Adventist HealthCare

TRAINING UPDATE

Lab Location:	SGMC, WOMC	**Date Distributed:**	10/28/21
Department:	Microbiology	**Due Date:**	11/11/21
		Implementation:	**10/27/21**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Blood Culture with Automated Detection (SGMC.M1008 v3)

Description of change(s):

Under Section 8.3, Procedure, step 6, B., #9 The worksheet names were added to facilitate Function MNG reporting.

9. Use function MNG to report negative blood cultures. This function must be run once per day on day shift.

SGMC Bactec: Type in worksheets
- BLCS
- GBLCS

WOMC Bactec: Type in worksheets
- BLC
- FBLC

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**Blood Culture with Automated Detection (BACTEC FX)**
Prepared by	Ron Master Date: 7/25/2019
Owner	Ron Master Date: 7/25/2019

Laboratory Approval	**Local Effective Date:**	
	Signature	**Date**
Refer to the electronic signature page for approval and approval dates.		

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Test Code
Culture, Blood	BACTEC™ FX Continuous Monitoring Fluorescent System	XBLC

Synonyms/Abbreviations
Blood culture, BACTEC™, Routine Blood Culture.

Department
Microbiology

2. ANALYTICAL PRINCIPLE

The BACTEC™ FX instrument is designed for the rapid detection of microorganisms in blood. Blood samples are drawn from patients and injected directly into BACTEC™ culture bottles. These bottles are then entered into the BACTEC™ FX for incubation and continuous automated monitoring. When microorganisms are present in culture vials, they metabolize nutrients in the culture medium, releasing carbon dioxide into the medium. A dye in the sensor at the bottom of the vial reacts with CO2. This modulates the amount of light that is absorbed by a fluorescent material in the sensor. A photo detector at each station measures the level of fluorescence, which corresponds to the amount of CO2 released by organisms. Then the measurement is interpreted by the system according to pre-programmed positivity parameters.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	**Collection:** Prior to inoculation, the broth media in the bottles should be clear. Do not use bottles containing broth that is cloudy. It is critical that blood specimens submitted for culture are collected aseptically. Contamination of specimen with skin flora can result in a false positive culture, which may be difficult to interpret clinically and lead to unnecessary antimicrobial therapy. Please refer to the online Laboratory Test Directory via hospital intranet for specific instructions related to specimen collection and the inoculation of bottles.

Component	Special Notations
	Timing: Before administering systemic antimicrobials, the collection of 2 separate sets of blood cultures is recommended when there is a fever combined with significant leukocytosis or leukopenia. Recommendations are as follows: **Systemic and localized infections** a. Suspected acute sepsis, meningitis, osteomyelitis, arthritis, or acute, untreated bacterial pneumonia: Obtain 2 sets of blood cultures from separate sites before starting antimicrobial therapy. b. Fever of unknown origin: obtain 2 sets of blood cultures initially and 1-2 additional sets 24-36 hours later. Note: The yield beyond 4 sets of blood cultures is negligible. c. Suspected early typhoid fever or brucellosis: owing to the low grade bacteremia present in these infections; obtain 4 sets of blood cultures (the same venipuncture site may be used) over a 24-36 hour period. **Infective endocarditis** a. Acute: obtain 3 sets of blood cultures during the first 1 – 2 hours of evaluation. b. Subacute: obtain 3 sets of blood cultures on the first day (ideally, 15 or more minutes apart; the same venipuncture site may be used). If all 3 sets are negative, obtain 2 additional sets of cultures. c. Culture-negative endocarditis: consult with the Quest Diagnostics Microbiology Technical Director, Quest Diagnostics Medical Director, and/or local medical staff after 5 negative sets of blood cultures. Special culture techniques may be required.

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Blood specimens inoculated into BACTEC™ PLUS Aerobic/F (silver label/gray cap) and PLUS Anaerobic/F bottles (purple label and cap), or BACTEC™ PEDS PLUS/F (silver label/pink cap) bottles.
-Other Acceptable	None
Collection Container	BACTEC™ PLUS Aerobic/F and PLUS Anaerobic/F bottles or BACTEC™ PEDS PLUS/F bottles.

Criteria	
Optimum Recommended Volume per BACTEC™ Bottle	**Neonates and Children 1 to 6 years:** In BACTEC™ PEDS PLUS/F bottles: 1.0 to 3.0 mL. blood/bottle. **Adults and children weighing >80 lb: In** BACTEC™ PLUS Aerobic/F and PLUS Anaerobic/F bottles: 8 to10 mL blood/bottle.
Minimum Volume per Bottle	BACTEC™ PEDS PLUS/F bottles: 0.5 mL blood/bottle is the minimum, but 1mL is preferred. BACTEC™ PLUS Aerobic/F and PLUS Anaerobic/F bottles: 3 mL blood/bottle is the minimum but not recommended, 8 mL is preferred.
Total Recommended Draw Volumes When Multiple Blood Culture Sets Are Drawn.	<u>These guidelines are to be used if multiple sets of blood cultures are to be inoculated.</u> • **Neonates to 1 year** – 0.5 to 1.5 mL, although at least 1 mL is preferred. • **Children 1 to 6 years:** 1 mL per year of age. • **Children weighing 30 to 80 lbs:** 10 to 20 mL • **Adults and children weighing >80 lb:** 30 to 40 mL
Transport Container	Same as collection container, at room temperature.
Stability & Storage Requirements	Store and transport inoculated bottles at room temperature. Do not refrigerate or freeze, and do not pre-incubate bottles prior to shipment. Bottles are stable for up to 48 hours after collection at room temperature or up to 20 hours if pre-incubated. If bottle(s) are received beyond these stated limits, a smear for Gram stain and sub-culture must be performed (Refer to section 8.3.2.D) prior to loading the specimen onto the BACTEC™. Refer to BACTEC™ FX Users' Manual for delayed vial entry process. In addition, after 5 days of incubation of delayed bottles, a terminal Gram stain must be prepared and read prior to issuing a final report of negative.
Timing Considerations	Refer to section 3.1
Sub-Optimal & Unacceptable Specimens & Actions to Take	• Blood specimens submitted in expired or refrigerated BACTEC™ bottles. • Blood specimen submitted with low volume (QNS) specimen. • Blood cultures submitted in any other tube, container, etc. Notify the ordering physician about unacceptable specimen to be recollected.
Compromising Physical Characteristics	None
Other Considerations	N/A

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier Number
BACTEC ™ Plus Aerobic/F Medium	BD, Cat. # 442192
BACTEC ™ Plus Anaerobic/F Medium	BD, Cat. # 442193
BACTEC ™ Peds Plus Medium	BD, Cat. # 442194
CDC Anaerobic 5% Sheep Blood Agar Plate (ANA BAP)	BD, Cat. # 221734
Chocolate II Agar Plate (GC II Agar with Hemoglobin and IsoVitaleX) (CHOC)	BD, Cat. # 221267
MacConkey Agar Plate (MAC)	BD, Cat. # 221270
Trypticase Soy Agar Plate, with 5% Sheep Blood (TSA II), (BAP)	BD, Cat. # 221261
Columbia CNA agar with 5% Sheep Blood	BD, Cat. # 221353

4.2 Reagent Preparation and Storage

Reagent	All BACTEC™ bottles listed in above table
Container	N/A
Storage	Store at 2-25°C in a dry location and out of direct sunlight.
Stability	Stable until stated expiration date.
Preparation	No reconstitution or dilution required. Refer to Specimen Collection Guide for instructions on collection of specimens.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Each case of media has a manufacturer's Quality Control certificate indicating the organisms tested and the acceptability of those tests. These certificates must be maintained as quality assurance/quality control documentation.

6.2 Control Preparation and Storage / Frequency / Tolerance Limits / Review Patient Data

N/A

6.3 Documentation

N/A

6.4 Quality Assurance Program

The laboratory participates in CAP proficiency testing and monitors contamination rates.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

BACTEC™ FX Blood Culture System

7.2 Equipment

1. BACTEC™ FX Fluorescent Series Instrument
2. BACTEC™ BD EpiCenter workstation
3. BACTEC™ printer
4. Class II Biological Safety Cabinet (BSC)
5. Incubator, 35 ± 2 ºC, with 5-10% CO_2
6. Bacti-cinerator or equivalent (optional)
7. Slide Warmer (optional)
8. Automated Gram stainer (optional)

