TITLE: MGIT 960 Analyzer	Revision Date: 07-April-2017	Issue Date: 07-April-2015
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Approved by: Gloria Badari, Director, Corporate Services and Chief Financial Officer	Signed by: (Original Signed Copy in Microbiology)	

PURPOSE:

To standardize the use of the MGIT 960.

INTRODUCTION:

The BACTEC™ MGIT™ 960 Instrument is an *in vitro* diagnostic analyzer designed for the rapid detection of Mycobacteria from clinical specimens. Samples are collected from patients, processed and inoculated into 7mL MGITs (Mycobacteria Growth Indicator Tubes). The 960 design contains 3 Drawers that can hold an inventory of 320 MGIT vials per drawer, all continuously incubated and analyzed for growth.

Principal behind the design: Mycobacteria present in MGITs metabolize nutrients and oxygen in the culture tube. The MGITs contain a liquid base and fluorescent indictor. Oxygen quenches the fluorescent compound, so as bacteria grow oxygen levels are consumed and decrease, releasing fluorescence which is detected by photo sensors in the instrument. The level of fluorescence detected corresponds to the amount of consumed oxygen in the tubes.

Automated detection: LEDs below the stations where the MGITs are placed are activated and photo sensors take readings in a test cycle once per hour. If fluorescence is detected, the MGIT tube in the station becomes flagged as “positive”, the instrument, alerts with an audible alarm and lights, and displays positivity on the LCD display. Length of incubation on the analyzer is 49 days (7 weeks). After this period of absent fluorescence, the tubes are automatically flagged as negative.

SPECIAL SAFETY PRECAUTIONS:

- Handle all patient samples and testing reagent using “Routine Practices”
- Please refer to the Northwest Territories Infection Prevention and Control Manual, march 2012
- Prior to testing all patient are to be identified as per I-0500 Use of Two Patient Identifiers.

ANALYZER INFORMATION:

Equipment	Information
BACTEC™ MGIT™ 960	
Manufacturer 	• Becton Dickinson (BD) • Serial # MG 3381
Maintenance	• Daily (or with every use) • Monthly • Periodic (perform as required)
Associated supplies for MGIT 960 analyzer:	
Thermometer (one per drawer, 3 per machine)	• Supplier: Becton Dickinson (BD)
Calibrator vials (one per row, 16 per Drawer)	• Supplier: Becton Dickinson (BD)

INSERTION OF MGITS INTO ANALYZER:

- Before placing freshly spiked MGITs into the 960, ensure the inoculated MGIT tubes have been sprayed or wiped down with Accel TB before removal from BSC.
- MGITs should be placed into instrument ASAP following decontamination and inoculation.

Step	Action
Reference: Section 4.5 "Entering New Tubes" in MGIT User Manual (page 4-7 and 4-8)	
1	Take test tube rack containing decontaminated MGITs to counter beside MGIT analyzer.
2	Open drawer A, B or C. Ideally, fill up the higher Drawers before placing fresh vials in lower drawers.
3	Tubes should be scanned into instrument using their barcodes before vial insertion (similar to Blood Culture instrument). Tubes will become anonymous tubes if their bar codes are not scanned.
4	Press the soft key below the LCD screen "tube entry"
5	The red light from the barcode scanner glows and tube is ready for scanning.
6	Scan the vial's barcode 1st, then the accession label. Tube may require some rotating for scanning to work.
7	Machine beeps once to indicate successful Station assigned. The Station LED will glow green. Place MGIT into this station.
8	Repeat Steps 6 & 7 for remaining vials
9	When all MGITs have been scanned and inserted into instrument, ensure all the vials are seated properly into stations and close the Drawer Door. Barcode scanner turns off.

REMOVING POSITIVE MGITS

- Instrument alarms any positives – sound is a constant and steady beep. To silence the alarm, press the SILENCE ALARM key
- The positive indicator lamp on the front of Drawer A, B or C will light up in red
- In the Summary window, the number of positives for each drawer will be displayed with a "+" sign.

