PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC60030 – VITEK 2 Quality Control	Policy Number:
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s): NA	
Effective Date:	Next Review Date:
Issuing Authority: Director, Laboratory and Diagnostic Imaging Services	Date Approved:
Accreditation Canada Applicable Standard: NA	

Uncontrolled When Printed

GUIDING PRINCIPLE:
Quality control is performed on VITEK 2 cards to ensure proper functioning on a weekly basis and to ensure new shipments have not deteriorated during shipping.

PURPOSE/RATIONALE:
This standard operating procedure describes the quality control procedure for the VITEK 2 instrument.

SCOPE/APPLICABILITY:
This procedure applies to Medical Laboratory Technologists (MLTs) performing quality control on the VITEK 2 instrument.

REAGENTS and/or MEDIA:
- VITEK AST-N390 cards
- VITEK AST-GP67 cards
- VITEK AST-ST03 cards
- VITEK GN, GP, NH, YST and ANC cards

SUPPLIES:
- 45% Saline
- Plastic VITEK tubes and caps
- Sterile swabs

EQUIPMENT:
- VITEK 2 instrument
- VITEK DENSICHEK
- Vortex mixer

SPECIAL SAFETY PRECAUTIONS:

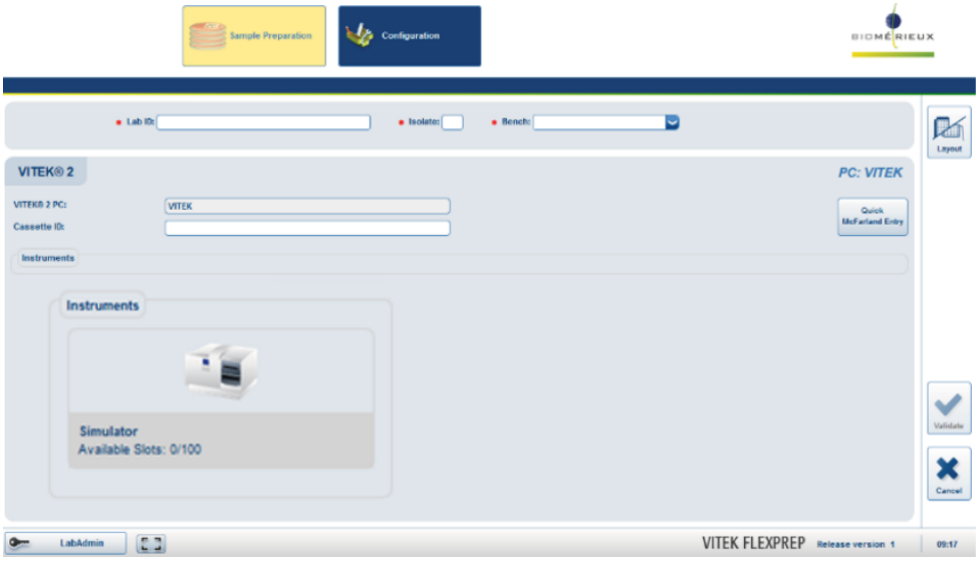
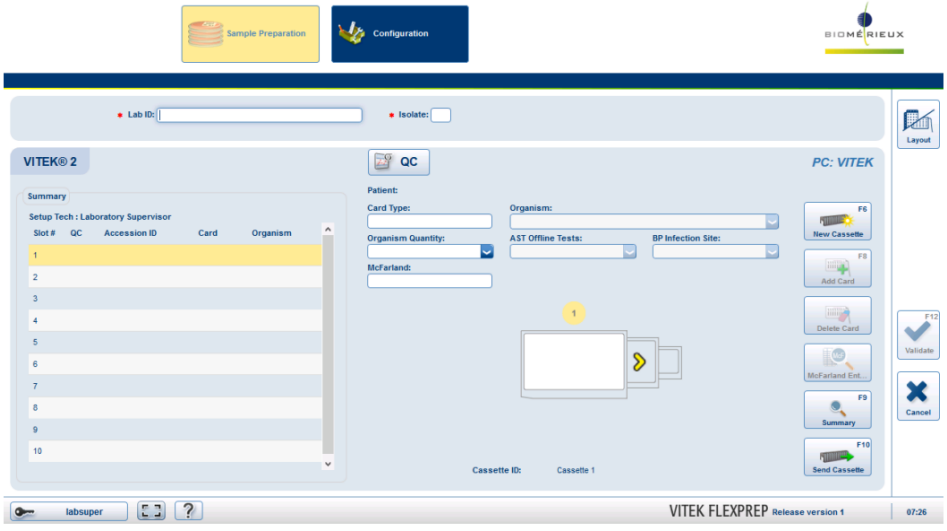
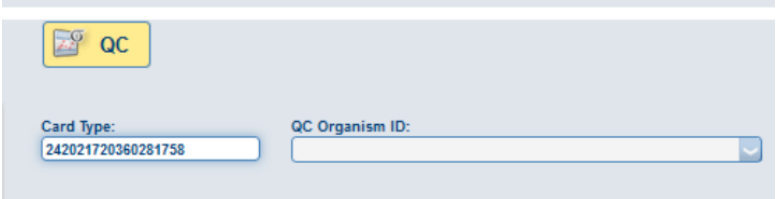
Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potentially infectious materials or cultures:

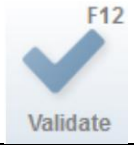
- Ensure that appropriate hand hygiene practices be used
- Lab gown must be worn when performing activities with potential pathogens
- Gloves must be worn when direct skin contact with infected materials is unavoidable
- Eye protection must be used when there is a known or potential risk of exposure 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.

