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	Quality Manual	
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Prepared by QA Committee		
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VITEK MANUAL

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Vitek 2 version 9.02 System Overview:

Vitek 2 is now divided into 3 subsystems which can be found on your PC desktop.

1. FLEXprep
 - a. For programming and loading isolates onto the Vitek instrument
2. Vitek 2 Web
 - a. For reviewing results and editing isolate data
3. Vitek 2 Systems
 - a. For detailed configuration and utility setup



The main navigational areas of the Vitek 2 Web system include:

1. Worklist
2. Cassette View
3. Patient View
4. Tools
5. Full screen
6. Help

To begin if the system has been logged out:


Press Ctrl-Alt-Delete.

To log into windows:

Enter Username: labsuper
Enter Password: Lab_Super

To log into the Vitek 2 system:

Find FLEXprep or Vitek 2 Web or Vitek 2 Systems on desktop
Enter Username: labsuper
Enter Password: Lab_Super

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Set Up of Vitek2 Cards:

Before each daily use, check Densichek or DensiCHEKplus with the appropriate standards.

For Densichek Model:

Densichek: reading within +/- 0.1 of the value printed on the Bioré standard tube.

Once monthly or as needed if McFarland standard reads out of range:

1. Press the adjustment button on the right side of the Densichek and insert the Calibration Standard tube and release the button.
2. Turn the standard one full rotation within the specified two second time interval.
3. The reading should be within +/- 0.1 of the value printed on the Calibration Standard tube.
4. If calibration fails, the reader cannot be used and must be returned to Bioré for repair.

For Densichk Plus Model:

DO NOT VORTEX DensiCHEKplus standards, invert tube to re-suspend.

DensiCHEKplus glass setting: zeroed to 0.00 McF standard, 0.5 McF standard within range of 0.44 to 0.56.

Occasionally the instrument may freeze. To reboot, remove then replace the batteries.

NOTE: it is important to rotate the tubes during reading.

Press the POWER button.


1. Press the MENU button.
2. Press the green READ button to move the upper flashing triangle to "GLASS".
3. Press the MENU button to save the setting.
4. To set the "blank" value, insert and turn the DensiCHEKplus Standards kit 0.0 McF standard one full rotation. If the reading does not occur, press the READ button to initiate reading and again turn the 0.0 McF standard one full rotation during reading. If the reading is not zero, press the "ZERO" key and rotate the 0.0 McF standard again during reading.

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5. Remove and reinsert the DensiCHEKplus Standards kit 0.0 McF, turning the tube one full rotation to check that it is zeroed correctly.
6. To set your 0.5 McFarland value, clean the 0.5 McFarland standard and invert 6 times to re-suspend. Insert and turn the 0.5 McFarland standard one full rotation. If the reading does not occur, press the READ button to initiate reading and again turn the 0.5 McFarland standard one full rotation during reading. Acceptable reading range for the 0.5 McFarland standard is 0.44 to 0.56.
7. If calibration fails, the reader cannot be used and must be returned to Bioré for repair.

Set zero reading for plastic tubes

1. Press the MENU button.
2. Press the READ button to move the upper flashing triangle to PLASTIC.
3. Press the MENU button to save the setting.
4. Insert and turn the blank plastic saline tube one full rotation. If the reading does not occur, press the READ button to initiate reading and again rotate the blank saline tube during reading. If the reading is not zero, press the “ZERO” key and rotate the blank saline tube again during reading.
5. If calibration fails, the reader cannot be used and must be returned to Bioré for repair.

McFarland Dilution of Organism:

For Gram negative bacilli, Staphylococcus species and Enterococcus species adjust McFarland turbidity to 0.5 to 0.63(± 0.1). For Haemophilus species, Neisseria species and Eikenella species adjust turbidity to 2.7 to 3.3 (± 0.1).

Set DENSICHEK PLUS to plastic tube setting for isolate suspensions


1. Use fresh 18 hour culture of organism.
2. Subculture frozen or freeze dried isolates twice before setting up any Vitek 2 cards.
3. Place a small barcode label near the top of a 3ml Vitek saline tube.
4. Inoculate organism into 3ml Vitek Saline tube, vortex and invert the tube 2 to 3 times to uniformly suspend inoculum.
 - IMPORTANT – cap tubes with lids during vortexing
5. Using the Densichek or DensiCHEKplus, insert and turn the tube one full rotation.
6. For heavy suspensions use additional saline from Vitek tubes to dilute.
7. Cards must be filled within 15 minutes of inoculum preparation.

