STEM CELL LABORATORY (STCL)

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Unloading the BacT-ALERT Microbiology System and Printing Reports

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STCLSTCL-EQUIP-011 (JA1)
UNLOADING THE BACT/ALERT MICROBIOLOGY SYSTEM AND PRINTING REPORTS

1 PURPOSE

1.1 To provide instruction to the STCL staff for unloading sterility cultures from the BacT/ALERT 3D Microbial Detection System and to give instruction for printing reports and handling of positive units.

2 INTRODUCTION

2.1 BacT/ALERT 3D Microbial Detection System is a totally automated test system capable of incubating, agitating, and continuously monitoring aerobic and anaerobic media inoculated with samples to be monitored for bacterial or fungal contamination.

3 SCOPE AND RESPONSIBILITIES

3.1 The Medical Director, Laboratory Management, and staff trained to unload the BacT/ALERT 3D Microbial Detection System and print reports are responsible for ensuring that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

4.1	ISBT	Barcode used as a unique identifier for cellular products
4.2	QA	Quality Assurance
4.3	ID	Identification
4.4	STCL	Stem Cell Laboratory
4.5	ABMT	Adult Bone Marrow Transplant
4.6	DHIS	Duke Hospital Information System
4.7	LN2	Liquid Nitrogen

5 MATERIALS

5.1 Supplies

5.1.1 Biohazard trash bin

5.1.2 Miscellaneous Requisition Form (for positive cultures, if applicable)

6 EQUIPMENT

6.1 BacT/ALERT 3D Microbial Detection System

6.2 Computer/Keyboard/Interface Box/Barcode Reader

6.3 Printer

7 SAFETY

7.1 Wear appropriate personal protective equipment when handling any/all potentially hazardous blood and body fluids to include, but not limited to, gloves, lab coats, etc.

8 PROCEDURE

8.1 Check the Status of BacT/ALERT 3D System on the Observa computer.

8.1.1 On the main screen "***Status screen***" of Observa computer click on the (+) next to the Observa Status folder.

8.1.1.1 Normal message will indicate when the last backup was completed and disk capacity remaining.

8.1.1.2 Replace disk with a formatted disk when # of backup remaining is not sufficient. Format a disk for backup by performing the following actions:

8.1.1.2.1 Minimize Observa screen.

8.1.1.2.2 Click on **[Lab Admin]**.

8.1.1.2.3 Right click on CD Drive **[E]**.

8.1.1.2.4 Place Disk to be formatted in the disk drive.

8.1.1.2.5 In CD format under Format Disk, click on **[Format],** choose **[Format ⊙]**.

8.1.1.2.6 Choose **[Start]**.

8.1.1.2.7 When complete, close out by pressing **[X]**.

8.1.1.2.8 Pull up Observa software minimized at the bottom of screen to return to the main screen menu.

8.1.2 On the main screen (Status screen) of the Observa computer click on the (+) beside Communication Status folder.

8.1.2.1 "*BacT/ALERT Communication is okay*" is a normal message.

8.1.2.2 If any message other than, "*BacT/ALERT communication is okay*" appears, investigate and resolve. It may be necessary to contact Biomerieux Support at 1-800-634-7656 for resolution and assistance.

8.2 Printing Unload Negative and Unload Positive Reports.

8.2.1 When the system has assigned a negative or positive status to the sample(s), the number of bottles is indicated in the Bottle Count Table/Unload Buttons section of the Main Screen on the BacT/ALERT 3D system.

8.2.2 When a culture status of **negative** has been assigned, log on to the Observa computer system by entering a User Name and Password.

Select [**Negative Bottle to Unload Report**] button. The system will automatically print a Negative Unload Report.

8.2.3 When a culture status of **positive** has been assigned, log on to the Observa computer system by entering a User Name and Password. Select the [**Positive Bottles to Unload Report**] button. The system will automatically print a Positive Unload Report.