PROCEDURE INSTRUCTIONS:

Step	Action
Performing quality control on the VITEK 2 instrument	
1	• VITEK 2 susceptibility card quality control is performed weekly by the Wednesday QC technologist, upon receipt of new cards and after bioMérieux preventative maintenance • VITEK 2 identification card quality control is performed upon receipt of new cards
2	Perform quality control testing with ATCC organisms and corresponding VITEK cards as per MIC60031-VITEK 2 Quality Control Job Aid.
3	Begin filling out MIC60032-QC Results Record-VITEK 2. Place on the urine bench to be completed the following day.
4	Allow cards to come to room temperature before opening the package liner.
5	From the Start menu on the VITEK 2 computer, select FLEXPREP to start the FLEXPREP application, or double-click the FLEXprep icon on the desktop: 
6	Enter the username **LabTech** and enter the password **Lab_Tech**. When the VITEK FLEXPREP opens, click the full screen icon on the bottom left to enter full screen mode: 

7	Starting at the Cassette Identification screen:  1. Click the **Bench** line and from the drop-down menu, select **QC**. 2. Enter the required **Cassette ID** for the cassette in use. 3. Press **Enter** on the keyboard.
8	Cassettes are defined in the **Cassette Definition** screen: 
9	Click the **QC** button: 
10	Click the **Card Type** field and enter the card's barcode. This can be done by scanning the barcode or entering it manually: 

	NOTE: The Card Type field will auto-populate with the card type when the barcode is recognized. The Shipment Date, Lot Number, and Expiration Date fields will populate if the user entered a shipment in the VITEK 2 Systems software. **NOTE:** If the user has not entered the shipment information, the system will prompt the user to enter the shipment information before proceeding.
11	Click the **QC Organism ID** line and start typing any portion of the organisms name and the drop-down menu will filter to the best matches available. Select the correct QC Organism ID for the card from the Organism drop-down field.
12	Set up cards as per procedure for card being quality controlled.
13	Click **Validate (F12)** to save the information and advance to the next card entry: 
14	Once each isolate has been defined in the cassette in VITEK FLEXPREP and the user has confirmed that the software matches the physical cassette, the cassette is ready to be sent to the VITEK 2 instrument. 1. Click the **Summary (F9)** button to access the **Cassette Summary** screen:  2. Review the details of each card slot and ensure the software matches the physical cassette. 3. Click **Back (F9)** to return to the **Cassette Definition** screen. **NOTE:** If any cards need to be edited, delete the isolate and re-enter the correct card information 4. Once each isolate has been defined in the cassette in VITEK FLEXPREP and the user has confirmed that the software matches the physical cassette, the cassette is ready to be sent to the VITEK 2 Systems instrument. Click the **Send Cassette (F10)** button:  5. The **Please confirm** dialog box will appear: 

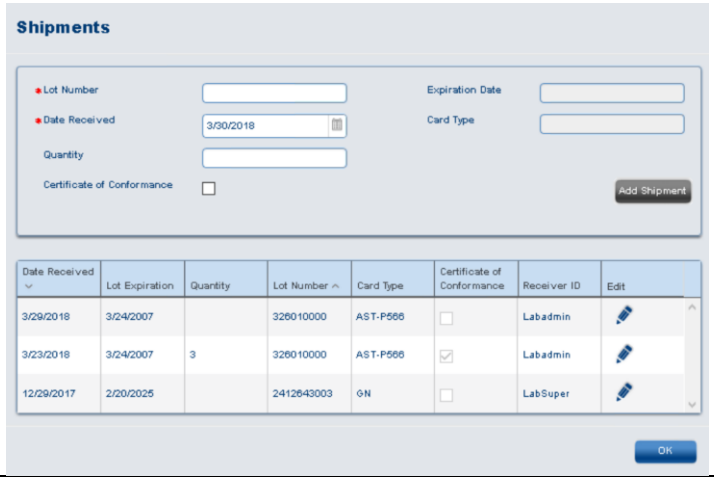
	NOTE: This dialog box does not apply as it shows the available instruments attached to the VITEK 2 PC and the STH Microbiology Laboratory only has 1 VITEK 2 instrument 6. Click **OK** to send the cassette. 7. An information box that says "Cassette information successfully sent to VITEK 2 Systems" will appear. 8. Click **OK** on the Confirmation dialog.
15	After the cards have been loaded onto the instrument, the cassette will travel back to the loading dock. Unload the cassette when light is flashing green.
16	Make purity plates using the grey or blue stick and BA plates labelled with labels from the "QC Stickers" binder. Incubate in the O_2 incubator.

