PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC71000 – BACTEC FX Instrument	Policy Number:
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s):	
Effective Date:	Next Review Date:
Issuing Authority: Director of Health Services	Date Approved:
Accreditation Canada Applicable Standard:	

GUIDING PRINCIPLE:
The BACTEC FX instrument is designed for the rapid detection of bacteria in clinical specimens. Samples are drawn from patients and injected directly into BACTEC culture vials, which are placed into the instrument for incubation and testing.

Blood cultures are collected from patients with suspected sepsis or bacteremia. The isolation of any organism(s) from a blood culture must be considered significant and correlated with the clinical picture Although primarily directed towards the processing of blood cultures, occasionally other specimen types (sterile fluids, abscess material, bone marrow, etc.) are received in blood culture vials. These bottles may be processed in the same manner as blood cultures.

The BACTEC FX instrument continuously monitors routine blood cultures for evidence of growth for 5 days. Negative results are auto verified as follows:

- No growth in 48 hours (preliminary)
- No growth in 5 days (final)

PURPOSE/RATIONALE:
This standard operating procedure describes the BACTEC FX instrument and its components.

SCOPE/APPLICABILITY:
This procedure applies to Medical Laboratory Technologists (MLTs) and Medical Laboratory Assistants (MLAs) processing specimens using the BACTEC FX Instrument.

SAMPLE INFORMATION:

Type	Blood culture vial
Source	Blood or sterile fluid

REAGENTS and/or MEDIA:

Type	• BACTEC Plus Aerobic/F Culture Vials • BACTEC Lytic/10 Anaerobic/F Culture Vials • BACTEC Peds Plus/F Culture Vials
Source	Becton Dickinson
Stability	Stable until date of expiration indicated on vial
Storage Requirements	Bottle storage before blood collection: • Room temperature
Criteria for rejection and follow up action	Do not use if: • The expiration date has passed • There are other signs of deterioration

EQUIPMENT

- BACTEC FX instrument

ENVIRONMENTAL CONTROLS:

- Operating temperature: 18°C to 30°C
- Relative humidity: 25% to 80%, non-condensing

SPECIAL SAFETY PRECAUTIONS:

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potential infectious materials or cultures.

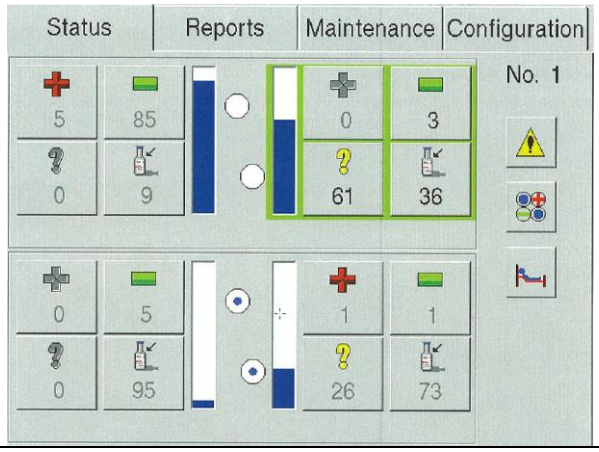
- Ensure that appropriate hang hygiene practices be used.
- Lab gown must be worn when performing activities with potential pathogens.
- Gloves must be worn when direct skin contact with infected materials is unavoidable.
- Eye protection must be used when there is a known or potential risk of exposure of splashes.
- All procedures that may produce aerosols, or involve high concentrations or large volumes should be conducted in a biological safety cabinet (BSC).
- The use of needles, syringes and other sharp objects should be strictly limited.

All patient specimens are assumed to be potentially infectious. Routine Practices must be followed. Since viable micro-organisms are used, all cultures must be handled with appropriate precautions. All equipment in contact with cultures should be decontaminated by appropriate methods.