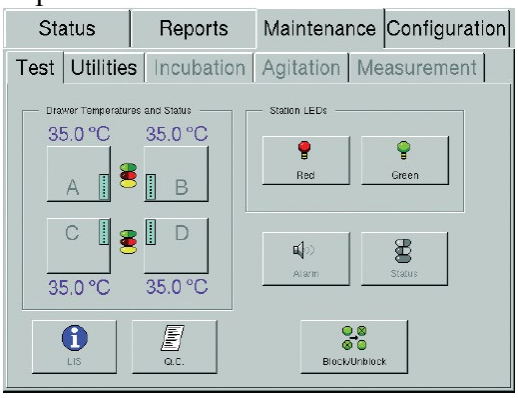
7.3 Supplies

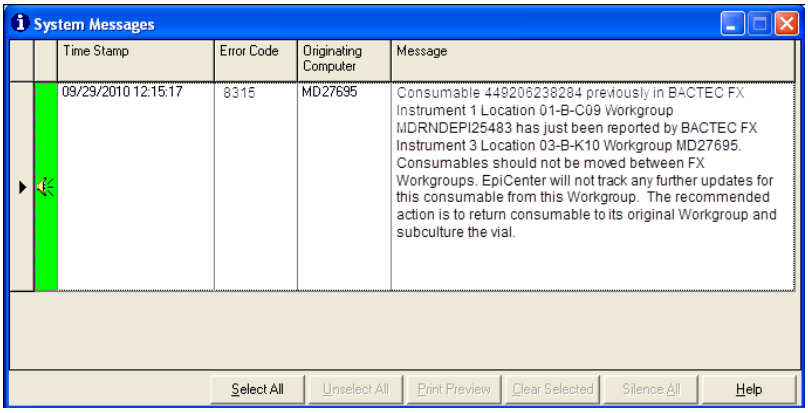
1. Bottle tray (tray holds blood culture bottles and attaches to instrument for ease of use) - Optional
2. BACTEC™ Vial/Thermometer
3. ITL Safety Subculture Unit – ITL Cat #A100720
4. Disposable Sterile Inoculating loops
5. Glass microscope slides
6. Alcohol wipes
7. Methanol (optional)
8. Coplin jar (optional)
9. BACTEC™ station blocker
10. Anaerobic Gas Generator Packs/Pouches

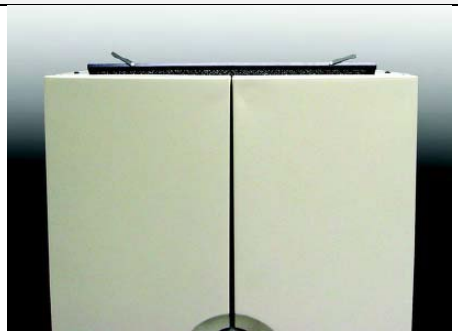
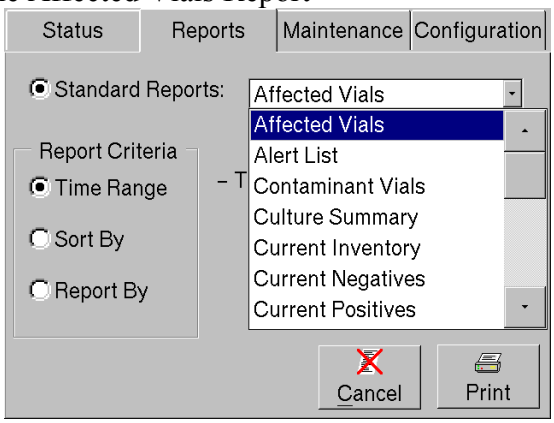
8. PROCEDURE

NOTE: Manipulations of bottles such as subculture and preparation of smears must be performed in a BSC. Refer to safety section 15.0 for specific information regarding blood culture bottles. Report all accidents to a supervisor.

The package insert for a new lot of bottles must be reviewed for any changes before the media is released for distribution.

8.1	**Instrument Maintenance**
1.	**DAILY MAINTENANCE**: The following procedures are performed at the start of each day's testing and recorded on the BACTEC FX Maintenance Log A. Check the paper supply to the printer. If the paper supply is low or exhausted, replace the paper as explained in the operating manual furnished separately. B. Tap the "Maintenance" tab. The Test display appears  C. Open drawer A. Then tap the "Red" button to illuminate the red station indicators. Make a note of any station that does not illuminate red D. Next tap the "Green" button to illuminate the green station indicators. Make a note of any station that does not illuminate green. E. Repeat steps C and D for each of the drawers in the system. F. Close the drawer G. Tap the "Alarm" button to verify that the audible alarm is functioning. H. Tap the "Status" button to illuminate the system status indicators on the mullions. Both sides of all the indicators (amber, red, and green) should illuminate. If any indicator does not light, contact your local BD representative for service. I. Repeat steps B through H on the second stack. J. Record the Information on the Maintenance Log. K. Check temperature readout in each cabinet using the digital thermometer vials.  Verify that the temperature of each rack is 35 ± 1.5°C. Turn off the digital thermometer after each reading. Record on the Maintenance Log. If any rack or cabinet is not within the specified temperature range, call BD Field Service. Ongoing patient bottles must be relocated to another rack or cabinet.

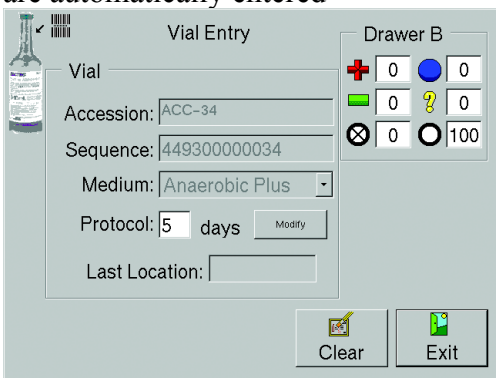
8.1	**Instrument Maintenance**
	L. Read and clear the EpiCenter System Messages. Select the "i" icon on the EpiCenter, select the messages to clear, select "Clear Selection." 
2.	**MONTHLY MAINTENANCE:** A. Replace the air filters. There are 4 filters on each stack (2 square silver filters and 2 long, black filters) B. Clean the filters so they are ready for use the next month. • Wash filters with a bacterial disinfectant. • Place filters on paper towels and dry thoroughly. • Store the clean filters for the next month. • Refer to BACTEC ™ FX Users' Manual for detailed instructions. • Record on the Maintenance Log.  

8.1	**Instrument Maintenance**
	 
3.	**SYSTEM ALERT** A yellow light on the front panel indicates a System Alert. • This must be resolved immediately. • Print the Affected Vials Report  • If vials are listed on this report, the vial(s) must be Gram stained and subcultured, then scanned and returned to the instrument.
NOTE: For a more detailed explanation of maintenance refer to the BACTEC ™ FX Manual.	

8.2	**Specimen / Reagent Preparation**
1.	A. Prior to inoculation, the broth media in the bottles should be clear. Do not use bottles containing broth that is cloudy. B. If bottle(s) are received beyond the stability limits, a smear for Gram stain and sub-culture must be performed (Refer to section 8.3.2.D) prior to loading onto the BACTEC™.

WARNING

VIALS SHOULD BE HANDLED WITH EXTREME CARE AT ALL TIMES. VIAL NECKS ARE SUSCEPTIBLE TO BREAKAGE IF THEY ARE STRUCK AGAINST ANOTHER OBJECT.

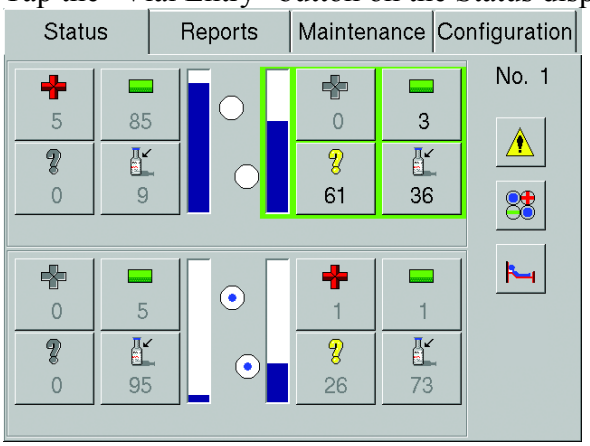
8.3	Test Run
1.	**LOADING INSTRUMENT:** A. Blood culture bottles must be placed onto the instrument as soon as possible after receipt into the laboratory B. Visually inspect all bottles for microbial growth, indicated by turbidity or gas. All specimens in such bottles must be Gram stained and subcultured using a subculture device in a BSC (refer to 8.3.2.D for performance of sub-culture). Smear negative specimens may be placed in the instrument. Carefully remove the subculture device in a BSC and dispose of device in a sharps container located in the BSC (refer to section 8.3.2.D). Smear positive specimens must be further processed as a routine positive blood culture in a BSC. C. Observe the rubber septa of bottles. If residual iodine is apparent, remove with 70% isopropyl alcohol prior to loading in the instrument. Make sure the bottom of bottle is not obscured in any way by a barcode label or tape. D. To ensure safe handling, a bottle tray may be used for transport of bottles to the instrument. **Entering Data And Loading Instrument** To enter vials in the instrument, select a drawer where there are available stations. (The number of available stations is shown below the "Vial Entry" icon on the Status display.) Then follow one of the two methods described below. **Method 1 (Vial Activated)** 1. Select a drawer that has available stations, and open that drawer 2. The barcode scanner turns on 3. Scan a vial sequence barcode label and the Sunquest accession number 4. The Vial Entry display appears and the Sequence, Media, and default Protocol are automatically entered  5. If you did not scan the Sunquest Accession #, scan or enter it now

8.3	Test Run

6. To change the protocol tap the "Modify" button, then tap the up arrow to increase or down arrow to decrease the protocol length. This may only be changed when incubation beyond 5 days is requested by a physician.
7. Place the vial into an available station (solid green indicator)

Method 2 (Icon Activated)

1. Select a drawer that has available stations, and open that drawer
2. Tap the "Vial Entry" button on the Status display (icon with bottle)



3. The Vial Entry display appears and the barcode scanner turns on
4. Scan the vial sequence barcode label and the Sunquest accession number
5. The Sequence, Media, and default Protocol are automatically entered
6. If you did not scan the Sunquest Accession #, scan or enter it now
7. To change the protocol tap the "Modify" button, then tap the up arrow to increase or down arrow to decrease the protocol length. This may only be changed when incubation beyond 5 days is requested by a physician.
8. Place the vial into an available station (solid green indicator)
9. When a vial is placed into the last available station in a drawer, the Activity Complete tone sounds (3 beeps).
10. To continue entering vials, select another drawer with available stations.

