PROGRAM Standard Operating Procedure – Laboratory Services	
Title: MIC70300 – VITEK DENSICHEK	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 Issuing Authority	Date Approved:
Accreditation Canada Applicable Standard: NA	

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GUIDING PRINCIPLE:
The VITEK DENSICHEK instrument is an accessory intended for use with the VITEK 2 to measure microorganism suspensions for AST and ID testing. The DENSICHEK measures the optical density of a microorganism suspension and provides values in McFarland units, proportional to the microorganism concentrations. DENSICHEK is intended to measure bacterial suspensions in 0.45-0.50% saline prepared in a polystyrene test tube.

PURPOSE/RATIONALE:
This standard operating procedure provides instructions on the use of the VITEK DENSICHEK and maintenance procedures applicable to the device.

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

SUPPLIES:
- 12 x 75 mm Polystyrene Test Tubes and Test Tube caps
- Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)

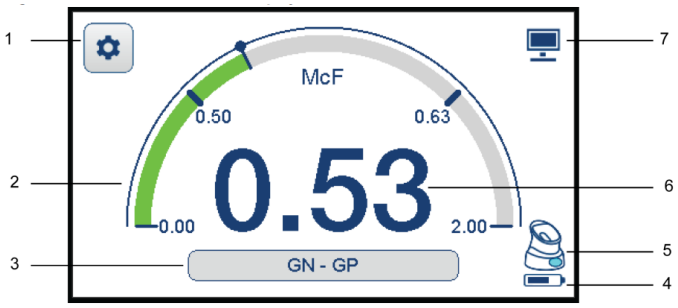
EQUIPMENT
- VITEK DENSICHEK Pod
- VITEK DENSICHEK Display Base

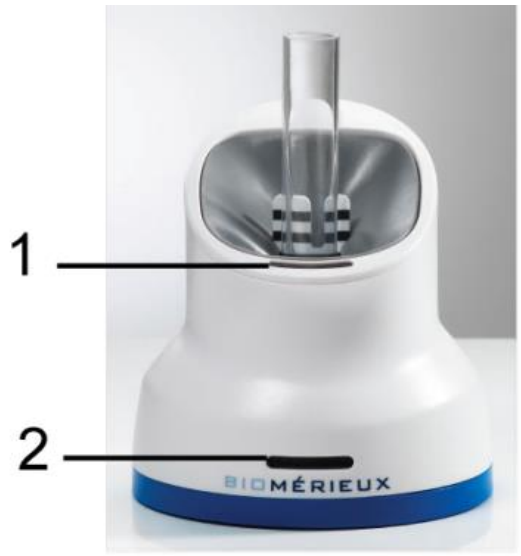
ENVIRONMENTAL CONTROLS:
- 15°C to 30°C
- 20% to 80% non-condensing

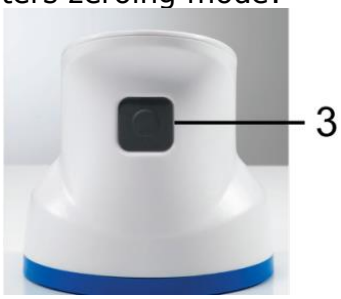
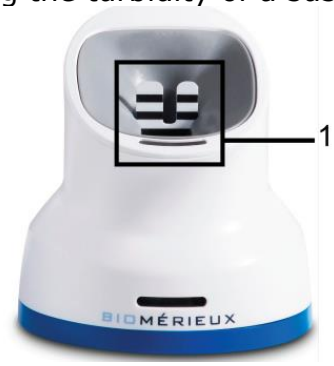
QUALITY CONTROL:

- The VITEK DENSICHEK should be zeroed every day to ensure accurate results are obtained throughout the day
- Calibration of the optics contained within the Pod should be performed monthly using the McFarland References

PROCEDURE INSTRUCTIONS:

Step	Action
VITEK DENSICHEK components	
1	The main components of the VITEK DENSICHEK include the Display Base, the Pod and the McFarland Reference Standards.
2	**Display Base:**  • The Display Base synchronizes to and charges the Pod • This base has a display screen that displays the McFarland reading measurement of the tube inserted into the Pod • When a Pod is synchronized to a Display Base, the McFarland Status light on the Pod matches the McFarland Meter color on the display screen • The Display Base includes a touch screen that consists of the following options:  1. Configuration button 2. McFarland Range Meter 3. Card Type button 4. Pod Battery Life icon 5. Pod Pairing Color icon 6. McFarland Value (Example:0.53 McFarland Reading) 7. PC Connection icon • Users can tap the Card Type button on the bottom of the display to select the appropriate card type

3	**The Pod:**  • The Pod optically reads the turbidity of a microorganism suspension and sends the information to the base unit, so the user has an assessment of the suspension • The Pod is intended to be used with polystyrene test tubes • The Pod has two lights on the front: one for the McFarland Status (1) and one for the status of the Pairing Connection to the base and the Pod (2) • The McFarland Status light corresponds with the McFarland value of the suspension: ➢ A green light indicates that the suspension is within the selected card type performance range ➢ A red light indicates that the suspension is above the selected card type performance range ➢ A yellow light indicates that the suspension is below the selected card type performance range ➢ No light indicates that a suspension is being measured with the N/A card selected, that the pod is in the process of taking a McFarland measurement, or that no measurement is in progress • The Pairing Connection light demonstrates connectivity by: ➢ A blinking red light or solid colored light that does not match that of the base unit indicates that the Pod is not synchronized to the base unit, or it is out of range from the base unit ➢ A solid colored light matching that of the base unit indicates that the Pod is synchronized to the base unit ➢ No illumination of the light indicates that the Pod is not charged ➢ A blinking colored light (excluding red) indicates that the Pod entered Power Save mode. If you want to exit Power Save mode, insert a test tube into the paired Pod, tap the display screen, or remove and re-seat the Pod on the base unit. The Pod will turn on again

	• The Pod contains a button on the back called the Pod Button. If the button is held down for approximately three seconds after the reading period has ended, and, while a saline tube or 0.0 McFarland reference is inserted, the Pod enters zeroing mode:  • A contrast plate is included with the Pod. The contrast plate can be used to aid in assessing the turbidity of a suspension:  **NOTE:** This contrast plate cannot be used as an alternative manual inoculation measurement method
4	**McFarland References:** • The McFarland References verify the calibration of the optics contained within the Pod • These references are dual-vials and labeled 0.0, 0.5, 2.0, and 3.0 McFarland • The McFarland References are used for the monthly DENSICHEK calibration

Step	Action
Zeroing the VITEK DENSICHEK	
1	Insert a saline-filled tube free of damage, scratches, or smudges into the front tube location of the Pod and press all the way down.
2	Rotate the tube for the full 2 second reading period, indicated by the dots on the screen. A numerical value is displayed.
3	If a value of 0.00 is not displayed, press and hold the button on the back of the Pod for approximately three seconds. The Tube Light will flash and the two second reading period begins. Rotate the tube for the full 2 second reading period, and 0.00 will appear on the screen.
4	If the value is 0.00, this indicates that the test tube is zeroed, and you can begin preparing suspensions.

