

	Agreement	No Agreement	No ID
Species Level	96.3%	2.4%	1.2%

Streptococci Susceptibility

The performance of the BD Phoenix Streptococci AST System was evaluated at four clinical trial sites using clinical isolates. Comparisons were made to AST results generated from reference broth microdilution panels prepared according to CLSI standard guidelines. Discrepant results were arbitrated by duplicate repeat testing in both systems.

ANTIMICROBIAL	CODE	EA N	EA %	CA N	CA %
Amoxicillin	AMX	1576	99.2	1576	99.7
Amoxicillin-Clavulanate	AMC	1564	97.9	1564	99.3
Ampicillin	AM	1569	98.0	1569	99.4
Cefepime	FEP	1571	97.6	1571	99.7
Cefotaxime	CTX	1578	98.5	1578	99.6
Ceftriaxone	CRO	1579	98.5	1579	99.8
Cefuroxime	CXM	1581	97.7	1581	98.8
Chloramphenicol	C	1587	97.4	1587	99.6
Clindamycin	CC	1591	94.0	1591	97.4
Daptomycin	DAP	1566	93.1	1566	99.9
Ertapenem*	ETP	1585	97.9	1585	99.6
Erythromycin	E	1577	93.2	1577	98.2
Garenoxacin*	GRN	1515	95.5	1515	99.7
Gatifloxacin	GAT	1587	95.1	1587	99.5
Gemifloxacin*	GEM	1592	98.9	1592	99.7
Gentamicin-Syn	GMS	1032	99.6	1032	99.6
Imipenem	IPM	1581	98.0	1581	99.6
Kanamycin-Syn	KS	1032	99.6	1032	99.6
Levofloxacin	LVX	1595	97.4	1595	99.8
Linezolid	LZD	1586	97.1	1586	99.4
Meropenem	MEM	1579	97.4	1579	99.7
Moxifloxacin*	MXF	1590	95.8	1590	99.6
Ofloxacin	OFX	1594	98.2	1594	98.7
Penicillin	P	1585	93.9	1585	98.5
Pristinamycin*	PR	1583	94.8	1583	99.8
Quinupristin-dalfopristin*	SYN	1581	97.3	1581	99.7
Streptomycin-Syn	STS	1031	99.9	1031	99.9
Teicoplanin*	TEC	1593	99.8	1593	99.9
Telithromycin*	TEL	1574	95.9	1574	98.5
Tetracycline	TE	1589	93.3	1589	97.6
Trimethoprim-Sulfamethoxazole	SXT	1008	93.8	1008	98.3
Vancomycin*	VA	1588	98.2	1588	99.9

* Ability to Detect Resistance Unknown

9.2.4 Identification of Yeast Species

The performance of the BD Phoenix Yeast identification was evaluated across multiple sites using pure colonies isolated from Sabouraud Dextrose Agar (SAB) and BD Trypticase Soy Agar with 5% Sheep Blood (TSA). Results from 519 (SAB) and 510 (TSA) clinical and challenge isolates were evaluated against conventional and molecular methods.

The BD Phoenix Yeast identification performance is outlined below:

	Source Media	Agreement	No Agreement	No ID
Genus/Species Level	SAB	95.2%	3.8%	1.0%
	TSA	96.5%	2.7%	0.8%

Additionally, testing was performed at multiple sites to demonstrate reproducibility. The identification results obtained using the BD Phoenix system were compared with expected results. This performance testing demonstrated inter-site reproducibility of ≥ 95%.

9.3 Limitations of the Procedure

See the package insert shipped with the panel for specific organism/antimicrobial limitations.

General

A Gram stain test is required for the selection of the appropriate BD Phoenix panel types. Accurate identification and/or AST results may not be made without this test.

Use only well-isolated bacterial or yeast colonies from one of the recommended primary isolation media. Use of mixed colonies could result in inaccurate identification and/or AST interpretations.

If the instrument inoculum density (for the panel type being used) is configured to 0.5, an inoculum density of 0.50–0.60 McFarland must be met. Only the BD BBL CrystalSpec or BD PhoenixSpec Nephelometer can be used to measure the inoculum density.

If the instrument inoculum density (for the panel type being used) is configured to 0.25, an inoculum density of 0.20–0.30 McFarland must be met. Only the BD PhoenixSpec Nephelometer can be used to measure the inoculum density for this range.

For identification of yeast, a suspension equivalent of 2.00–2.40 McFarland standard must be met and prepared only with the BD PhoenixSpec Nephelometer. Use of alternate methods for suspension preparation may cause erroneous identification results.

BD Phoenix panels can be read only by the BD Phoenix M50 instrument. Visual interpretation of the BD Phoenix panels is not possible. Any attempt to manually interpret results from the panel may lead to misidentification and/or inaccurate AST interpretations.

Panels must be placed into the BD Phoenix M50 instrument within 30 minutes of inoculation.

For the most reliable results, it is recommended that the QC organisms be subcultured at least twice on two consecutive days onto TSA with 5% Sheep Blood before use in the BD Phoenix system.

Identification

The unique panel environment combined with the shortened incubation time may result in BD Phoenix panel reactions varying from those obtained using conventional biochemical media.

Antimicrobial Susceptibility Testing

AST Indicator solution may be added to the AST broth tubes and stored in the dark for up to 8 hours prior to use. Use only one free-falling drop of the AST Indicator solution from the dropper bottle. If more than one drop is added inadvertently, discard the tube and use a fresh tube of AST broth.

After the addition of BD Phoenix AST Indicator Solution to the AST broth tubes, mix by inversion. DO NOT VORTEX. Vortexing may cause air bubbles to form in the AST broth, which can result in inappropriate filling of the BD Phoenix panel during inoculation.

Because of the low probability of occurrence some organisms included in the ID taxa are not included in the AST database. These organisms will display the message Organism not included in the AST database, perform alternate method.

For some organism/antimicrobial combinations, the absence of resistant strains precludes defining any result categories other than susceptible. For strains yielding results suggestive of a nonsusceptible category, organism identification and antimicrobial susceptibility test results should be confirmed. Subsequently, the isolates should be saved and submitted to a reference laboratory that will confirm the result using the CLSI reference microbroth dilution method.

The use of CHROMagar Orientation may produce false susceptibility results when testing erythromycin with gram-positive organisms. Antimicrobial susceptibility results should be confirmed using BD Trypticase Soy Agar with 5% Sheep Blood.

This media type [Chocolate Agar] should not be used for Streptococcal identification with SMIC/ID panels. Chocolate Agar may be used for Streptococcal susceptibility testing only.

The use of Columbia Agar with 5% Horse Blood may produce significantly higher MIC for SXT with *Streptococcus* species, which may result in false resistance. Antimicrobial susceptibility test results should be confirmed using BD Trypticase Soy Agar with 5% Sheep Blood.

> NOTE
>
> MIC results for isolates without a genus and species identified in the BD Phoenix results Final ID field may not be valid.
>
> When changing the BD Phoenix Final ID from an organism not claimed in the AST Taxa list to an organism that is claimed in the AST Taxa, the MIC and Interpretation results will be based on the Final ID that is claimed in the AST Taxa.

9.4 Organism Codes, Short Names, Long Names

Long Name	Short Name	Code
Achromobacter denitrificans	Achr. denitrificans	ALCDEN
Achromobacter piechaudii	Achr. piechaudii	ALCPIE
Achromobacter species	Achr. species	ACHRSPE
Achromobacter xylosoxidans	Achr. xylosoxidans	ALCXYL

Long Name	Short Name	Code
Acinetobacter baumannii	Acinet. baumannii	ACINBAU
Acinetobacter baumannii/calcoaceticus complex	Acinet. baumannii/calco. cplx	ACINBCX
Acinetobacter baumannii/haemolyticus	Acinet. baumannii/haemolyticus	ACINBAUHAE
Acinetobacter calcoaceticus	Acinet. calcoaceticus	ACINCAL
Acinetobacter haemolyticus	Acinet. haemolyticus	ACINHAE
Acinetobacter johnsonii	Acinet. johnsonii	ACINJOH
Acinetobacter junii	Acinet. junii	ACINJUN
Acinetobacter lwoffii	Acinet. lwoffii	ACINLWO
Acinetobacter lwoffii/haemolyticus	Acinet. lwoffii/haemol.	ACINLWOHAE
Acinetobacter radioresistens	Acinet. radioresistens	ACINRAD
Acinetobacter species	Acinet. species	ACINSPE
Actinobacillus lignieresii	Actinob. lignieresii	ACTBLIG
Actinobacillus suis	Actinob. suis	ACTBSUI
Actinobacillus ureae	Actinob. ureae	ACTBURE
Aerococcus species	Aeroc. species	AERCSPE
Aerococcus urinae	Aeroc. urinae	AERCURI
Aerococcus viridans	Aeroc. viridans	AERCVIR
Aeromonas allosaccharophila	Aerom. allosaccharophila	AERMALL
Aeromonas caviae	Aerom. caviae	AERMCAV
Aeromonas eucrenophila	Aerom. eucrenophila	AERMEUC
Aeromonas hydrophila	Aerom. hydrophila	AERMHYD
Aeromonas hydrophila group	Aerom. hydrophila gr.	AERMHYDGR
Aeromonas jandaei	Aerom. jandaei	AERMJAN
Aeromonas media	Aerom. media	AERMMED
Aeromonas salmonicida	Aerom. salmonicida	AERMSAL
Aeromonas salmonicida ssp *achromogenes*	Aerom. salmonic. ssp ach.	AERMSALA
Aeromonas salmonicida ssp *masoucida*	Aerom. salmonic. ssp mas.	AERMSALM
Aeromonas salmonicida ssp *pectinolytica*	Aerom. salmonic. ssp pec.	AERMSALPE
Aeromonas salmonicida ssp *salmonicida*	Aerom. salmonic. ssp sal.	AERMSALSA
Aeromonas salmonicida ssp *smithia*	Aerom. salmonic. ssp smit.	AERMSALSM

Long Name	Short Name	Code
Aeromonas schubertii	Aerom. schubertii	AERMSCH
Aeromonas species	Aerom. species	AERMSPE
Aeromonas trota	Aerom. trota	AERMTRO
Aeromonas veronii bv *sobria*	Aerom. veronii bv sobria	AERMVERS
Aeromonas veronii bv *veronii*	Aerom. veronii bv veronii	AERMVERV
Alcaligenes faecalis	Alc. faecalis	ALCFAE
Alcaligenes faecalis ssp *faecalis*	Alc. faecalis ssp faecalis	ALCFAEF
Alcaligenes species	Alc. species	ALCSPE
Alloiococcus otitis	All. otitis	ALLOTI
Arcanobacterium haemolyticum	Arcan. haemolyticum	ARCAHAE
Bacillus cereus	Baci. cereus	BACICER
Bacillus circulans	Baci. circulans	BACICIR
Bacillus coagulans	Baci. coagulans	BACICOA
Bacillus licheniformis	Baci. licheniformis	BACILIC
Bacillus megaterium	Baci. megaterium	BACIMEG
Bacillus pumilus	Baci. pumilus	BACIPUM
Bacillus subtilis	Baci. subtilis	BACISUB
Bacillus thuringiensis	Baci. thuringiensis	BACITHU
Bergeyella zoohelcum	Ber. zoohelcum	BERZOO
Bordetella bronchiseptica	Bord. bronchiseptica	BORBROS
Brevibacillus brevis	Brevs. brevis	BACIBRE
Brevibacterium species	Brevm. species	BREISPE
Brevundimonas diminuta	Brevu. diminuta	BREUDIM
Brevundimonas species	Brevu. species	BREUSPE
Brevundimonas vesicularis	Brevu. vesicularis	BREUVES
Burkholderia caryophylli	Burk. caryophylli	BURCAR
Burkholderia cepacia complex	Burk. cepacia complex	BURCEP
Burkholderia cepacia/Ralstonia pickettii	Burk. cepacia/Ral. pickettii	BURCEPRALPIC
Burkholderia gladioli	Burk. gladioli	BURGLA
Burkholderia glathei	Burk. glathei	BURGLT
Burkholderia graminis	Burk. graminis	BURGRA
Burkholderia multivorans	Burk. multivorans	BURMUL
Burkholderia phenazinium	Burk. phenazinium	BURPHE
Burkholderia pyrrocinia	Burk. pyrrocinia	BURPYR
Burkholderia species	Burk. species	BURSPE

Long Name	Short Name	Code
Burkholderia species/*Ralstonia* species	Burk. species/Ral. species	BURSPERALSPE
Candida albicans	Can. albicans	CANALB
Candida apicola	Can. apicola	CANAPI
Candida boidinii	Can. boidinii	CANBOI
Candida bracarensis	Can. bracarensis	CANBRA
Candida catenulata	Can. catenulata	CANCAT
Candida ciferrii	Can. ciferrii	CANCIF
Candida dubliniensis	Can. dubliniensis	CANDUB
Candida firmetaria	Can. firmetaria	CANLAM
Candida freyschussii	Can. freyschussii	CANFRE
Candida glabrata	Can. glabrata	TORGLA
Candida guilliermondii	Can. guilliermondii	CANGUI
Candida guilliermondii var *membranaefaciens*	Can. guillier. var membranaef.	CANGUIM
Candida haemulonii	Can. haemulonii	CANHAE
Candida inconspicua	Can. inconspicua	CANINC
Candida kefyr	Can. kefyr	CANKEF
Candida krusei	Can. krusei	CANKRU
Candida lipolytica	Can. lipolytica	CANLIP
Candida lusitaniae	Can. lusitaniae	CANLUS
Candida magnoliae	Can. magnoliae	CANMAG
Candida melibiosica	Can. melibiosica	CANMEL
Candida membranifaciens	Can. membranifaciens	CANMEM
Candida norvegensis	Can. norvegensis	CANNOR
Candida parapsilosis complex	Can. parapsilosis complex	CANPARPX
Candida pararugosa	Can. pararugosa	CANPARR
Candida pelliculosa	Can. pelliculosa	CANPEL
Candida pulcherrima	Can. pulcherrima	CANPUL
Candida rugosa	Can. rugosa	CANRUG
Candida sake	Can. sake	CANSAK
Candida sphaerica	Can. sphaerica	CANSPH
Candida tropicalis	Can. tropicalis	CANTRO
Candida utilis	Can. utilis	CANUTI
Candida viswanathii	Can. viswanathii	CANVIS
Candida zeylanoides	Can. zeylanoides	CANZEY

Long Name	Short Name	Code
Cardiobacterium hominis	Card. hominis	CARHOM
CDC group Vb-3	CDC Vb-3	CDCVb3
Cedecea davisae	Ced. davisae	CEDDAV
Cedecea lapagei	Ced. lapagei	CEDLAP
Cedecea neteri	Ced. neteri	CEDNET
Cedecea species	Ced. species	CEDSPE
Cedecea species 3	Ced. species 3	CEDSPE3
Cedecea species 5	Ced. species 5	CEDSPE5
Cellulomonas turbata	Cell. turbata	OERTUR
Cellulosimicrobium cellulans	Cellulo. cellulans	OERXAN
Chromobacterium violaceum	Chrom. violaceum	CHROVIO
Chryseobacterium gleum	Chryseob. gleum	CHRBGLE
Chryseobacterium indologenes	Chryseob. indologenes	CHRBIND
Chryseobacterium scophthalmum	Chryseob. scophthalmum	CHRBSCO
Chryseobacterium species	Chryseob. species	CHRBSPE
Citrobacter amalonaticus	Cit. amalonaticus	CITAMA
Citrobacter braakii	Cit. braakii	CITBRA
Citrobacter farmeri	Cit. farmeri	CITFAR
Citrobacter freundii	Cit. freundii	CITFRE
Citrobacter gillenii	Cit. gillenii	CITSPE10
Citrobacter koseri	Cit. koseri	CITKOS
Citrobacter murliniae	Cit. murliniae	CITSPE11
Citrobacter rodentium	Cit. rodentium	CITSPE9
Citrobacter sedlakii	Cit. sedlakii	CITSED
Citrobacter species	Cit. species	CITSPE
Citrobacter werkmanii	Cit. werkmanii	CITWER
Citrobacter youngae	Cit. youngae	CITYOU
Comamonas terrigena	Coma. terrigena	COMTER
Comamonas testosteroni	Coma. testosteroni	COMTES
Corynebacterium amycolatum	Cory. amycolatum	CORAMY
Corynebacterium amycolatum/minutissimum	Cory. amycolatum/minutissimum	CORAMYMIN
Corynebacterium amycolatum/striatum	Cory. amycolatum/striatum	CORAMYSTR
Corynebacterium bovis	Cory. bovis	CORBOV
Corynebacterium diphtheriae	Cory. diphtheriae	CORDIP

