PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC70000 – VITEK 2 Instrument	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	

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GUIDING PRINCIPLE:
The VITEK 2 System is intended for the automated quantitative or qualitative antimicrobial susceptibility testing of isolated colonies for most clinically significant aerobic gram-negative bacilli, *Staphylococcus* spp., *Enterococcus* spp., *Streptococcus* spp., and clinically significant yeast.

The VITEK 2 System is also intended for the automated identification of most clinically significant anaerobic organisms and *Corynebacterium* species, fermenting and non-fermenting gram-negative bacilli, gram-positive organisms, fastidious organisms and yeasts.

PURPOSE/RATIONALE:
This standard operating procedure describes the VITEK 2 instrument and its components.

SCOPE/APPLICABILITY:
This standard operating procedure applies to Medical Laboratory Technologists (MLTs) processing specimens using the VITEK 2 Instrument.

SAMPLE INFORMATION:
- Refer to card specific VITEK 2 procedures for sample information

REAGENTS and/or MEDIA:
- Refer to card specific VITEK 2 procedures for reagent information

SUPPLIES:
- Refer to card specific VITEK 2 procedures for supply information

EQUIPMENT

- VITEK 2
- VITEK DENSICHEK

ENVIRONMENTAL CONTROLS:

- Operating temperature: 20°C to 30°C
- Relative humidity: 20% to 80%, non-condensing

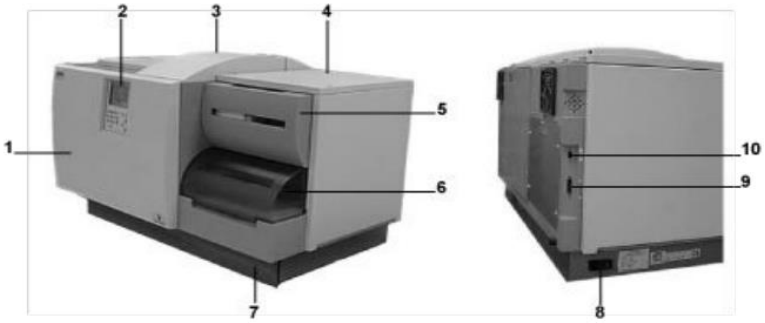
SPECIAL SAFETY PRECAUTIONS:

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

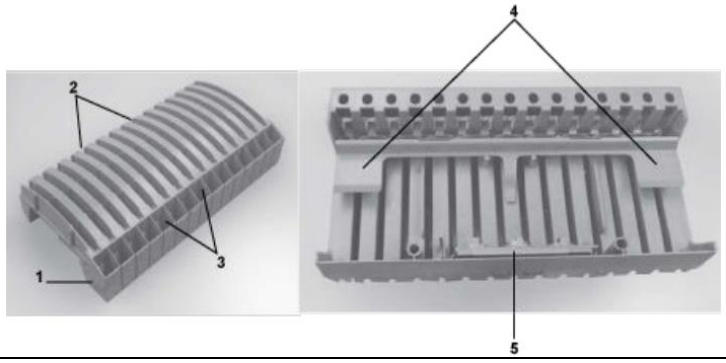
All patient specimens are assumed to be potentially infectious. Routine Practices must be followed. Since viable micro-organisms are used, all cultures must be handled with appropriate precautions. All equipment in contact with cultures should be decontaminated by appropriate methods.

PROCEDURE INSTRUCTIONS:

External controls and access doors to the interior of the instrument	
	
1	**Front Access Door:** • Provides access to the diluter, pipette tip container and a portion of the test card transport system • The door opens from the right side
2	**User Interface Screen and Keypad:** • This screen and keypad comprise the User Interface system
3	**Saline Access Door:** • Provides access to the sterile saline bag • The door lifts from the front and stays in the open position