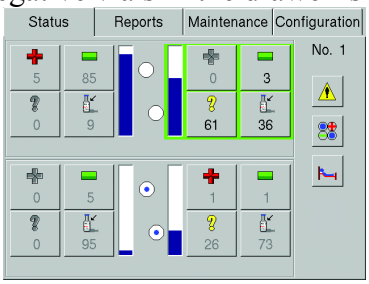
Inserting Vials in the Instrument

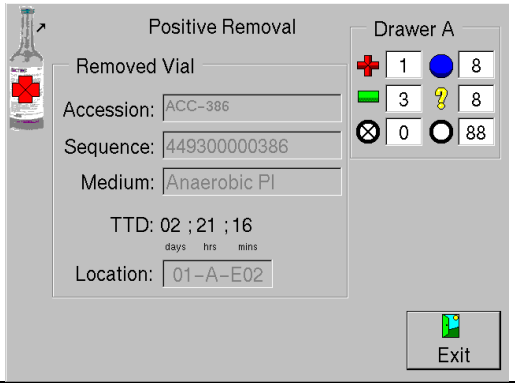
Before inserting vials into the stations, visually inspect all vials for evidence of microbial growth including hemolysis, turbidity, and excess gas pressure (causing the vial septum to bulge outward). All such vials should be treated as positives; they should be stained and subcultured.

A vial presence sensor immediately senses the insertion of a vial in a station and the instrument updates the station LED indication and the status shown on the LCD.

Once vials are placed in their stations, you should avoid moving them to other stations unnecessarily.

Make sure all vials are fully inserted in the stations before closing the drawer.

8.3	Test Run
	Avoid opening the drawer unnecessarily. Drawers should not remain open longer than 10 minutes. * **ANYTIME A BOTTLE IS REMOVED IT MUST BE SCANNED BEFORE BEING RETURNED TO THE INSTRUMENT** * IF THERE ARE ANONYMOUS VIALS IN THE DRAWER, DO NOT PERFORM NEGATIVE VIAL REMOVAL UNTIL ALL ANONYMOUS VIALS HAVE BEEN RESOLVED. Anonymous Vials must be identified through ID Anonymous before they can be removed as Out-of-Protocol Negative. The instrument will not call Anonymous Vials Negative. * IDENTIFY ANONYMOUS VIALS TO THE SYSTEM AS SOON AS POSSIBLE using the ID(entify) Anonymous Vials activity. The instrument is able to apply medium specific positivity criteria when the medium type is known, and can apply these specific criteria to collected test readings. In addition, the protocol is adjusted (if necessary) to the default for that medium type once the vial is identified.
2.	**POSITIVE AND NEGATIVE VIALS** **A. Notification of positive and negative vials** 1. The system notifies you of new positive cultures in several ways: a. Positive Vial audible alarm sounds b. Station Indicators: FLASHING RED or FLASHING AMBER / RED (alternating) - Anonymous Positive c. Message box appears on screen d. Positive vial system indicator for that drawer illuminates e. On the Status display, the “positives” icon is active (color is red, not grayed out) and the number of positive vials in the drawer is shown 2. Out-of-Protocol (Final) Negatives are indicated by the following: a. Negative vial system indicator for that drawer illuminates b. On the Status display, the “negatives” icon is active and the number of negative vials in the drawer is shown  c. Station indicators: FLASHING GREEN

8.3	Test Run
	THE INSTRUMENT MUST BE ON STATUS SCREEN BEFORE REMOVING VIALS.
3.	**Removing positive vials**: 1. Select a drawer that has positive stations, and open the drawer by pulling it out. a. The barcode scanner turns on. b. All positive, final negative, available, and anonymous (all variations) are indicated by the appropriate lit or flashing station indicators. c. Tap the "remove positives" button on the Status display,  OR Remove a vial from a FLASHING RED (positive) or FLASHING AMBER / FLASHING RED (anonymous-positive) station d. The Positive Removal display appears. (If an anonymous positive vial was removed, the ID Anonymous display appears. Scan the sequence and accession for the anonymous positive vial and tap the "Save" button. Then tap the "Exit" button to return to the Positive Removal display.) 

8.3	Test Run
4.	**Processing Positive Vials** 1. Remove the vial from the instrument and place in a biological safety cabinet. **Perform the following steps in a Biological Safety Cabinet**: 2. Invert the vial to mix the contents. 3. Clean the bottle septum with an alcohol pad. Allow to air dry. 4. Observe **"Universal Safety Precautions"** to vent each presumptive positive blood culture vial. Use a Safety SubCulture Unit to vent the bottle. This will allow for equilibration of pressure prior to withdrawing liquid from the bottle. 5. Carefully open the sterile package and remove the Safety SubCulture Unit. 6. Insert the Safety SubCulture Unit through the de-contaminated, clean, dry septum and remove the white filter cap. Do not discard the cap. 7. Tilt the bottle to dispense the inoculum onto each plate and slide. CAUTION: some bacteria can produce gas and the blood will pour out quickly rather than a drop at a time. Occasionally the Safety SubCulture Unit will become clogged. If this happens change the Safety SubCulture Unit. 8. Prepare a smear for Gram stain by placing a small drop onto a clean glass microscope slide. Use a loop to spread the drop to produce a thin, even smear. Allow the smear to dry completely. Heat fix slides prior to removal from BSC. 9. Subculture by placing several drops of broth onto the appropriate plates. Streak plates in order to achieve isolated colonies. All subculture plates should be incubated at 35±2ºC. BAP and CHOC plates require 5-10% CO2, and ANA BAP plates require anaerobic atmosphere. 10. Replace the white filter cap then remove and discard the Safety SubCulture Unit in a sharps biohazard container. 11. Label plates with barcode labels (do not cover media type) and write the type of bottle (AER, ANA, or PEDS), date plated, and tech code near the bottom edge of the plate where it will not be covered by labels. Use a pencil to label a slide with accession number, patient last name, type of bottle (AER, ANA, or PEDS) and date positive. 12. See Gram Stain procedure for staining with Previ or Wescor Gram stainer and reporting gram stains. 13. See section 10.5 for reporting procedure. 14. Order XIDS (for aerobic bottles) or XIDSN (for anaerobic bottles) using the same accession number as the XBLC order. Printed labels should be used for plating positive bottles. 15. Write Gram stain results on plate 16. Media

Bottle Type	Required Media
BACTEC ™ PLUS AEROBIC/F	BAP, CHOC, MAC, CNA
BACTEC ™ PLUS ANAEROBIC/F	ANA BAP, CHOC, AEROBIC BAP, MAC, CNA
BACTEC ™ PEDS PLUS	BAP, CHOC, MAC, CNA

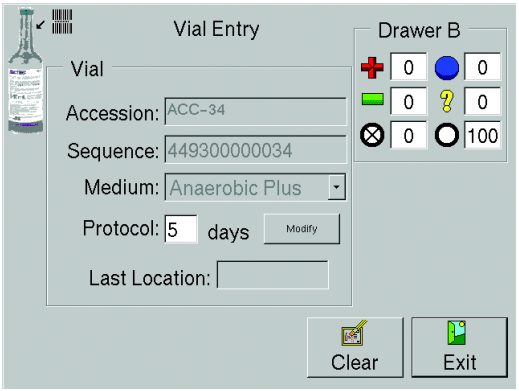
5. **SMEAR NEGATIVE (NOS)**

Smear negative **(NOS)** bottles must be returned to the instrument.

- Carefully remove the subculture device and dispose in sharps biohazard waste.
- Bottles which have flagged as positive but have no organisms seen on Gram stain must be returned to their original positions on the instrument within 5 hours, however, IF THE BOTTLE IS OUT OF THE INSTRUMENT MORE THAN 20 MINUTES, READINGS WILL BE MISSED. Therefore, the bottle should be returned to the instrument as soon as possible.

NOTE: If the bottle is not returned to the instrument within 5 hours, the associated demographic data is removed from the database. The protocol for that bottle must be modified to reflect the remaining incubation time. Refer to the BACTEC ™ FX Users' Manual for instructions on vial re-entry.

1. Open the drawer and scan the bottle and LIS barcode labels. The original station will be indicated by flashing green and red LEDs changing to solid green and red LEDs and the station will be displayed under Last Location on the Vial Entry display.