Long Name	Short Name	Code
Corynebacterium jeikeium	Cory. jeikeium	CORJEI
Corynebacterium kutscheri	Cory. kutscheri	CORKUT
Corynebacterium matruchotii	Cory. matruchotii	CORMAT
Corynebacterium minutissimum	Cory. minutissimum	CORMIN
Corynebacterium propinquum	Cory. propinquum	CORPRO
Corynebacterium pseudodiphtheriticum	Cory. pseudodiphth.	CORPSD
Corynebacterium pseudotuberculosis	Cory. pseudotuberc.	CORPST
Corynebacterium renale	Cory. renale	CORREN
Corynebacterium striatum	Cory. striatum	CORSTR
Corynebacterium ulcerans	Cory. ulcerans	CORULC
Corynebacterium urealyticum	Cory. urealyticum	CORURE
Corynebacterium xerosis	Cory. xerosis	CORXER
Cosenzaea myxofaciens	Cosen. myxofaciens	PROTMYX
Cronobacter sakazakii complex	Cronob. sakazakii complex	ENTBSAK
Cryptococcus albidus	Cryp. albidus	CRYALB
Cryptococcus humicola	Cryp. humicola	CRYHUM
Cryptococcus laurentii	Cryp. laurentii	CRYLAU
Cryptococcus luteolus	Cryp. luteolus	CRYLUT
Cryptococcus neoformans	Cryp. neoformans	CRYNEO
Cryptococcus terreus	Cryp. terreus	CRYTER
Cryptococcus uniguttulatus	Cryp. uniguttulatus	CRYUNI
Cupriavidus gilardii	Cup. gilardii	RALGIL
Cupriavidus pauculus	Cup. pauculus	CDCIVC2
Delftia acidovorans	Delf. acidovorans	COMACI
Dermabacter hominis	Dermab. hominis	DERBHOM
Dermacoccus nishinomiyaensis	Derm. nishinomiyaen.	MICNIS
Edwardsiella hoshinae	Ed. hoshinae	EDWHOS
Edwardsiella ictaluri	Ed. ictaluri	EDWICT
Edwardsiella species	Ed. species	EDWSPE
Edwardsiella tarda	Ed. tarda	EDWTAR
Edwardsiella tarda biogroup 1	Ed. tarda biogr. 1	EDWTAR1
Eikenella corrodens	Eik. corrodens	EIKCOR
Elizabethkingia meningoseptica	Eliz. meningosept.	CHRBMEN
Empedobacter brevis	Emp. brevis	EMPBRE

Long Name	Short Name	Code
Enterobacter aerogenes	Enterob. aerogenes	ENTBAER
Enterobacter asburiae	Enterob. asburiae	ENTBASB
Enterobacter cancerogenus	Enterob. cancerogenus	ENTBCAN
Enterobacter cloacae	Enterob. cloacae	ENTBCLO
Enterobacter cloacae ssp *dissolvens*	Enterob. cloacae ssp dissolven	ENTBDIS
Enterobacter hormaechei	Enterob. hormaechei	ENTBHOR
Enterobacter kobei	Enterob. kobei	ENTBKOB
Enterobacter nimipressuralis	Enterob. nimipressuralis	ENTBNIM
Enterobacter species	Enterob. species	ENTBSPE
Enterococcus asini	Enteroc. asini	ENTCASI
Enterococcus avium	Enteroc. avium	ENTCAVI
Enterococcus casseliflavus	Enteroc. casseliflavus	ENTCCAS
Enterococcus casseliflavus/gallinarum	Enteroc. cassel./gallin.	ENTCCASGAL
Enterococcus cecorum	Enteroc. cecorum	ENTCCEC
Enterococcus columbae	Enteroc. columbae	ENTCCOL
Enterococcus dispar	Enteroc. dispar	ENTCDIS
Enterococcus durans	Enteroc. durans	ENTCDUR
Enterococcus durans/faecium	Enteroc. durans/faecium	ENTCDURFAI
Enterococcus faecalis	Enteroc. faecalis	ENTCFAA
Enterococcus faecalis/faecium	Enteroc. faecalis/faecium	ENTCFAAFAI
Enterococcus faecium	Enteroc. faecium	ENTCFAI
Enterococcus flavescens	Enteroc. flavescens	ENTCFLA
Enterococcus gallinarum	Enteroc. gallinarum	ENTCGAL
Enterococcus gilvus	Enteroc. gilvus	ENTCGIL
Enterococcus haemoperoxidus	Enteroc. haemoperoxidus	ENTCHAE
Enterococcus hirae	Enteroc. hirae	ENTCHIR
Enterococcus hirae/faecium	Enteroc. hirae/faecium	ENTCHIRFAI
Enterococcus malodoratus	Enteroc. malodoratus	ENTCMAL
Enterococcus moraviensis	Enteroc. moraviensis	ENTCMOR
Enterococcus mundtii	Enteroc. mundtii	ENTCMUN
Enterococcus pallens	Enteroc. pallens	ENTCPAL
Enterococcus pseudoavium	Enteroc. pseudoavium	ENTCPSE
Enterococcus raffinosus	Enteroc. raffinosus	ENTCRAF
Enterococcus raffinosus/avium	Enteroc. raffinosus/avium	ENTCRAFAVI

Long Name	Short Name	Code
Enterococcus ratti	Enteroc. ratti	ENTCRAT
Enterococcus saccharolyticus	Enteroc. saccharolyticus	ENTCSAC
Enterococcus species	Enteroc. species	ENTCSPE
Enterococcus sulfureus	Enteroc. sulfureus	ENTCSUL
Erysipelothrix rhusiopathiae	Ery. rhusiopathiae	ERYRHU
Escherichia coli	Esch. coli	ESCCOL
Escherichia coli serotype O111	Esch. coli O111	ESCCOL0111
Escherichia coli serotype O157	Esch. coli O157	ESCCOL0157
Escherichia fergusonii	Esch. fergusonii	ESCFER
Escherichia hermannii	Esch. hermannii	ESCHER
Escherichia species	Esch. species	ESCSPE
Escherichia vulneris	Esch. vulneris	ESCVUL
Ewingella americana	Ew. americana	EWIAME
Exophiala dermatitidis	Exo. dermatitidis	WANDER
Exophiala species	Exo. species	EXOSPE
Gardnerella vaginalis	Gard. vaginalis	GARVAG
Gemella haemolysans	Gem. haemolysans	GEMHAE
Gemella morbillorum	Gem. morbillorum	GEMMOR
Gemella species	Gem. species	GEMSPE
Geotrichum species	Geo. species	GEOSPE
Globicatella sanguinis	Glob. sanguinis	GLOSAN
Gram-negative rod unidentified enteric	GNR unident. enteric	GNRUNIE
Gram-negative rod unidentified nonfermenter	GNR unident. NF	GNRUNINF
Grimontia hollisae	Grim. hollisae	VIBHOL
Hafnia alvei	Haf. alvei	HAFALV
Hafnia alvei group 1	Haf. alvei gr. 1	HAFALV1
Helcococcus kunzii	Helco. kunzii	HELCKUN
Hortaea werneckii	Hor. werneckii	HORWER
Hyphopichia burtonii	Hyphop. burtonii	PICBUR
Kingella denitrificans	King. denitrificans	KINDEN
Kingella kingae	King. kingae	KINKIN
Klebsiella granulomatis	Kleb. granulomatis	CALYGRA
Klebsiella oxytoca	Kleb. oxytoca	KLEOXY
Klebsiella ozaenae	Kleb. ozaenae	KLEPNEO

Long Name	Short Name	Code
Klebsiella pneumoniae	Kleb. pneumoniae	KLEPNEP
Klebsiella rhinoscleromatis	Kleb. rhinoscleromatis	KLEPNER
Klebsiella species	Kleb. species	KLESPE
Kloeckera species	Kloeck. species	KLOSPE
Kluyvera ascorbata	Kluyvera ascorbata	KLUASC
Kluyvera cryocrescens	Kluyvera cryocres.	KLUCRY
Kluyvera georgiana	Kluyvera georgiana	KLUGEO
Kluyvera intermedia	Kluyvera intermedia	ENTBINT
Kluyvera species	Kluyvera species	KLUSPE
Kocuria kristinae	Koc. kristinae	MICKRI
Kocuria rosea	Koc. rosea	MICROS
Kocuria varians	Koc. varians	MICVAR
Kosakonia cowanii	Kosak. cowanii	ENTBCOW
Kytococcus sedentarius	Kyto. sedentarius	MICSED
Lactococcus garvieae	Lactoc. garvieae	LACCGAR
Lactococcus lactis ssp *cremoris*	Lactoc. lactis ssp crem.	LACCLACC
Lactococcus lactis ssp *hordniae*	Lactoc. lactis ssp hord.	LACCLACH
Lactococcus lactis ssp *lactis*	Lactoc. lactis ssp lactis	LACCLACL
Lactococcus plantarum	Lactoc. plantarum	LACCPLA
Lactococcus raffinolactis	Lactoc. raffinolactis	LACCRAF
Lactococcus species	Lactoc. species	LACCSPE
Leclercia adecarboxylata	Lec. adecarboxylata	LECADE
Leifsonia aquatica	Leif. aquatica	CORAQU
Lelliottia amnigena	Lell. amnigena	ENTBAMN
Lelliottia amnigena biogroup 1	Lell. amnigena biogr. 1	ENTBAMN1
Lelliottia amnigena biogroup 2	Lell. amnigena biogr. 2	ENTBAMN2
Leminorella grimontii	Lem. grimontii	LEMGRI
Leminorella richardii	Lem. richardii	LEMRIC
Leuconostoc citreum	Leu. citreum	LEUCIT
Leuconostoc lactis	Leu. lactis	LEULAC
Leuconostoc mesenteroides ssp *cremoris*	Leu. mesenter. ssp crem.	LEUMESC
Leuconostoc mesenteroides ssp *mesenteroides*	Leu. mesenter. ssp mes.	LEUMESM
Leuconostoc pseudomesenteroides	Leu. pseudomesenter.	LEUPSE
Leuconostoc species	Leu. species	LEUSPE

Long Name	Short Name	Code
Listeria grayi	Lis. grayi	LISGRA
Listeria innocua	Lis. innocua	LISINN
Listeria ivanovii	Lis. ivanovii	LISIVA
Listeria monocytogenes	Lis. monocytogenes	LISMON
Listeria monocytogenes/innocua	Lis. monocytogenes/innocua	LISMONINN
Listeria species	Lis. species	LISSPE
Listeria welshimeri	Lis. welshimeri	LISWEL
Lysinibacillus sphaericus	Lysini. sphaericus	BACISPH
Macrococcus caseolyticus	Macroc. caseolyticus	STACAS
Magnusiomyces capitatus	Magnus. capitatus	BLACAP
Malassezia furfur complex	Mal. furfur complex	MALFURX
Malassezia pachydermatis	Mal. pachydermatis	MALPAC
Malassezia sympodialis	Mal. sympodialis	MALSYM
Mannheimia haemolytica	Mann. haemolytica	PASHAE
Methylobacterium extorquens	Methylob. extorquens	METEXT
Micrococcus luteus	Microc. luteus	MICLUT
Micrococcus lylae	Microc. lylae	MICLYL
Millerozyma farinosa	Mill. farinosa	PICFAR
Moellerella wisconsensis	Moel. wisconsensis	MOEWIS
Moraxella (Branhamella) catarrhalis	Morax. (Bran.) cat.	MORABRACAT
Moraxella species	Morax. species	MORASPE
Morganella morganii	Morg. morganii	MORGMOR
Morganella morganii ssp *morganii*	Morg. morg. ssp morg.	MORGMORM
Morganella morganii ssp *morganii* biogroup 1	Morg. morg. ssp morg. biog. 1	MORGMORM1
Morganella morganii ssp *sibonii*	Morg. morg. ssp sibonii	MORGMORS
Morganella species	Morg. species	MORGSPE
Myroides odoratimimus	Myr. odoratimimus	MYRODI
Myroides odoratus	Myr. odoratus	MYRODA
Myroides odoratus/odoratimimus	Myr. odoratus/odoratimimus	MYRODAODI
Myroides species	Myr. species	MYRSPE
Neisseria animaloris	Nei. animaloris	CDCEF4a
Neisseria zoodegmatis	Nei. zoodegmatis	CDCEF4b
Ochrobactrum anthropi	Och. anthropi	OCHANT
Oligella ureolytica	Olig. ureolytica	OLIURO

Long Name	Short Name	Code
Oligella urethralis	Olig. urethralis	OLIURT
Paenibacillus alvei	Paen. alvei	PAEALV
Paenibacillus macerans	Paen. macerans	PAEMAC
Pantoea agglomerans	Pan. agglomerans	PANAGG
Pantoea ananatis	Pan. ananatis	ERWANA
Pantoea dispersa	Pan. dispersa	PANDIS
Pantoea species	Pan. species	PANSPE
Pantoea stewartii	Pan. stewartii	PANSTE
Pantoea stewartii ssp *indologenes*	Pan. ste. ssp indologenes	PANSTEI
Pantoea stewartii ssp *stewartii*	Pan. ste. ssp stewartii	PANSTES
Paracoccus yeei	Parac. yeei	CDCEO2
Pasteurella aerogenes	Past. aerogenes	PASAER
Pasteurella multocida	Past. multocida	PASMUL
Pasteurella pneumotropica	Past. pneumotropica	PASPNE
Pediococcus acidilactici	Ped. acidilactici	PEDACI
Pediococcus damnosus	Ped. damnosus	PEDDAM
Pediococcus dextrinicus	Ped. dextrinicus	PEDDEX
Pediococcus parvulus	Ped. parvulus	PEDPAR
Pediococcus pentosaceus	Ped. pentosaceus	PEDPEN
Pediococcus species	Ped. species	PEDSPE
Photobacterium damselae	Photob. damselae	PHOBDAM
Plesiomonas shigelloides	Ples. shigelloides	PLESHI
Pluralibacter gergoviae	Plural. gergoviae	ENTBGER
Pragia fontium	Prag. fontium	PRAFON
Proteus hauseri	Prot. hauseri	PROTHAU
Proteus mirabilis	Prot. mirabilis	PROTMIR
Proteus penneri	Prot. penneri	PROTPEN
Proteus species	Prot. species	PROTSPE
Proteus vulgaris	Prot. vulgaris	PROTVUL
Proteus vulgaris/penneri	Prot. vulgaris/penneri	PROTVULPEN
Prototheca wickerhamii	Protot. wick.	PROHWIC
Prototheca zopfii	Protot. zopfii	PROHZOP
Providencia alcalifaciens	Prov. alcalifaciens	PROVALC
Providencia heimbachae	Prov. heimbachae	PROVHEI
Providencia rettgeri	Prov. rettgeri	PROVRET

Long Name	Short Name	Code
Providencia rustigianii	Prov. rustigianii	PROVRUS
Providencia species	Prov. species	PROVSPE
Providencia stuartii	Prov. stuartii	PROVSTU
Pseudomonas aeruginosa	Pseud. aeruginosa	PSEAER
Pseudomonas alcaligenes	Pseud. alcaligenes	PSEALC
Pseudomonas fluorescens	Pseud. fluorescens	PSEFLU
Pseudomonas fluorescens/putida	Pseud. fluorescens/putida	PSEFLUPUT
Pseudomonas luteola	Pseud. luteola	CHRMLUT
Pseudomonas mendocina	Pseud. mendocina	PSEMEN
Pseudomonas monteilii	Pseud. monteilii	PSEMON
Pseudomonas oryzihabitans	Pseud. oryzihabitans	FLAIORY
Pseudomonas pertucinogena	Pseud. pertucinogena	PSEPER
Pseudomonas pseudoalcaligenes	Pseud. pseudoalcaligenes	PSEPSE
Pseudomonas pseudoalcaligenes ssp *pseudoalcaligenes*	Pseud. pseudoal. ssp pseud.	PSEPSEP
Pseudomonas putida	Pseud. putida	PSEPUT
Pseudomonas species	Pseud. species	PSESPE
Pseudomonas stutzeri	Pseud. stutzeri	PSESTU
Pseudomonas veronii	Pseud. veronii	PSEVER
Rahnella aquatilis	Rah. aquatilis	RAHAQU
Ralstonia pickettii	Ral. pickettii	BURPIC
Ralstonia solanacearum	Ral. solanacearum	BURSOL
Ralstonia species	Ral. species	RALSPE
Raoultella ornithinolytica	Rao. ornithinolytica	KLEORN
Raoultella planticola	Rao. planticola	KLEPLA
Raoultella species	Rao. species	RAOSPE
Raoultella terrigena	Rao. terrigena	KLETER
Rhizobium radiobacter	Rhizob. radiobacter	AGRRAD
Rhodococcus equi	Rhodoc. equi	RHOCEQU
Rhodotorula glutinis	Rhodot. glutinis	RHOTGLU
Rhodotorula minuta	Rhodot. minuta	RHOTMIN
Rhodotorula mucilaginosa var *mucilaginosa*	Rhodot. mucilag. var mucilag.	RHOTMUCM
Rothia dentocariosa	Roth. dentocariosa	ROTDEN
Rothia mucilaginosa	Roth. mucilaginosa	STOMUC
Saccharomyces cerevisiae	Sac. cerevisiae	SACCER

