

PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC70200 – VITEK 2 ID and AST Cards	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:

VITEK 2 Gram-negative (GN) and Gram-positive (GP) identification cards are based on established biochemical tests measuring carbon source utilization, enzymatic activities and resistance. Results are available in approximately 8-10 hours.

VITEK 2 antimicrobial susceptibility test (AST) cards are intended for use for the automated quantitative and qualitative antimicrobial susceptibility testing of most clinically significant aerobic or facultative Gram-negative bacilli, *Staphylococcus* species, *Enterococcus* species and *Streptococcus* species. Minimum inhibitory concentrations (MICs) are determined using antimicrobial concentrations derived from serial twofold (doubling) dilutions. An interpretive criterion (Susceptible, Intermediate, or Resistant) is assigned to MIC results, based on CLSI guidelines, to aid in the direction of therapy.

PURPOSE/RATIONALE:

This standard operating procedure provides instructions on setting up VITEK 2 ID and AST cards.

SCOPE/APPLICABILITY:

This standard operating procedure applies to Medical Laboratory Technologists (MLTs) using ID and AST cards on the VITEK 2 instrument.

SAMPLE INFORMATION:

Type	Gram-negative and Gram-positive organisms
Source	18 to 24 hour culture

REAGENTS and/or MEDIA:

Type	VITEK 2: <ul style="list-style-type: none">• GN card• GP card• AST-N390 card• AST-GP67 card• AST-ST03 card
Stability	Stable until date of expiration indicated on the container
Storage Requirements	Store at 2°C to 8°C
Criteria for rejection	Do not use if: <ul style="list-style-type: none">• The expiration date has passed• There are other signs of deterioration

SUPPLIES:

- 0.45% 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:



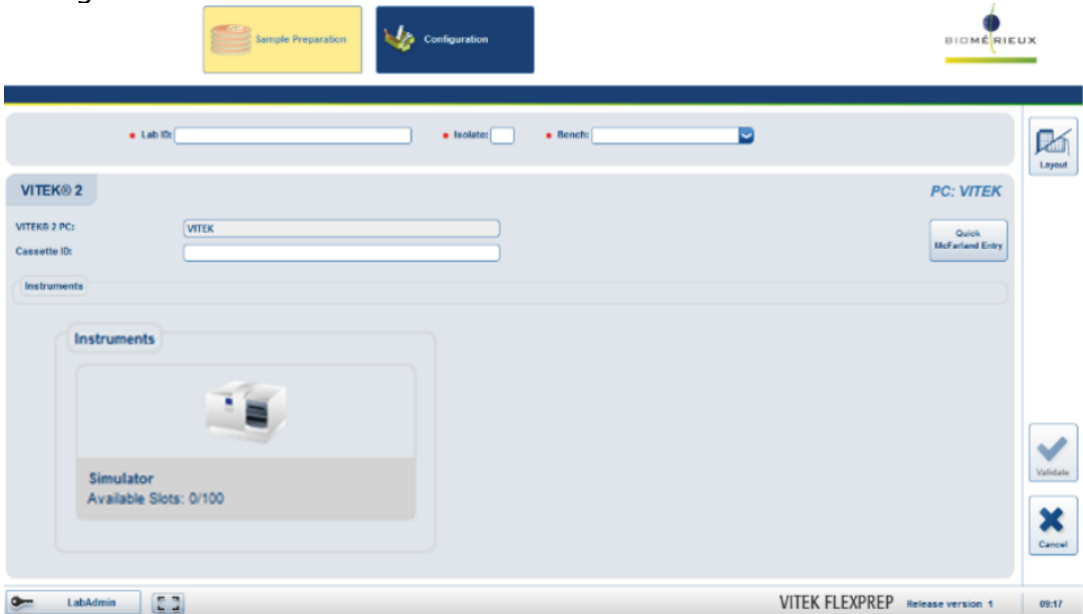
- Ensure that appropriate hand hygiene practices be used
- Lab gown must be worn when performing activities with potential pathogens
- Gloves must be worn when direct skin contact with infected materials is unavoidable
- Eye protection must be used when there is a known or potential risk of exposure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