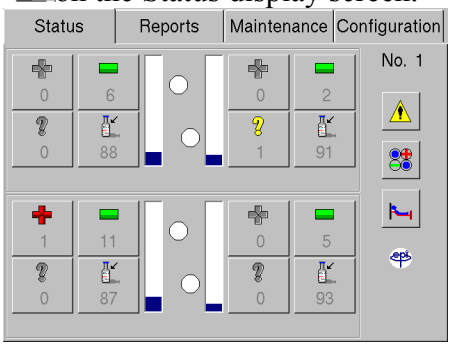


2. SELECT "YES" TO "WOULD YOU LIKE TO CHANGE THE STATUS TO ONGOING WHEN THE VIAL IS REINSERTED?"

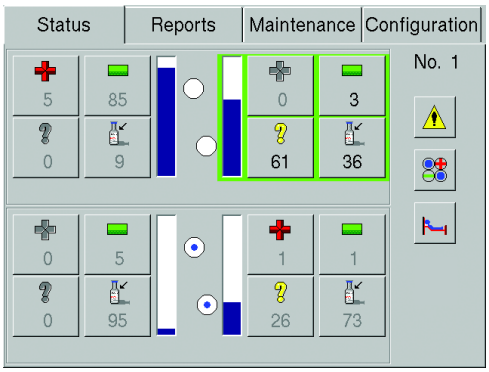
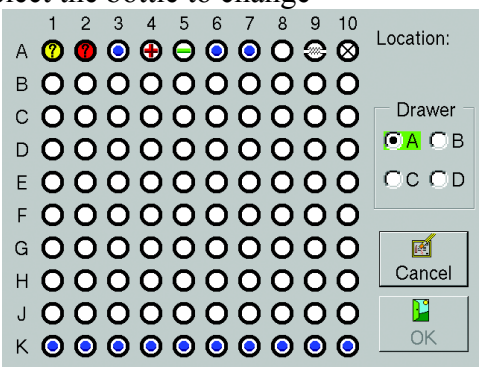
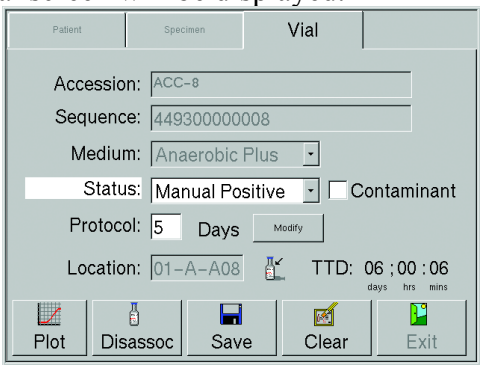
   VE 18: Last known status of sequence scanned was POSITIVE. Would you like to change the status to ONGOING when the vial is re-inserted?

   YES NO

3. Place bottle in designated position.
4. Do not order XIDS or XIDSN and do not record the NOS Gram stain result in the LIS.
5. Print a workcard and label the subculture plates with barcode labels (do not cover media type) and write the type of bottle (AER, ANA, or PEDS), date and time plated, and tech code near the bottom edge of the plate where it will not be covered by labels. Complete the Positive Blood Culture Worksheet.
6. Place the Positive Blood Culture Worksheet and plates together in the incubator in a biohazard bag. File the slides in the current Gram stain slide box.

8.3	Test Run
	7. Check plates at least once per shift for growth and record reading on the Positive Blood Culture Worksheet. Hold plates from smear negative aerobic bottles for 48 hours and 72 hours for anaerobic bottles if no growth 8. If a bottle which has been returned to the BACTEC due to NOS is again flagged as positive by the instrument, a Gram stain and plating of the bottle must be performed again. 9. If growth detected on plates, perform a gram stain of the colonies and follow instructions in section 10.5. **IF NOS BOTTLE RETURNED TO INSTRUMENT IS DETECTED AS POSITIVE BY THE BACTEC A SECOND TIME, A GRAM STAIN AND SUBCULTURE OF THE BOTTLE MUST BE PERFORMED AGAIN.**
6.	**NEGATIVE CULTURES:** A. Negative cultures may exist as ongoing negatives (< 5 days incubation) and out-of-protocol negatives (Final ≥ 5 days incubation). They are displayed on the instrument status screen as follows: 1. Ongoing negatives are identified by the number displayed under the bottle icon  on the Status display screen.  2. Out-of-protocol negatives ready to be removed from the instrument will be displayed as the number below the  icon on the display screen.

8.3	Test Run
	B. **Removing Final Negative bottles** 1. Select a drawer that has negative stations, and Open the instrument drawer. Only open 1 drawer at a time. 2. All positive, final negative, and anonymous (all variations) are indicated by the appropriate flashing station indicators. 3. Find the station(s) with FLASHING GREEN STATION LED's and remove the bottle(s). 4. These vials do not have to be scanned (and the scanner does not turn on). Any vials left in the instrument remain in the database as negatives. 5. Counters on the display are updated dynamically as vials are removed. 6. The "activity complete" tone (triple beep) will sound when all Out-of-Protocol (Final) have been removed from that drawer. 7. Close instrument drawer once all bottles have been removed. 8. Repeat steps 1-7 for other drawers if indicated. 9. Use function MNG to report negative blood cultures. This function must be run once per day on day shift. SGMC Bactec: Type in worksheets • BLCS • GBLCS WOMC Bactec: Type in worksheets • BLC • FBLC 10. Negative cultures are reported as "No bacteria or yeast at 5 days" via MNG function once per day.

8.3	Test Run
7.	**Changing Vial Status to Manual Negative or Manual Positive** • Select the vial to be changed by selecting the Drawer View icon on the Status Screen (middle icon on the right)   • Next select the bottle to change 
7.	• Then select “OK” • The Vial screen will be displayed.  • Change the status to Manual Negative or Manual Positive • Select “Save”

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

All data is interpreted by the instrument's computer system.

10.2 Rounding / Units of Measure / CRR

N/A

10.3 Review Patient Data

Review patient results for unusual patterns, trends or distributions in patient results. Those would include: an unusually high percentage of positive or negative culture results, a high number of false positive bottles, or a high recovery rate of an unusual organism. Computer aided tools should be used when available.

10.4 Repeat Criteria and Resulting

N/A

10.5 Reporting in the LIS

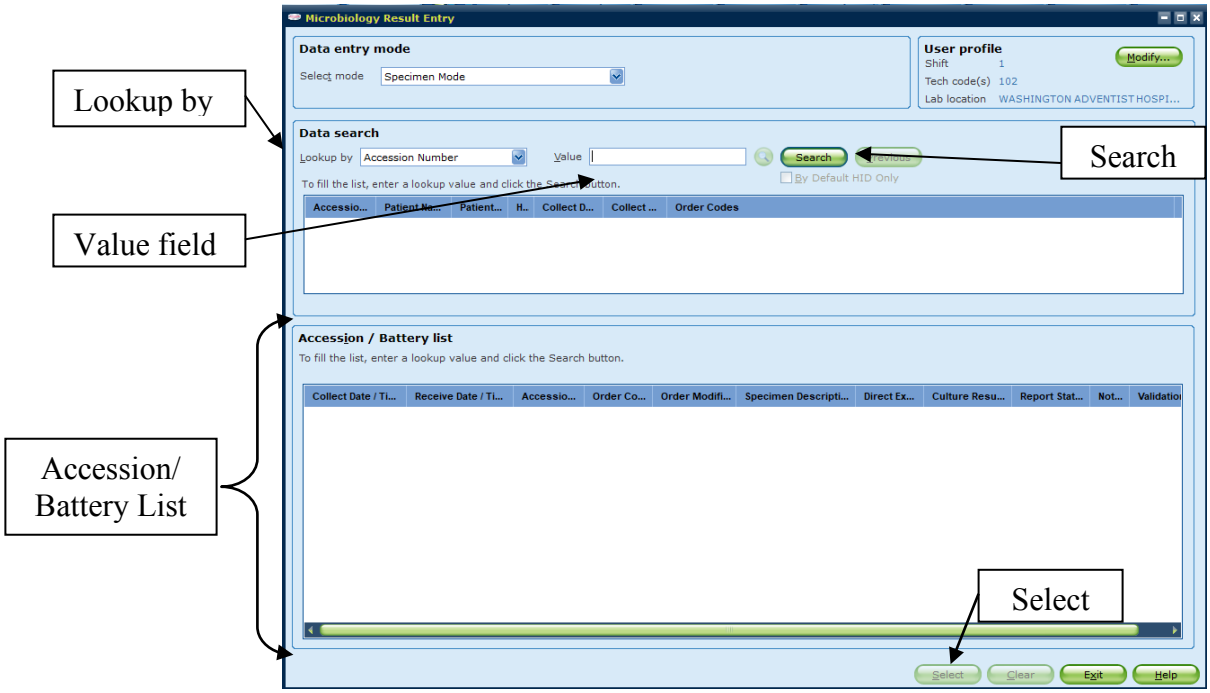
A. Blood Culture Order Sections

1. The Blood culture test code is XBLC
   Code XBLC consists of:
   - SDES - specimen description
   - SREQ - special request, **Notes**:
     - This is usually a "HIDE" test, which doesn't display on reports unless a special request is added
     - If the blood culture was collected using a Steripath device, then the 33 digit Steripath device number is noted here. Steripath devices are ONLY used in the Emergency Dept.
   - IDST - ID & Sensitivity (This will be defaulted with "HIDE" as the result. It will be changed to "has been added" if the culture is positive.)
   - CULT - culture result (This will either be resulted as No Growth on the negative cultures or be resulted with the Gram Stain results on the positives)
   - RPT - report status (Pending, Preliminary, or Final)

2. The test code **does not include** an individual test code for gram stain.

B. Positive Gram Stain: First Positive Bottle of a Set

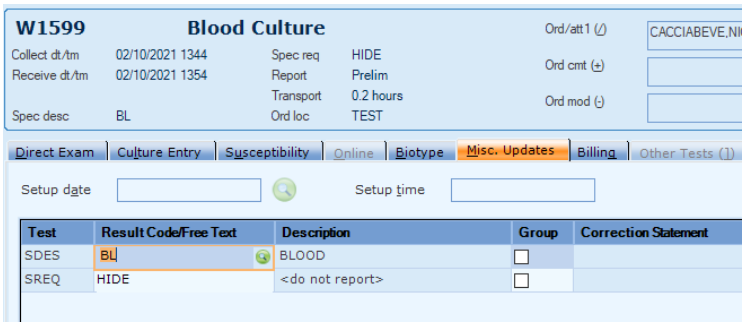
1. Print the Workcard
   a. Log in to Sunquest GUI. Click on "Micro Result Entry" and enter the accession number in the "Value" field. Press enter or click "Search". To search for the specimen by a different identifier, click the arrow for the drop down menu on the "Lookup by" field and search by name, medical record number, etc.



b. The accession data will appear in the lower part of the screen in the "Accession/Battery List". If the highlighted accession is the correct one, press **enter,** or click on it, or press **ALT + S.**

c. System will display the result entry screen. The screen opens automatically to the "Culture Entry" tab.

d. Click on the **Misc Updates** tab.