Long Name	Short Name	Code
Salmonella enterica ssp *arizonae*	Salm. enterica ssp arizonae	SALCHOA
Salmonella enterica ssp *diarizonae*	Salm. enterica ssp diarizonae	SALCHOD
Salmonella enterica ssp *enterica* serovar *Choleraesuis*	Salm. enterica sv Choleraesuis	SALCHOC
Salmonella enterica ssp *enterica* sv *Gallinarum* bv *Gallinarum*	Salm. Gallinarum	SALGAL
Salmonella enterica ssp *enterica* sv *Gallinarum* bv *Pullorum*	Salm. Pullorum	SALPUL
Salmonella enterica ssp *enterica* sv *Paratyphi* A	Salm. Paratyphi A	SALPARA
Salmonella enterica ssp *enterica* sv *Typhi*	Salm. Typhi	SALTYP
Salmonella enterica ssp *houtenae*	Salm. enterica ssp houtenae	SALCHOH
Salmonella enterica ssp *indica*	Salm. enterica ssp indica	SALCHOI
Salmonella enterica ssp *salamae*	Salm. enterica ssp salamae	SALCHOS
Salmonella species	Salm. species	SALSPE
Serratia entomophila	Ser. entomophila	SERENT
Serratia ficaria	Ser. ficaria	SERFIC
Serratia fonticola	Ser. fonticola	SERFON
Serratia grimesii	Ser. grimesii	SERGRI
Serratia liquefaciens	Ser. liquefaciens	SERLIQ
Serratia marcescens	Ser. marcescens	SERMAR
Serratia odorifera	Ser. odorifera	SERODO
Serratia odorifera 1	Ser. odorifera 1	SERODO1
Serratia odorifera 2	Ser. odorifera 2	SERODO2
Serratia plymuthica	Ser. plymuthica	SERPLY
Serratia proteamaculans ssp *proteamaculans*	Ser. proteamac. ssp proteam.	SERPROP
Serratia proteamaculans ssp *quinovora*	Ser. proteamac. ssp quino.	SERPROQ
Serratia rubidaea	Ser. rubidaea	SERRUB
Serratia species	Ser. species	SERSPE
Shewanella algae	Shew. algae	SHEALG
Shewanella putrefaciens	Shew. putrefaciens	SHEPUT
Shewanella species	Shew. species	SHESPE

Long Name	Short Name	Code
Shigella boydii	Shig. boydii	SHIBOY
Shigella dysenteriae	Shig. dysenteriae	SHIDYS
Shigella flexneri	Shig. flexneri	SHIFLE
Shigella sonnei	Shig. sonnei	SHISON
Shigella species	Shig. species	SHISPE
Shimwellia blattae	Shim. blattae	ESCBLA
Sphingobacterium multivorum	Sphingob. multivorum	SPHBMUL
Sphingobacterium multivorum/thalpophilum	Sphb. multivorum/thalpophilum	SPHBMULTHA
Sphingobacterium species	Sphingob. species	SPHBSPE
Sphingobacterium spiritivorum	Sphingob. spiritivorum	SPHBSPI
Sphingobacterium thalpophilum	Sphingob. thalpophilum	SPHBTHA
Sphingomonas paucimobilis	Sphingom. paucimobilis	SPHMPAU
Sporobolomyces salmonicolor	Sporobol. salmonicolor	SPOBSAL
Staphylococcus arlettae	Staph. arlettae	STAARL
Staphylococcus aureus	Staph. aureus	STAAUE
Staphylococcus aureus ssp *anaerobius*	Staph. aureus ssp anaerob.	STAAUEAN
Staphylococcus aureus ssp *aureus*	Staph. aureus ssp aureus	STAAUEAU
Staphylococcus auricularis	Staph. auricularis	STAAUI
Staphylococcus capitis	Staph. capitis	STACAI
Staphylococcus capitis ssp *capitis*	Staph. capitis ssp capitis	STACAIC
Staphylococcus capitis ssp *urealyticus*	Staph. capitis ssp urealyt.	STACAIU
Staphylococcus caprae	Staph. caprae	STACAP
Staphylococcus carnosus	Staph. carnosus	STACAR
Staphylococcus carnosus ssp *carnosus*	Staph. carn. ssp carn.	STACARC
Staphylococcus carnosus ssp *utilis*	Staph. carn. ssp utilis	STACARU
Staphylococcus chromogenes	Staph. chromogenes	STACHR
Staphylococcus chromogenes/hyicus	Staph. chromogenes/hyicus	STACHRHYI
Staphylococcus coagulase-negative	Staph. coag. neg.	STACNEG
Staphylococcus coagulase-positive	Staph. coag. pos.	STACPOS
Staphylococcus cohnii	Staph. cohnii	STACOH
Staphylococcus cohnii ssp *cohnii*	Staph. cohnii ssp cohnii	STACOHC

Long Name	Short Name	Code
Staphylococcus cohnii ssp *urealyticum*	Staph. cohnii ssp urealyt.	STACOHU
Staphylococcus condimenti	Staph. condimenti	STACON
Staphylococcus delphini	Staph. delphini	STADEL
Staphylococcus epidermidis	Staph. epidermidis	STAEPI
Staphylococcus equorum	Staph. equorum	STAEQU
Staphylococcus felis	Staph. felis	STAFEL
Staphylococcus fleurettii	Staph. fleurettii	STAFLE
Staphylococcus gallinarum	Staph. gallinarum	STAGAL
Staphylococcus haemolyticus	Staph. haemolyticus	STAHAE
Staphylococcus haemolyticus/lugdunensis	Staph. haemol./lugdun.	STAHAELUG
Staphylococcus hominis	Staph. hominis	STAHOM
Staphylococcus hominis ssp *hominis*	Staph. hom. ssp hom.	STAHOMH
Staphylococcus hominis ssp *novobiosepticus*	Staph. hom. ssp novo.	STAHOMN
Staphylococcus hyicus	Staph. hyicus	STAHYI
Staphylococcus intermedius	Staph. intermedius	STAINT
Staphylococcus kloosii	Staph. kloosii	STAKLO
Staphylococcus lentus	Staph. lentus	STALEN
Staphylococcus lugdunensis	Staph. lugdunensis	STALUG
Staphylococcus lutrae	Staph. lutrae	STALUT
Staphylococcus muscae	Staph. muscae	STAMUS
Staphylococcus pasteuri	Staph. pasteuri	STAPAS
Staphylococcus pettenkoferi	Staph. pettenkoferi	STAPET
Staphylococcus piscifermentans	Staph. piscifermentans	STAPIS
Staphylococcus pulvereri	Staph. pulvereri	STAPUL
Staphylococcus saccharolyticus	Staph. saccharolyticus	STASAC
Staphylococcus saprophyticus	Staph. saprophyticus	STASAP
Staphylococcus saprophyticus ssp *bovis*	Staph. sap. ssp bovis	STASAPB
Staphylococcus saprophyticus ssp *saprophyticus*	Staph. sap. ssp saprophyticus	STASAPS
Staphylococcus schleiferi	Staph. schleiferi	STASCH
Staphylococcus schleiferi ssp *coagulans*	Staph. schleiferi ssp coagul.	STASCHC

Long Name	Short Name	Code
Staphylococcus schleiferi ssp *schleiferi*	Staph. schleiferi ssp schleif.	STASCHS
Staphylococcus sciuri	Staph. sciuri	STASCI
Staphylococcus sciuri ssp *carnaticus*	Staph. sciuri ssp carnaticus	STASCIC
Staphylococcus sciuri ssp *rodentium*	Staph. sciuri ssp rodentium	STASCIR
Staphylococcus sciuri ssp *sciuri*	Staph. sciuri ssp sciuri	STASCIS
Staphylococcus simulans	Staph. simulans	STASIM
Staphylococcus species	Staph. species	STASPE
Staphylococcus succinus	Staph. succinus	STASUC
Staphylococcus succinus ssp *casei*	Staph. suc. ssp casei	STASUCCA
Staphylococcus succinus ssp *succinus*	Staph. suc. ssp succinus	STASUCSU
Staphylococcus vitulinus	Staph. vitulinus	STAVIT
Staphylococcus warneri	Staph. warneri	STAWAR
Staphylococcus warneri/pasteuri	Staph. warneri/pasteuri	STAWARPAS
Staphylococcus xylosus	Staph. xylosus	STAXYL
Stenotrophomonas maltophilia	Sten. maltophilia	STEMAL
Streptococcus acidominimus	Strep. acidominimus	STRACI
Streptococcus agalactiae (Strep. group B)	Strep. agalactiae (Str. gr. B)	STRAGA
Streptococcus alactolyticus	Strep. alactolyticus	STRALA
Streptococcus alpha-hemolytic	Strep. alpha-hemolytic	STRAHE
Streptococcus anginosus	Strep. anginosus	STRANG
Streptococcus anginosus (previously milleri) group	Strep. anginosus (milleri) gr.	STRANGGR
Streptococcus beta-hemolytic ACG (large colony)	Strep. beta-hemo ACG (lg col)	STRBHE
Streptococcus canis	Strep. canis	STRCAN
Streptococcus constellatus	Strep. constellatus	STRCON
Streptococcus constellatus ssp *constellatus*	Strep. con ssp constellatus	STRCONCO
Streptococcus constellatus ssp *pharyngis*	Strep. con ssp pharyngis	STRCONPH
Streptococcus criceti	Strep. criceti	STRCRC
Streptococcus cristatus	Strep. cristatus	STRCRS
Streptococcus downei	Strep. downei	STRDOW

Long Name	Short Name	Code
Streptococcus dysgalactiae	Strep. dysgalactiae	STRDYS
Streptococcus dysgalactiae ssp *dysgalactiae*	Strep. dysgal. ssp dysgal.	STRDYSDY
Streptococcus dysgalactiae ssp *equisimilis*	Strep. dysgal. ssp equis.	STRDYSEM
Streptococcus dysgalactiae/canis	Strep. dysgal./canis	STRDYSCAN
Streptococcus equi	Strep. equi	STREQU
Streptococcus equi ssp *equi*	Strep. equi ssp equi	STREQUE
Streptococcus equi ssp *zooepidemicus*	Strep. equi ssp zooepid.	STREQUZ
Streptococcus equinus	Strep. equinus	STREQN
Streptococcus ferus	Strep. ferus	STRFER
Streptococcus gallolyticus	Strep. gallolyticus	STRGAL
Streptococcus gallolyticus ssp gallolyticus	Strep. galloly. ssp galloly.	STRBOVI
Streptococcus gallolyticus ssp *macedonicus*	Strep. galloly. ssp macedon.	STRMAC
Streptococcus gallolyticus ssp *pasteurianus*	Strep. galloly. ssp pasteur.	STRGALP
Streptococcus gallolyticus ssp *pasteurianus/infantarius*	Strep. galloly. ssp pas./infa.	STRBOVII
Streptococcus gallolyticus/infantarius	Strep. galloly./infa.	STRBOV
Streptococcus gordonii	Strep. gordonii	STRGOR
Streptococcus group A (small colony)	Strep. group A (sm col)	STRGRAS
Streptococcus group A (*Strep. pyogenes*)	Strep. group A (Str. pyogenes)	STRGRA
Streptococcus group B (*Strep. agalactiae*)	Strep. group B (Str. agalact.)	STRGRB
Streptococcus group C (large colony)	Strep. group C (lg col)	STRGRC
Streptococcus group C (small colony)	Strep. group C (sm col)	STRGRCS
Streptococcus group C/G (large colony)	Strep. group C/G (lg col)	STRGRCG
Streptococcus group C/G (small colony)	Strep. group C/G (sm col)	STRGRCGS
Streptococcus group CFG (small colony)	Strep. group CFG (sm col)	STRGRCFG

Long Name	Short Name	Code
Streptococcus group D *(non-enterococcus)*	Strep. group D (non-enteroc.)	STRGRDNE
Streptococcus group E	Strep. group E	STRGRE
Streptococcus group F	Strep. group F	STRGRF
Streptococcus group G (large colony)	Strep. group G (lg col)	STRGRG
Streptococcus group G (small colony)	Strep. group G (sm col)	STRGRGS
Streptococcus group L	Strep. group L	STRGRL
Streptococcus hyointestinalis	Strep. hyointestinalis	STRHYO
Streptococcus infantarius	Strep. infantarius	STRINA
Streptococcus infantarius ssp *coli*	Strep. infa ssp coli	STRINACO
Streptococcus infantarius ssp *infantarius*	Strep. infa ssp infantarius	STRINAIN
Streptococcus infantis	Strep. infantis	STRINF
Streptococcus iniae	Strep. iniae	STRINI
Streptococcus intermedius	Strep. intermedius	STRINR
Streptococcus milleri group	Strep. milleri gr.	STRMILGR
Streptococcus mitis	Strep. mitis	STRMIT
Streptococcus mitis group	Strep. mitis gr.	STRMITGR
Streptococcus mitis/oralis	Strep. mitis/oralis	STRMITORA
Streptococcus mitis/pneumoniae	Strep. mitis/pneum.	STRMITPNE
Streptococcus mutans	Strep. mutans	STRMUT
Streptococcus mutans group	Strep. mutans gr.	STRMUTGR
Streptococcus oralis	Strep. oralis	STRORA
Streptococcus parasanguinis	Strep. parasanguinis	STRPAR
Streptococcus peroris	Strep. peroris	STRPER
Streptococcus pneumoniae	Strep. pneumoniae	STRPNE
Streptococcus porcinus	Strep. porcinus	STRPOR
Streptococcus pyogenes (Strep. group A)	Strep. pyogenes (Str. gr. A)	STRPYO
Streptococcus ratti	Strep. ratti	STRRAT
Streptococcus salivarius	Strep. salivarius	STRSAL
Streptococcus salivarius group	Strep. salivarius gr.	STRSALGR
Streptococcus salivarius ssp *thermophilus*	Strep. salivar. ssp thermoph.	STRTHE
Streptococcus sanguinis	Strep. sanguinis	STRSAN

Long Name	Short Name	Code
Streptococcus sanguinis group	Strep. sanguinis gr.	STRSANGR
Streptococcus sobrinus	Strep. sobrinus	STRSOB
Streptococcus species	Strep. species	STRSPE
Streptococcus suis	Strep. suis	STRSUI
Streptococcus uberis	Strep. uberis	STRUBE
Streptococcus vestibularis	Strep. vestibularis	STRVES
Streptococcus viridans beta-hemolytic (small colony)	Strep. vir. beta-hemo (sm col)	STRBHES
Streptococcus viridans group	Strep. viridans gr.	STRVIRGR
Suttonella indologenes	Sutto. indologenes	SUTIND
Tatumella ptyseos	Tat. ptyseos	TATPTY
Trichosporon asahii	Tric. asahii	TRIASA
Trichosporon inkin	Tric. inkin	TRIINK
Trichosporon loubieri	Tric. loubieri	TRILOU
Trichosporon mucoides	Tric. mucoides	TRIMUC
Trichosporon ovoides	Tric. ovoides	TRIOVO
Trueperella pyogenes	True. pyogenes	ACTMPYO
Vibrio alginolyticus	Vib. alginolyticus	VIBALG
Vibrio cholerae	Vib. cholerae	VIBCHO
Vibrio fluvialis	Vib. fluvialis	VIBFLU
Vibrio metschnikovii	Vib. metschnikovii	VIBMET
Vibrio mimicus	Vib. mimicus	VIBMIM
Vibrio parahaemolyticus	Vib. parahaemolyticus	VIBPAR
Vibrio vulnificus	Vib. vulnificus	VIBVUL
Weeksella virosa	Week. virosa	WEEVIR
Yersinia aldovae	Yer. aldovae	YERALD
Yersinia bercovieri	Yer. bercovieri	YERBER
Yersinia enterocolitica	Yer. enterocolitica	YERENT
Yersinia enterocolitica group	Yer. enterocolitica gr.	YERENTGR
Yersinia frederiksenii	Yer. frederiksenii	YERFRE
Yersinia intermedia	Yer. intermedia	YERINT
Yersinia kristensenii	Yer. kristensenii	YERKRI
Yersinia mollaretii	Yer. mollaretii	YERMOL
Yersinia pseudotuberculosis	Yer. pseudotuberculosis	YERPSE
Yersinia rohdei	Yer. rohdei	YERROH

Long Name	Short Name	Code
Yersinia ruckeri	Yer. ruckeri	YERRUC
Yersinia species	Yer. species	YERSPE
Yokenella regensburgei	Yok. regensburgei	YOKREG
Zygosaccharomyces bailii	Zyg. bailii	ZYGBAI

9.5 Panel Information

The panels described below are:

- Panel Insert for BD Phoenix GN Panels
- BD Phoenix Automated Microbiology System
- BD Phoenix™ NMIC/ID Panels
- BD Phoenix™ NMIC Panels
- BD Phoenix™ NID Panels
- BD Phoenix™ UNMIC Panels
- BD Phoenix™ UNMIC/ID Panels

9.5.1 Panel Information: Intended Use

The BD Phoenix Automated Microbiology System is intended for the in vitro rapid identification (ID) and quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of Gram Negative aerobic and facultative anaerobic bacteria belonging to the family *Enterobacteriaceae* and non-*Enterobacteriaceae*.