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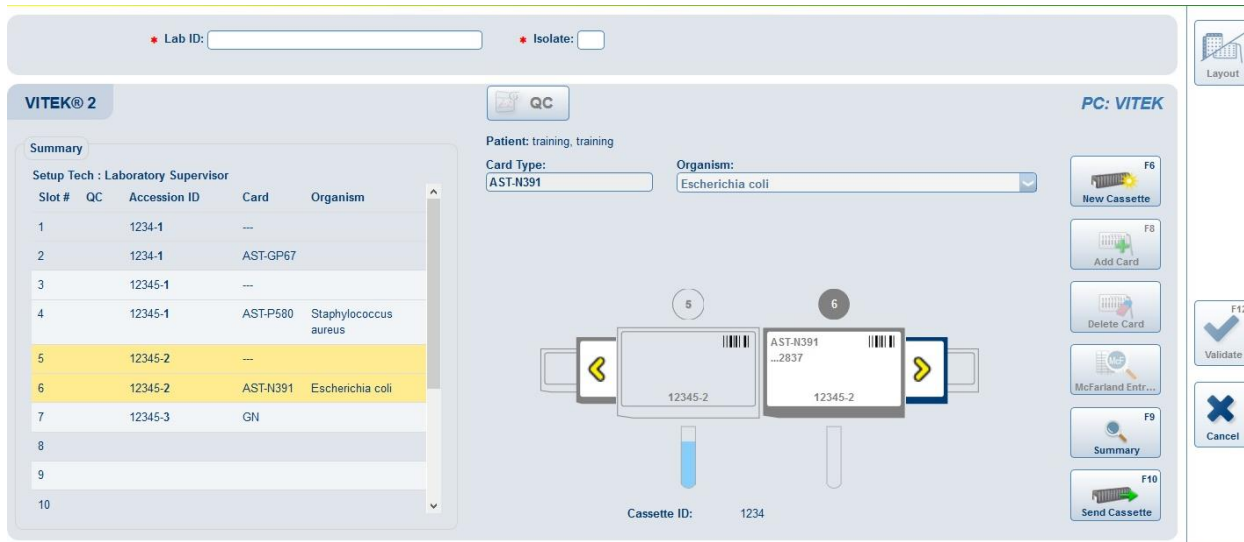
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8. Card types include Identification and Antimicrobial Susceptibility Testing (AST).

Programming on FLEXprep



Useful keys:

- F6** New cassette
- F9** Alternate through screens for editing/reviewing cassette
- F10** Send cassette information to Vitek 2 systems


1. Locate FLEXprep on desktop.
2. Login using username: labsuper
 Password: Lab_Super
3. Under “Cassette ID” scan or enter cassette ID
 - a. If message “cassette ID is not unique” pops up on the screen, this means the cassette has been used that day. The unique ID of the cassette will ensure no other tech is using the same ID simultaneously.
 - b. Click OK to delete all information previously on cassette.
4. For ID cards only, use only the inoculum tube.
 1. Place the inoculum tube into the cassette.
 2. Use the barcode reader to scan the order number. The isolate number defaults to “1”. To change the isolate number type in the new isolate number and press the enter key.

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3. Scan the Vitek ID card barcode and insert the blue tube portion (hockey stick) of the Vitek card into the inoculum. Always check the left side summary screen (highlighted in yellow) to check current positions.
 4. If you have additional cards to set up, press F12 (validate) to move to the next position. Otherwise, press F9 to review the cassette information. Carefully check that the LIS order number, isolate number, card type and carrier position match the F9 summary screen. Press F9 again if you need to return to the cassette to add or alter any data.
 - a. Note: to toggle between slot numbers on the cassette, use the ← and → arrows highlighted in yellow.
 - b. To edit isolate date after you have verified it (F12) you must click “delete card” on the right hand side and rescan the isolate and card information.
 5. After ensuring all information on summary screen is correct and matches your carrier, press F10 to send cassette information to Vitek 2 instrument.
 - a. A popup will say “All cassette data will be sent to this instrument, do you want to send cassette?” Click OK.
 - b. A popup should come up immediately that reads “Cassette data sent successfully” Click OK.
5. For ID cards mated with susceptibility cards, use the inoculum tube and an empty 12x75mm tube.
1. For ID with susceptibility cards, place the inoculum tube followed by an empty tube into the cassette.
 2. Use the barcode reader to scan the order number. Change the isolate number if needed, as above.
 3. Scan the Vitek ID card barcode and insert the blue tube portion (hockey stick) of the Vitek card into the inoculum. Press F8/Add Card to add susceptibility card.
 4. Scan the susceptibility card barcode and place the gray tube portion (hockey stick) of the Vitek card into the empty tube.
 5. Always check the left side summary screen (highlighted in yellow) to check current positions.
 6. If you have additional cards to set up, press F12 (validate) to move to the next position. Otherwise, press F9 to review the cassette

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information. Carefully check that the LIS order number, isolate number, card type and carrier position match the F9 summary screen. Press F9 again if you need to return to the cassette to add or alter any data.

- c. Note: to toggle between slot numbers on the cassette, use the ← and → arrows highlighted in yellow.
 - d. To edit isolate date after you have verified it (F12) you must click on the card for the isolate you wish to change and select “delete card” on the right hand side and rescan the isolate and card information. (the isolate number will automatically increase by one every time you scan the isolate number unless you refresh the screen, manually change back to the correct isolate number)
6. After ensuring all information on summary screen is correct and matches your carrier, press F10 to send cassette information to Vitek 2 instrument.
 - a. A popup will say “All cassette data will be sent to this instrument, do you want to send cassette?” Click OK.
 - b. A popup should come up immediately that reads “Cassette data sent successfully” Click OK.
6. For susceptibility cards only, use the inoculum tube and an empty 12x75mm tube.
 1. Place the inoculum tube followed by an empty tube into the cassette.
 2. Use the barcode reader to scan the order number. Change the isolate number if needed, as above.
 3. Scan the susceptibility card barcode. FLEXprep will automatically assign the susceptibility card to the empty tube position following the inoculum tube. Place the gray tube portion (hockey stick) of the Vitek card into the empty tube.
 4. A VitekMS identification will link to the susceptibility card through the Myla interface.
 - a. NOTE: If there is no VitekMS identification, you must enter an identification in the “Organism” field on FLEXprep. Either type in the organism name or use ∨∧ arrows to find organism ID.