QUALITY CONTROL:

- Refer to MIC60030-VITEK 2 Quality Control for VITEK 2 QC procedures
- Refer to MIC60031-VITEK 2 Quality Control Job Aid
- Record all results on MIC60032-QC Results Record-VITEK 2

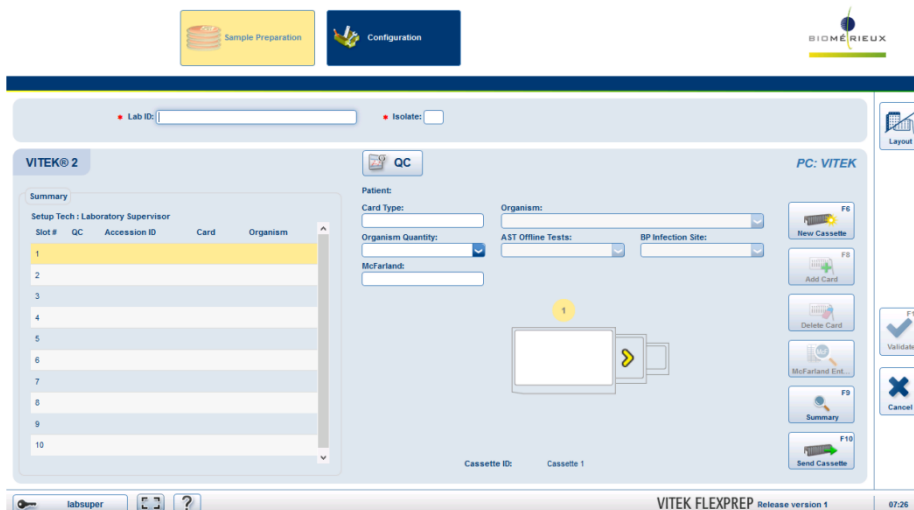
PROCEDURE INSTRUCTIONS:

Step	Action
Setting up GN, GP, AST-N390, AST-GP67 and AST-ST03 cards on VITEK 2	
1	Allow cards to come to room temperature before opening the package liner.
2	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: <div style="text-align: center;">  </div>
3	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: <div style="text-align: center;">  </div>
4	Starting at the Cassette Identification screen: <div style="text-align: center;">  </div> <ol style="list-style-type: none"> 1. Select the required Bench from the drop down menu. 2. Enter the required Cassette ID for the cassette in use. 3. Press Enter on the keyboard.
5	There are three possible scenarios for defining card types in a cassette: <ol style="list-style-type: none"> 1. Single ID Card. 2. ID Card with AST Card. 3. Single AST Card. Each scenario involves a slightly different method of data entry. All scenarios require the user to validate the isolate before defining the next isolate or sending the cassette.

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6

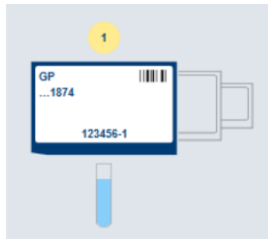
Cassettes are defined in the Cassette Definition screen:



7

Single ID Card Setup:

1. The Bench name and Cassette ID are entered in the Cassette Identification screen. This information will auto-populate into the Cassette Definition screen.
2. Enter the Lab ID by scanning the LIS barcode label.
3. Enter or change the Isolate number.
4. Write the last 4 numbers of the accession number on a VITEK plastic tube and fill with 3 mL of saline. Place the tube in the cassette slot.
5. Click the **Card Type** field and enter the VITEK 2 card information by scanning the VITEK 2 card barcode. The card type should auto-populate in the Card Type field when the barcode is recognized.
6. Once the card type is entered, a graphic of the isolate will be displayed. The graphic includes both a card and test tube:



7. Place the ID card in the cassette slot with blue stick pointing up.
 8. The Organism and AST Offline Tests fields will be unavailable for entry on an ID card.
 9. Select isolated colonies from a primary isolation plate and inoculate the tube to obtain a **0.48 to 0.63 McFarland** concentration.
 10. Cap tube and vortex. If suspension is too heavy, dispense saline into an extra tube to use as a diluent. If suspension is too light, add more colonies from the plate.
- NOTE:** Do NOT dilute bacterial suspensions directly from the dispensette
11. Remove cap and place the blue stick into the McFarland dilution tube and ensure the stick protrudes into the tube.

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12. Press Validate (F12) to move to the next position in the cassette:



ID Card with AST Card Setup:

1. The Bench name and Cassette ID are entered in the Cassette Identification screen. This information will auto-populate into the Cassette Definition screen.
2. Enter the Lab ID by scanning the LIS barcode label.
3. Enter or change the Isolate number.
4. Write the last 4 numbers of the accession number on a VITEK plastic tube and fill with 3 mL of saline. Place the tube in the cassette slot.
5. Click the **Card Type** field and enter the VITEK 2 card information by scanning the VITEK 2 card barcode. The card type should auto-populate in the Card Type field when the barcode is recognized.
6. Once the card type is entered, a graphic of the isolate will be displayed. The graphic includes both a card and test tube:



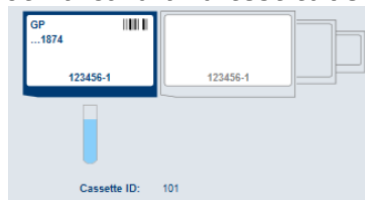
8

NOTE: Do not click Validate. If Validate is clicked, the ID card will validate as a single card and cannot be paired with an AST card

7. Place the ID card in the cassette slot with blue stick pointing up.
8. Click Add Card (F8) to add an AST card to the ID card:



9. Click the Card Type field and enter the barcode number by scanning the VITEK 2 card barcode. The card type should auto-populate in the Card Type field when the barcode is recognized.
10. Once the card type is entered, a graphic of the isolate will be displayed. The graphic includes both a card and test tube:



11. Place the AST card in the cassette slot with the empty tube with the grey stick protruding into the empty tube.

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12. Select isolated colonies from a primary isolation plate and inoculate the first tube to obtain a **0.48 to 0.63 McFarland** concentration.
13. Cap tube and vortex. If suspension is too heavy, dispense saline into an extra tube to use as a diluent. If suspension is too light, add more colonies from the plate.
- NOTE:** Do NOT dilute bacterial suspensions directly from the dispensette
14. Remove cap and place the blue stick into the McFarland dilution tube and ensure the stick protrudes into the tube.
15. Press Validate (F12) to move to the next position in the cassette:



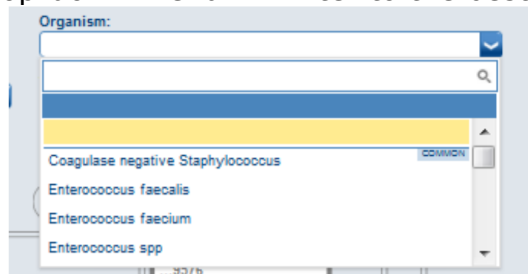
Single AST Card Setup:

1. The Bench name and Cassette ID are entered in the Cassette Identification screen. This information will auto-populate into the Cassette Definition screen.
2. Enter the Lab ID by scanning the LIS barcode label.
3. Enter or change the Isolate number.
4. Write the last 4 numbers of the accession number on a VITEK plastic tube and fill with 3 mL of saline. Place the tube in the cassette slot.
5. Click the **Card Type** field and enter the VITEK 2 card information by scanning the VITEK 2 card barcode. The card type should auto-populate in the Card Type field when the barcode is recognized.
6. Once the card type is entered, a graphic of the isolate will be displayed. If auto dilute is enabled, the first slot shows a test tube filled with saline (no card), and the second slot shows the AST card and an empty tube:




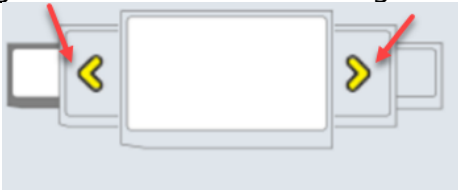


9

7. Place the AST card in the cassette slot with the empty tube with the grey stick protruding into the empty tube.
8. Click the **Organism** field and start typing any portion of an organism name and the drop-down menu will filter to the best matches available:



9. Select the desired organism name.

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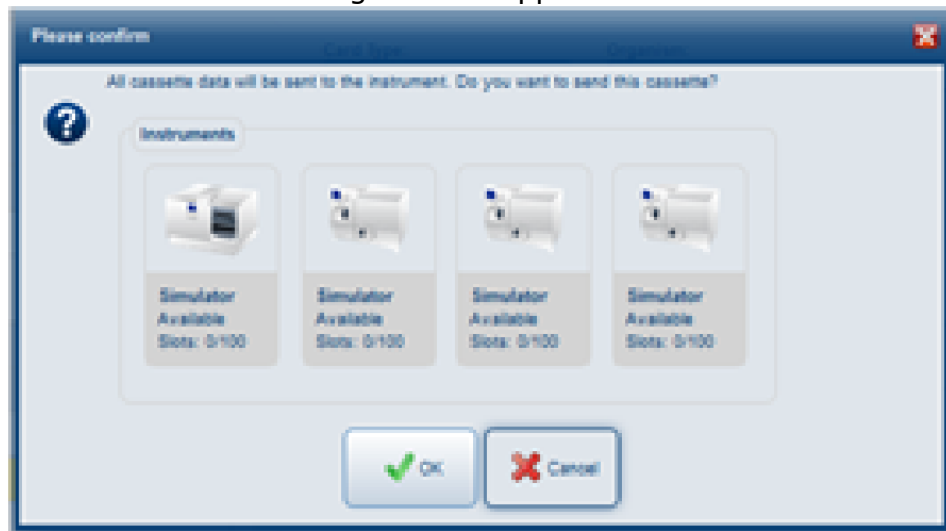
	<p>10. Select isolated colonies from a primary isolation plate and inoculate the first tube to obtain a 0.48 to 0.63 McFarland concentration.</p> <p>11. Cap tube and vortex. If suspension is too heavy, dispense saline into an extra tube to use as a diluent. If suspension is too light, add more colonies from the plate.</p> <p>NOTE: Do NOT dilute bacterial suspensions directly from the dispensette</p> <p>12. Remove cap from tube.</p> <p>13. Press Validate (F12) to move to the next position in the cassette:</p> 
10	<p>Card types may not be modified once they have been validated. To change card type information, the card must be deleted and a new card with the correct information must be created. If an AST card that was paired with an ID card is deleted, both cards will be deleted and must be recreated.</p>
11	<p>Deleting a card:</p> <p>1. Use the Left and Right Arrow buttons to navigate to the correct card:</p>  <p>2. Click the card to be deleted graphic. The graphic will turn yellow:</p>  <p>3. To delete an AST card paired to an ID card, select only the AST card.</p> <p>4. Click the Delete Card button.</p> <p>NOTE: If the card graphic has not been selected, the Delete Card button will be greyed out</p> <p>5. Click OK on the Confirmation dialog.</p>
12	<p>Sending a Cassette to VITEK 2:</p> <p>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.</p> <p>1. Click the Summary button (F9) to access the Cassette Summary screen:</p>  <p>2. Review the details of each card slot and ensure the software matches the physical cassette.</p>

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3. Click **Back** to return to the **Cassette Definition** screen if needed.
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** button (F10):








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.