Step	Action
Preparing organism suspensions	
1	When preparing a test tube to measure the McFarland value of a cultured isolate, you must select the correct range type for the VITEK card being setup. Refer to MIC70420-VITEK 2 Card Job Aid for specific card ranges.
2	Ensure the Pod is paired with the base by verifying that the Pod and the Display Base both have the same solid color pairing light.
3	Press the Card Type button on the Display Base screen, until the desired card type appears.
4	Ensure the test tubes are free of damage, scratches, and debris.
5	Select a tube and fill with 3 mL of saline. Add the microorganism to the saline-filled tube, cap the tube and mix on the vortex until a homogenous solution is achieved.
6	Insert the prepared sample into the front tube location of the Pod and press it all the way down. Once the instrument begins the two second reading period, designated by the dots on the Display Base screen, rotate the tube for the full 2 seconds. The McFarland value is measured and displayed on the Display Base screen.
7	If the #.## screen appears on the Display Base screen, this means either the swab is blocking the lens, a clump of specimen is blocking the lens, or the suspension is too heavy.
8	• A green light indicates that the suspension is within the selected card type performance range • A red light indicates that the suspension is above the selected card type performance range • A yellow light indicates that the suspension is below the selected card type performance range
9	Refer to MIC70200-VITEK 2 ID and AST Cards, MIC70210-VITEK 2 YST Card, MIC70220-VITEK 2 NH Card or MIC70230-VITEK 2 ANC Card if the McFarland suspension needs to be adjusted. **NOTE:** Saline should never be added to the tube directly from the dispensette **NOTE:** The sample tube should be removed from the Pod before adding saline to the suspension
10	Remove the suspension for ID and AST testing.

Step	Action
VITEK DENSICHEK cleaning	
1	**Cleaning the Display Base Touch Screen**: • Wipe the Display Base Touch Screen using a Chlorox wipe • Dry with a dry gauze square
2	**Cleaning the Display Base and Pod**: • Wipe the Display Base and the Pod using a Chlorox wipe • Allow the devices to dry • Perform a McFarland Reference Check

3	**Cleaning the Pod Windows:** • Remove Pod from the base • Dampen a cotton swab with 10% bleach solution and then squeeze out any excess liquid • Carefully wipe each window of the front tube location (1):  **NOTE:** Be cautious not to bend any parts inside • Visually inspect the tube locations to ensure no debris remains • Allow Pod to completely air dry • Perform McFarland Reference Check

Step	Action
Performing McFarland Reference Checks	
1	Ensure the McFarland References are free of damage, scratches, and debris before use.
2	Insert the 0.00 McFarland Reference into the instrument so that the tube with the McFarland Reference value faces you and is in the front tube location of the Pod.
3	The device illuminates the tube and measures the McFarland Reference. The McFarland value appears on the screen, along with the LOT number of the McFarland Reference .
4	Press and hold the button on the back of the Pod until the Tube Light flashes and the two second reading period begins. After the reading period ends, the McFarland value appears as 0.00 on the screen.
5	Insert the next McFarland Reference into the instrument.
6	When the screen displays the McFarland value, confirm that the value displays with a green colored meter gauge. If the meter gauge displays as the color red, the McFarland Check has failed. Clean the McFarland Reference tube and try again. If the problem persists, try another McFarland Reference set or notify the Technical Supervisor for assistance.
7	Document the value on MIC70110-Maintenance Record-VITEK 2.
8	Remove the McFarland Reference. The McFarland meter disappears when the tube is removed.

9	Repeat steps 5 to 8 for each McFarland Reference (0.5, 2.0, 3.0).
10	The McFarland Reference check is complete.
11	Values for McFarland References should be:

McFarland Reference	Acceptable Range	Explanation
0.0 McF	N/A	This McFarland Reference must be used before inserting a 0.5, 2.0, or 3.0 McFarland Reference
0.5 McF	0.39 - 0.61 McF	This value represents the McFarland value for GP/GN cards
2.0 McF	1.81 - 2.19 McF	This value represents the McFarland value for YST cards
3.0 McF	2.75 - 3.25 McF	This value represents the McFarland value for NH and ANC cards

CROSS-REFERENCES:

- MIC70110-Maintenance Record-VITEK 2

REFERENCES:

1. bioMerieux. (2022-02). *VITEK DENSICHEK User Manual*, 048641-02

APPROVAL:

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Date

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REVISION HISTORY:

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