4	**Top-Right Access Door:** • Provides access to the optics and the carousel • The door lifts from the front and stays in the open position • The top-right access door cannot be opened unless the Waste Collection door is opened first • This door is secured by two screws and requires a flathead screwdriver to open
5	**Waste Collection Door:** • Provides access to the Waste Collection Station where ejected test cards are removed from the instrument • The door is held in place magnetically and lowers from the top
6	**Cassette Load/Unload Door:** • Provides access to the Cassette Load/Unload station • The door slides up to open • A mechanism prevents opening of this door at inappropriate times
7	**Bottom Access Door:** • Provides access to the drip pan • The door is held in place magnetically and must be pulled down to open
8	**AC Power Switch and Cord Receptacle:** • This switch supplies power to the VITEK 2 instrument
9	**Workstation Connection:** • This connector port accepts the cable that connects the VITEK 2 to the workstation computer
10	**UPS Connection:** • This cable connector port connects VITEK 2 to an uninterruptable power supply (UPS) • The connection allows the UPS to notify the VITEK 2 instrument of a power loss so the VITEK 2 can start appropriate procedures

Cassettes



1	**Cassette Base:** • The base of a cassette is specially shaped to fit into a boat. The shape of the cassette base matches the well on the top of a boat. This ensures that the two units move as one through the VITEK 2 • The shape also ensures that the cassette can only be put into a boat in the proper orientation

2	**Test Card Slots:** • The top portion of a cassette is divided into 15 test card slots that can hold various combinations of VITEK 2 test cards
3	**Test Tube Holders:** • The front portion of a cassette has 15 wells that hold test tubes for inoculum
4	**Test Tube Release:** • Test tubes are held securely in the cassette by a retaining bar • A release lever is provided for easy disposal of used test tubes
5	**Button Memory:** • For systems using a Smart Carrier Station, each cassette is fitted with a special memory chip, called the button memory • The memory chip needs to remain on the cassette even if not being used

Cassette Load/Unload Station

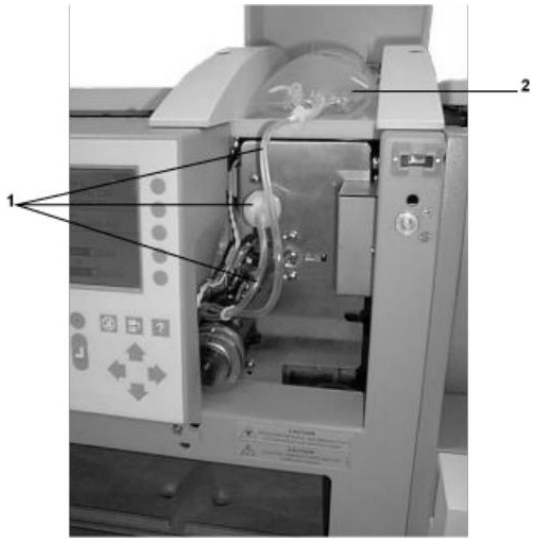
1	**Cassette load/unload door:** • Door slides up to open
2	**Green Indicator Light:** • Light status ON-the cassette load door is unlocked • Light status OFF-the cassette load door is locked and cannot be opened • Light status BLINKING-an empty cassette has arrived at the station and the cassette load door is unlocked

Boats

1	**Test Card Filling:** • Above the cassette well, there is a flat surface that extends around the perimeter of the boat. This surface becomes the base of the vacuum chamber when the boat reaches the Filler station

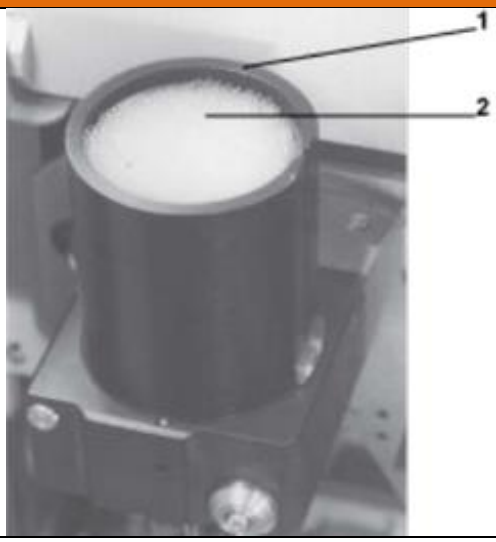
2	**Test Card Transport:** • The top surface of a boat forms a specially shaped well into which a cassette is placed. The shape of the well conforms to the base of a cassette, providing it with a secure platform on which to ride • The two pins in the well ensure that the cassette is placed into the boat only in the proper orientation • An arrow is molded into the surface of the well to show the proper orientation of the boat when placed in the instrument
3	**Spill Prevention:** • The well in the top of the boat catches any spills from the cassette
4	**Base Supports:** • Each boat stands on four low-friction feet, providing a surface on which the boat can easily move
5	**Notched Base:** • The base of each boat is notched in several places • These notches are used by the VITEK 2 test card transport mechanisms that move the boats through the module