QUALITY CONTROL:

- Refer to MIC60010-Microbiology Quality Control for quality control procedures

PROCEDURE INSTRUCTIONS:

Step	Action
Instrument components	
1	**BACTEC FX Instrument:** • The BACTEC FX instrument is composed of 2 drawers: A and B • Drawers are divided into columns and rows of stations • Columns are numbered 1 to 10 from left to right • Rows are lettered A to K excluding I • There are a total of 100 stations in each drawer
2	**Status display:** • The Status display is the main display shown when no other operation has been initiated or is in progress • Once a drawer is opened, you can initiate the major instrument activities from the Status display. Vial entry, remove positive vials, remove negative vials and identify anonymous vials can be initiated for any drawer in the instrument 
3	**System indicators:** • Each instrument has its own set of system indicators • The system indicators are located on the front of the center of the instrument • The system indicators inform you of various states in the instrument:

Indicator Colour	State	Meaning
Yellow – light in unison for instrument	On	• System Alert • Indicator remains on until the condition is corrected/addressed
Green – one each for left and right drawers	On	• Out of protocol negative vial • Indicator remains lit until all negative vials are removed through the Remove Negative Vials activity
Red – one for each left and right drawers	On	• Positive vial • Indicator remains lit until all positive vials are moved through the Remove Positive

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Station indicators:

- Each station has a set of LED indicators that inform you of the stations or vials status
- The status indicator is located above each station
- The color (red, green or yellow) and state (on, flashing or off) indicate the conditions

Colour	State	Meaning
Red	Flashing	Positive vial
Green	Flashing	Negative vial
Yellow	Flashing	Anonymous vial
Red **Yellow**	Flashing	Positive anonymous vial
Green	On	Available station

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Vial statuses:

- The status conveys information about the vial
- The status of vials is displayed on the drawer view display

Status	Icon	Meaning	How indicated
Available		There is no vial in the station	Station indicators: GREEN
Blocked		User has manually blocked the station	Station indicators: OFF
Negative		Vial completed protocol with no evidence of positivity	Station indicators: FLASHING GREEN
Ongoing		Vial is in the instrument and is in protocol	Station indicators: OFF
Positive		Instrument has detected evidence of microbial growth	Station indicators: FLASHING RED
Anonymous		Vial was physically placed in instrument without its barcode sequence number being scanned	Station indicators: FLASHING YELLOW

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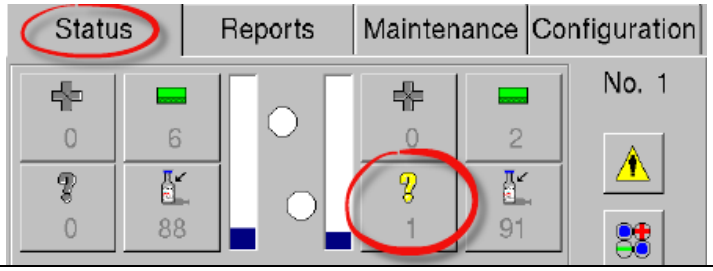
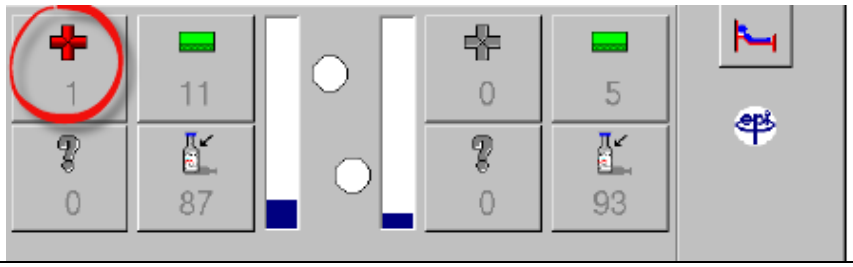
Audible tones and alarms:

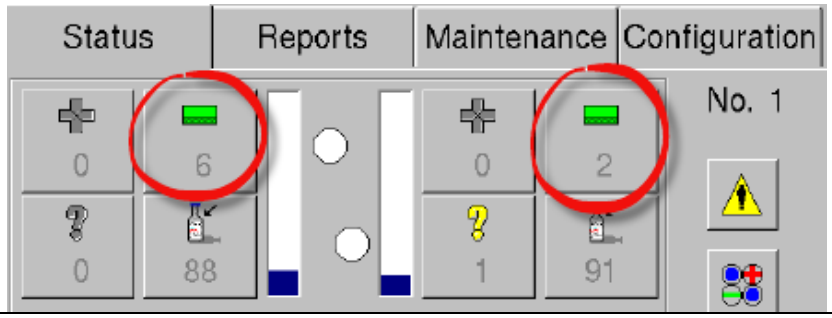
- Numerous different sounds are generated by the BACTEC FX as you perform operations. Each sound is unique

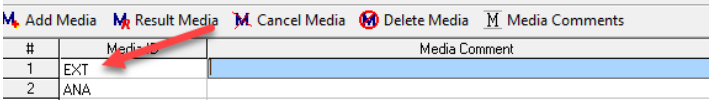
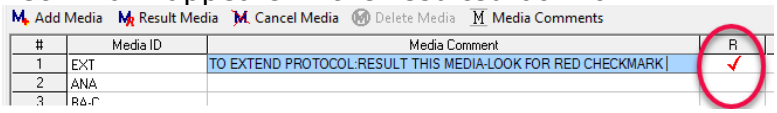
Type	Example	Sound
Activity complete	All negative vials were removed	High pitched tone repeated 3 times
Activity error	Did not scan accession barcode after scanning sequence barcode	Single high beep
Anonymous	Anonymous vial entered	Short buzz sound
Drawer ajar	The door is not closed	2 tones, high then low frequency, repeating
Positive vial	A positive vial is detected	Pulsing fading sound, repeated
Vial entry	A vial was entered	High pitch chirp sound

Step	Action
Loading vials into the BACTEC FX	
1	Open the drawer. Ensure that the Status screen is displayed and the barcode scanner turns on.
2	Scan the vial sequence barcode (vial barcode) and the accession barcode (LIS label).
3	Place the vial into any available slot (solid green light) in the instrument.
4	Scan and place any other bottles that need to be loaded.
5	Close drawer when finished.
6	Delayed entry of bottles may lead to delayed results. Best practices dictate that bottles should be placed into the BACTEC as soon as possible after collection. • All bottles received >24 hours after collection need to be subcultured to ensure growth is not present. Refer to MIC10230-Microbiology Specimen Processing
7	Vials can be placed into available (GREEN indicator) stations without being scanned into the instrument. Vials that are not scanned are called "anonymous" vials. Ongoing anonymous vials that reach the end of their protocol must be identified before the instrument will assign a negative status. See below.

Step	Action
Identifying anonymous vials	
1	Select the drawer that has anonymous station(s). The Status screen will indicate which drawer houses the anonymous vial: • *Example below: 1 Anonymous Vial is in Drawer B, zero Anonymous Vials in Drawer A.* 
2	Open the drawer and locate station(s) with a flashing Yellow LED. If the station flashes YELLOW and RED, then the vial is also POSITIVE. Remove the vial.
3	The ID Anonymous display appears and the barcode scanner turns on.
4	Ensure the vial has an accession barcode. If not, accession the sample and place the barcode on the vial.
5	Scan the vial sequence barcode (vial barcode) and the accession barcode.
6	Place the vial in the FLASHING GREEN station (station from which the vial was pulled).
7	Repeat with any additional anonymous vials.

Step	Action
Removing positive vials	
1	Select the drawer that has the positive station(s). The Status screen will indicate which drawer houses the positive vial: • *Example below: 1 Positive Vial is in Drawer A, no Positive Vials in Drawer B:* 
2	Open the drawer and locate the station(s) with a flashing Red LED and remove the vial(s).
3	The Positive Removal display appears. Scan the vial sequence barcode (vial barcode). You must scan each positive vial that you pull out in order for the instrument to re-light positive stations.
4	When all positive vials are removed from the drawer, the Activity Complete tone sounds.
5	Positive vials may be returned to the BACTEC RX if no bacteria are seen in the gram-stain for up to 5 hours after the vial has been removed. Refer to MIC20500-Gram stain resulting in LIS-Blood Cultures.