9.5.2 Summary and Explanation of the Test

Micromethods for the biochemical identification of microorganisms were reported as early as 1918[1]. Several publications reported on the use of the reagent-impregnated paper discs and micro-tube methods for differentiating enteric bacteria[1-9]. The interest in miniaturized identification systems led to the introduction of several commercial systems in the late 1960s, and they provided advantages in requiring little storage space, extended shelf life, standardized quality control, and ease of use.

Many of the tests used in the BD Phoenix ID panels are modifications of the classical methods. These include tests for fermentation, oxidation, degradation and hydrolysis of various substrates. In addition to these, the Phoenix system utilizes chromogenic and fluorogenic substrates as well as single carbon source substrates in the identification of organisms[10,11]. The modern broth microdilution test used today has origins in the tube dilution test used in 1942 by Rammelkamp and Maxon to determine in vitro antimicrobial susceptibility testing of bacterial isolates from clinical specimens[12].

The broth dilution technique involves exposing bacteria to decreasing concentrations of antimicrobial agents in liquid media by serial two-fold dilutions. The lowest concentration of an antimicrobial agent in which no visible growth occurs is defined as the minimal inhibitory concentration (MIC). The introduction in 1956 of a microtitrator system, using calibrated precision spiral wire loops and droppers for making accurate dilutions rapidly allowed Marymont and Wentz to develop a serial dilution antimicrobial susceptibility test (AST)[13]. The microtitrator system was accurate and allowed the reduction in volumes of antimicrobial agents. The term

microdilution appeared in 1970 to describe the MIC tests performed in volumes of 0.1 mL or less of antimicrobial solution[14]. The Phoenix AST is a modified miniaturized version of the micro-broth doubling dilution technique. Susceptibility testing in the BD Phoenix system is performed through determination of bacterial growth in the presence of various concentrations of the antimicrobial agent tested.

9.5.3 Principles of Procedure

A sealed and self-inoculating molded polystyrene tray, with 136 micro-wells containing dried reagents, serves as the Phoenix disposable. The combination panel includes an ID side with dried substrates for bacterial identification and an AST side with varying concentrations of antimicrobial agents, growth and fluorescent controls at appropriate well locations.

The BD Phoenix system utilizes an optimized colorimetric redox indicator for AST, and a variety of colorimetric and fluorometric indicators for ID. The AST Broth is cation-adjusted (e.g., Ca++ and Mg++) to optimize susceptibility testing performance. The BD Phoenix panel is comprised of a 51 well ID side and an 85 well AST side. The ID side contains 45 wells with dried biochemical substrates and two fluorescent control wells. The AST side contains 84 wells with dried antimicrobial agents and one growth control well. Panels are available as

- ID only (BD Phoenix™ NID Panels and BD Phoenix™ PID Panels),
- AST only (BD Phoenix™ NMIC Panels and BD Phoenix™ MIC Panels),
- ID/AST combination (BD Phoenix™ NMIC/ID Panels and BD Phoenix™ PMIC/ID Panels)
- BD Emerge Panels

Unused wells are reserved for future use. BD Phoenix panels are inoculated with a standardized inoculum. Organism suspensions must be prepared only with the BBL™ CrystalSpec™ nephelometer, the BD PhoenixSpec™ nephelometer, or the BD Phoenix™ AP instrument. Once inoculated, panels are placed into the instrument and continuously incubated at 35 °C. The instrument tests panels every 20 minutes: on the hour, at 20 minutes past the hour, and again at 40 minutes past the hour up to 16 hours if necessary. Phoenix panels are read only by the instrument. Phoenix panels cannot be read manually

Bacterial Identification

The ID portion of the Phoenix panel utilizes a series of conventional, chromogenic, and fluorogenic biochemical tests to determine the identification of the organism. Both growth-based and enzymatic substrates are employed to cover the different types of reactivity in the range of taxa. The tests are based on microbial utilization and degradation of specific substrates detected by various indicator systems. Acid production is indicated by a change in the phenol red indicator when an isolate is able to utilize a carbohydrate substrate. Chromogenic substrates produce a yellow color upon enzymatic hydrolysis of either p-nitrophenyl or p-nitroanilide compounds. Enzymatic hydrolysis of fluorogenic substrates results in the release of a fluorescent coumarin derivative. Organisms that utilize a specific carbon source reduce the resazurin-based indicator. In addition, there are other tests that detect the ability of an organism to hydrolyze, degrade, reduce, or otherwise utilize a substrate.

For a complete list of taxa that comprises the BD Phoenix ID Database see **Section 9.7 Taxa for ID/AST Determination**.

Antimicrobial Susceptibility Testing

The BD Phoenix AST method is a broth based microdilution test. The BD Phoenix system utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent 15. Continuous measurements of changes to the indicator as well as bacterial turbidity are used in the determination of bacterial growth.

Each AST panel configuration contains several antimicrobial agents with a wide range of two-fold doubling dilution concentrations. Organism identification is used in the interpretation of the MIC values of each antimicrobial agent producing Susceptible, Intermediate, or Resistant (SIR) result classifications. For a complete list of taxa that comprises the BD Phoenix AST results see **Section 9.7 Taxa for ID/AST Determination**.

For a detailed list of antimicrobial agents and concentrations available for susceptibility testing see **Section 9.5.4 List of Antimicrobial Agents in BD Phoenix Panels**.

There are antimicrobial agents for use with the BD Phoenix System that are not proven to be effective for treating infections for all organisms listed in the taxa. The components required for testing using the BD Phoenix system include:

- BD Phoenix panels with panel closures
- BD Phoenix ID Broth
- BD Phoenix AST Broth
- BD Phoenix AST Indicator solution
- BD Phoenix Inoculation Station
- BD Phoenix Panel Carrier
- BD BBL™ CrystalSpec™ nephelometer, the BD PhoenixSpec™ nephelometer, or the BD Phoenix™ AP instrument
- 25 µL pipettor and tips

Prior to inoculation the BD Phoenix panel is placed on the Inoculation Station with the inoculation ports at the top for filling. Separate inocula are added manually to the ID and AST ports. The inocula flow down the panel in serpentine fashion, filling the panel wells as the liquid front progresses toward the pad. The pad absorbs excess inoculum. Closures are manually inserted in the fill ports. An air admittance port is located in the divider area of the panel lid to ensure adequate oxygen tension in the panel for the duration of the test.

9.5.4 List of Antimicrobial Agents in BD Phoenix Panels

Gram Negative

Antimicrobic			Available Concentrations		
			Gram Negative	Gram Positive	Strep
Aminoglycoside	Amikacin	AN	0.5–64	0.5–64	N/A
Beta-lactam	Amoxicillin	AMX	0.5–32	**0.25–32**	0.125–32
Beta-lactam	Amoxicillin-Clavulanate (f)	AXC	0.5/2–32/2	**0.25/2–32/2**	N/A

Antimicrobic			Available Concentrations		
			Gram Negative	Gram Positive	Strep
Beta-lactam	Amoxicillin-Clavulanate	AMC	0.5/0.25–32/16	**0.25/0.125–32/16**	0.125/0.06–32/16
Beta-lactam	Ampicillin	AM	0.5–32	**0.0625–32**	0.0625–32
Beta-lactam	Ampicillin-Sulbactam (f)	SXA	0.5/8–32/8	0.5/8–32/8	N/A
Beta-lactam	Ampicillin-Sulbactam	SAM	1/0.5–32/16	**0.5/0.25–32/16**	N/A
Aminoglycoside	Arbekacin	ARB	0.25–16	0.25–16	N/A
Macrolides Lincosmides Streptogramins	Azithromycin	AZM	N/A	**0.06–8**	N/A
Beta-lactam	Aztreonam	ATM	0.5–64	**N/A**	N/A
Beta-lactam	Cefaclor	CEC	N/A	**0.5–32**	N/A
Beta-lactam	Cefazolin	CZ	0.5–32	0.5–32	N/A
Beta-lactam	Cefdinir	CDR	0.125–4	0.125–4	N/A
Beta-lactam	Cefditoren	CDN	0.125–8	0.125–8	N/A
Beta-lactam	Cefepime	FEP	0.125–64	**1–64**	0.0625–4
Beta-lactam	Cefetamet-pivoxil	CAT	0.25–16	**N/A**	N/A
Beta-lactam	Cefixime	CFM	0.125–8	**N/A**	N/A
Beta-lactam	Cefmetazole	CMZ	2–64	1–64	N/A
Beta-lactam	Cefoperazone	CFP	0.5–64	1–64	N/A
Beta-lactam	Cefoperazone-Sulbactam	SCP	0.5/8–64/8	N/A	N/A
Beta-lactam	Cefotaxime	CTX	0.5–64	1–64	0.0625–4
Beta-lactam	Cefotetan	CTT	2–64	1–64	N/A
Beta-lactam	Cefotiam	CFT	0.5–64	0.5–64	N/A
Beta-lactam	Cefoxitin	FOX	0.5–64	1–64	N/A
Beta-lactam	Cefozopran	CFZ	N/A	1–64	N/A
Beta-lactam	Cefpirome	CPO	0.5–64	0.5–64	N/A
Beta-lactam	Cefpodoxime	CPD	0.125–8	0.5–8	N/A
Beta-lactam	Cefsulodin	CFS	1–64	N/A	N/A
Beta-lactam	Ceftaroline	CPT	N/A	0.0625–4	N/A
Beta-lactam	Ceftazidime	CAZ	0.5–64	1–64	N/A
Beta-lactam	Ceftibuten	CTB	0.5–32	N/A	N/A
Beta-lactam	Ceftizoxime	ZOX	0.5–64	1–64	N/A

Antimicrobic			Available Concentrations		
			Gram Negative	Gram Positive	Strep
Beta-lactam	Ceftriaxone	CRO	0.5–64	1–64	0.0625–4
Beta-lactam	Cefuroxime	CXM	1–64	1–64	0.125–4
Beta-lactam	Cephalexin	CN	1–64	0.5–64	N/A
Beta-lactam	Cephalothin	CF	1–64	0.5–64	N/A
Phenicol	Chloramphenicol	C	1–32	1–32	1–32
Quinolone	Ciprofloxacin	CIP	0.125–4 For organisms except Salmonella spp.	0.125–4	N/A
	Ciprofloxacin	CIP	0.015–4 For Salmonella spp.		
Macrolides Lincosamides Streptogramins	Clarithromycin	CLR	N/A	0.06–8	N/A
Macrolide Lincosamide	Clindamycin	CC	N/A	0.12–8	0.03–4
Cyclic peptide	Colistin	CL	0.5–4	N/A	N/A
Cyclic lipopeptide	Daptomycin	DAP	N/A	0.125–32	0.03–16
Tetracycline	Doxycycline	D	N/A	0.25–16	N/A
Beta-lactam	Ertapenem	ETP	0.0625–4	0.25–32	0.0625–4
Macrolide Lincosamide	Erythromycin	E	N/A	0.125–8	0.015–4
Fosfomycin	Fosfomycin	FF	16–256	8–256	N/A
Fusidane	Fusidic Acid	FA	N/A	0.5–32	N/A
Quinolone	Garenoxacin	GRN	0.125–16	0.25–8	0.03125–4
Quinolone	Gatifloxacin	GAT	0.25–8	0.25–8	0.0625–8
Quinolone	Gemifloxacin	GEM	0.125–8	0.125–2	0.0625–8
Aminoglycoside	Gentamicin	GM	0.5–16	0.5–16	N/A
Aminoglycoside	Gentamicin-Syn	GMS	N/A	500	250–1,000
Aminoglycoside	Gentamicin-Syn (SFM)	GMF	N/A	250	N/A
Beta-lactam	Imipenem	IPM	0.0625–16	0.5–16	0.015–4
Aminoglycoside	Isepamycin	ISP	0.5–32	N/A	N/A

Antimicrobic			Available Concentrations		
			Gram Negative	Gram Positive	Strep
Aminoglycoside	Kanamycin	K	0.5–64	0.5–64	N/A
Aminoglycoside	Kanamycin-Syn	KS	N/A	250	250–1,000
Quinolone	Levofloxacin	LVX	0.25–8	0.25–8	0.25–16
Macrolides Lincosamides Streptogramin	Lincomycin	L	N/A	0.5–16	N/A
Oxazolidinone	Linezolid	LZD	N/A	0.25–32	0.25–16
Quinolone	Lomefloxacin	LOM	0.25–8	0.25–8	N/A
Beta-lactam	Mecillinam	MEC	0.5–32	N/A	N/A
Beta-lactam	Meropenem	MEM	0.125–32	0.5–16	0.03125–2
Tetracycline	Minocycline	MI	0.5–16	1–32	N/A
Beta-lactam	Moxalactam	MOX	1–64	1–64	N/A
Quinolone	Moxifloxacin	MXF	0.125–8	0.25–8	0.0625–8
Pseudomonic acid	Mupirocin	MUP	N/A	0.0625–8	N/A
Pseudomonic acid	Mupirocin High level	MUH	N/A	256	N/A
Quinolone	Nalidixic Acid	NA	1–32	N/A	N/A
Aminoglycoside	Netilmicin	NET	0.5–32	0.5–32	N/A
Nitrofuran	Nitrofurantoin	FM	8–512	16–512	N/A
Quinolone	Norfloxacin	NOR	0.25–16	0.25–16	N/A
Quinolone	Ofloxacin	OFX	0.25–8	0.25–8	0.5–16
Beta-lactam	Oxacillin	OX	N/A	0.06–4	N/A
Quinolone	Pefloxacin	PEF	0.25–8	0.25–8	N/A
Beta-lactam	Penicillin G	P	N/A	0.0625–32	0.03125–8
Beta-lactam	Piperacillin	PIP	0.5–128	1–128	N/A
Beta-lactam	Piperacillin-Tazobactam	TZP	0.5/4–128/4	1/4–128/4	N/A
Macrolides Lincosamides Streptogramin	Pristinamycin	PR	N/A	0.25–4	0.0625–4
Macrolides Lincosamides Streptogramin	Quinupristin-Dalfopristin	SYN	N/A	0.5–4	0.125–8
Rifamycin	Rifampin	RA	N/A	0.25–32	N/A
Aminoglycoside	Streptomycin-Syn	STS	N/A	1,000	250–1,000

Antimicrobic			Available Concentrations		
			Gram Negative	**Gram Positive**	**Strep**
Aminoglycoside	Streptomycin-Syn (SFM)	STF	N/A	250	N/A
Glycopeptide	Teicoplanin	TEC	N/A	0.5–32	1–32
Ketolide	Telithromycin	TEL	N/A	0.03125–8	0.0625–4
Beta-lactam	Temocillin	TEM	2 – 32	N/A	N/A
Tetracyclinee	Tetracycline	TE	0.5–16	0.5–16	0.0625–16
Beta-lactam	Ticarcillin	TIC	1–128	1–128	N/A
Beta-lactam	Ticarcillin-Clavulanate	TIM	1/2–128/2	1/2–128/2	N/A
Glycylcycline	Tigecycline	TGC	0.25–16	0.03125–4	N/A
Aminoglycoside	Tobramycin	NN	0.12–16	1 –16	N/A
Folate Antagonist	Trimeth-Sulfa (DIN)	STG	0.4/7.6–12.8/243.2	0.4/7.6–12.8/243.2	N/A
Folate Antagonist	Trimethoprim	TMP	0.5–16	0.5–16	N/A
Folate Antagonist	Trimethoprim-Sulfamethoxazole	SXT	0.5/9.5–16/304	0.5/9.5–16/304	0.06/1.19–16/304
Glycopeptide	Vancomycin	VA	N/A	0.5–32	0.0625–32

BOLD = Different range for Gram Negative and Gram Positive

NOTE

MIC dilutions appearing in this manual are actual serial 2-fold dilution concentrations. MIC values appearing on reports may be rounded.