Step	Action
Reference: Section 4.7 "Positive and Negative Specimens" in MGIT User Manual (page 4-17 → 4-21)	
1	Take an empty test tube rack to counter beside MGIT analyzer.
2	Locate drawer with the red "+" indicator light. Open Drawer. Positive tubes inside the Drawer will have flashing alternating red/green station lights.
3	Touch the "remove positives tubes" soft key under LCD display. Tubes require barcode scanning for their removal from instrument (similar to Blood Culture instrument). Barcode scanner will glow red.
4	Remove one vial → scan the MGIT vial's barcode (not the accession barcode label). Tube may require some rotating for scanning to work. Station indicator light from positive vial should stop flashing green and red after successfully scanning from instrument.
5	Place vial into test tube rack.
6	Move onto next positive MGIT tube. Repeat Step 4 and 5 for remaining positives.
7	When all positives are removed from machine: • Instrument alerts user with 3 beeps • Barcode scanner turns off • Drawer positive indicator light turns off
	Print out the Positive Vial Report. Press the Printer Icon soft key Once the paperwork successfully prints, press the "OK" soft key to clear the list.
8	Close Drawer.
9	Place positive MGITs in "Positives" rack inside Mycobacteria incubator for referral to Provincial Lab.

REMOVING NEGATIVE MGITS (OUT-OF-PROTOCOL NEGATIVES)

- Out-of-protocol negative MGITs are vials that have reached their 49 day incubation length (7 weeks). Ongoing negatives should never be removed from the MGIT before machine prompts to do so.
- Instrument alarms any negative vials – sound is a single beep.
- The negative indicator lamp on the front of Drawer A, B or C will light up in green
- In the Summary window, the number of out-of-protocol negatives for each drawer will be displayed with a "-" sign.

Step	Action
Reference: Section 4.7 "Positive and Negative Specimens" in MGIT User Manual (page 4-17 → 4-21)	
1	Take an empty test tube rack to counter beside MGIT analyzer.
2	Locate drawer with the green "-" indicator light. Open Drawer. Negative tubes inside the Drawer will have flashing green station lights.
3	Touch the "remove positives tubes" soft key under LCD display and then the "batch remove negative tubes" soft key. Negative vials do NOT require barcode scanning for their removal from instrument.
4	Remove one vial with a greens station indicator light → place in test tube rack → remove next negative vial, repeat until all out-of-protocol negative MGITs are removed from instrument. Batch removal allows for removal of all final negatives at once. Must remove all negatives with flashing green stations from Drawer before closing drawer or else the tubes will become anonymous. Green station indicator lights from positive should turn off after successfully removed from instrument.
5	When all the negatives are removed, press the "OK" soft key under the LCD screen.
6	Print out the Negative Vial Report. Press the Printer Icon soft key

	Once the paperwork successfully prints, press the "OK" soft key to clear the list. Check Growth Units. If GU > 0, a Kinyoun stain should be performed. Note: Growth unit is low enough not to flag positive so it's reasonably safe to open culture and manipulate.
7	When all the negatives are removed, the instrument beeps 3 times.
8	Close Drawer.
9	Remove negatives from test tube rack and place all negatives inside double lined Biohazard Bag for autoclaving.

MAINTENANCE PROCEDURE:

Daily Maintenance (with use):

- Record data before Mycobacteria processing, or during processing while samples are centrifuging.
- Record on BACTEC MGIT Instrument Maintenance Log.

Step	Action
Reference: Section 6.2.1 "Daily Maintenance" in MGIT User Manual (page 6-2→ 6-5)	
1	**Check Printer paper supply**. Restock if necessary. Paper is on top of the machine.
2	**Check Thermometers.** Perform 1st before verifying lights. Opening drawers affects temperature. • One thermometer/drawer. Start at Drawer A → locate thermometer vial → place finger on Station so it's location does not become "lost". Read thermometer reading through vial → return in proper station. • Record keeping: Check off A, B and C boxes under Check Temperature probes in the Instrument Maintenance Log • If results are not as expected → check the accuracy of the Thermometer against a calibrated and QC'd thermometer, and check the digital temperature

	reading on the MGIT. Thermometer may require replacement. Machine will give an error code E02 if it detects any discrepancies. Refer to page 7-3 in Manual for Temperature Alarm possible causes and resolutions.
3	**Verify operation of Drawer indicator lamps.** Ensure all Drawers are closed before starting. • Press Maintenance soft key below LCD Display → press "Test Drawer Indicators" → A, B and C Drawer lights should glow. Alarm indicator light should glow. • Record keeping: Check off A, B and C boxes under Check Drawer Indicators in the Instrument Maintenance Log • If results are not as expected → contact BD representative to arrange for replacement of malfunctioning indicator.
4	**Verify operation of Station indicator lamps.** Open one Drawer at time starting with Drawer A • Press the soft key below LCD screen "test green LEDs" → Station lights should glow green. Press soft key again to extinguish lights. Press soft key "test red LEDs" → Station lights should glow red. Press soft key again to extinguish lights. Close drawer. Repeat for B and C Drawers. • Record keeping: Check off A R/G, B R/G and C R/G boxes under Check Station Indicators in the Instrument Maintenance Log • If results are not as expected → block station that does not have dual Green and Red station lights. Record station blocked in Log. Refer to Section 6.2.3.2 Blocking a Station in MGIT 960 User Manual.