Dispenser



1	**Dispenser Assembly:** • The dispenser assembly consists of a plastic dispensing chamber and two sections of plastic tubing • One section of tubing leads from the dispensing chamber and is attached to the sterile saline bag • The other section of tubing also leads from the dispensing chamber but is attached to an air pump. It is fitted with a filter to prevent particulate contamination
2	**Sterile Saline:** • The top of the VITEK 2 instrument has a compartment designed to hold a one-liter bag of sterile saline • This is enough saline to process about 330 AST cards

Pipettor

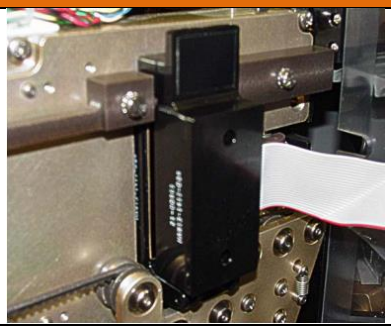


1	**Container:** • The container holds up to 350 pipette tips • It has an internal mechanism that ensures proper delivery of each pipette tip to the displacement pump
2	**Disposable Pipette Tips:** • To prevent contamination, VITEK 2 uses single-use, disposable pipette tips

Carousel

1	As the carousel rotates, each test card moves into the reading position every 15 minutes. A mechanical device called the Reader Head conveys the test card through the optics stations.
2	After the reading cycle, the test card returns to its slot in the carousel, where it continues to incubate until its next read cycle.
3	The carousel is divided into four sections so it can be easily removed for periodic cleaning.

Transmittance Optics

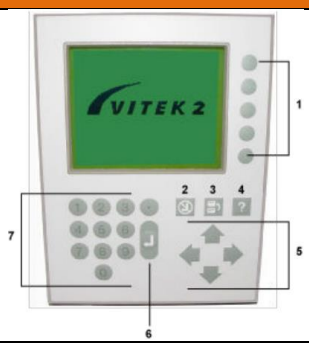


1	• The transmittance optics uses visible light to directly measure organism growth • These optics are based on an initial light reading of a well before significant growth has begun • Light transmittance samplings of the same well every 15 minutes measure organism growth by how much light is prevented from going through the well
2	• The optics use light emitting diodes (LEDs) that produce light at the appropriate wavelengths, and silicon photodetectors to capture the transmitted light • The system is self-calibrating

Waste Collection Station

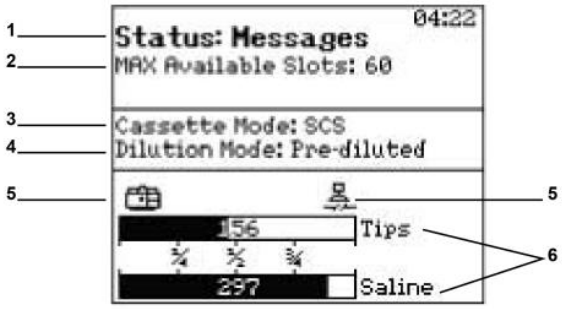
1	• Access the Waste Collection Station by opening the waste collection door on the front of the VITEK 2 instrument.
2	• Keep the Waste Collection Station door closed except when test cards are being removed from the station.