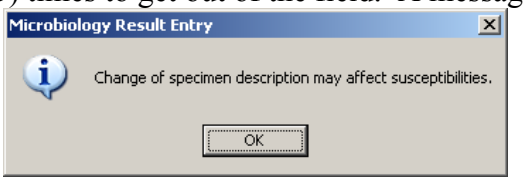
e. Double click on the **SDES** result and change BL to **BLUD**

IMPORTANT:

The site of draw, if available, is noted after "BL-". When changing the specimen description to **BLUD**, include any free text that is reported after the **BL**.

Example: If "BL-;right arm" is shown, then change to "BLUD-;right arm". This information is important to physicians and Infection Prevention in determining if a positive blood culture is a contaminant or not.

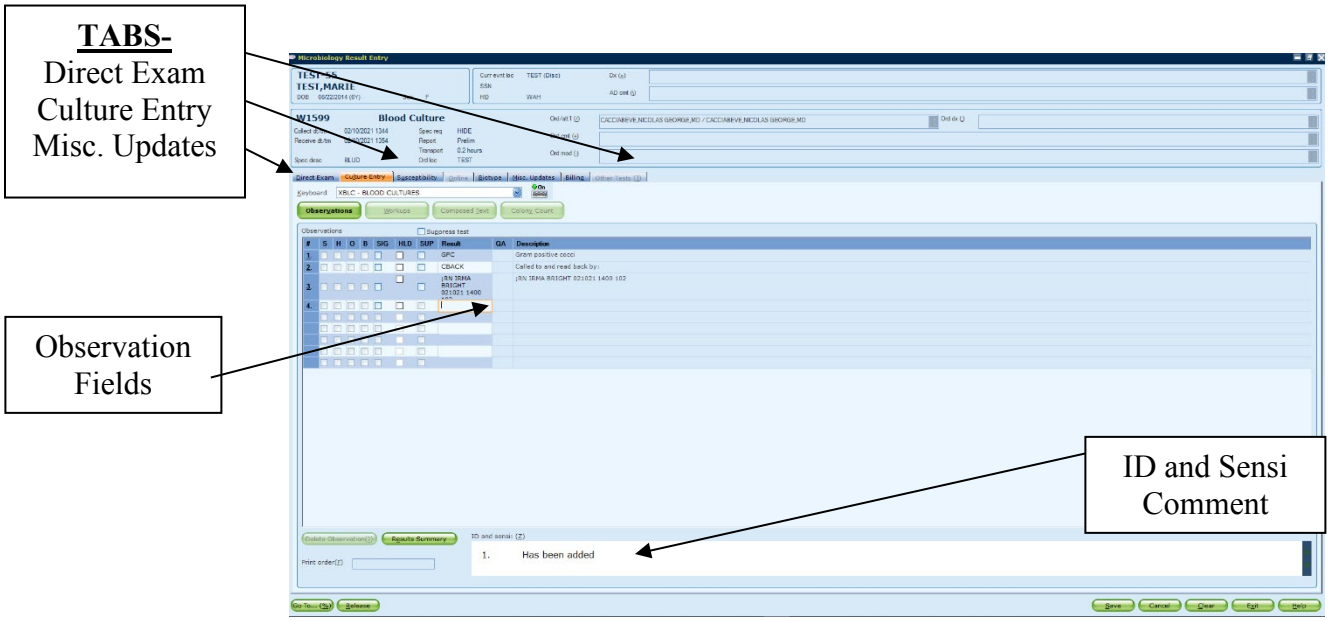
f. Press tab three (3) times to get out of the field. A message will appear that reads :



g. Click **OK**.
h. Select **Save** and
i. Select **Save** again to exit.
j. From the Sunquest GUI screen go to Order Entry
k. Change "Lookup by:" to Accession Number
l. In the "Value" field, enter the accession number of the XBLC
m. Click **Search**
n. Click **Select** or ALT+C
o. Click "**Reprint Labels**" or ALT+L

p. Click "**Select All**" or ALT+S
q. Click "**Print**" or ALT+P
r. Click "**OK**"
s. **Exit.** After saving this, XBLC will generate Micro work cards. These are used to label the plates and worksheet with the Sunquest barcode label and for two technologists to record their codes and gram stain results.
t. Label plates with barcode labels (do not cover media type) and write the type of bottle (AER, ANA, or PEDS), date plated, and tech code near the bottom edge of the plate where it will not be covered by labels. Use a pencil to label a slide with accession number, patient last name, type of bottle (aer, ana, ped) and date positive.

2. Enter the ID and Susceptibility Note
   a. From the "Microbiology Result Entry" screen, Click on the **Direct Exam** tab.
   b. Arrow up to Observation line 1. (It will be default resulted as HIDE)
   c. Press **H (TADD)** which will expand to "Has been added."
   d. DO **NOT** enter your gram stain results at this time.
      Note: Blood culture gram stain results are entered under the "Culture Entry" tab.
   e. Tab down to an empty observation field.
   f. Select **Save** to exit **or** click the **Culture Entry** tab to continue with entering gram stain results.



3. Perform BCID - Refer to BCID SOP (**BioFire® FilmArray® Blood Culture Identification (BCID) Panel**) for ordering and performing

4. Perform Gram Stain

5. Compare Gram Stain morphology with BCID instrument report, if any targets are detected.
   - If consistent, then report out gram stain.
   - If gram and ID do not correlate, then review gram stain again with another tech to make a determination. If needed consult with Group Lead/Tech in Charge.

6. Result the Gram Stain
   a. From the "Microbiology Result Entry" screen, click on the **Culture Entry** tab. **Note**: Only gram stains for Blood Cultures are resulted in this field, result all other gram stains under the "Direct Exam" tab.
   b. Enter the gram stain result on the first observation line. One observation per line (one organism). **Do <u>NOT</u> go to the <u>Direct Exam</u> tab to result the Gram Stain.**
   c. After you have entered gram stain result, tab down to the next observation line.
   d. If a BCID is performed then select the "." key. The "." key will populate BCIDP (BCID testing performed) as the observation. You can also press the ";" key (this takes you off the keyboard) and type in BCIDP. Then tab down to the next observation line.
   e. Type the following:
   ;CBACK<tab> ;; (Nurse or Dr.'s first and last names) **on** (month, day, and time), **by** (tech code). This will expand to "Called to and read back by:"
   f. Notify the appropriate nurse or doctor and document the call.
   g. Press the "/" to finalize the culture. This will finalize the gram stain, and another order will be added to enter the ID and Susceptibility results.

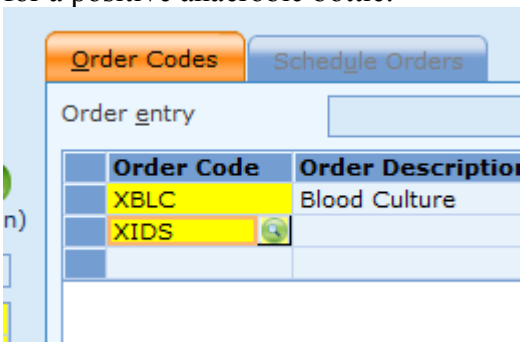
h. Click on **Save** or press **ALT+ S**.
i. Write the gram stain result on each plate.

7. Notification
   a. Positive Blood Cultures must be called to a nurse or doctor 24 hours a day, 7days a week
   b. Inpatient results are called to the floor.
   c. Outpatient results are called to the doctor's office during office hours and to the physician on call after hours.
   d. ER patients who have been discharged are called to the ER charge nurse.
   e. The first positive report on all positive gram stains must be called to the nurse or physician **BY A TECHNOLOGIST**.

      ALL POSITIVE GERMANTOWN EMERGENCY CENTER GRAM STAINS MUST BE CALLED TO THE CHARGE NURSE AT THE SGMC EMERGENCY DEPT TO ENSURE TIMELY FOLLOW UP.

      Positive gram stains and cultures for both GEC and SGMC ER patients, not admitted, are called and faxed to the SGMC ER charge nurse.

8. Order the ID and Susceptibility
   a. The identification and susceptibility test code **MUST BE ORDERED ON THE ORIGINAL BLOOD CULTURE ACCESSION NUMBER.**
   b. Log into Sunquest GUI/Order Entry and enter the accession number for the positive bottle.
   c. Add test code **XIDS** for a positive aerobic bottle or pediatric bottle and /or test code **XIDSN** for a positive anaerobic bottle.



   d. Click on SAVE and then SAVE again

Note: THIS IS THE *ONLY* CIRCUMSTANCE WHERE ADDING ADDITIONAL MICROBIOLOGY ORDERS TO THE SAME ACCESSION NUMBER IS ALLOWED.