In general, the BD Phoenix M50 instrument provides a MIC for all organisms at any of the concentrations defined on a specific panel. For certain drug and organism combinations in the following tables, a specific minimum/maximum MIC is reported even if there is a lower/higher concentration on the panel.

Antimicrobial	Organism	Min MIC	Max MIC
		(µg/mL)	**(µg/mL)**
Gram Negative			
Amikacin	*Morganella morganii*	2	
Amoxicillin-Clavulanic Acid (fixed clav. acid conc.)	*Proteus mirabilis*	1/2	
Amoxicillin-Clavulanic Acid (variable clav. acid conc.)	*Proteus mirabilis*	2/1	

Antimicrobial	Organism	Min MIC	Max MIC
		(µg/mL)	(µg/mL)
Arbekacin	*Enterobacter aerogenes*	1	
	Morganella morganii	1	
	Providencia ssp.	1	
Cefdinir	*Proteus mirabilis*	0.25	
Cefixime	*Proteus mirabilis*	0.5	
	Providencia ssp.	0.5	
Cefotiam	*Citrobacter freundii*	2	
	Proteus mirabilis	4	
	Providencia ssp.	4	
Ceftazidime-Avibactam	*Acinetobacter* ssp.	0.25	8
	Hafnia alvei	1	32
	Pantoea spp.	2	32
Fosfomycin w/G6P	*Pseudomonas aeruginosa*	16	64
Fosfomycin w/G6P	*Serratia* spp.	32	256
Imipenem	*Achromobacter* spp.	2	
Garenoxacin	*Stenotrophomonas maltophilia*	1	
Kanamycin	*Proteus mirabilis*	4	
Meropenem	*Aeromonas* spp.	0.25	
	Burkholderia spp.	0.5	
	Proteus mirabilis	0.5	
Ticarcillin	*Proteus mirabilis*	4	
Gram Positive			
Amikacin	*Staphylococcus epidermidis*	8	
	Staphylococcus other*	8	
Amoxicillin	*Staphylococcus aureus*	2	
	Staphylococcus epidermidis	2	
Ampicillin	*Staphylococcus aureus*		1
	Enterococcus other**	1	
Ampicillin-Sulbactam (f) (SXA)	*Staphylococcus epidermidis*	1	
Ampicillin-Sulbactam (SAM)	*Enterococcus* other**	2	
Cefotetan	*Staphylococcus epidermidis*	8	
Ceftriaxone	*Staphylococcus aureus*	2	

Antimicrobial	Organism	Min MIC	Max MIC
		(µg/mL)	(µg/mL)
Cephalexin	*Staphylococcus epidermidis*	1	
Daptomycin	*Enterococcus casseliflavus/gallinarum*	2	
Lincomycin	*Enterococcus* other**	1	8
Netilmicin	*Staphylococcus epidermidis*	2	
Minocycline**	*Enterococcus* other**	1	32
	Staphylococcus other**	1	32
Norfloxacin	*Enterococcus* other**	2	
Penicillin	*Staphylococcus aureus*		1
	Staphylococcus epidermidis		1
	Enterococcus other**	2	
Piperacillin	*Staphylococcus epidermidis*	2	
Teicoplanin	*Staphylococcus epidermidis*	2	
Ticarcillin	*Staphylococcus epidermidis*	4	
	Staphylococcus other*	4	
Ticarcillin/Clavulanate	*Staphylococcus aureus*	4/2	
Trovafloxacin	*Enterococcus faecium*	1	
Streptococci			
Daptomycin	*Viridans* group	0.25	

* Coagulase negative *Staphylococcus* other than *S. epidermidis*

** *Enterococcus* sp. other than *E. faecalis* and *E. faecium*

9.6 List of Reagents and Principles Employed in the BD Phoenix System

9.6.1 Gram Negative

SUBSTRATE NAME	CODE	PRINCIPLE
L-PHENYLALANINE-AMC	A_LPHET	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a fluorescent coumarin or 4-methylumbelliferone derivative.
4MU-N-ACETYL-BD-GLUCOSAMINIDE	M_NAG	
L-GLUTAMIC ACID-AMC	A_LGTA	
L-TRYPTOPHAN-AMC	A_LTRY	
L-PYROGLUTAMIC ACID-AMC	A_LPYR	
L-PROLINE-AMC	A_LPROB	
L-ARGININE-AMC	A_LARGH	
ARGININE-ARGININE-AMC	A_ARARR	
GLYCINE-AMC	A_GLYB	
L-LEUCINE-AMC	A_LLEUH	
LYSINE-ALANINE-AMC	A_LYALD	
GLUTARYL-GLYCINE-ARGININE-AMC	A_GUGAH	
GLYCINE-PROLINE-AMC	A_GLPRB	
COLISTIN	C_CLST	Resistance to the antimicrobial agent results in a reduction of the resazurin based indicator.
POLYMYXIN B	C_PXB	
D-MANNITOL	C_DMNT	Utilization of a carbon source results in a reduction of the resazurin based indicator.
CITRATE	C_CIT	
ACETATE	C_ACT	
ADONITOL	C_ADO	
MALONATE	C_MLO	
ALPHA-KETOGLUTARIC ACID	C_KGA	
TIGLIC ACID	C_TIG	
FLUORESCENT POSITIVE CONROL	FLR_CTL	Control to standardize fluorescent substrate results.
FLUORESCENT POSITIVE CONROL	FLR_CTL	
L-PROLINE-NA	N_LPROT	Enzymatic hydrolysis of the colorless amide substrate releases yellow p-nitroaniline.
GAMMA-L-GLUTAMYL-NA	N_LGGH	

SUBSTRATE NAME	CODE	PRINCIPLE
BIS (PNP) PHOSPHATE	P_BPHO	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow p-nitrophenol.
PNP-BD-GLUCOSIDE	P_BDGLU	
BETA-ALLOSE	R_BALL	Utilization of carbohydrate results in lower pH and change in indicator (phenol red).
N-ACETYL-GALACTOSAMINE	R_NGA	
N-ACETYL-GLUCOSAMINE	R_NGU	
SORBITOL	R_DSBT	
SUCROSE	R_DSUC	
GALACTURONIC ACID	R_GRA	
MALTULOSE	R_MTU	
L-RHAMNOSE	R_LRHA	
BETA-GENTIOBIOSE	R_BGEN	
DEXTROSE	R_DEX	
D-GALACTOSE	R_DGAL	
D-FRUCTOSE	R_DFRU	
D-GLUCONIC ACID	R_DGUA	
D-MELIBIOSE	R_DMLB	
L-ARABINOSE	R_LARA	
METHYL-B-GLUCOSIDE	R_MBGU	
ORNITHINE	S_ORN	Utilization of ornithine results in pH rise and change in fluorescent indicator.
UREA	S_URE	Hydrolysis of urea and the resulting ammonia change results in pH rise and change in fluorescent indicator.
ESCULIN	T_ESC	Hydrolysis of esculin results in a black precipitate in the presence of ferric ion.

9.6.2 Gram Positive

SUBSTRATE NAME	CODE	PRINCIPLE
4MU-BD-CELLOBIOSIDE	M_BDCEL	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a fluorescent coumarin or 4-methylumbelliferone derivative.
L-ALANINE-AMC	A_LALT	
4MU-BD-GLUCOSIDE	M_BDGLU	
L-PROLINE-AMC	A_LPROB	
L-PYROGLUTAMIC ACID-AMC	A_LPYR	
L-PHENYLALANINE-AMC	A_LPHET	
L-TRYPTOPHAN-AMC	A_LTRY	
4MU-PHOSPHATE	M_PHOS	
METHIONINE-AMC	A_META	
4MU-AD-GLUCOSIDE	P_ADGLU	
ARGININE-ARGININE-AMC	A_ARARR	
GLYCINE-PROLINE-AMC	A_GLPRB	
4MU-BD-GLUCURONIDE	M_BDGLC	
L-LEUCINE-AMC	A_LLEUH	
4MU-N-ACETYL-BD-GLUCOSAMINIDE	M_NAG	
L-ARGININE-AMC	A_LARGH	
4MU-PHOSPHATE (with Trehalose)	M_PHOT	
L-HISTIDINE-AMC	A_LHIST	
L-ISOLEUCINE-AMC	A_LISO	
4MU-BD-GALACTOSIDE	M_BDGAL	
COLISTIN	C_CLST	Resistance to the antimicrobial agent results in a reduction of the resazurin based indicator.
POLYMYXIN B	C_PXB	

SUBSTRATE NAME	CODE	PRINCIPLE
D-GLUCONIC ACID	C_DGUA	Utilization of a carbon source results in a reduction of the resazurin based indicator.
3-METHYL GLUTARIC ACID	C_3MGA	
D-FRUCTOSE	C_DFRU	
IMINODIACETIC ACID	C_IMN	
ALPHA-KETOGLUTARIC ACID	C_KGA	
D-MANNITOL	C_DMNT	
3-METHYLADIPIC ACID	C_MAA	
THYMIDINE	C_THY	
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.
FLUORESCENT POSITIVE CONTROL	FLR_CTL	
ALANINE-ALANINE-PNA	N_ALALH	Enzymatic hydrolysis of the colorless amide substrate releases yellow p-nitroaniline.
L-PROLINE-PNA	N_LPROT	
VALINE-ALANINE-PNA	N_VAALA	
PNP-AD-GLUCOSIDE	P_PAGLU	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow p-nitrophenol.
PNP-PHOSPHATE	P_PHOL	
BETA-GENTIOBIOSE	R_BGEN	Utilization of carbohydrate results in lower pH and change in indicator (phenol red).
D-SUCROSE	R_DSUC	
MALTOTRIOSE	R_MTT	
N-ACETYL-GLUCOSAMINE	R_NGU	
D-TREHALOSE	R_DTRE	
D-TAGATOSE	R_DTAG	
MALTOSE	R_MAL	
DEXTROSE	R_DEX	
METHYL-α-D-GLUCOSIDE	R_MGP	
UREA	S_URE	Hydrolysis of urea and the resulting ammonia change results in pH rise and change in fluorescent indicator.
ESCULIN	T_ESC	Hydrolysis of esculin results in a black precipitate in the presence of ferric ion.
NITROCEFIN	L_NCF	Enzymatic hydrolysis of the ß-Lactam ring results in a color change.

9.6.3 Streptococci Panel

SUBSTRATE NAME	CODE	PRINCIPLE
AMYGDALIN	R_AMY	Utilization of carbohydrate results in lower pH and change in indicator (Phenol red).
D-GALACTOSE	R_DGAL	
D-MANNITOL	R_DMTL	
D-RAFFINOSE	R_DRAF	
D-SORBITOL	R_DSBT	
D-TREHALOSE	R_DTRE	
DEXTRIN	R_DXN	
N-ACETYL-GLUCOSAMINE	R_NGU	
PHENYL GLUCOSIDE	R_PHG	
SALICIN	R_SAL	
ONP-BD-GLUCOSIDE	O_BOGLU	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow p-nitrophenol.
PNP-AD-GALACTOSIDE	P_ADGAL	
PNP-BD-CELLOBIOSIDE	P_CELB	
PNP-BD-GALACTOSIDE	P_GALB	
PNP-AD-GLUCOSIDE	P_PAGLU	
PNP-PHOSPHATE	P_PHOL	
ALANINE-ALANINE-PNA	N_ALALH	Enzymatic hydrolysis of the colorless amide substrate releases yellow p-nitroanilide.
VALINE-ALANINE-PNA	N_VAALA	
L-LYSINE-PNA	N_LLYSB	
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.
FLUORESCENT POSITIVE CONTROL	FLR_CTL	
THYMIDINE	THY	Utilization of a carbon source resulting in a reduction of the indicator (Resazurin based).
PULLULAN	PUL	
D-TREHALOSE	TRL	
D-LACTOSE	DLAC	

SUBSTRATE NAME	CODE	PRINCIPLE
LYSINE-AMC	A_LYSA	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a fluorescent coumarin or 4-methylumbelliferone derivative.
SERINE-TYROSINE-AMC	A_SETY	
L-CITRULLINE-AMC	A_LCTU	
L-PYROGLUTAMIC ACID-AMC	A_LPYR	
ISOLEUCINE-AMC	A_LISO	
L-TRYPTOPHAN-AMC	A_LTRY	
L-VALINE-AMC	A_LVAL	
ARGININE-ARGININE-AMC	A_ARARR	
LYSINE-ALANINE-AMC	A_LYALD	
ASPARAGINE-AMC	A_APGT	
L-ARGININE-AMC	A_LARGH	
L-HISTIDINE-AMC	A_LHIST	
ALANINE-AFC	Z_ALFT	
4MU-BD-CELLOBIOSIDE	M_BDCEL	
4MU-BD-GLUCOSIDE	M_BDGLU	
4MU-PHOSPHATE	M_PHOS	
4MU-AD-GLUCOSIDE	M_ADGLU	
4MU-BD-GLUCURONIDE	M_BDGLC	
4MU-N-ACETYL-BD-GLUCOSAMINE	M_NAG	
4MU-PHOSPHATE (with trehalose)	M_PHOT	
4MU-BD-GALACTOSIDE	M_BDGAL	
ESCULIN	T_ESC	Hydrolysis of esculin results in a black precipitate in the presence of ferric ion.

9.6.4 Yeast Panel

SUBSTRATE NAME	CODE	PRINCIPLE
PNP-BD-GLUCOSIDE	P_BDGLU	Enzymatic hydrolysis of the colorless aryl substituted glycoside releases yellow p-nitrophenol.
PNP-AD-GLUCOSIDE	P_PAGLU	
ONP-BD-GLUCOSIDE	O_BOGLU	
L-SORBOSE	C_LSBO	Utilization of a carbon source results in a reduction of the resazurin based indicator.
DEXTROSE	C_DEX	
D-MANNITOL	C_DMNT	
D-SUCROSE	C_DSUC	
METHYL-AD-GLUCOPYRANOSIDE	C_MGP	
N-ACETYL-BD-GLUCOSAMINIDE	C_NAG	
DEXTROSE	R_DEX	Utilization of carbohydrate results in lower pH and change in indicator (phenol red).
D-FRUCTOSE	R_DFRU	
D-GALACTOSE	R_DGAL	
SUCROSE	R_DSUC	
D-TREHALOSE	R_DTRE	
MALTOTRIOSE	R_MTT	
ESCULIN	T_ESC	Hydrolysis of esculin results in a black precipitate in the presence of ferric ion.
FLUORESCENT NEGATIVE CONTROL	Z_FTST	Control to check for fluorescent interference.
FLUORESCENT POSITIVE CONTROL	FLR_CTL	Control to standardize fluorescent substrate results.
FLUORESCENT POSITIVE CONTROL	FLR_CTL	
GAMMA-L-GLUTAMYL-NA	N_LGGH	Enzymatic hydrolysis of the colorless amide substrate releases yellow p-nitroaniline.
L-PROLINE-PNA	N_LPROT	

SUBSTRATE NAME	CODE	PRINCIPLE
ASPARAGINE-AMC	A_APGT	Enzymatic hydrolysis of the amide or glycosidic bond results in the release of a fluorescent coumarin or 4-methylumbelliferone derivative.
L-ARGININE-AMC	A_LARGH	
L-GLUTAMINE-AMC	A_LGLNB	
L-TYROSINE-AMC	A_LTYO	
L-HISTIDINE-AMC	A_LHIST	
ORNITHINE-AMC	A_ORN	
THREONINE-AMC	A_THR	
HYDROXY PROLINE-AMC	A_LHYP	
4MU-N-ACETYL-BD-GLUCOSAMINE	M_NAG	
4MU-AD-GLUCOSIDE	M_ADGLU	
4MU-PHOSPHATE	M_PHOS	
LYSINE-ALANINE-AMC	A_LYALD	
GLYCINE-ARGININE-AMC	A_GLARH	
ALANINE-AFC	Z_ALFT	
GLYCINE-AMC	A_GLYB	
L-CITRULLINE-AMC	A_LCTU	
L-GLUTAMIC ACID-AMC	A_LGTA	
L-VALINE-AMC	A_LVAL	
L-ALANINE-AMC	A_LALT	
L-PROLINE-AMC	A_LPROB	
L-TRYPTOPHAN-AMC	A_LTRY	
H-B-ALANINE-AMC	A_HBALT	
4MU-BD-CELLOBIOSIDE	M_BDCEL	
4MU-BD-GLUCOSIDE	M_BDGLU	
GLYCINE-PROLINE-AMC	A_GLPRB	
LYSINE-PROLINE-AMC	A_LYPRA	
BENZYL-L-CYSTEINE-AMC	A_BZLCY	
AMINO ACID	S_GTN	Utilization of the amino acid results in a change in fluorescence.
UREA	S_URE	Hydrolysis of urea and the resulting ammonia change results in pH rise and change in fluorescent indicator.