Keypad and Screen

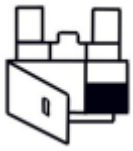


1	**Option Buttons:** • Use these buttons to select menu options or other specified functions
2	**Undo Key:** • Use it to cancel the last action performed
3	**Previous Screen Key:** Use this key to: • Exit from a screen or function to its menu • Return to a previous screen in a function • Go from a sub-menu to its previous menu • Go from the Main Menu to the Status screen
4	**Help (?) Key:** • Press this key at any time to access the error/message queue
5	**Arrow Keys**: Use these keys to: • Scroll a screen or menu • Move the cursor on screen **NOTE:** When arrow keys are active, their icons appear on the display
6	**Enter Key:** • Use this key to complete data entries, or when instructed to do so on a screen
7	**Numeric Keys:** • Use these keys to enter a number onto a screen

Instrument Status Field



1	**Status Field:** • OK-This status means that all of the subsystems in the instrument are working normally, and that the instrument is ready to accept test cards • Warming-This status is seen after the instrument is turned on. It means that the incubation temperature in the Reader Station has not reached its specified temperature. Test cards cannot be processed until this status changes to OK • Messages-This status indicates that there is an error message in the error/message queue that has not been viewed. Press the Help (?) key to view the error/message queue • Errors-This status appears after the error/message queue is accessed if the error condition has not been resolved. This status can be cleared only by resolving the condition that generated the original message

<table>
<tr><td></td><td colspan="3">• Cleaning-This status indicates that either all four boats, or at least one carousel section, have been removed for cleaning. Test card processing cannot resume unless all carousel sections, or at least one boat, are replaced</td></tr>
<tr><td>2</td><td colspan="3">MAX Available Slots field:
• Indicates the number of unoccupied slots in the instrument
• You can load one or more cassettes containing up to that number of test cards
• If you load more than that number, some of the test cards will not be processed unless additional slots become available by the time the test cards reach the carousel</td></tr>
<tr><td>3</td><td colspan="3">Cassette Names Field:
• When the instrument is in Cassette Only mode (VITEK 2 Status Screen in Cassette Only Mode), this field displays the name of the most recently used cassette. That cassette name is applied to all cassettes</td></tr>
<tr><td>4</td><td colspan="3">Dilution Mode Indicator:
• The Dilution Mode Indicator field (VITEK 2 Status Screen in Cassette Only Mode) displays when the instrument is in Cassette Only mode
• The field then tells you whether the instrument is set to the Automatic or Pre-Diluted dilution mode
• This field should be checked before loading a cassette</td></tr>
<tr><td rowspan="5">5</td><td colspan="3">Status Screen Icons:</td></tr>
<tr><td>  </td><td>VITEK 2 Instrument Icon</td><td>This icon represents the VITEK 2 instrument. It shows when one of the access doors is open. These include the front access door on the front of the instrument, and the top-right access door.</td></tr>
<tr><td>  </td><td>Cassette Icon</td><td>Indicates a cassette is processing through the Bar Code Reader and Button Memory Reader stations. Its presence reminds you to stay near the instrument to ensure that the cassette does not experience any load errors.</td></tr>
<tr><td>  </td><td>Power Fail Icon</td><td>Indicates that the instrument is being powered by the UPS battery only. While the instrument is in this condition, no new cassettes may be loaded. Cassette processing continues for 20 minutes, or until the UPS battery runs low, whichever comes first.</td></tr>
<tr><td>  </td><td>Low Battery Icon</td><td>Indicates the UPS has low batteries. All processing is halted immediately.</td></tr>
</table>

		Lost Communications Icon	Indicates the instrument has lost communications with the host computer. The amount of time after host communications has been lost before an error is generated, is 1 hour
7	**Monitoring Pipette Tips and Saline:** • For each disposable, the Status screen displays a bar graph and a number (Pipette Tips Status) • As the disposables are used, the bar graphs begin to decrease • The graphs are marked to show levels of ¼, ½, and ¾ capacity • The number associated with the graph (156 in Pipette Tips Status) decreases at the same time • When the number goes under 40, the value changes to Low		

INTERPRETATION OF RESULTS:

- Refer to card specific VITEK 2 procedures for the interpretation of results

REPORTING INSTRUCTIONS:

- Refer to card specific VITEK 2 procedures for the reporting of results

CROSS-REFERENCES:

NA

REFERENCES:

1. bioMérieux. (2020-04). *VITEK 2 Instrument User Manual*, 041387-02

APPROVAL:

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Date

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Director, Laboratory and Diagnostic Imaging Services

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	01 Oct 24	Initial Release	L. Steven