Step	Action
Loading GN, GP, AST-N390, AST-GP67 and AST-ST03 cards	
1	Check that the green Cassette Load Station light is on. A blinking light indicates that a cassette must be unloaded before loading a new cassette. If the light is off, the instrument is not ready to accept a cassette.
2	To avoid jams and terminated cards, check that: <ol style="list-style-type: none"> 1. The blue and grey sticks are inside tubes. 2. The caps on the McFarland Standard tubes are removed. 3. The cards are sitting level in the cassette slots. 4. The cassette is seated properly in the boat when loaded onto the instrument.

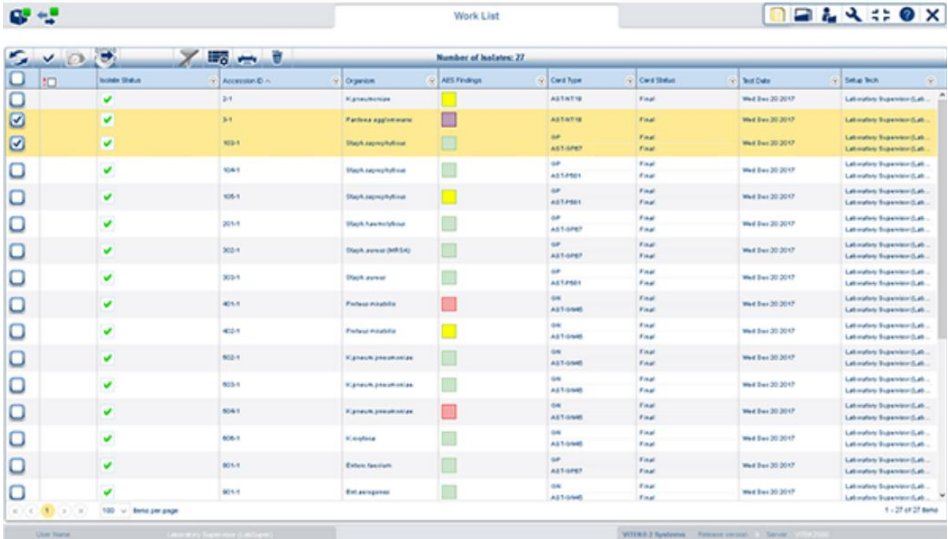
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3	After loading the cassette, wait for the "happy sound." If the VITEK 2 detects a discrepancy in the number of cards on the cassette, the cassette will be returned to the Cassette Load Station and will not be processed.
4	After the cards are loaded, the cassette will travel back to the loading dock. Unload the cassette when light is flashing green.
5	Bring the cassette back to the VITEK 2 setup bench. From the Start menu on the VITEK 2 computer, select VITEK 2 SYSTEMS to start the VITEK 2 SYSTEMS application, or double-click the VITEK 2 SYSTEMS icon on the desktop: 
6	On the VITEK 2 SYSTEMS Web application, select Cassette view: 
7	The columns in Cassette view include a Filter icon that will allow users to filter the cassettes listed in Cassette view. Filters can be cleared from all columns using the Clear Filter icon: 
8	Clear the Filters and select the filter icon for the Bench column to filter the cassettes by bench:  Select the bench you are working on to list the cassette you have last set up.
9	Find the cassette and select the expand button to view the cassette isolates:  The expand button is on the right hand side in the Cassette Status column.
10	Ensure the samples listed in the cassette summary match the accession numbers written on the tubes. Make purity plates using the blue or grey stick and appropriate media.

Step	Action
Reviewing GN, GP, AST-N390, AST-GP67 and AST-ST03 cards	
1	From the Start menu on the VITEK 2 computer, select VITEK 2 SYSTEMS to start the VITEK 2 SYSTEMS application, or double-click the VITEK 2 SYSTEMS icon on the desktop: 



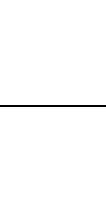
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2 Work List view is automatically displayed upon login to VITEK 2 Systems Web. From Work List view, you can browse through the isolate results in the active workspace:





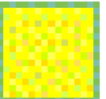





3 From the Work List, click on the "Clear Filters" button to clear the filters and:
 1. Filter the results by date and select yesterday's date.
 2. Filter the results by bench and select the correct bench name.