Step	Action
Removing negative vials	
1	Select the drawer that has the negative station(s). The Status screen will indicate which drawer houses the negative vial(s): • *Example below: 6 Negative Vials are in Drawer A and 2 Negative Vials are in Drawer B.* 
2	Open the drawer and locate the station(s) with a flashing Green LED stations and remove the vial(s). These vials do not have to be scanned.
3	Counters on the display are updated dynamically as vials are removed.
4	When all negative vials are removed from the drawer, the Activity Complete tone sounds.

Step	Action
Extending incubation time of vials	
1	On the BACTEC Status screen, tap the Drawer View button: 
2	Select the desired station and select OK.
3	Select Modify and the Modify Protocol box pops up: 
4	Change the protocol to 10 days and select OK. Select Save to save the changes.
5	In the LIS, under results entry, scan the order number to access the plate log/test comments. If a set of bottles has been collected, both bottles will need to be modified: ➢ In plate log (Media Comments), look for the EXT media ID:  ➢ Double click in the resulted box (R) for the EXT Media ID so that a red check mark appears in the resulted box for EXT:  ➢ This alerts the LIS to stop the 5 day reporting ➢ Save the order to save the changes made
6	If culture is negative: • A 48 hour negative preliminary report will be automatically released • A 10 day no growth final report will automatically be released Manual reporting negative bottles on extended protocol is not required.

Step	Action
Resolving system alert	
1	A system alert is indicated by a yellow LED indicator on both drawers of the instrument. This alert usually indicates a power failure or communication interruption.
2	• Check the instrument for an error message: ➢ Touch the ⚠ button and view the Alert List ➢ Power interruptions will display the following alerts: ○ Reboot Reason: Powerfail ○ The instrument has lost connectivity to the server ○ EpiCenter Communications failure ➢ Refer to the BACTEC FX Instrument User Manual for alert descriptions

3	• Log into Epicentre computer: ➢ Log-in to Windows. When power goes out, Windows will re-boot and require re-login again ➢ Icon will display:  Communication should RESYNC  after logging into Windows (should take about one minute after logging in) ➢ A System Message window should pop-up displaying the errors. Click the x button to close or delete them ➢ The yellow system indicator lights on BACTEC door will stop glowing

Step	Action
Disassociating vials	
1	If a vial record contains an accession number, it is considered associated to that accession. The disassociate function enables you to break the link between a vial and an accession number. This can be useful when troubleshooting sample errors.
2	From the status display, tap the Culture button: 
3	The Culture-Patient display appears.
4	Tap the Vial tab to access the Culture-Vial display.
5	Scan the sequence number (bottle barcode) of the vial.
6	Tap the Disassociate button to disassociate the vial from the accession number.
7	Return to the Status display.
8	Open the drawer and proceed to load the vial into the instrument.
9	Scan the bottle barcode and then scan the accession barcode.
10	Place the bottle in any available slot in the instrument.

Step	Action
Associating vials	
1	If a vial has been loaded into the instrument without an accession number, the vial needs to be associated with the accession number.
2	From the status display, tap the Culture button: 
3	The Culture-Patient display appears.
4	Tap the Specimen tab to access the Culture-Specimen display.
5	In the accession field, scan the accession number.
6	Scan the vial sequence barcode you want to attach.
7	Tap the Save button to save the association.

CROSS-REFERENCES:

- MIC10230-Microbiology Specimen Processing
- MIC20500-Gram stain resulting in LIS – Blood Cultures
- MIC60010-Microbiology Quality Control

REFERENCES:

1. Becton Dickinson and Company. (2011/02). *BD BACTEC FX Instrument User Manual*, 8005110

APPROVAL:

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Date

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REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	06 Nov 17	Initial Release	L. Steven
2.0	26 Mar 19	Updated to reflect addition of disassociating and associating vials	L. Steven
3.0	16 Jun 21	Procedure reviewed and added to NTHSSA policy template	L. Steven