9.7 Taxa for ID/AST Determination

9.7.1 Gram Negative (0.5 McFarland)

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Achromobacter denitrificans	AST
Achromobacter piechaudii	AST
Achromobacter species	ID/AST
Achromobacter xylosoxidans	AST
Acinetobacter baumannii[2]	ID/AST
Acinetobacter baumannii/calcoaceticus complex[2]	ID/AST
Acinetobacter baumannii/haemolyticus	AST
Acinetobacter calcoaceticus	AST
Acinetobacter haemolyticus	ID/AST
Acinetobacter johnsonii	AST
Acinetobacter junii	AST
Acinetobacter lwoffii	ID/AST
Acinetobacter lwoffii/haemolyticus	ID/AST
Acinetobacter radioresistens	AST
Acinetobacter species	ID/AST
Actinobacillus lignieresii	ID
Actinobacillus suis	ID
Actinobacillus ureae	ID
Aeromonas allosaccharophila	AST
Aeromonas caviae	ID/AST
Aeromonas eucrenophila	AST
Aeromonas hydrophila	ID/AST
Aeromonas hydrophila group	AST
Aeromonas jandaei	AST
Aeromonas media	AST
Aeromonas salmonicida	AST
Aeromonas salmonicida ssp *achromogenes*	AST
Aeromonas salmonicida ssp *masoucida*	ID/AST
Aeromonas salmonicida ssp *pectinolytica*	AST
Aeromonas salmonicida ssp *salmonicida*	ID/AST
Aeromonas salmonicida ssp *smithia*	ID/AST
Aeromonas schubertii	ID/AST

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Aeromonas species	AST
Aeromonas trota	AST
Aeromonas veronii bv *sobria*	ID/AST
Aeromonas veronii bv *veronii*	ID/AST
Alcaligenes faecalis	ID/AST
Alcaligenes faecalis ssp *faecalis*	AST
Alcaligenes species	AST
Bergeyella zoohelcum	ID
Bordetella bronchiseptica	ID
Brevundimonas diminuta	ID/AST
Brevundimonas species	AST
Brevundimonas vesicularis	ID/AST
Burkholderia caryophylli	AST
Burkholderia cepacia complex	ID/AST
Burkholderia cepacia/Ralstonia pickettii	ID/AST
Burkholderia gladioli	ID/AST
Burkholderia glathei	AST
Burkholderia graminis	AST
Burkholderia multivorans	AST
Burkholderia phenazinium	AST
Burkholderia pyrrocinia	AST
Burkholderia species	AST
Burkholderia species/Ralstonia species	ID/AST
Cardiobacterium hominis	ID
CDC group Vb-3	ID
Cedecea davisae	ID/AST
Cedecea lapagei	ID/AST
Cedecea neteri	ID/AST
Cedecea species	AST
Cedecea species 3	AST
Cedecea species 5	AST
Chromobacterium violaceum	ID
Chryseobacterium gleum	ID/AST
Chryseobacterium indologenes	ID/AST
Chryseobacterium scophthalmum	AST
Chryseobacterium species	AST

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Citrobacter amalonaticus	ID/AST
Citrobacter braakii	ID/AST
Citrobacter farmeri	ID/AST
Citrobacter freundii	ID/AST
Citrobacter gillenii	AST
Citrobacter koseri	ID/AST
Citrobacter murliniae	AST
Citrobacter rodentium	AST
Citrobacter sedlakii	ID/AST
Citrobacter species	AST
Citrobacter werkmanii	ID/AST
Citrobacter youngae	ID/AST
Comamonas terrigena	ID
Comamonas testosteroni	ID
Cosenzaea myxofaciens	AST
Cronobacter sakazakii complex	ID/AST
Cupriavidus gilardii	AST
Cupriavidus pauculus	ID/AST
Delftia acidovorans	ID/AST
Edwardsiella hoshinae	ID/AST
Edwardsiella ictaluri	ID/AST
Edwardsiella species	AST
Edwardsiella tarda	ID/AST
Edwardsiella tarda biogroup 1	AST
Eikenella corrodens	ID
Elizabethkingia meningoseptica	ID/AST
Empedobacter brevis	ID
Enterobacter aerogenes[2]	ID/AST
Enterobacter asburiae	ID/AST
Enterobacter cancerogenus	ID/AST
Enterobacter cloacae[2]	ID/AST
Enterobacter cloacae ssp *dissolvens*	AST
Enterobacter hormaechei	ID/AST
Enterobacter kobei	AST
Enterobacter nimipressuralis	AST
Enterobacter species	AST

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Escherichia coli[2]	ID/AST
Escherichia coli serotype O111	AST
Escherichia coli serotype O157	AST
Escherichia fergusonii	ID/AST
Escherichia hermannii	ID/AST
Escherichia species	AST
Escherichia vulneris	ID/AST
Ewingella americana	ID
Gram-negative rod unidentified *enteric*	AST
Gram-negative rod unidentified nonfermenter	AST
Grimontia hollisae	ID
Hafnia alvei	ID/AST
Hafnia alvei group 1	AST
Kingella denitrificans	ID
Kingella kingae	ID
Klebsiella granulomatis	AST
Klebsiella oxytoca[2]	ID/AST
Klebsiella ozaenae	ID/AST
Klebsiella pneumoniae[2]	ID/AST
Klebsiella rhinoscleromatis	ID/AST
Klebsiella species	AST
Kluyvera ascorbata	ID/AST
Kluyvera cryocrescens	ID/AST
Kluyvera georgiana	AST
Kluyvera intermedia	ID/AST
Kluyvera species	AST
Kosakonia cowanii	AST
Leclercia adecarboxylata	ID/AST
Lelliottia amnigena	AST
Lelliottia amnigena biogroup 1	ID/AST
Lelliottia amnigena biogroup 2	ID/AST
Leminorella grimontii	ID
Leminorella richardii	ID
Mannheimia haemolytica	ID
Methylobacterium extorquens	ID
Moellerella wisconsensis	ID/AST

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Moraxella (Branhamella) catarrhalis	ID
Moraxella species	ID
Morganella morganii[2]	ID/AST
Morganella morganii ssp *morganii*	AST
Morganella morganii ssp *morganii* biogroup 1	AST
Morganella morganii ssp *sibonii*	AST
Morganella species	AST
Myroides odoratimimus	AST
Myroides odoratus	AST
Myroides odoratus/odoratimimus	ID/AST
Myroides species	AST
Neisseria animaloris	ID
Neisseria zoodegmatis	ID
Ochrobactrum anthropi	ID/AST
Oligella ureolytica	ID
Oligella urethralis	ID
Pantoea agglomerans	ID/AST
Pantoea ananatis	AST
Pantoea dispersa	AST
Pantoea species	AST
Pantoea stewartii	AST
Pantoea stewartii ssp *indologenes*	AST
Pantoea stewartii ssp *stewartii*	AST
Paracoccus yeei	ID
Pasteurella aerogenes	ID
Pasteurella multocida	ID
Pasteurella pneumotropica	ID
Photobacterium damselae	ID
Plesiomonas shigelloides	ID
Pluralibacter gergoviae	ID/AST
Pragia fontium	ID
Proteus hauseri	AST
Proteus mirabilis[2]	ID/AST
Proteus penneri	ID/AST
Proteus species	AST
Proteus vulgaris	ID/AST

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Proteus vulgaris/penneri	ID/AST
Providencia alcalifaciens	ID/AST
Providencia heimbachae	AST
Providencia rettgeri	ID/AST
Providencia rustigianii	ID/AST
Providencia species	AST
Providencia stuartii	ID/AST
Pseudomonas aeruginosa2	ID/AST
Pseudomonas alcaligenes	AST
Pseudomonas fluorescens	ID/AST
Pseudomonas fluorescens/putida	AST
Pseudomonas luteola	ID/AST
Pseudomonas mendocina	ID/AST
Pseudomonas monteilii	AST
Pseudomonas oryzihabitans	ID/AST
Pseudomonas pertucinogena	AST
Pseudomonas pseudoalcaligenes	ID/AST
Pseudomonas pseudoalcaligenes ssp *pseudoalcaligenes*	AST
Pseudomonas putida	ID/AST
Pseudomonas species	ID/AST
Pseudomonas stutzeri	ID/AST
Pseudomonas veronii	AST
Rahnella aquatilis	ID
Ralstonia pickettii	ID/AST
Ralstonia solanacearum	AST
Ralstonia species	AST
Raoultella ornithinolytica	ID/AST
Raoultella planticola	AST
Raoultella species	AST
Raoultella terrigena	AST
Rhizobium radiobacter	ID
Salmonella enterica ssp *arizonae*	ID/AST
Salmonella enterica ssp *diarizonae*	AST
Salmonella enterica ssp *enterica serovar Choleraesuis*	ID/AST
Salmonella enterica ssp *enterica* sv *Gallinarum*	ID/AST

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
bv *Gallinarum*	
Salmonella enterica ssp *enterica* sv *Gallinarum* bv *Pullorum*	ID/AST
Salmonella enterica ssp *enterica* sv *Paratyphi* A	ID/AST
Salmonella enterica ssp *enterica* sv *Typhi*	ID/AST
Salmonella enterica ssp *houtenae*	AST
Salmonella enterica ssp *indica*	AST
Salmonella enterica ssp *salamae*	AST
Salmonella species	ID/AST
Serratia entomophila	AST
Serratia ficaria	ID/AST
Serratia fonticola	ID/AST
Serratia grimesii	AST
Serratia liquefaciens	ID/AST
Serratia marcescens[2]	ID/AST
Serratia odorifera	AST
Serratia odorifera 1	ID/AST
Serratia odorifera 2	ID/AST
Serratia plymuthica	ID/AST
Serratia proteamaculans ssp *proteamaculans*	AST
Serratia proteamaculans ssp *quinovora*	AST
Serratia rubidaea	ID/AST
Serratia species	AST
Shewanella algae	AST
Shewanella putrefaciens	ID/AST
Shewanella species	AST
Shigella boydii	ID/AST
Shigella dysenteriae	ID/AST
Shigella flexneri	ID/AST
Shigella sonnei	ID/AST
Shigella species	ID/AST
Shimwellia blattae	AST
Sphingobacterium multivorum	ID/AST
Sphingobacterium multivorum/thalpophilum	ID/AST
Sphingobacterium species	AST
Sphingobacterium spiritivorum	ID/AST

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Sphingobacterium thalpophilum	ID/AST
Sphingomonas paucimobilis	ID/AST
Stenotrophomonas maltophilia[2]	ID/AST
Suttonella indologenes	ID
Tatumella ptyseos	ID
Vibrio alginolyticus	ID
Vibrio cholerae	ID
Vibrio fluvialis	ID
Vibrio metschnikovii	ID
Vibrio mimicus	ID
Vibrio parahaemolyticus	ID
Vibrio vulnificus	ID
Weeksella virosa	ID
Yersinia aldovae	AST
Yersinia bercovieri	AST
Yersinia enterocolitica	ID/AST
Yersinia enterocolitica group	AST
Yersinia frederiksenii	ID/AST
Yersinia intermedia	ID/AST
Yersinia kristensenii	ID/AST
Yersinia mollaretii	AST
Yersinia pseudotuberculosis	ID/AST
Yersinia rohdei	AST
Yersinia ruckeri	ID/AST
Yersinia species	AST
Yokenella regensburgei	ID

*Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (see **Section 5.9.6 Custom Interpretation Rule Set Sub-Tab**).

[1]Not all species encountered during clinical performance evaluations.

[2]Organism encountered in clinical trials and ≥ 20 strains available for antimicrobial/organism performance analysis.

9.7.2 Gram Negative (0.25 McFarland)

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Achromobacter species	ID/AST
Acinetobacter baumannii/calcoaceticus complex	ID/AST
Acinetobacter haemolyticus	ID/AST
Acinetobacter lwoffii	ID/AST
Actinobacillus lignieresii	ID
Actinobacillus suis	ID
Actinobacillus ureae	ID
Aeromonas caviae	ID/AST
Aeromonas hydrophila	ID/AST
Aeromonas salmonicida ssp *masoucida*	ID/AST
Aeromonas salmonicida ssp *salmonicida*	ID/AST
Aeromonas salmonicida ssp *smithia*	ID/AST
Aeromonas schubertii	ID/AST
Aeromonas veronii bv *sobria*	ID/AST
Aeromonas veronii bv *veronii*	ID/AST
Alcaligenes faecalis	ID/AST
Bergeyella zoohelcum	ID
Bordetella bronchiseptica	ID
Brevundimonas diminuta	ID/AST
Brevundimonas vesicularis	ID/AST
Burkholderia cepacia complex	ID/AST
Burkholderia gladioli	ID/AST
Cardiobacterium hominis	ID
CDC group Vb-3	ID
Cedecea davisae	ID/AST
Cedecea lapagei	ID/AST
Cedecea neteri	ID/AST
Chromobacterium violaceum	ID
Chryseobacterium gleum	ID/AST
Chryseobacterium indologenes	ID/AST
Citrobacter amalonaticus	ID/AST
Citrobacter braakii	ID/AST
Citrobacter farmeri	ID/AST
Citrobacter freundii	ID/AST

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Citrobacter koseri	ID/AST
Citrobacter sedlakii	ID/AST
Citrobacter werkmanii	ID/AST
Citrobacter youngae	ID/AST
Comamonas terrigena	ID
Comamonas testosteroni	ID
Cronobacter sakazakii complex	ID/AST
Cupriavidus pauculus	ID/AST
Delftia acidovorans	ID/AST
Edwardsiella hoshinae	ID/AST
Edwardsiella ictaluri	ID/AST
Edwardsiella tarda	ID/AST
Eikenella corrodens	ID
Elizabethkingia meningoseptica	ID/AST
Empedobacter brevis	ID
Enterobacter aerogenes	ID/AST
Enterobacter asburiae	ID/AST
Enterobacter cancerogenus	ID/AST
Enterobacter cloacae	ID/AST
Enterobacter hormaechei	ID/AST
Escherichia coli	ID/AST
Escherichia fergusonii	ID/AST
Escherichia hermannii	ID/AST
Escherichia vulneris	ID/AST
Ewingella americana	ID
Grimontia hollisae	ID
Hafnia alvei	ID/AST
Klebsiella oxytoca	ID/AST
Klebsiella ozaenae	ID/AST
Klebsiella pneumoniae	ID/AST
Klebsiella rhinoscleromatis	ID/AST
Kluyvera ascorbata	ID/AST
Kluyvera cryocrescens	ID/AST
Kluyvera intermedia	ID/AST
Leclercia adecarboxylata	ID/AST
Lelliottia amnigena biogroup 1	ID/AST