8.3 Unloading negative bottles from the BacT/ALERT 3D System

8.3.1 Press the [**Unload -**] button. The Unload Mode screen appears.

8.3.2 Unload the negative bottles identified by the instrument by opening a drawer with the green light illuminated. Once the drawer is opened each cell to be unloaded will be illuminated with a green light. **Note:** Alternate between incubators while unloading and limit the bottle unload time to no more than two minutes in one area so that the temperature does not drop.

8.3.3 Visually verify the bottle identity and accession number from the bottle with the bottle ID and accession number on the screen.

8.3.4 Culture bottles will remain in the instrument for a the pre-determined number of days at loading before being determined as Negative.

8.3.4.1 For all cellular products the bottles must be incubated for a minimum of 5 full days before unloading and reporting as Negative.

8.3.5 Discard the bottles into the biohazard trash bin. Press √ button when complete.

8.4 Unloading positive bottles from the BacT/ALERT 3D System

8.4.1 Press the [**Unload +**] button. The Unload Mode Screen appears.

8.4.2 Unload the positive bottles identified by the instrument by opening a drawer with the green light illuminated. Once the drawer is opened each cell to be unloaded will be illuminated with a green light. Remove each bottle indicated one at a time and scan the bottle ID to verify the bottle's identity.

8.4.3 Visually verify the bottle identity and accession number from the bottle with the bottle ID and accession number on the screen.

8.4.4 Press √button when complete.

8.4.5 Indicate the positive bottle by recording "+ ***culture***" on the *BacT/ALERT Log FRM1* in the Comments section next to the positive bottle ID.

8.5 Printing Chart Copies

8.5.1 A Chart Copy report will serve as the permanent record of sterility results.

8.5.2 To print a Chart Copy report for all bottles unloaded during the course of a day, log on to the Observa computer system by entering user name and password. Press **[Log on]**. Select **[Chart Copy Report]**.

8.5.3 The Chart Copy(ies) will automatically be printed.

8.5.4 Verify that the bottles listed on the Unload Report(s) were unloaded and a Chart Copy report is present. Initial and date the Unload Report(s) and file in the BacT/ALERT notebook.

8.5.5 Enter the sterility results in the EMMES database and file the hard copy of the Chart Copy with the appropriate patient file.

8.6 Printing An Individual Chart Copy Report

8.6.1 In the event that a specific Chart Copy must be printed, log on to the Observa system by entering user name and password then select the **[Data Management]** tab.

8.6.2 Information can be accessed by either the Accession # (ISBT barcode) or Bottle ID Data (choose accordingly from the drop down menu). Click on **[Show Search]**. Click on the drop down box beside accession number/bottle id and choose **[Contains]** or **[is equal to]**. When using Accession Data; you will be prompted to enter an accession number. When using Bottle ID Data, scan the culture bottle barcode from the *FRM1 BacT/ALERT Log*. Click on **[Run]**.

8.6.3 When the appropriate results for that accession number or culture bottle barcode are displayed on the screen, select **[Run Report]** at the bottom of the screen.

8.6.4 From the drop down menu that is displayed, a window will open; select **[Chart Copy Report]** and click on **[Print]**.

8.6.5 Return to the Status Screen to Log off.

8.6.6 Enter the sterility results in the EMMES database and file the hard copy of the Chart Copy with the appropriate patient file.

8.7 Subculturing Positive Cultures and Organism Identification

8.7.1 All positive bottles identified as having a "positive culture" will be forwarded to the Duke Clinical Microbiology Laboratory for sub culturing, so that the organism can be identified, and sensitivities obtained.

8.7.2 **NOTE**: For all clinical products, e-mail the medical team and text page the attending physician (when appropriate) immediately upon identification of a positive (+) culture bottle(s) in the STCL.

8.7.3 Place positive bottles in a zip lock biohazard bag.

8.7.4 Generate a DHIS requisition (or complete a manual requisition requesting a General Culture +/- and retain the orange control copy). Order a stat gram stain and culture/sensitivity. Include instructions on the requisition for the Micro Lab to call or page designated laboratory

staff so results of the gram stain can be reported to the clinical team as soon as those results are available.