Monthly:

- Change air filter. Record on BACTEC MGIT Instrument Maintenance Log, Located in Appendix at the back in this SOP.
- Filters must be kept clean for proper airflow. If airflow is restricted, the internal temperature may excessively increase and affect Mycobacteria recovery, or

internal components may heat up possibly causing hardware damage and malfunctions.

Step	Action
Reference: Section 6.2.2 "Periodic Maintenance" in MGIT User Manual (page 6-2→ 6-5)	
1	**Wear PPE.**
2	Pull machine out of nook to gain access to faceplate and filter.
3	**Locate & remove bottom faceplate.** Faceplate location: At the bottom. Grasp faceplate by the finger holes, pull out. Requires a bit of force.
4	**Locate filter.** Behind faceplate.
5	**Remove dirty filter.** Lift filter up slightly, and pull on bottom of filter towards you. (Lift "up and "out). Lower the filter out of its housing. Set aside for cleaning.
6	**Insert clean filter.** Slide new filter into housing. Insert the top first, then push in the bottom porting. Push machine back into nook.
7	**Clean & Dry filter**. Rinse dirty filter in Accel TB, followed by water. Place in Mycobacteria incubator to dry off.
8	**Once dry, place clean filter into cabinet for next month.**
9	**Record Keeping.** Initial and date when filter was replaced on the Instrument Maintenance Log.

Replacing Calibrators:

- Change BEFORE expiration.
- Record Old and new lots of Calibrator vials on Calibrator Log sheet

- Must remove ALL calibrators and replace with new lots. There is one calibrator per row, and 16 rows per Drawer (Rows A → S).

Step	Action
Reference: Section 6.2.2.2 "Calibrator Replacement" in MGIT User Manual (page 6-9→ 6-10)	
1	Record lot # and Expiration date of new calibrators on Instrument Calibration Log. Write on a placard (to be taped beside the MGIT Drawer) the expiry date and lot # of the calibrator.
2	Open Drawer containing soon-to-be-expired calibrators.
3	Calibrators are located on the very left side of the Drawer under a black protective cover. Remove protective cover from the calibrators. • To remove, lift the four black push-pull fasteners that hold it in place, and lift the cover off
4	Remove the old calibrators inside the MGIT and place into Biohazard Bag for autoclaving.
5	Keep Drawer open and place the new calibrators in the calibrator station.
6	Close Drawer. Repeat Steps 1→ 6 to replace calibrators in other drawers.
7	Tell the MGIT computer that new calibrators have been installed → Locate the "maintenance" soft key below LCD display → press button four times until soft key displays 5/5 (replace calibrator tubes).
8	Re-open the Drawer door where the new calibrators have been placed.
9	Since we're replacing all indictors/drawer at once, ensure the reading-out displays: X/*00 – where X is the Drawer letter → press "OK" soft key. Now the software recognizes that the calibrators were replaced.
10	Replace protective cover. Close Drawer.
11	Repeat Steps 7→ 10 to replace calibrators in other drawers.
12	Place the calibrator placard on Drawer.

MGIT vials.

MGIT BBL tubes are QC exempt; therefore in-house QC is not required.

Performance is verified by the manufacturer before shipment.

VALIDATION

- The MGIT 960 has been successfully evaluated for performance in 2014.

Validation approved of by a consulting medical microbiologist at Dynalife Dx. See binder for data and sign-off sheets.

TROUBLESHOOTING

- Machine will display error codes on the LCD display.

Refer to Section 7 – Troubleshooting in User Manual to identify possible causes error causes and resolutions. If the problems cannot be solved using the instructions in the Manual, contact the BD representative.

REFERENCES:

- BBL™ MGIT™ product insert: Mycobacteria Growth Indicator Tube 7 mL. With BACTEC™ MGIT ™ 960 Supplement Kit.
- Company, Becton Dickinson. (2010). *BACTEC MGIT Instrument User's Manual* (Document # MA0117 ed.). Sparks, Maryland, USA: BENEX Limited Rineanna House.

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	27-JAN-2015	Initial Release	L. Driedger
	03Feb2015	Review	S. Webber