9. Order BCIDA (Aerobic Bottle) or BCIDN (Anaerobic Bottle) under a NEW accession number. Refer to **BioFire® FilmArray® Blood Culture Identification (BCID) Panel** procedure.

C. Positive Gram Stain: Second Positive Bottle of a Set

1. If the gram stain result is the same as the first bottle **in the set,** there is no need to call the unit. Enter the gram stain result and tech ID on the worksheet only.

Note: DO NOT PERFORM ANOTHER BCID

2. If the Gram stain result from the second bottle of a set is the same as the result from the first bottle **of the set,** a second read by another technologist is not required. Document the Gram stain result and tech ID on the worksheet and document the result and that the previous bottle was positive with same result.
3. Order the ID and Susceptibility on the same accession number using Test code **XIDS** for aerobic or pediatric bottles or **XIDSN** for anaerobic bottles. Refer to steps in B.5 above.
4. Label plates with barcode labels (do not cover media type) and write the type of bottle (AER, ANA, or PEDS), date plated, and tech code near the bottom edge of the plate where it will not be covered by labels. Follow procedure for sending plates.
5. If the Gram stain is different from the bottle previously reported, result the gram stain in Sunquest. Use code ADD (Addendum report) and free text "gram stain of additional bottle in set". CALL all Addended results and document. Refer to steps in B.4 above.
   Note: PERFORM ANOTHER BCID
   Order BCIDA (Aerobic bottle) or BCIDN (Anaerobic bottle)

D. Positive Gram Stain: Second Set from a Patient Drawn on Same Day

1. If the Gram stain result from a **second set** is the same as the result from the first set **of blood cultures from the same patient drawn on the same day,** there is no need to call the unit a second time.
   Note: DO **NOT** perform another BCID

2. If the Gram stain result from a subsequent set is the same as the result from a **previous set on the same patient,** a second read by another technologist is not required. Document the Gram stain result and tech ID on the worksheet and document that the previous set was positive with the same Gram stain result and record the accession number of the previous set. Result the Gram stain in Sunquest. Refer to steps in B.4 above.
   If the Gram stain result is different than reported on the previous set, follow the procedure in **B. Positive Gram Stain: First Positive Bottle of a Set**
   Note: PERFORM ANOTHER BCID
   Order BCIDA (Aerobic bottle) or BCIDN (Anaerobic bottle)

Order the ID and Susceptibility using Test code **XIDS** for aerobic or pediatric bottles or **XIDSN** for anaerobic bottles. Refer to steps in B.5 above.

E. Prepare Plates for Sendout

1. One set of blood culture plates per biohazard bag.
2. **Be sure to file the worksheet (which should include the gram stain results and tech codes of the two techs who read the slide) and the gram stain slide in established area.**
3. Plates are to be placed in the incubator until courier arrives for pickup.
4. Positive blood culture bottles are to be maintained at room temperature at the site reading the gram stain until the organism and sensitivity have been finalized by the reference site.
5. Place BCID instrument printout in bag along with plates
6. Give bag to accessioning staff to perform ROB and FES.

F. Overdue Log

- Test codes **XIDS and XIDSN** are defined to worksheet **XBLC**. The number of days overdue is 6 days on this worksheet.
- Test codes **BCIDA** and **BCIDN** are defined to worksheets SIM2 and WIM2. There are no days overdue on the worksheet since testing would be performed at time of ordering.

11. EXPECTED VALUES

11.1 Reference Ranges

No growth

11.2 Critical Values

All positive blood cultures are critical values. The technologist reading the gram stain is responsible to make the first call to the unit/physician following the Laboratory Critical Value policy.

11.3 Standard Required Messages

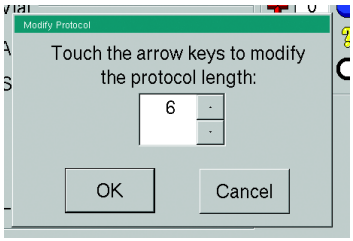
None established

12. CLINICAL SIGNIFICANCE

The detection of microorganisms in a patient's blood has diagnostic and prognostic importance. When bacteria multiply at a rate that exceeds the capacity of the reticuloendothelial system to remove microorganisms, bacteremia results. Bacteria usually enter the blood from extravascular sites via lymphatic vessels. Direct entry of bacteria into the bloodstream occurs as well with intravascular infections, such as infective endocarditis, infected arterio-venous fistulas, mycotic aneurysms, suppurative phlebitis, infected IV catheters, and infected indwelling arterial catheters. The clinical pattern of bacteremia can be transient, intermittent, or continuous, and bacterial sepsis constitutes one of the most serious infectious diseases. The expeditious detection and identification of blood-borne bacterial pathogens is one of the most important functions of the diagnostic microbiology laboratory.

13. PROCEDURE NOTES

- If *Francisella* is suspected, recovery (once plated) may require increased incubation time (up to 5 days).
- Blood cultures submitted for the isolation of *Brucella* sp. received in BACTEC ™ bottles should be held for at least 10 days. Open a drawer, scan the bar codes, before inserting the vial, select MODIFY on the Vial Entry Screen, change the Protocol to 10 days, select "OK", then insert the vial. Terminal subcultures on BAP should be performed on negative blood cultures prior to discard. Subculture plates should be held for at least 7 days.



- **FDA status**: Cleared
- **Validated test Modifications**: None

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

Qualitative test, reported as No Growth or bacteria (genus and/or species) isolated.

14.2 Precision

Not applicable

14.3 Interfering Substances

- Although the BACTEC ™ Plus Aerobic/F Medium and the BACTEC ™ Peds Plus Medium contain resins to counter-act the activity of antimicrobials, neutralization is dependent upon dosage levels and timing of specimen collection. Antimicrobial therapy initiated prior to the collection of specimens may result in a false negative culture.

14.4 Clinical Sensitivity/Specificity/Predictive Values

- Refer to the package insert and data on file.
- Although the BACTEC ™ Plus Aerobic/F Medium and the BACTEC ™ Peds Plus Medium may support *Candida* spp. and some rapid growing *Mycobacterium* spp., media specific for the recovery of fungus and mycobacteria are recommended.
- Some fastidious organisms, such as *Haemophilus* species, require growth factors, such as NAD or V factor, which are provided by the blood specimen itself. If the blood specimen volume is less than 3.0 mL, or if a non-bloody body fluid is submitted in BACTEC™ bottles, an appropriate supplement maybe required for recovery of these organisms. BACTEC™ brand FOS™ (Fastidious Organism Supplement) or sterile whole human blood may be used as nutritional supplements.
- Also see Section 13 Procedure Notes.

15. SAFETY

Refer to the safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

Additional blood culture safety instructions:

- Appropriate Personal Protective Equipment (PPE) must be worn at all times when handling blood culture specimens. Lab coat and gloves must be worn when loading or unloading the BACTEC™ instrument. The use of face shields for handling inoculated blood culture bottles is optional.
- Blood culture bottles should be handled with care at all times. The bottle necks are susceptible to breakage if they are struck against another object. Take extra care when loading or unloading bottles from the BACTEC™ instrument since you will be grasping the neck of the bottles to perform these steps.
- **All Gram stains prepared from Blood culture bottles must BE PROCESSED IN A BSC. This includes the following:**
  - Always use a subculture device to perform subculture and slide preparation. (Refer to section 8.3.2.D.) **Never use a standard syringe with needle attached.**
  - Prepare slide for Gram stain and allow to completely air dry while still under the BSC. Heat fix or methanol fix slides under BSC prior to removal from hood. **NOTE**: Methanol fixation may be accomplished by dipping dried smear in a Coplin jar of methanol, and then allowing to air dry. Ensure that the Coplin jar is not placed near incinerator.
- Subculture bottles and inoculate plates while in the BSC.
- For disposal place bottle into biohazard sharps container or suitable impermeable biohazard container.
- Handle all subcultures from blood cultures, which exhibit colony morphology or Gram stain appearance not readily familiar or typical of *Bacillus anthracis*, *Francisella tularensis, Yersinia pestis*, *Brucella sp*., *Neisseria meningiditis*, *Mycobacterium sp*., or the hyphal form of molds, in a BSC until uncommon virulent pathogens have been ruled out. Plates should be sealed with tape and or put into biohazard bags during incubation to avoid unnecessary exposure.
- If Gram stain of blood culture bottle shows large gram positive bacilli, small gram negative coccobacilli, gram negative diplococci, beaded gram positive bacilli, or hyphal elements, seal the subculture plates with laboratory film or tape closed. All handling of subcultures from these bottles are to be performed in a BSC until virulent pathogens can be ruled out.

Report all accidents and injuries to your supervisor or the Environmental, Health and Safety Manager/Specialist.