8.7.5 Insert the requisition form in the ziplock biohazard bag and place in the bucket in the ABMT Clinical Lab to be transported to microbiology. If after 17:00, positive culture bottles should be placed in the clinical drop box located in the ABMT lobby. All samples must be placed in the box prior to 19:00 for pick-up.

8.7.6 Results, as they are available, will be updated in the hospital information system and therefore available to the clinical team.

8.7.7 The "stat" gram stain result should be reported, via e-mail, to the attending physician immediately upon notification of the result. The antibiotic coverage of the recipient/donor can be evaluated to ensure coverage is adequate, based on the findings of the gram stain. If the positive culture is obtained from a clinical product that has been collected before a recipient's transplant, the physician may opt to collect additional cells from that recipient/donor before taking the recipient to transplant.

8.7.8 Document the date, time, and person contacted regarding the positive culture results. This information should be filed in the laboratory records and updated in the STCL's EMMES Database system.

8.7.9 A notation should be recorded on the laboratory file reflecting that the cellular product tested positive when cultured.

8.7.10 If an attending physician has determined that a cellular product with a positive culture should by infused to the recipient, initiate a *Non-Conforming Product* form and obtain the appropriate signatures authorizing the infusion of the non-conforming product.

8.7.11 If a cellular product with a positive culture has been cryopreserved, make sure that the product is stored in a LN2 vapor freezer since vapor storage is considered a "**virtual quarantine**". If the contaminated product is going to be used in the future and is currently stored in the liquid phase of LN2, it will need to be relocated to a designated vapor LN2 freezer to ensure that cross-contamination risks are minimized.

8.7.12 If a cellular product with a positive culture has been identified by the attending physician for discard, initiate a *Record of Discard* and follow the steps as outlined in *Non-Conforming Products – Receipt, Processing, Distribution, and Disposition.*

8.7.13 Complete the required information in the Cultures Positive spreadsheet. Culture results will be monitored on a monthly basis for the detection of trends and the isolation of specific organisms that might identify a system error in collection or processing. The STCL's positivity rate should by $\leq 5\%$.

8.7.14 Sterility results are gathered and reported at the joint QA Committee meeting currently held the 4th Tuesday of each month.

8.8 Lot Acceptance

8.8.1 Upon arrival of a new lot of aerobic or anaerobic culture bottles, use 2 aerobic and 2 anaerobic culture bottles per incubator and test for sterility of the culture media.

8.8.1.1 Label the bottles as 1, 2, 3, and 4.

8.8.1.2 Complete *FRM1 BacT/ALERT Log.*

8.8.1.2.1 Record Study ID, Date, and Time.

8.8.1.2.2 Record Lot number and Bottle number in ID Number or Name Column. (i.e. 1227572-1 for bottle 1.)

8.8.1.2.3 Record product type as Lot Acceptance.

8.8.1.2.4 Remove the Bottle ID label and apply in the Barcode column.

8.8.1.3 Unload bottles when testing is complete and file the chart copies with related supply management documents located in the Certificates of Analysis notebook.

8.8.1.4 All results should be negative. If results are not negative quarantine the lot and send the positive bottle to Clinical Microbiology for sub culturing. If sub culturing indicates no growth, release the lot from quarantine. If subculture is positive notify QA so that Biomerieux customer service can arrange for investigation and corrective action of the lot. Complete *FR3 Unacceptable Supply Product/Recall Log Corrective Action Log* for any lots not acceptable.

9 RELATED DOCUMENTS/FORMS

9.1 FRM1 BacT/ALERT Log

9.2 Non-Conforming Product form

9.3 FRM1 Record of Discard

9.4 Non-Conforming Products – Receipt, Processing, Distribution, and Disposition

9.5 FRM3 Unacceptable Supply Product /Recall Log Corrective Action Log

10 REFERENCES

10.1 BacT/ALERT User Manual

11 REVISION HISTORY

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