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4. **Check that the cassette is properly seated, all caps are off the tubes, Vitek card hockey sticks are inside the suspension and susceptibility tubes and all cards are even.**
5. After loading the cassette, wait for the happy sound. If you do not hear the happy sound, the cassette will return to the loading dock where it will remain for **10 minutes only**. If no action is taken within 10 minutes, the cassette will be processed. Cards with load errors will **NOT** be processed and will return to the loading dock. Remove the cassette, correct errors and return to the Vitek2 loading dock.

Batch loading cassettes into the Vitek 2 system:

If three or four cassettes are ready to load at the same time, you may select Batch loading.

1. Check to be sure tips, saline and ID/Sens slots are enough for all cards in the batch.
2. Access the Batch Load function on the main menu.
3. If three or four boats are available, the screen will ask you to choose 3 or 4 cassettes to load.
4. The screen will indicate Load cassette number 1, etc. Follow the onscreen instructions.
5. The boats will be accepted one by one and then transported through bar coding, filling and reading one by one.
6. Be sure to listen for the happy sounds for each cassette, before leaving the instrument. If you do not hear the happy sound, the cassette will return to the Cassette loading Station. Remove the cassette and place it back on the Smart Carrier station. Correct errors and return to the Vitek2 loading dock.

Unloading Vitek Cassettes from Vitek 2 system

1. Flashing green light at loading door signals a cassette is ready for unloading
2. Open the loading door
3. Remove cassette
4. For each isolate, use the “straw” from AST dilution tube to inoculate a purity plate

Reviewing cassette after unloading on Vitek


It is imperative that all isolate information is logged on FLEXprep and sent (F10) to Vitek instrument.

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The Vitek will NOT alarm if there is no isolate information available, it will continue to perform testing based on the cards on the cassette (ID/AST).

Cassette view is a list of every cassette loaded onto the Vitek instrument. You can filter through the list by cassette status/ load date/ Vitek #

To ensure your cassette information was sent to Vitek successfully:

1. Click on Vitek 2 Web on your desktop
2. Click “Cassette View” on toolbar
3. Click Funnel icon to remove all filters
4. Click Cassette Status and filter by incomplete
 - a. Any cassette loaded on Vitek instrument with missing or incomplete information will show up here, you must correct the data before discarding the tubes on your cassette
5. Select your isolate and click edit (find your isolate and select edit next to cassette and select accession ID)
6. You can now enter accession ID/organism ID/ isolate # etc.
7. Click OK
 - a. Isolate should no longer be under “incomplete”

Note: If you notice incomplete cards after you have thrown out tubes in your cassette then you must delete/eject those cards and prepare your tubes again.

- Check your worklists often in SOFT LIS to see what work is pending

Vitek 2 Maintenance:

1. Daily instrument maintenance
2. Daily review
3. Daily DensiCHEK calibration
4. Monthly DensiCHEK cleaning
5. Monthly maintenance
6. Pipette/Saline replacement
 - a. Dispenser/pipetter diagnostic test

Daily instrument maintenance:


1. Remove the waste tray and discard the cards. Replace waste tray carefully to ensure it is properly seated.
2. At the instrument, press the “Menu” button, followed by “Display instrument QC status” button.
3. Note section A and B temperatures and the optical system status and record in the LIS Vitek QC.

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4. Press the “Menu” button twice to return to the main screen.

Daily review


Review cards setup on previous workday to identify incomplete cards/ missing data/ terminated cards.

1. From the toolbar, select WORKLIST.
2. Click “Clear all filters” (Large Funnel Icon)
3. Test date → change to yesterday’s date → Click “apply filter”
4. Isolate status → select “qualified” → Click “apply filter”



An orange and red square indicates missing data:

1. No patient name:
 - Check the LIS: if there is no isolate number, add it now. The download should be automatic. If there already is an isolate number or if there was no automatic download after you have added the isolate number, you will need to do a manual download (see below).
2. No organism identification/low discrimination:
 - Print out reports.
3. No accession number/isolate number/patient information
 - If there is no patient identifier associated with a card then delete the isolate as identity can no longer be confirmed. Technologists will have to check their pending work to see which isolate is missing information.
4. Terminated antibiotics
 - Click Card Status → Select “Terminated” → Apply filter
 - Print out reports

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Note: as the orders are corrected they will disappear from this work list

To print data/preliminary worklist:

1. Select data you would like to print using check boxes on left hand side of worklist or click “select all”
2. Click printer icon → Select “lab report” → Click printer icon again

Note: Reviewed order results remain in the active session for a set number of days before they automatically transfer to long term storage. Once an order is in long term storage the results may not be re-interpreted.

Daily DensiCHEK PLUS calibration



Performed by individual benches; each densicheck PLUS’s calibration must be checked each morning before use and recorded in the LIS QC program.

Each standard must fall within their defined acceptable range.

Standard	Acceptable Range	
0.5 McF	0.44	0.56
2.0 McF	1.85	2.15
3.0 McF	2.79	3.21

NOTES:

- The densicheck PLUS **MUST** be set to glass or plastic according to the tube Being used.
- Mix standards well by inversion
- When reading or blanking, always slowly rotate the tube one full rotation while The instrument displays a series of dashes. This will help to reduce the variation in readings due to irregularities in the tubes.
- When making suspensions, periodically recheck a blank plastic tube to verify zero is set correctly.
- See [Densicheck PLUS diagram](#) below for an explanation of display and keypad functions

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Densicheck PLUS Model:

Display and Keypad Functions

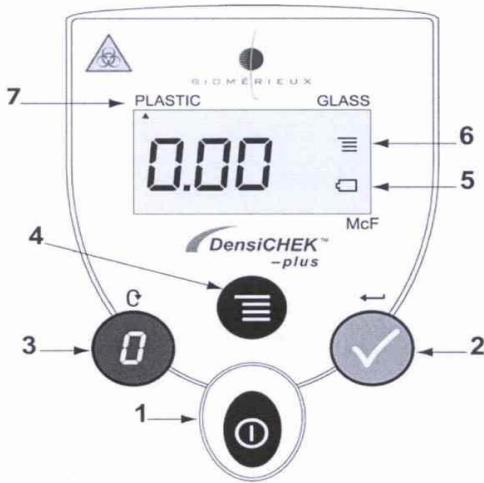



Figure 1-3: DensiCHEK™ Plus Display

- 1 – Power Key
- 2 – Read/Enter Key. Allows the user to manually initiate a reading. In menu mode, selects a menu option.
- 3 – Zero/ Scroll Key. In measurement mode, sets the instrument to zero. In menu mode, scrolls through menu options. Also scrolls when entering or editing the time.
- 4 – Menu Key. Enter/Exit the menu mode.
- 5 – Battery Low Indicator. Displayed when 10% battery life remaining for alkaline and 2% for NiMH is remaining. When flashing, the batteries are too low to complete measurements.
- 6 – Menu Indicator. Displayed when in Menu Mode.
- 7 – Tube Type Setting. Indicates one of two tube type settings. The instrument default is set to Plastic. If the left triangle is displayed, the PLASTIC tube setting is being used. If the right triangle is displayed, the GLASS tube setting is being used.

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Changing pipette tips and saline:

Pipetter/Diluter Accessory Kit (tips and tubing) and 0.45% saline bag.

Detailed procedures for changing VT2 tips and saline can be found in the VT2 Instrument Manual. (Section 7.3 to 7.9) After changing the tips and saline, a Dispenser/Pipetter diagnostic Test must be performed (**not** the Dispenser/Pipetter **Volumetric** Test), following the detailed procedures in the VT2 Instrument Manual. (Section 8.19 to 8.20).

A warning alarm will sound when the instrument tip and/or saline count drops below 40 indicating low stock. Do not change the tips and saline until approximately 10 to 15 tips are left. If there are an insufficient quantity of tips and/or saline, the cassette will not be processed and will return to the Vitek2 loading dock. Load the cassette in the other instrument.

If there are cards in the transport system, you will have to wait until they have been finished before you can change the tips and saline.

Change the tips and saline as follows:

Enter the lot number and expiry dates of the saline and Pipetter/Diluter Accessory kit in the Vitek QC program.

At the Vitek2 instrument screen press:

“Menu”, “Utilities”, “Maintenance”, “change pipette tips”.

At the prompt “About to change pipette tips. Do you wish to continue?” Choose “Yes” or, to stop, choose “No”.

If you choose “Yes”, the Vitek2 screen will show “Proceed with pipette tip change”.

Use aseptic technique (wear gloves) to avoid contamination and fingerprints on the saline dispensing tube.



1. Tip the Vitek2 pipette holder upward, then lift up and remove it.
2. Discard remaining tips.
3. To open the pipette tip container, hold the front and back together (to avoid it springing open), then lift up the top flap.

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4. Invert the Vitek2 tip holder upside down over the tip container and flip both over, allowing the tips to fall into the Vitek2 tip holder.
5. If the tips are not even, tap the holder gently on the side with your hand or use a sterile loop to even the tips.
6. Reseat the Vitek2 tip holder and tip it back into place.
7. Press “Done”.
8. On the Vitek2 screen you will see “Performing Pipetter self-check”.

If more detailed instructions are needed, refer to the Vitek2 online manual and/or the Vitek2 Instrument User’s Manual.

At the Vitek2 instrument screen press: “change saline”.

At the prompt “About to change saline. Do you wish to continue?” Choose “Yes” or, to stop, choose “No”. If you choose “Yes”, the Vitek2 screen will show “Proceed with saline change”.

1. Move the dispenser tube locking mechanism backward and remove the used dispenser tube, filter lines and saline bag.
2. Unwrap and place the saline bag onto the Vitek2 platform.
3. Using the replacement tubing and dispenser tube from the Pipetter/Diluter Accessory kit, move the dispenser tube locking mechanism backward and aseptically insert the new dispenser tube making sure it is properly seated..
4. Release the locking mechanism.
5. Replace the filter.
6. Remove the covers from the remaining tubing and saline bag, and insert the tubing tip into the saline bag. Make sure tubing is not be twisted.
Be carefully not to drop the tip covers into the instrument.
7. Press the primer button to fill the tubing and the dispensing tube to the upper shoulder.
8. Lift the saline bag and hold it below the level of the primer button. Press the primer button slightly to lower the saline level to the lower shoulder of the dispenser tube.
9. Use a Kimwipe to gently clean the dispenser tube. Press “Done”. The instrument will “Perform a dispenser self-check” and return to the maintenance menu, if successful.


If more detailed instructions are needed, refer to the Vitek2 online manual and/or the Vitek2 Instrument User’s Manual.

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Dispenser/pipetter diagnostic test

Perform every time the saline and tips are replaced.

Place 3 mls. Saline in cassette slots 1 and 3, and empty tubes in slots 2, 4 and 5 in a cassette. Smart carrier station entry is not required.

At the Vitek2 instrument screen press:

“Menu”, “Utilities”, “Diagnostics”, “Diagnostics/Pipettor”.

At the prompt “About to perform dispense pipettor test... Do you wish to continue?” Choose “Yes” or, to stop, choose “No”.