16. RELATED DOCUMENTS

Critical Values, Laboratory policy
Gram Stain, Microbiology procedure
Blood Culture Protocol, Phlebotomy procedure
Video Microscope (NetCam), Microbiology procedure
FES, Processing Microbiology Orders, Specimen Processing procedure
Current package inserts for BD BACTEC ™ Plus Media
BACTEC FX Maintenance Log (AG.F457)
Positive Blood Culture Worksheet (AG.F211)
Microbiology Stain Referral and Consult Form (AG.F555)

17. REFERENCES

- BACTEC™ Plus Aerobic/F and Plus Anaerobic/F Culture Vials Insert. Rev. PP-088 (2008/01) BD Diagnostics.
- BACTEC™ Peds Plus/F Culture Vials Insert.Rev. PP-091(2008/01) . BD Diagnostics.
- BACTEC FX System User's Manual. Document Number 8005110 (2015/06). BD Diagnostics.
- Dunne, W.M., F.S. Nolte, and M.L. Wilson. 1997. Cumitech 1B, Blood Culture III. Coordinating ed., J. Hindler. American Society for Microbiology. Washington D.C.
- Isenberg, H.D., Editor-in-Chief. 2004. Clinical Microbiology Procedures Handbook. American Society for Microbiology. Washington D.C.
- Miller, J.M., H.T. Holmes, and K. Krisher, General Principles of Specimen Collection and Handling. In Murray, P.R. *et al.* Manual of Clinical Microbiology 8th ed., p. 59-60. American Society of Microbiology Press Washington DC.
- Murray, P.R., E.J. Baron, J.H. Jorgensen, M. L. Landry and M.A. Pfaller. 2007. Manual of Clinical Microbiology, 9th ed., American Society for Microbiology, Washington, D.C.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
1	2/22/21	4.1, 8.3	Added CNA agar	M Sabonis	R Master
		10.5	Updated screen shots		
		10.5 B-6.b,c	Gram stain reporting-removed reference to "cell type + quantity" and "noted all observations"		
1	2/22/21	10.5 B,C,D	Updated to include BCID		
1	2/22/21	10.5 E,F,G	Removed ROB and FES. Added put BCID printout with plates, deliver to accessioning. Added worksheets for BCIDA/BCIDN	M Sabonis	R Master
		19	Updated labeling from 1-4 to A-D		
		Add. C	Updated for BCID		
2	10/12/21	8.3, 6-B,9	Added worksheets, by site, to use when performing Sunquest MNG	M Sabonis	R Master

19. ADDENDA

Addendum	Title
A	ITL Safety SubCulture Unit Quick Guide
B	Microbiology Blood Culture Keyboard
C	Positive Blood Culture Work Up Flow Chart
D	Anonymous Vial Resolution

Safety SubCulture Unit — Quick Guide

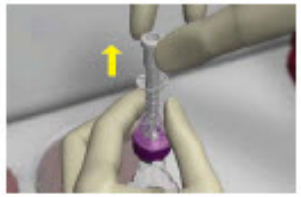
Note: This document is a product use reference guide. Please consult the package insert for the complete Instructions for Use.

Insert SCU

A) Remove SCU from package and position tip at center of disinfected bottle stopper.

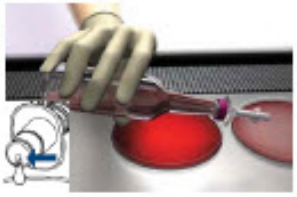
B) Hold bottle with one hand. With other hand, press down on SCU flanges to pierce bottle top.

Note: The SCU will not sit flush with the stopper.

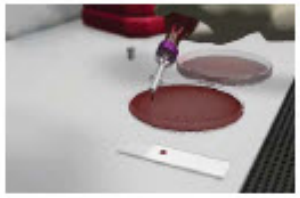


C) Hold SCU in place with one hand and using other hand, pull up on white filter cap to remove.

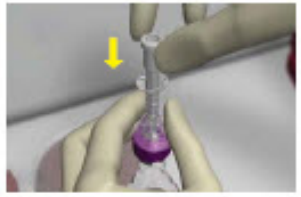
Drop Method



A) Position SCU sampling channel close to media plate or slide.

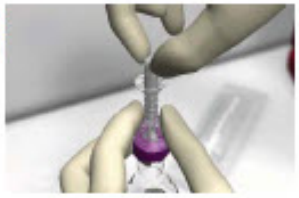


B) Tilt bottle to dispense drop.



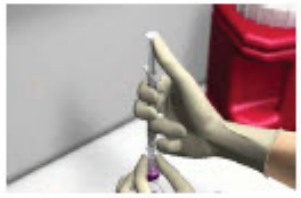
C) Replace white filter cap when finished dispensing drops.

Syringe Method



A) Aseptically remove the sampling channel. For example, place an alcohol wipe over insert and pull up with finger tips.

B) Insert male end of syringe into female luer of SCU. Invert bottle and syringe and withdraw required volume into syringe.



C) Upright bottle and syringe. Pull up on syringe plunger to clear any remaining culture in the SCU.

D) Replace white filter cap as described above in the Drop Method. Dispense sample from syringe.

Remove and Discard SCU

A) Hold bottle with one hand and with other hand twist and pull up on SCU to remove.

Discard into appropriate bio-hazard container.

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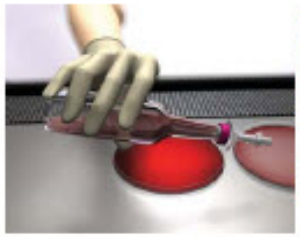
Sharps Safety & Best Practice

FTM-ITLAP-004 REV01

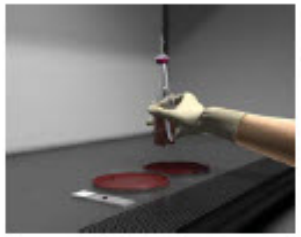
Safety SubCulture Unit — Tips & Tricks

General Guidelines

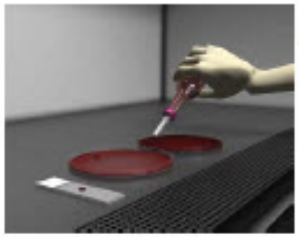


Tilt bottle to smaller angle (approx. 30-45 degrees) above horizontal for better control of drop size and speed.

Note: Gaseous samples tend to flow more quickly.

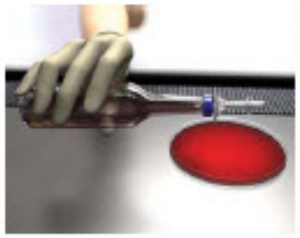


Prepare to upright bottle quickly to cut off the drop size and rate.

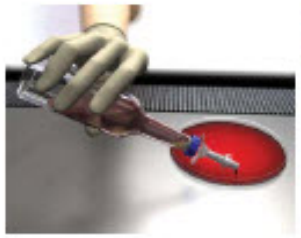


When dispensing to a series of slides or other media, dispense drops sequentially without uprighting the bottle between drops.

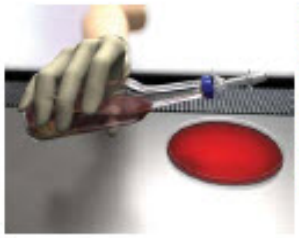
Resin Media



To reduce potential clogging, turn the bottle horizontal allowing the resin to settle along the side of the bottle prior to dispensing drops.

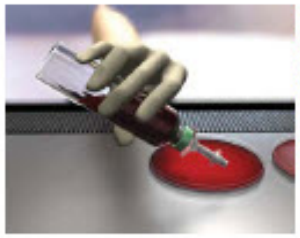


Increase the angle of the bottle to dispense drops.

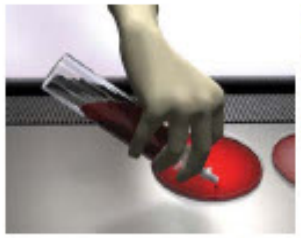


If resin obstructs the SCU tip inside the bottle, tilt the wide end of the bottle downward to clear the resin from the tip. Allow the resin to settle along the side of the bottle prior to dispensing additional drops.

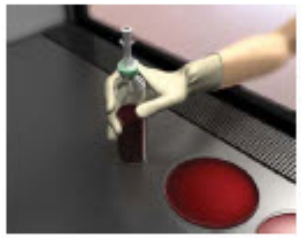
Charcoal Media



To reduce potential clogging, tilt the bottle approx. 30-45 degrees above horizontal. Do not invert the bottle, as this may increase clogging.



Clogging may be cleared by gently pressing the base of the SCU against the septum while the bottle is at a slight angle.



Clogging may also be cleared by replacing the SCU filter cap and gently tapping the base of the bottle on a counter.

An alternative is to use the syringe method.