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Lelliottia amnigena biogroup 2	ID/AST
Leminorella grimontii	ID
Leminorella richardii	ID
Mannheimia haemolytica	ID
Moellerella wisconsensis	ID/AST
Morganella morganii	ID/AST
Myroides odoratus/odoratimimus	ID/AST
Neisseria animaloris	ID
Neisseria zoodegmatis	ID
Ochrobactrum anthropi	ID/AST
Oligella ureolytica	ID
Oligella urethralis	ID
Pantoea agglomerans	ID/AST
Paracoccus yeei	ID
Pasteurella aerogenes	ID
Pasteurella multocida	ID
Pasteurella pneumotropica	ID
Photobacterium damselae	ID
Plesiomonas shigelloides	ID
Pluralibacter gergoviae	ID/AST
Pragia fontium	ID
Proteus mirabilis	ID/AST
Proteus penneri	ID/AST
Proteus vulgaris	ID/AST
Proteus vulgaris/penneri	ID/AST
Providencia alcalifaciens	ID/AST
Providencia rettgeri	ID/AST
Providencia rustigianii	ID/AST
Providencia stuartii	ID/AST
Pseudomonas aeruginosa	ID/AST
Pseudomonas fluorescens	ID/AST
Pseudomonas luteola	ID/AST
Pseudomonas mendocina	ID/AST
Pseudomonas oryzihabitans	ID/AST
Pseudomonas putida	ID/AST
Pseudomonas stutzeri	ID/AST

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Rahnella aquatilis	ID
Ralstonia pickettii	ID/AST
Raoultella ornithinolytica	ID/AST
Rhizobium radiobacter	ID
Salmonella enterica ssp *arizonae*	ID/AST
Salmonella enterica ssp enterica serovar Choleraesuis	ID/AST
Salmonella enterica ssp *enterica* sv *Gallinarum* bv *Gallinarum*	ID/AST
Salmonella enterica ssp *enterica* sv *Gallinarum* bv *Pullorum*	ID/AST
Salmonella enterica ssp *enterica* sv *Paratyphi* A	ID/AST
Salmonella enterica ssp *enterica* sv *Typhi*	ID/AST
Salmonella species	ID/AST
Serratia ficaria	ID/AST
Serratia fonticola	ID/AST
Serratia liquefaciens	ID/AST
Serratia marcescens	ID/AST
Serratia odorifera 1	ID/AST
Serratia odorifera 2	ID/AST
Serratia plymuthica	ID/AST
Serratia rubidaea	ID/AST
Shewanella putrefaciens	ID/AST
Shigella boydii	ID/AST
Shigella dysenteriae	ID/AST
Shigella flexneri	ID/AST
Shigella sonnei	ID/AST
Sphingobacterium multivorum	ID/AST
Sphingobacterium spiritivorum	ID/AST
Sphingobacterium thalpophilum	ID/AST
Sphingomonas paucimobilis	ID/AST
Stenotrophomonas maltophilia	ID/AST
Suttonella indologenes	ID
Tatumella ptyseos	ID
Vibrio alginolyticus	ID
Vibrio cholerae	ID
Vibrio fluvialis	ID

GRAM NEGATIVE TAXA[1]	ID, AST, ID/AST*
Vibrio metschnikovii	ID
Vibrio mimicus	ID
Vibrio parahaemolyticus	ID
Vibrio vulnificus	ID
Weeksella virosa	ID
Yersinia enterocolitica	ID/AST
Yersinia frederiksenii	ID/AST
Yersinia intermedia	ID/AST
Yersinia kristensenii	ID/AST
Yersinia pseudotuberculosis	ID/AST
Yersinia ruckeri	ID/AST
Yokenella regensburgei	ID
* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (see **Section 5.9.6 Custom Interpretation Rule Set Sub-Tab**). [1]Not all species encountered during clinical performance evaluations [2]Organism encountered in clinical trials and ≥ 20 strains available for antimicrobial/organism performance analysis	

9.7.3 Gram Positive (0.5 McFarland)

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Aerococcus urinae	ID
Aerococcus viridans	ID
Alloiococcus otitis	ID
Arcanobacterium haemolyticum	ID
Bacillus cereus	ID
Bacillus circulans	ID
Bacillus coagulans	ID
Bacillus licheniformis	ID
Bacillus megaterium	ID
Bacillus pumilus	ID
Bacillus subtilis	ID
Bacillus thuringiensis	ID
Brevibacillus brevis	ID
Brevibacterium species	ID
Cellulomonas turbata	ID
Cellulosimicrobium cellulans	ID

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Corynebacterium amycolatum	ID
Corynebacterium amycolatum/minutissimum	ID
Corynebacterium amycolatum/striatum	ID
Corynebacterium bovis	ID
Corynebacterium diphtheriae	ID
Corynebacterium jeikeium	ID
Corynebacterium kutscheri	ID
Corynebacterium matruchotii	ID
Corynebacterium minutissimum	ID
Corynebacterium propinquum	ID
Corynebacterium pseudodiphtheriticum	ID
Corynebacterium pseudotuberculosis	ID
Corynebacterium renale	ID
Corynebacterium striatum	ID
Corynebacterium ulcerans	ID
Corynebacterium urealyticum	ID
Corynebacterium xerosis	ID
Dermabacter hominis	ID
Dermacoccus nishinomiyaensis	ID
Enterococcus asini	AST
Enterococcus avium	ID/AST
Enterococcus casseliflavus	ID/AST
Enterococcus casseliflavus/gallinarum	ID/AST
Enterococcus cecorum	AST
Enterococcus columbae	AST
Enterococcus dispar	AST
Enterococcus durans	ID/AST
Enterococcus durans/faecium	AST
Enterococcus faecalis	ID/AST
Enterococcus faecalis/faecium	AST
Enterococcus faecium	ID/AST
Enterococcus flavescens	AST
Enterococcus gallinarum	ID/AST
Enterococcus gilvus	AST
Enterococcus haemoperoxidus	AST
Enterococcus hirae	ID/AST

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Enterococcus hirae/faecium	AST
Enterococcus malodoratus	AST
Enterococcus moraviensis	AST
Enterococcus mundtii	AST
Enterococcus pallens	AST
Enterococcus pseudoavium	AST
Enterococcus raffinosus	ID/AST
Enterococcus raffinosus/avium	AST
Enterococcus ratti	AST
Enterococcus saccharolyticus	AST
Enterococcus species	AST
Enterococcus sulfureus	AST
Erysipelothrix rhusiopathiae	ID
Gardnerella vaginalis	ID
Gemella haemolysans	ID
Gemella morbillorum	ID
Globicatella sanguinis	ID
Helcococcus kunzii	ID
Kocuria kristinae	ID
Kocuria rosea	ID
Kocuria varians	ID
Kytococcus sedentarius	ID
Lactococcus garvieae	ID
Lactococcus lactis ssp *cremoris*	ID
Lactococcus lactis ssp *hordniae*	ID
Lactococcus lactis ssp *lactis*	ID
Lactococcus plantarum	ID
Lactococcus raffinolactis	ID
Leifsonia aquatica	ID
Leuconostoc citreum	ID
Leuconostoc lactis	ID
Leuconostoc mesenteroides ssp *cremoris*	ID
Leuconostoc mesenteroides ssp *mesenteroides*	ID
Leuconostoc pseudomesenteroides	ID
Listeria grayi	ID
Listeria innocua	ID

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Listeria ivanovii	ID
Listeria monocytogenes	ID
Listeria monocytogenes/innocua	ID
Listeria welshimeri	ID
Lysinibacillus sphaericus	ID
Macrococcus caseolyticus	ID
Micrococcus luteus	ID
Micrococcus lylae	ID
Paenibacillus alvei	ID
Paenibacillus macerans	ID
Pediococcus acidilactici	ID
Pediococcus damnosus	ID
Pediococcus dextrinicus	ID
Pediococcus parvulus	ID
Pediococcus pentosaceus	ID
Rhodococcus equi	ID
Rothia dentocariosa	ID
Rothia mucilaginosa	ID
Staphylococcus arlettae	AST
Staphylococcus aureus	ID/AST
Staphylococcus aureus ssp *anaerobius*	AST
Staphylococcus aureus ssp *aureus*	AST
Staphylococcus auricularis	ID/AST
Staphylococcus capitis	ID/AST
Staphylococcus capitis ssp *capitis*	ID/AST
Staphylococcus capitis ssp *urealyticus*	ID/AST
Staphylococcus caprae	ID/AST
Staphylococcus carnosus	ID/AST
Staphylococcus carnosus ssp *carnosus*	AST
Staphylococcus carnosus ssp *utilis*	AST
Staphylococcus chromogenes	ID/AST
Staphylococcus chromogenes/hyicus	ID/AST
Staphylococcus coagulase-negative	AST
Staphylococcus coagulase-positive	AST
Staphylococcus cohnii	ID/AST
Staphylococcus cohnii ssp *cohnii*	ID/AST

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Staphylococcus cohnii ssp *urealyticum*	ID/AST
Staphylococcus condimenti	AST
Staphylococcus delphini	AST
Staphylococcus epidermidis	ID/AST
Staphylococcus equorum	ID/AST
Staphylococcus felis	ID/AST
Staphylococcus fleurettii	AST
Staphylococcus gallinarum	ID/AST
Staphylococcus haemolyticus	ID/AST
Staphylococcus haemolyticus/lugdunensis	ID
Staphylococcus hominis	ID/AST
Staphylococcus hominis ssp *hominis*	AST
Staphylococcus hominis ssp *novobiosepticus*	AST
Staphylococcus hyicus	ID/AST
Staphylococcus intermedius	ID/AST
Staphylococcus kloosii	ID/AST
Staphylococcus lentus	ID/AST
Staphylococcus lugdunensis	ID/AST
Staphylococcus lutrae	AST
Staphylococcus muscae	AST
Staphylococcus pasteuri	ID/AST
Staphylococcus pettenkoferi	ID/AST
Staphylococcus piscifermentans	AST
Staphylococcus pulvereri	AST
Staphylococcus saccharolyticus	AST
Staphylococcus saprophyticus	ID/AST
Staphylococcus saprophyticus ssp *bovis*	AST
Staphylococcus saprophyticus ssp *saprophyticus*	AST
Staphylococcus schleiferi	ID/AST
Staphylococcus schleiferi ssp *coagulans*	ID/AST
Staphylococcus schleiferi ssp *schleiferi*	ID/AST
Staphylococcus sciuri	ID/AST
Staphylococcus sciuri ssp *carnaticus*	AST
Staphylococcus sciuri ssp *rodentium*	AST
Staphylococcus sciuri ssp *sciuri*	AST
Staphylococcus simulans	ID/AST

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Staphylococcus species	AST
Staphylococcus succinus	AST
Staphylococcus succinus ssp *casei*	AST
Staphylococcus succinus ssp *succinus*	AST
Staphylococcus vitulinus	ID/AST
Staphylococcus warneri	ID/AST
Staphylococcus warneri/pasteuri	AST
Staphylococcus xylosus	ID/AST
Streptococcus acidominimus	ID
Streptococcus agalactiae (Strep. group B)	ID
Streptococcus anginosus	ID
Streptococcus canis	ID
Streptococcus constellatus	ID
Streptococcus cristatus	ID
Streptococcus dysgalactiae ssp *dysgalactiae*	ID
Streptococcus dysgalactiae ssp *equisimilis*	ID
Streptococcus equi	ID
Streptococcus equi ssp *equi*	ID
Streptococcus equi ssp *zooepidemicus*	ID
Streptococcus equinus	ID
Streptococcus gallolyticus ssp *gallolyticus*	ID
Streptococcus gallolyticus ssp *pasteurianus/infantarius*	ID
Streptococcus gallolyticus/infantarius	ID
Streptococcus gordonii	ID
Streptococcus group C/G (large colony)	ID
Streptococcus intermedius	ID
Streptococcus mitis	ID
Streptococcus mitis/pneumoniae	ID
Streptococcus mutans	ID
Streptococcus oralis	ID
Streptococcus parasanguinis	ID
Streptococcus pneumoniae	ID
Streptococcus porcinus	ID
Streptococcus pyogenes (Strep. group A)	ID
Streptococcus salivarius	ID

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Streptococcus sanguinis	ID
Streptococcus sobrinus	ID
Streptococcus uberis	ID
Streptococcus vestibularis	ID
Trueperella pyogenes	ID
Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (see **Section 5.9.6 Custom Interpretation Rule Set Sub-Tab**). [1]Not all species encountered during clinical performance evaluations.	

9.7.4 Gram Positive (0.25 McFarland)

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Aerococcus urinae	ID
Aerococcus viridans	ID
Alloiococcus otitis	ID
Dermacoccus nishinomiyaensis	ID
Enterococcus avium	ID/AST
Enterococcus casseliflavus	ID/AST
Enterococcus durans	ID/AST
Enterococcus faecalis	ID/AST
Enterococcus faecium	ID/AST
Enterococcus gallinarum	ID/AST
Enterococcus hirae	ID/AST
Enterococcus raffinosus	ID/AST
Gemella haemolysans	ID
Gemella morbillorum	ID
Globicatella sanguinis	ID
Helcococcus kunzii	ID
Kocuria kristinae	ID
Kocuria rosea	ID
Kocuria varians	ID
Kytococcus sedentarius	ID
Lactococcus lactis ssp *cremoris*	ID
Lactococcus lactis ssp *hordniae*	ID
Lactococcus plantarum	ID
Leuconostoc citreum	ID
Leuconostoc lactis	ID

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Leuconostoc mesenteroides ssp *mesenteroides*	ID
Listeria innocua	ID
Listeria monocytogenes	ID
Micrococcus caseolyticus	ID
Micrococcus luteus	ID
Micrococcus lylae	ID
Pediococcus acidilactici	ID
Pediococcus damnosus	ID
Pediococcus dextrinicus	ID
Pediococcus parvulus	ID
Pediococcus pentosaceus	ID
Rothia mucilaginosa	ID
Staphylococcus aureus	ID/AST
Staphylococcus auricularis	ID/AST
Staphylococcus capitis	ID/AST
Staphylococcus caprae	ID/AST
Staphylococcus carnosus	ID/AST
Staphylococcus chromogenes	ID/AST
Staphylococcus cohnii ssp *cohnii*	ID/AST
Staphylococcus cohnii ssp *urealyticum*	ID/AST
Staphylococcus epidermidis	ID/AST
Staphylococcus equorum	ID/AST
Staphylococcus felis	ID/AST
Staphylococcus gallinarum	ID/AST
Staphylococcus haemolyticus	ID/AST
Staphylococcus hominis	ID/AST
Staphylococcus hyicus	ID/AST
Staphylococcus intermedius	ID/AST
Staphylococcus kloosii	ID/AST
Staphylococcus lentus	ID/AST
Staphylococcus lugdunensis	ID/AST
Staphylococcus pasteuri	ID/AST
Staphylococcus saprophyticus	ID/AST
Staphylococcus schleiferi ssp *coagulans*	ID/AST
Staphylococcus schleiferi ssp *schleiferi*	ID/AST

GRAM POSITIVE TAXA[1]	ID, AST, ID/AST*
Staphylococcus sciuri	ID/AST
Staphylococcus simulans	ID/AST
Staphylococcus vitulinus	ID/AST
Staphylococcus warneri	ID/AST
Staphylococcus xylosus	ID/AST
Streptococcus agalactiae (Strep. group B)	ID
Streptococcus anginosus	ID
Streptococcus constellatus	ID
Streptococcus cristatus	ID
Streptococcus equi	ID
Streptococcus gallolyticus ssp *gallolyticus*	ID
Streptococcus gallolyticus ssp *pasteurianus/infantarius*	ID
Streptococcus gallolyticus/infantarius	ID
Streptococcus gordonii	ID
Streptococcus group C/G (large colony)	ID
Streptococcus intermedius	ID
Streptococcus mitis	ID
Streptococcus mutans	ID
Streptococcus oralis	ID
Streptococcus parasanguinis	ID
Streptococcus pneumonia	ID
Streptococcus porcinus	ID
Streptococcus pyogenes (Strep. group A)	ID
Streptococcus salivarius	ID
Streptococcus sanguinis	ID
Streptococcus sobrinus	ID
Streptococcus uberis	ID
Streptococcus vestibularis	ID
*Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (see **Section 5.9.6 Custom Interpretation Rule Set Sub-Tab**). [1]Not all species encountered during clinical performance evaluations.	