If you choose “Yes”. The Vitek2 screen will show “Load test cassette now”.

The dispenser/pipetter diagnostic test is a visual test as well as an electronic test. While the instrument is performing this test, you must open the front left door of the instrument and visually check the saline dispenser for any of the abnormal conditions listed below:

IMPORTANT: Ensure there is no sunlight shining directly on the saline dispenser.

1. Look for repeated back and forth movement while the saline dispense is in the upright position. The saline dispenser should move smoothly up and down when filling each empty tube (positions 2, 4 and 5).
2. Look for saline remaining in the saline dispenser tube when it returns to the upright position.
3. Look for a saline stream and/or drops released from the saline dispenser tube when it is filling with saline.
4. Look for a saline stream and/or drops released from the saline dispenser tube as it returns to the upright position.
5. Look for lower volumes of saline while saline is being dispensed, comparing tubes 2, 4 and 5 to each other. (Tubes 1 and 3 will have somewhat higher volumes).
6. Observe the instrument user interface for Pipetter error 21 or any Dispenser errors.

If more detailed instructions are needed, refer to the Vitek2 online manual and/or the Vitek2 Instrument User’s Manual.


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Monthly Maintenance

1. Ensure that processing of all cards is complete and all cards are ejected from the instrument.
2. MAX available slots must be 120
3. General cleaning of the instrument and its parts can be accomplished with warm water and approved cleaning solutions. Rinse areas well and dry thoroughly. If decontamination is necessary (spill or contamination), use a 10% Sodium Hypochlorite solution. Rinse well and dry thoroughly.

Cleaning Cassettes, Waste card collection tray and Drip Pan

- **Cassettes:**
 1. Turn an empty cassette over so that its underside is facing you
CAUTION: Applying pressure upward can cause damage to cassette memory module.
 2. Apply a slight inward pressure to the plastic tab that extends from the memory module.
 3. At the same time, pull the button memory module away from the cassette.
 4. Clean the metal contacts with an alcohol wipe.
 5. Clean the cassettes with a soap solution.
 6. Rinse in water and dry thoroughly.
 7. Replace the button memory.
- **Waste card collection**
 1. Open the Waste Collection door and remove the Tray.
 2. Empty the Tray into Biohazard bin if any cards are present.
 3. Clean with a soap solution or 10% Sodium Hypochlorite. Rinse in water and dry thoroughly before returning it to the instrument.
 4. Close the Waste Collection door.
- **Drip Pan**
 1. Lower the bottom access door.
 2. Grasp the handle of the drip pan and carefully pull it from the instrument.
 3. Clean with a soap solution or 10% Sodium Hypochlorite and rinse with plain water to remove the soap or Hypochlorite residue.
 4. Holding the pan by its handle, push it into the space provided under the front of the instrument.
 5. Close the access door

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Cleaning Carousel

1. Select: **Main menu> Utilities> Maintenance>Cleaning> Carousel Cleaning.** A screen will appear allowing you to select a Reader (either A or B) Start with Reader A.
2. Carousel Cleaning –Preparing for Section Removal will appear.
3. Select Continue.
4. The following message appears- **Remove incubator access door now.**
5. Open the Waste Collection door for the carousel to be cleaned.
6. Open the top access door for the section to be cleaned.
7. Remove the incubator access cover from the carousel. The message on the screen will change to **Preparing for Section Removal.** The carousel has moving parts that rotate into position. Wait until the carousel stops moving.
8. When the carousel is in position, the screen displays **Remove Section Now.** Remove the carousel section and **Press here after completion** function key to confirm the removal of the section. The carousel turns so you can remove the next section. The message **Preparing for Section Removal** displays on the screen again. Repeat this procedure until all four sections are removed. Carefully replace the incubator access cover.
9. Thoroughly clean the four sections with a soap solution rinse with water and dry completely on clean cart in walk-in **Incubator** or If use **Dryer** then temperature should not exceed to 85°C.
10. Replace the carousel sections by opening the Top Access Door and removing the carousel cover. Select the Main Menu>Maintenance>Cleaning carousel, **Replace Carousel, Yes.** Remove the incubator access cover now, carousel will rotate into position for section replacement. Replace carousel section back into instrument as described in Vitek 2 XL User Manual.
11. Press Done when the section is in place. The carousel turns 90° to move the first section out of the way. The message **Rotating Carousel: Please wait** displays on the screen.
12. Repeat this procedure until all four sections are replaced. Carefully replace the incubator access cover and close top user access door.
13. Perform procedure for Reader B.

Cleaning Boats, Base Pan, Vacuum Seal , Vacuum Chamber and Optics

Cleaning Boats:


1. Access the Boat Cleaning function
2. **Main Menu> Utilities> Maintenance> Cleaning> Boat Cleaning**
3. Press **Remove Boat.**

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4. The system moves a boat to the boat dock and when it is ready for removal a message appears.
5. Open the front access door.
6. A boat will be positioned below the Dispenser/Pipettor Station.
7. Remove the boat and press the **Press here after completion** button.
8. Repeat until all 4 boats have been removed and close the front access door.
9. Perform system shutdown: **Main menu> Utilities> Maintenance>Shutdown**. Turn off power cycle.
10. Clean the boats with a soap solution. Rinse in water and dry thoroughly.
11. While system is tuned off **Exterior, Interior** and **Optics** can be cleaned.