INTERPRETATION OF RESULTS:

Step	Action
Reviewing quality control on the VITEK 2 instrument	
1	All QC isolates must be reviewed and approved.
2	From the Start menu on the VITEK 2 computer, select VITEK 2 Web to start the VITEK 2 Web application, or double-click the VITEK 2 Web icon on the desktop: 
3	Enter the username **LabTech** and enter the password **Lab_Tech**.
4	**Work List** view is automatically displayed upon login to VITEK 2 Systems Web. From Work List view, you can browse through the isolate results in the active workspace.
5	To filter Work List view, so that only QC isolates are displayed: 1. Select the **Select a QC Reference ID to Filter** checkbox in the Accession ID column. 2. Click **Apply Filter**.
6	All QC isolates in the active workspace will be displayed unless one specific QC Reference ID was entered. QC isolates can be further filtered utilizing any of the columns in Work List view, including Organism, Card Type, Date Tested, Lot Number, and Isolate Status.
7	Review the QC result printouts from the VITEK to determine if the results were acceptable. Non-acceptable results will be bold with an * in the "Actual" column.
8	QC results waiting to be reviewed are preceded by the **To Be Reviewed** icon: 

9	QC results can be reviewed individually or reviewed as a batch.
10	<u>To review results individually</u>: • Select a specific QC test by double clicking the QC order • This will take you to the **QC Isolate Detail** view • Select the **Review** icon to review the results  • The **"Select Result Report Type"** dialogue box will appear. Select the **"Cancel"** button on the bottom right corner • This will take you back to the QC Isolate Detail view • Once the result is reviewed, the status icon will change to approved  • Select the "**Back"** icon on the top left side of the tool bar to return to the Work List view  • As each QC test is reviewed, the order will be removed from the Work List view
11	<u>To review results as a batch</u>: • Select the checkbox for each QC isolate that you want to review in Work List view • Select the **Review** icon to review the results  • A dialogue box will appear stating: "All of the selected isolates will be flagged as reviewed. Continue?" Select **OK** • The **"Select Result Report Type"** dialogue box will appear. Select the **"Cancel"** button on the bottom right corner • As the QC batch is reviewed, the orders will be removed from the Work List view
12	If the QC results are acceptable, complete MIC60032-QC Results Record-VITEK 2.
13	If the QC testing results are unacceptable: • Record the issue on MIC60032-QC Results Record-VITEK 2 by marking "No" in the **QC OK** column and entering the repeat testing date in the **Repeat QC Date** column • Examine the purity plate to confirm whether the organism is pure • If the purity plate is pure, repeat the quality control testing • If the purity plate shows a mixed culture, inspect the original QC plate: ➢ If the original QC plate is also mixed, re-subculture from the slant or plates as applicable and repeat QC testing • If the subculture continues to show a mixed culture, subculture the QC isolate from the glycerol bead and proceed with QC testing

14	If the repeat QC testing is acceptable, complete MIC60032-VITEK 2 Quality Control Results record with a checkmark in "Repeat OK" column and the reviewing technologist's initials in the "Review Tech" column. Place in the VITEK 2 Quality Control binder in month QC completed.
15	If the repeat QC testing is still unacceptable: • Ensure correct QC organism was used to inoculate the card • Check purity plate to ensure QC organism is not mixed • Re-sub QC organism from glycerol beads • Contact bioMérieux to determine if issues with card exist • Do not use card for patient isolates • Notify the Technical Supervisor, Microbiology for resolution • Until the problem is resolved, it may be necessary to use an alternate susceptibility or identification testing method

Step	Action
Recording new shipments of VITEK 2 cards	
1	From the Work List view, select the **Tools** icon to open the Tools view: 
2	From the Tools view, click the **Shipments** icon to open the Shipments screen: 
3	Enter the lot number by manually entering or scanning the barcode number located on the VITEK 2 card box: **NOTE:** If manually entering a 10-digit lot number, the final digit must be between 0 and 4 to be valid
4	Select the date shipment was received.
5	Enter the quantity received.
6	Click **Add Shipment**. The system software adds the shipment information.
7	Click **OK** to exit the Shipments screen.

CROSS-REFERENCES:

- MIC60031-VITEK 2 Quality Control Job Aid
- MIC60032-QC Results Record-VITEK 2

REFERENCES:

1. bioMérieux. (2018-02). *VITEK FLEXPREP Software User Manual,* 048984
2. bioMérieux. (2018-03). *VITEK Systems Web Software User Manual,* 045555

APPROVAL:

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Date

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REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	15 Sep 17	Initial Release	L. Steven
2.0	06 Oct 19	Procedure reviewed	L. Steven
3.0	05 Jul 21	Procedure reviewed and added to NTHSSA policy template	L. Steven
4.0	03 Jul 23	Procedure reviewed	L. Steven
5.0	01 Oct 24	Procedure updated to reflect new VITEK FLEXPREP software	L. Steven