Isolate Status Icons:

4		Preliminary	<ul style="list-style-type: none"> Isolate still receiving raw data readings from the instrument isolate is not final
		Preliminary, Qualified	<ul style="list-style-type: none"> Isolate with missing information Isolates in this status are automatically removed from the active workspace if not fixed Qualified with a green indicator means two or more isolates in the active workspace share the same Lab ID and isolate number This condition must be resolved in order to move the isolate to the approved state
		Final, Qualified	<ul style="list-style-type: none"> Isolate with missing information Isolates in this status are automatically removed from the active workspace if not fixed Qualified with a red indicator means information is missing. Examples of missing information include: <ul style="list-style-type: none"> <<Low Discrimination>> <<Slash line>> ID and AST Offline Tests Missing Required Offline Tests Missing Organism

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		To Be Reviewed	<ul style="list-style-type: none"> Isolate is final and needs to be reviewed Click the Review Results icon: 
		Approved	<ul style="list-style-type: none"> Isolate is final and approved
5	If the Isolate status is not approved, double click the order in the worklist to resolve the issue. Once the issue is resolved, print the results page and click the Back icon to navigate back to Work List.		
6	<u>AES Confidence Levels for AST Cards:</u>		
		Consistent	<ul style="list-style-type: none"> One or more phenotypes proposed with no changes to MIC values Therapeutic interpretation changes may also be indicated
		Consistent with Corrections	<ul style="list-style-type: none"> One or more phenotypes proposed when including an MIC value change or a test value change in the AES analysis The tested MIC value or test value is reported Therapeutic interpretation changes may also be indicated
		Inconsistent	<ul style="list-style-type: none"> Phenotypes cannot be proposed Antibiogram is inconsistent with the AES knowledge base
		Expert Analysis Not Performed	<ul style="list-style-type: none"> Phenotypes cannot be proposed Phenotypes for the tested organism are not described in the AES knowledge base
		No Breakpoints Defined	<ul style="list-style-type: none"> None of the tested antibiotics in the active parameter set have breakpoints defined
7	If the AES confidence level is not consistent or consistent with corrections, double click the order in the worklist to resolve the issue. Once the issue is resolved, print the results page and click the Back icon to navigate back to Work List.		

CROSS-REFERENCES:

- MIC60030-VITEK 2 Quality Control
- MIC60031-VITEK 2 Quality Control Job Aid
- MIC60032-QC Results Record-VITEK 2

REFERENCES:

1. bioMérieux. (2020-04). *VITEK 2 Instrument User Manual*, 041387-02
2. bioMérieux. (2018-02). *VITEK FLEXPREP Software User Manual*, 048984
3. bioMérieux. (2022-02). *VITEK DENSICHEK User Manual*, 048641-02
4. bioMérieux. (2021-05). *VITEK 2 GN package insert*, 044066-05

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5. bioMérieux. (2021-04). *VITEK 2 GP* package insert, 043900-04
6. bioMérieux. (2018-08). *VITEK 2 AST-N390* package insert, 051371-01
7. bioMérieux. (2018-01). *VITEK 2 AST-GP67* package insert, 045513-01
8. bioMérieux. (2021-08). *VITEK 2 AST-ST03* package insert, 046698-03

APPROVAL:

Date

Director, Laboratory and Diagnostic Imaging Services

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	22 Nov 17	Initial Release	L. Steven
2.0	06 Oct 19	Updated to reflect new AST-N390 cards	L. Steven
3.0	04 Aug 21	Procedure reviewed and added to NTHSSA policy template	L. Steven
4.0	01 Oct 24	Procedure reviewed and updated to reflect new AST-ST03 cards and new FLEXPREP software	L. Steven

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