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Sharps Safety & Best Practice

FTM-ITLAP-004 REV01

Addendum B

BLOOD CULTURE KEYBOARD
Result / Modifier Keys
[used for resulting XBLC, except Direct Exam tab]

ESC	F1 EXIT MAILBOX	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11 EXIT	F12

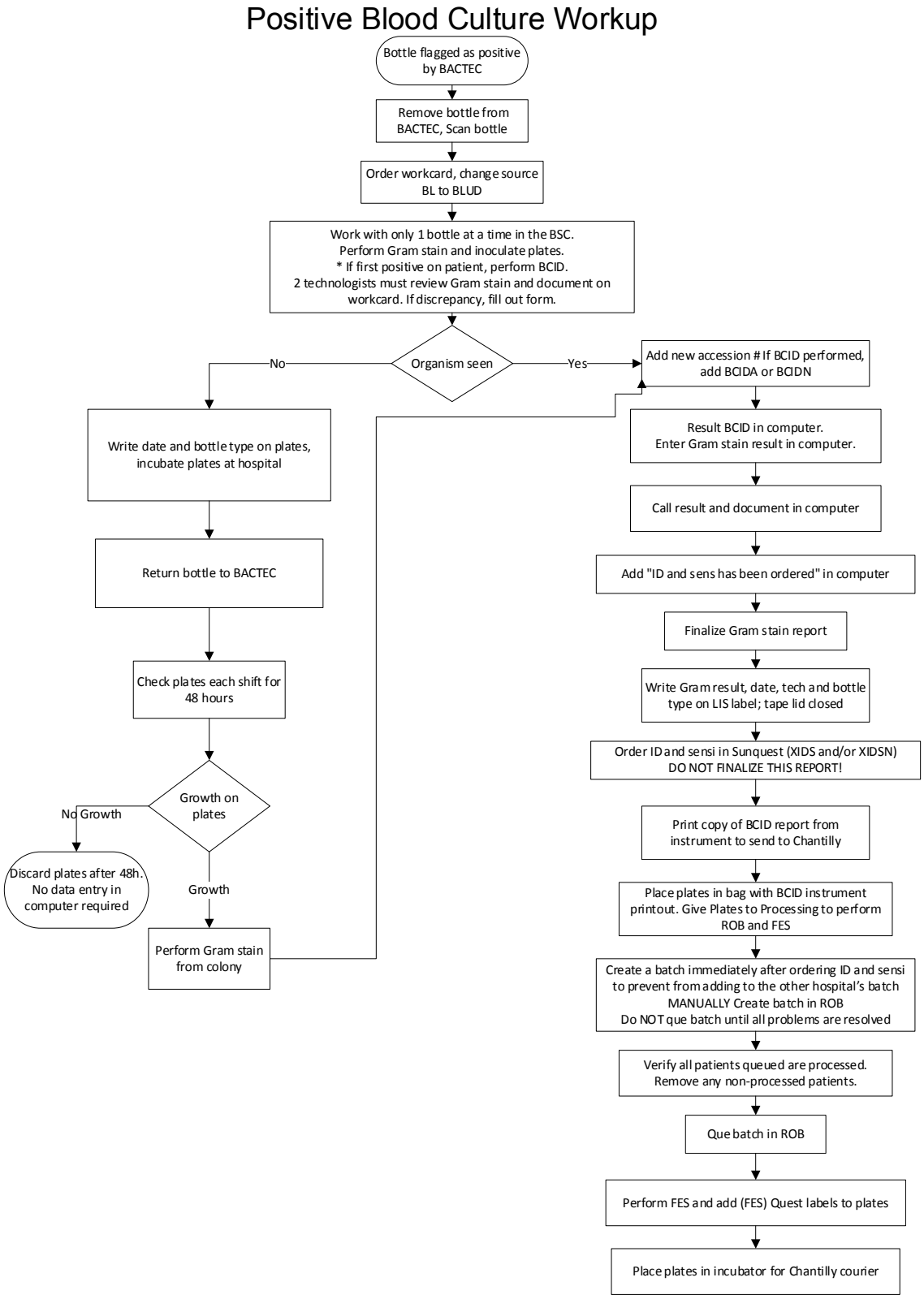
! 1 **RARE**	@ 2 **FEW**	# 3 **MOD**	$ 4 **MANY**	% 5 **NOCO**	^ 6 **NTY**	& 7 **HYPH**	* 8 **YPSU**	(9 **GT**	) 0 **GNCB**	-	+	Back Space ←

Q **CLUE**	W **WBCS**	E **EPIT**	R **RBCP**	T **TRIC**	Y **YST**	U **GPR**	I **GNR**	O **NOS**	P **POSIT**	{ / [**UNIN**	}] **INVAL**	\	

A **PCPR**	S **GPRD**	D **GNDC**	F **BGPR**	G **GPCN**	H **GPC**	J **CHAIN**	K **CLUST**	L **PAR**	; **OTHR**	‘	ENTER

Z **INTRA**	X **EXTRA**	C **GNC**	V **GVCB**	B **GVR**	N **ng** n **HIDE**	M **GNCB**	,	. **BCIDP**	/ **fnl** ? **PREVR**

Addendum C


Positive Blood Culture Workup
Bottle flagged as positive by BACTEC
Remove bottle from BACTEC, Scan bottle
Order workcard, change source BL to BLUD
Work with only 1 bottle at a time in the BSC.
Perform Gram stain and inoculate plates.
* If first positive on patient, perform BCID.
2 technologists must review Gram stain and document on workcard. If discrepancy, fill out form.
Organism seen
No
Yes
Write date and bottle type on plates, incubate plates at hospital
Return bottle to BACTEC
Check plates each shift for 48 hours
Growth on plates
No Growth
Discard plates after 48h. No data entry in computer required
Growth
Perform Gram stain from colony
Add new accession # If BCID performed, add BCIDA or BCIDN
Result BCID in computer.
Enter Gram stain result in computer.
Call result and document in computer
Add "ID and sens has been ordered" in computer
Finalize Gram stain report
Write Gram result, date, tech and bottle type on LIS label; tape lid closed
Order ID and sensi in Sunquest (XIDS and/or XIDSN)
DO NOT FINALIZE THIS REPORT!
Print copy of BCID report from instrument to send to Chantilly
Place plates in bag with BCID instrument printout. Give Plates to Processing to perform ROB and FES
Create a batch immediately after ordering ID and sensi to prevent from adding to the other hospital's batch
MANUALLY Create batch in ROB
Do NOT que batch until all problems are resolved
Verify all patients queued are processed.
Remove any non-processed patients.
Que batch in ROB
Perform FES and add (FES) Quest labels to plates
Place plates in incubator for Chantilly courier

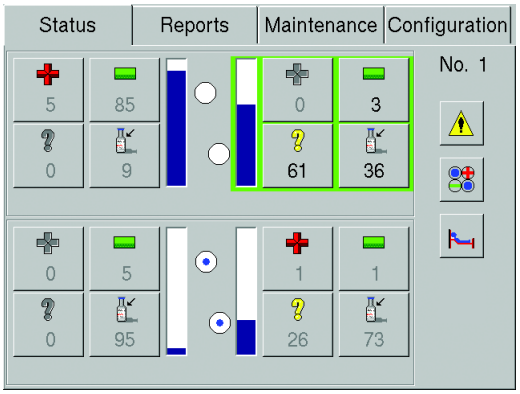
Addendum D

Anonymous Vial Entry

Vials can be placed into available (GREEN indicator) stations without being scanned into the instrument; however, THIS SHOULD NEVER BE DONE. If no Sunquest accession bar code is available, scan the bottle bar code (sequence number) before inserting in the instrument. This becomes an Orphan vial.

Vials that are not scanned into the instrument are called “anonymous” vials.

Anonymous vials are indicated with a yellow question mark on the Status Screen or a yellow light above the station.

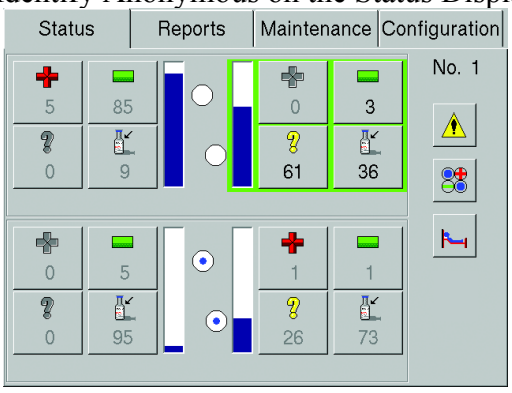


Anonymous vials are recognized by the instrument when they are placed in stations, but are assigned an “unknown” medium type and the default protocol of 5 days. Anonymous vials are evaluated with general positivity criteria. They cannot use the specific positivity criteria tied to the characteristics of the medium since the instrument does not know the medium type, therefore growth detection may be delayed.

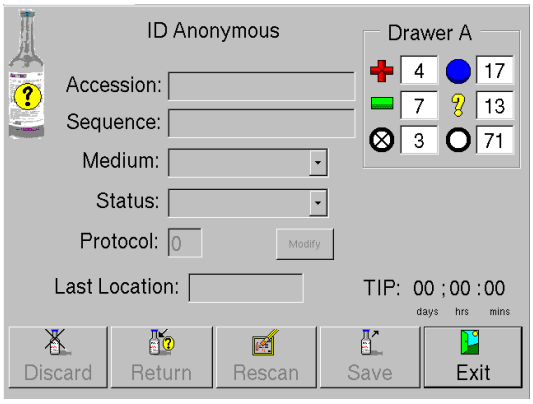
RESOLVING ANONYMOUS VIALS

ID Anonymous Vials

1. Select a drawer that has anonymous stations and open that drawer
2. Anonymous vials are indicated with a FLASHING YELLOW or FLASHING YELLOW/RED alternating station light.
3. Select Identify Anonymous on the Status Display by pressing the yellow .



4. The ID Anonymous screen is displayed.



5. Scan the vial sequence (bottle) bar code label
6. The medium, default Protocol, and Time in Protocol are automatically entered.
7. Scan or enter the Sunquest accession number
8. Place the vial in the FLASHING GREEN station (station from which vial was pulled)
9. Three beeps are heard when all Anonymous Vials have been identified.

NOTE: **Once an anonymous vial has been placed in the instrument, do not remove the vial and reenter it without identifying it (ID Anonymous activity).**

If an Anonymous Vial is accidentally removed (anonymous workflow opens), the vial sequence must be scanned into the instrument before placing the vial back into the instrument.

- If vial is a Positive Anonymous, scan vial. Tap Save and remove.
- If an Anonymous Vial is removed and placed back into the instrument without scanning the vial sequence, the protocol is restarted for that vial.
- If an Anonymous Vial is removed and not identified, all electronic data is lost for that vial.