Exterior:

- Limit amount of liquid applied to the surfaces. Ingress of liquid into the instrument could result in loss of instrument function and shock hazard.
- Use Kimtech Wipes with a soap solution or 3-25% Hydrogen Peroxide solution and wipe off any dust and dirt from the top, front and side surfaces of the instrument.
- Wipe off all access doors.
- Use a separate wipe with plain water and wipe the surface again to remove any soap or 3-25% Hydrogen Peroxide residue. Make sure it's dry thoroughly.

Interior (Base Pan, Vacuum Seal, and Vacuum Chamber):

- The **base pan** is the surface on which the boats move. The **vacuum seal** is the bottom surface of the **vacuum chamber** where the chamber makes contact with the boat. Dampen Kimtech Wipes with soap water or 3-25% Hydrogen Peroxide and wipe off any dirt or dust from these areas.
- Using plain water, wipe the same surfaces again to remove soap or 3-25% Hydrogen Peroxide residue.
- Use Kimtech Wipes to dry thoroughly.

Optics:

CAUTION: Do not wear powdered latex gloves while cleaning the optics. The gloves that contain a powder can interfere with the optics.


- Change your gloves
- Open the Waste Collection Doors and Lift the top access doors for both reader A & B.
- This exposes the transmittance optics. Start with **Reader A** optic.
- Using your right hand, grasp the optics unit and Pull down the unit. Inspect the glass on all surfaces for cracks or scratches.
- Clean the glass surfaces Upper (Emitter) and Lower (Detector) using a quality, lint-free lens paper or Kimtech Wipes. It should be cleaned and shiny, If foreign material

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remains, take alcohol wipe make sandwich with lint-free lens paper or Kimtech wipes and repeat Cleaning


- Dry the surface with a lens paper or Kimtech Wipes again.
- Pull up the Optic unit back into place. The units will hit the magnet into place when secured.
- Perform same procedure for **Reader B**
- Close Waste Collection door and Top User Access Door.
Note: Recommendation is to perform Optics cleaning while system is shutdown. Optics Cleaning Procedure can be performed while system is turned on but just make sure there is no cards are running.

Before opening the optics go to **Main Menu> Utilities> Maintenance> Cleaning>Optics Cleaning>**

Now you can open and Perform same cleaning procedure as above.

Once it's completed press **Cleaning completed.**

12. Turn on power cycle and wait until system initialized. Access the **Boat Cleaning** function.
13. Press **Replace Boats.**
14. Open the front access door and replace the boat below the Pipettor Station. Ensure the arrow on the boat is pointing towards machine.
15. Press the **Press here after completion** button.
16. Repeat until all four boats have been replaced.
17. Perform **Optic** Diagnostic Test.
18. Perform **Card Transport** Diagnostic test.

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Monthly Maintenance of Densichek

Cleaning Densichek Plus

The surface of the DensiChek Plus may be cleaned by using a Kimtech Wipes with 3-25% hydrogen peroxide solution.

CAUTION: Do not use alcohol to clean the instrument. Use of alcohol may damage the reading lens.

Test Tube Adaptor and Reading Chamber

The test tube adaptor can be removed by lifting it out of the reading chamber.

1. Remove the test tube adaptor from the reading chamber.
2. Dampen Kimtech Wipes with cleaning solution of 3-25% hydrogen peroxide and clean the adaptor thoroughly.
3. Leave adaptor on lint-free cloth or wipes for 5 minutes to air dry completely.
4. Use a cotton swab and cover with Kimtech Wipes add little amount of 3-25% Hydrogen Peroxide and then squeeze out any excess liquid then clean reading chambers **gently**.
5. Use Kimtech Wipes to clean circular windows on opposite sides to reading chambers.


Cleaning New Densichek with base

Cleaning the Lens

1. Remove Pod from base.
2. Use a cotton swab cover with Kimtech Wipes and little amount of 3-25% Hydrogen Peroxide and then squeeze out any excess liquid. Carefully wipe each window of the front tube location. **Be cautious not bend the metal switch tab.**
3. Carefully wipe the tube light windows at the base of the front tube location. Carefully wipe the RFID window at the base of the back tube location.
4. Visually inspect the tube locations to ensure no debris remains. Allow Pod to completely air dry.

Cleaning the base

1. Use a Kimtech Wipe with 3-25% Hydrogen peroxide and clean the all the surface and touch screen
2. Leave the base for 5 mins to Dry completely.

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Troubleshooting

Biomerieux Technical Support

Contact the Biomerieux Technical Support Customer Service Hotline for all technical support or information.

Technical Support phone #: 1-800-361-7321

They may require the following information which can be found on the front of each Vitek analyzer:

- Customer number: 2013444
- Vitek system number: 152947
- Vitek #1 serial No: VTK2XL 5505
- Vitek #2 serial No: VTK2XL 5462

Manual download from the LIS

1. From the LIS main menu, click on “Interfaces”.
2. Double click on instrument menu.
3. Highlight Myla, click on “Create Loadlist”.
4. “Way of Classifying Orders” choose “All Orders”.
5. Choose “From date”.
6. Enter “From order” number.
7. Click “OK”.
8. Click “Add All”.
9. Click “OK”.
10. To mark order(s) to download:
 - Options:
 1. Use the space bar.
 2. Right click on the order.
 3. Type in the order number.
11. Click on “Download selected Order(s)” icon.

To Search for a Result:


1. From toolbar, select WORKLIST
2. Click “Clear all filters” (Large Funnel Icon)
3. Click “Accession ID”

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- a. Enter or scan lab ID
- b. You can also filter by patient ID or patient name

To change an isolate number:

1. Click on the isolate number field and select the new isolate number.
2. A confirmation window will appear. Choose “OK” or “Cancel”.
3. Click “Transfer isolate data”.