9.7.5 Streptococci

STREPTOCOCCI TAXA[1]	ID, AST, ID/AST*
Streptococcus acidominimus	ID/AST
Streptococcus agalactiae (Strep. group B)	ID/AST
Streptococcus alactolyticus	AST
Streptococcus alpha-hemolytic	AST
Streptococcus anginosus	ID/AST
Streptococcus anginosus (previously milleri) group	ID/AST
Streptococcus beta-hemolytic ACG (large colony)	AST
Streptococcus canis	ID/AST
Streptococcus constellatus	ID/AST
Streptococcus constellatus ssp *constellatus*	AST
Streptococcus constellatus ssp *pharyngis*	AST
Streptococcus criceti	AST
Streptococcus cristatus	ID/AST
Streptococcus downei	AST
Streptococcus dysgalactiae	AST
Streptococcus dysgalactiae ssp *dysgalactiae*	ID/AST
Streptococcus dysgalactiae ssp *equisimilis*	ID/AST
Streptococcus dysgalactiae/canis	ID/AST
Streptococcus equi	ID/AST
Streptococcus equi ssp equi	ID/AST
Streptococcus equi ssp zooepidemicus	ID/AST
Streptococcus equinus	ID/AST
Streptococcus ferus	AST
Streptococcus gallolyticus	AST
Streptococcus gallolyticus ssp *gallolyticus*	ID/AST
Streptococcus gallolyticus ssp *macedonicus*	AST
Streptococcus gallolyticus ssp *pasteurianus*	AST
Streptococcus gallolyticus ssp *pasteurianus/infantarius*	ID/AST
Streptococcus gallolyticus/infantarius	AST
Streptococcus gordonii	ID/AST
Streptococcus group A (small colony)	AST
Streptococcus group A (Strep. pyogenes)	AST

STREPTOCOCCI TAXA[1]	ID, AST, ID/AST*
Streptococcus group B (Strep. agalactiae)	AST
Streptococcus group C (large colony)	AST
Streptococcus group C (small colony)	AST
Streptococcus group C/G (large colony)	ID/AST
Streptococcus group C/G (small colony)	AST
Streptococcus group CFG (small colony)	AST
Streptococcus group D (non-enterococcus)	AST
Streptococcus group E	AST
Streptococcus group F	AST
Streptococcus group G (large colony)	AST
Streptococcus group G (small colony)	AST
Streptococcus group L	AST
Streptococcus hyointestinalis	AST
Streptococcus infantarius	AST
Streptococcus infantarius ssp *coli*	AST
Streptococcus infantarius ssp *infantarius*	AST
Streptococcus infantis	AST
Streptococcus iniae	AST
Streptococcus intermedius	ID/AST
Streptococcus milleri group	AST
Streptococcus mitis	ID/AST
Streptococcus mitis group	ID/AST
Streptococcus mitis/oralis	AST
Streptococcus mitis/pneumoniae	ID/AST
Streptococcus mutans	ID/AST
Streptococcus mutans group	AST
Streptococcus oralis	ID/AST
Streptococcus parasanguinis	ID/AST
Streptococcus peroris	AST
Streptococcus pneumoniae	ID/AST
Streptococcus porcinus	ID/AST
Streptococcus pyogenes (Strep. group A)	ID/AST
Streptococcus ratti	AST
Streptococcus salivarius	ID/AST
Streptococcus salivarius group	AST
Streptococcus salivarius ssp *thermophilus*	AST

STREPTOCOCCI TAXA[1]	ID, AST, ID/AST*
Streptococcus sanguinis	ID/AST
Streptococcus sanguinis group	AST
Streptococcus sobrinus	ID/AST
Streptococcus species	AST
Streptococcus suis	AST
Streptococcus uberis	ID/AST
Streptococcus vestibularis	ID/AST
Streptococcus viridans beta-hemolytic (small colony)	AST
Streptococcus viridans group	AST
* Taxa for AST interpretation may vary depending on the user-selected Interpretation Rule Set (see **Section 5.9.6 Custom Interpretation Rule Set Sub-Tab**). [1]Not all species encountered during clinical performance evaluations.	

9.7.6 Yeast

YEAST TAXA[2]	SABDX SABEM SABHI	CHOC COLSB TSASB
Candida albicans	√	√
Candida apicola	√	√
Candida boidinii	√	
Candida bracarensis	√	
Candida catenulata	√	√
Candida ciferrii	√	√
Candida dubliniensis	√	√
Candida firmetaria	√	√
Candida freyschussii	√	√
Candida glabrata	√	√
Candida guilliermondii	√	√
Candida guilliermondii var *membranaefaciens*	√	√
Candida haemulonii	√	√
Candida inconspicua	√	√
Candida kefyr	√	√
Candida krusei	√	√
Candida lipolytica	√	√
Candida lusitaniae	√	√

YEAST TAXA[2]	SABDX SABEM SABHI	CHOC COLSB TSASB
Candida magnoliae	√	√
Candida melibiosica	√	√
Candida membranaefaciens	√	√
Candida norvegensis	√	√
Candida parapsilosis complex	√	√
Candida pararugosa	√	√
Candida pelliculosa	√	√
Candida pulcherrima	√	√
Candida rugosa	√	√
Candida sake	√	√
Candida sphaerica	√	
Candida tropicalis	√	√
Candida utilis	√	√
Candida viswanathii	√	√
Candida zeylanoides	√	√
Cryptococcus albidus	√	√
Cryptococcus humicola	√	√
Cryptococcus laurentii	√	
Cryptococcus luteolus	√	√
Cryptococcus neoformans	√[1]	√
Cryptococcus terreus	√	
Cryptococcus uniguttulatus	√	√
Exophiala dermatitidis	√	√
Exophiala species	√	√
Geotrichum species	√	√
Hortaea werneckii	√	√
Hyphopichia burtonii	√	√
Kloeckera species	√	
Magnusiomyces capitatus	√	√
Malassezia furfur complex	√	
Malassezia pachydermatis	√	
Malassezia sympodialis	√	
Millerozyma farinosa	√	√
Prototheca wickerhamii	√	√
Prototheca zopfii	√	√

YEAST TAXA[2]	SABDX SABEM SABHI	CHOC COLSB TSASB
Rhodotorula glutinis	√	√
Rhodotorula minuta	√	√
Rhodotorula mucilaginosa var *mucilaginosa*	√	√
Saccharomyces cerevisiae	√	√
Sporobolomyces salmonicolor	√	√
Trichosporon asahii	√	√
Trichosporon inkin	√	
Trichosporon loubieri	√	
Trichosporon mucoides	√	√
Trichosporon ovoides	√	
Zygosaccharomyces bailii	√	

[1]With an ID result of Cryptococcus neoformans and a substrate profile that may be indicative of C. gattii, the following message will print: The instrument produced an ID result of Cryptococcus neoformans with a profile that may be indicative of C. gattii. Recommend testing to rule out C. gattii.

[2]Not all species encountered during clinical performance evaluations.

10 Replacement Parts

The following items may be ordered by contacting your local BD representative (see **Section 12 International Contacts**).

Catalog Number	Item
443809	Barcode Scanner (external)
443866	System Software
441107	BD Phoenix™ Update Data (PUD) Software
443390	Barcode Scanner Stand
443842	Air Filter
443575	BD Phoenix™ M50 System User's Manual
443894	Quick Reference Guide
443431	Laser Printer
448984	Temperature Standard Panel

11 Appendix: Installation

This section describes the following:

WARNING

PROTECTION PROVIDED BY THIS EQUIPMENT MAY BE IMPAIRED IF THE EQUIPMENT IS USED IN A MANNER NOT CONSISTENT WITH THE INSTRUCTIONS IN THIS MANUAL.

CAUTION

The intake filter at the lower front right corner of the BDPhoenixM50 instrument must remain unobstructed at all times. Restricted air flow may cause excessive temperatures in the instrument, which can affect test results and possibly cause hardware malfunctions

11.1 Instrument Installation

The BD Phoenix M50 Instrument must be installed only by BD representatives.

CAUTION

Due to the size and weight of the BD Phoenix M50 instrument, at least two people are required to lift the instrument in the absence of a mechanical lifting device.

The BD Phoenix M50 instrument should be installed in an area that is free from undue vibration, direct sunlight, high humidity, dust, temperature extremes, and corrosive or explosive vapors or gases. The system will operate within specifications in room temperatures between 18–30 °C (64.4–86 °F). Relative humidity should be between 20% and 80% (non-condensing). The left, rear, and right sides of the instrument should be placed at least three inches from any wall. Environments which exceed these limits could adversely affect the performance of the system components.

The carousel should maintain its temperature to within plus or minus 1.5 °C of the temperature controller's setting (35 °C). This accuracy can be assured only if the room temperature meets the requirements given above.

Use of earthquake anchoring is strongly recommended in areas susceptible to earthquake activity.

A stacking kit is required when stacking two instruments on top of one another. (Installation Category II and Pollution Degree 2 as per IEC 664.)

Figure 52 Example to Two Phoenix M50 Instruments Stacked

11.2 System Startup

Whenever power is applied to the system, it is initialized, performs self-diagnostics, and reports any problems to the user through alerts. If any files are missing or corrupted which would prevent proper operation of the system, the startup process is aborted. If not, the computer loads the operating system and user interface, and begins the warmup period (indicated by the Instrument is warming up icon). Afterwards, the system awaits the initiation of panel testing.

The temperature standard panel should be left in the instrument at least 45 minutes before reading it when the instrument is first powered up.

11.3 Language Selection

A BD representative performs the language setting at installation. Supported languages include:

- Chinese
- Czech
- Danish
- English
- French
- German
- Hungarian
- Italian
- Japanese
- Korean
- Norwegian
- Polish
- Portuguese
- Russian
- Slovak
- Spanish
- Thai
- Turkish

11.4 Instrument Specification Charts

Physical Dimensions	
Height	21 in (535 mm)
Width	32 in (815 mm)
Depth	30 in (765 mm)
Clearance–Right	21.5 in (546 mm)
Clearance–Left, Rear	3 in (76 mm)
Clearance–Front	18 in (457 mm)

Physical Dimensions	
Weight–Empty	118 lb (53.5 kg)
Weight–Full	127 lb (57.6 kg)

Environmental Requirements	
Non-Operating Storage	
Temperature	-17.8–65 °C (0–149 °F)
Humidity	20–80% RH, non-condensing
Operating Conditions	
Temperature	18–30 °C (64.4–86 °F)
Humidity	20–80% RH, non-condensing
Locations	Level surface, No direct sunlight, No direct heat
Altitude (evaluated for safety)	2,000 m
Noise	at 1 m ≤ 55 dBA using ANSI Type 2 sound meter

Electrical Requirements	
Input Voltage	100–240 VAC
Input Current	6 Amp
Input Line Frequency	50/60 Hz

Instrument Heat Output at Input Voltage = 120 VAC	
Ambient Temperature	**BTU/hr**
18 °C	648
24 °C	464
30 °C	287

Optical Specifications
Peak Wavelengths
428 nm to 623 nm, visible spectrum
375 nm, UV Excitation
410–640 nm Bandpass, UV Emission

12 International Contacts

BD
7 Loveton Circle
Sparks, Maryland 21152 USA
Voice: (410) 316-4000 • Fax: (410) 527-0244
Technical Service and Support: 1-800-638-8663
Customer Service: 1-800-675-0908
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Voice: 52 5 237 1200 • Fax: 52 5 237 1287

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Singapore 639461
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Australian Sponsor:
Becton Dickinson Pty Ltd.
4 Research Park Drive
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North Ryde, NSW 2113 Australia

	**www.bd.com/e-labeling** **Key-code: 443575**	
	EU:	**+800 135 79 135**
	GR	00 800 161 220 577 99
	HR	+800 135 79 135
	IS	800 8996
	LT	880 030 728
	RO	0800 895 084
	SK	0800 606 287
	TR	00800 142 064 866
	LI	+31 20 796 5692
	MT	+31 20 796 5693
	Non-EU:	**+31 20 794 7071**
	US	+1 855 236 0910
	CA	+1 855 805 8539
	AR, CO, UY, AU, NZ, RU	+800 135 79 135
	BR	0800 5911 055

13 Glossary

A

AIO
All-in-one

Alert Indicator
LED indicator that represents the current alert status. It may stay off, blink or remain on to indicate various conditions of the instrument.

AST
Antimicrobial Susceptibility Test(ing)

ATCC
American Type Culture Collection

B

BD Phoenix AST Indicator
An oxidation-reduction indicator used to signify microbial metabolism in the BD Phoenix panels. The indicator changes from blue to pink as initial reduction occurs. Further reduction causes the indicator to change from pink to colorless.

breakpoint
An interpretation of panel MIC data that which produces Susceptible, Intermediate, or Resistant result classifications. Breakpoints in the MIC data are established by the Clinical and Laboratory Standards Institute (CLSI) and other groups.

C

caddy
Accessory device used to transport inoculated panels to the instrument for loading.

carousel

CLSI
Clinical and Laboratory Standards Institute

CNA
Colistin Nalidixic Acid agar

D

demographic data
Accession information for a panel record

DTG
Drug Test Group

E

EMB
Eosin Methylene Blue agar

error station
Station that has sustained an optical or electromechanical error and has been blocked.

EUCAST
European Committee on Antimicrobial Susceptibility Testing

H

HE
Hektoen Enteric media agar

I

ID
Microbial Identification

ID/AST combination (combo) panel
The disposable device that contains all reagents needed for both ID and AST.

inoculation station
The inoculation station holds three BD Phoenix panels at the appropriate angle for optimal fill. The station also holds six broth tubes total, two per organism tested. One tube is for dilution of colony growth for Identification, the other for AST.

Instrument Door/Panel Button Status
The instrument has an indicator that provides the current panel button and door status to the user.

Instrument Summary Group
This is the information that appears in the center of the header which appears on all screens of the BD Phoenix M50 instrument.

instrument test cycle
A complete test of all sample panels located in the carousel, resulting in color and/or fluorescence data values being recorded for each pertinent well of each panel.

Isolation Mode
The condition that exists when communication between the BD Phoenix M50instrument and the AIO PC is lost. Isolation Mode is designed to allow the ID/AST system to avoid test cycle gaps when the AIO PC is temporarily disconnected from the instrument.

M

MIC
Minimum Inhibitory Concentration; the lowest concentration of an antimicrobic which prohibits continued growth of the tested organism.

N

Needs Attention
Panels in the instrument's database that have encountered a condition that requires operator attention.

normalizer
A reference panel for use in the BD Phoenix M50 instrument. The Normalizer panel contains a matrix of visible light absorber and fluorescent material in panel-well format, which is used to correct individual well signals for losses occurring in the optical system.

O

orphan
A panel with a valid sequence number, but no associated accession number and isolate number.

P

panel carrier
The plastic carousel insert, which clips each BD Phoenix sample panel into place. The carousel contains 52 inserts, 26 in each of two tiers.

panel dataset
Each panel's set of color and fluorescence measurements, the panel's position identifier, test time stamps, and error flags are recorded for each test cycle throughout the test protocol. The test parameters determining each well's results are keyed by the individual barcode label signifying the panel type, and hence the type of test.

Panel In/Out Indicator
An indicator on the instrument that provides the current panel button and door status to the user.

panel presence detection threshold
Each inventory scan or test cycle, the instrument looks for both the barcode label of a panel in each carousel position and panel well data, color or fluorescence. If either is detected the instrument declares a panel logically present in that location. A panel without a valid barcode to provide panel type information will not be processed, but will be flagged as a Needs Attention candidate.

PB
Blood plate

PEA
Phenylethyl Alcohol agar

PHI
Protected Health Information

PII
Personally Identifiable Information

position
The station. The physical location of the BD Phoenix panel within the instrument. This identifier includes instrument number, carousel tier letter, and numeric position on that tier.

R

rapid results
AST Result obtained within 16 hours of panel inoculation.

related panel
Panels with the same accession number and isolate number are related.

Resistance Marker
Condition that is triggered when specific results indicate antimicrobic resistance. The action of some BDXpert rules is to trigger Resistance Markers; other rules may be called as a result of a specific Resistance Marker being triggered.

RGB
Red, Green and Blue. A shorthand representation of the visible light sources / wavelength regions used to interrogate the BD Phoenix panel.

S

sample
A specimen contained in a BD Phoenix panel. In practice, this would be a processed and resuspended dilution of microbiological growth from primary isolation culture in either ID diluent or AST broth which is then poured into the test panel.

sequence number
A count of the number of readings taken by the instrument for a given sample well in a particular test panel, initialized to zero at the time of panel entry.

SFM
Société Française de Microbiologie

SIR
Susceptible, Intermediate, or Resistant; refers to breakpoint AST categories. See also Breakpoint.

station
The instrument carousel is divided vertically into two tiers (A:B; or C:D), each of which holds 26 panels. With one location occupied by a Normalizer panel, 25 locations per tier can accommodate test panels. This means that test panels can populate 50 total locations. Each location is assigned a tier letter and a number to determine the location on the tier. Indicator LEDs located behind each panel indicate station status (see Station Indicators).

T

TSA
BD Trypticase Soy Agar

X

XLD
Xylose Lysine Deoxycholate agar

14 Index

A

B

E

G

I

L

P

R

S

T

U

Y