To choose a “Low Discrimination” identification or to change an identification:

1. Click on the “<<Low Discrim>>” field or identification field and select the identification.
2. A confirmation window will appear. Choose “OK” or “Cancel”. If you have chosen “OK” the isolate will be automatically re-analyzed.
3. Click “Transfer isolate data”.

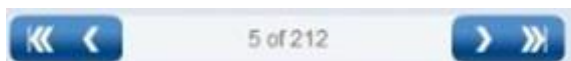
To change the order number:


Changing the order number on VITEK 2XL is not recommended. If there is any confusion of order number mix-up, repeat the ID and/or sensitivity setup. In rare situations, where changing the order number is warranted, follow the procedure below.

1. You can delete the order number by clicking on the order number field and using the backspace or by highlighting the number and pressing the “delete” key.
2. Enter the new order number.
3. A confirmation window will appear. Choose “OK” or “Cancel”. If you have chosen “OK” the isolate will be automatically re-analyzed.
4. Click “Transfer isolate data”.

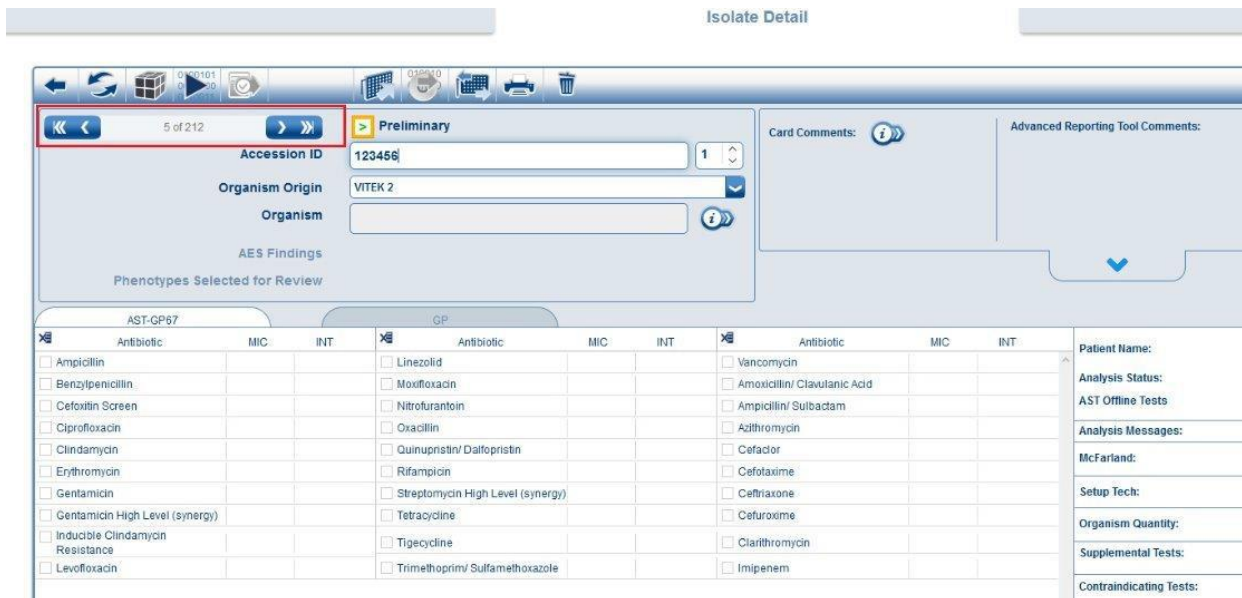
When performing an edit to an order number (also known as an **Accession ID** in VITEK® 2 Software 9.02 in Firefox Web Browser), in the Isolate Detail View, the user is reminded to use good practice and perform the change on one isolate at a time. The recommended workflow when editing the Accession ID, is to click outside the edit box or to press the tab key on the keyboard to save the change, after the edit is complete. The ‘Enter’ key will not apply the change.

DO NOT use navigation arrow keys



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Currently, in the Firefox web browser *ONLY*, the use of the navigation arrow keys (located immediately above the "Accession ID" field name) pushes the edited field (e.g. Accession ID) to the next Isolate in the work list rather than the intended isolate.



To enter on AST Offline test:

1. Click on the "AST Offline Tests field". Choose "Beta-Lactamase +" or "Beta-Lactamase-".
2. A "confirmation" window will appear. Choose "OK" or "Cancel". If you have chosen "OK" the order will be automatically re-analyzed.
3. If you want to transfer a finalized isolate, click on the "Transfer isolate data" icon Click on "Enter Isolate View".

To delete an individual card still "in progress":


1. From the toolbar, select WORKLIST
2. Click "Clear all filters" (Large Funnel Icon)
3. Click on small funnel icon next to "Accession ID"
4. Enter or scan the order number
5. Click Apply Filter
6. Click on order you wish to edit
7. Click on Eject Cards
8. Select whether you wish to eject Isolate or AST card

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9. A confirmation window will appear, choose “OK” or “Cancel”
 - i. Note: this action is not reversible

To delete a completed individual card or entire order (ID card/AST card):

1. From the toolbar, select WORKLIST
2. Click “Clear all information”
3. Click on small funnel icon next to “Accession ID”
4. Enter or scan the order number
5. Click Apply Filter
6. Click on order you wish to edit
7. Click on Delete Isolate
8. Select whether you wish to delete Isolate or AST card
9. A confirmation window will appear, choose “OK” or “Cancel”
 - i. Note: this action is not reversible

Printing Vitek Results

1. From the toolbar, select WORKLIST
2. Click “Clear all filters” (Large Funnel Icon)
3. Click on small funnel icon next to “Accession ID”
4. Enter or scan the order number
 - a. You can also find a report using accession ID/ patient name/ date tested
5. Click Apply Filter
6. Select report(s) you would like to print
 - a. You can batch print by selecting multiple reports
7. Click the printer icon
8. Select “Lab Report” and/or detailed report “AST 67/391/580 Card Detailed Report”
9. Click the printer icon
10. Click OK

Searching for an Order in Long-Term Data Storage:

Note: orders in long term storage may not be re-interpreted.


1. From the toolbar, select TOOLS
2. Select Long-Term Data Storage.
3. Click “Clear all filters” (Large Funnel Icon)
4. Search criteria:

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1. For Patient ID enter MRN.
2. For Accession ID enter order number.
3. Patient last name
4. Test date
5. Click on order.

Quality Control

Instrument QC Status report:

Refer to “Daily Instrument Maintenance”.

To register new shipments of ID/AST cards:

1. Login to Vitek 2 Web
2. From the toolbar, select “TOOLS”
3. Click on “Shipments”.
4. Enter lot number and date received (duplicate lots will all be isolate 1).
5. Check off “certificate of conformance”
6. Click “add shipment”

Note: All QC cards must use only ATCC numbers to be included in the QC program.
Non-ATCC numbers will appear only in the patient data program and cannot be moved to the QC program.

Vitek ID Card QC

QC must be performed on GN/GP upon receipt of new shipment of cards by QC bench.

Note: QC must be performed on both Vitek #1 and Vitek #2 instruments

To program QC of GN/GP cards:


1. Login to FLEXprep
2. Scan or enter cassette ID
3. Click “QC” – FLEXprep will automatically register isolate as QC organism
4. Scan GN or GP ID card
5. Select ATCC strain
 - a. For GP card setup:
 - i. ATCC 700327 Enterococcus casseliflavus
 - ii. ATCC 19258 Streptococcus salivarius ssp. thermophilus
 - b. For GN card setup:
 - i. ATCC 700323 Enterobacter hormaechei

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- ii. ATCC 17666 *Stenotrophomonas maltophilia*
6. *Refer to Programming on FLEXprep section 4 for steps on how to setup and load ID cards*

Vitek Susceptibility Card QC

Vitek 67/391/580 susceptibility cards must have QC performed on receipt of new shipment of cards, weekly, and after Bioré preventive maintenance.

Note: QC must be performed on both Vitek #1 and Vitek #2 instruments

To program QC of 67/391/580 cards:

1. Login to FLEXprep
2. Scan or enter cassette ID
3. Click “QC” – FLEXprep will automatically register isolate as QC organism
4. Scan AST 67/391/580 susceptibility card
5. Select ATCC strain
 - a. For 67 card setup:
 - i. ATCC 29212 *Enterococcus faecalis*
 - ii. ATCC 29213 *Staphylococcus aureus*
 - iii. ATCC 51299 *Enterococcus faecalis*
 - b. For 391 card setup:
 - i. ATCC 27853 *Pseudomonas aeruginosa*
 - ii. ATCC 35218 *Escherichia coli*
 - iii. ATCC 25922 *Escherichia coli*
 - c. For 580 card setup:
 - i. ATCC 29212 *Enterococcus faecalis*
 - ii. ATCC 29213 *Staphylococcus aureus*
 - iii. ATCC BA977 *Staphylococcus aureus*
 - iv. ATCC BAA1026 *Staphylococcus aureus*
 - v. ATCC BAA976 *Staphylococcus aureus*
6. *Refer to Programming on FLEXprep section 6 for steps on how to setup and load susceptibility cards*

Reviewing susceptibility cards with QC deviation


1. From the toolbar, select WORKLIST
2. Click “Clear all filters” (Large Funnel Icon)
3. Click on small funnel icon next to “Accession ID”.
4. Check off 2nd box, “Select a QC reference ID to filter”
 - a. Apply filter
 - i. Note: you do not need to select a specific QC ID, just check the box

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5. Filter again by selecting “QC Dev”
 - a. This will show you all cards that did not pass QC
6. Click to open a card
7. Under card comments, click “edit comment” and enter actions to be taken for failed QC (ex. Repeat card).
8. Print all reports for the QA senior or charge technologist.
9. Click on “Review” icon (check mark)
 - a. Status should be changed from “to be reviewed” (green check mark) to “reviewed” (solid green).



Reviewing susceptibility cards that passed QC

1. From the toolbar, select WORKLIST
2. Click “Clear all filters” (Large Funnel Icon)
3. Click “Accession ID”.
4. Check off 2nd box, “Select a QC reference ID to filter”
 - a. Apply filter
 - i. Note: you do not need to select a specific QC ID, just check the box
5. Click to open a card
6. Click on “Review” icon (check mark)
 - a. Status should be changed from “to be reviewed” (green check mark) to “reviewed” (solid green).



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Approved

QC Reference ID: ATCCBAA977, Staphylococcus aureus

Expected Organism: Staph.aureus BAA977

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Record of Edited Revisions

Manual Section Name: Vitek2 XL

Page Number / Item	Date of Revision	Signature of Approval
New	Aug 31, 2022	

Full document review included in all updates. Biennial review conducted when no revision had been made within 2 years.

Page Number / Item	Date of Revision	Edited by:
Updated monthly maintenance section	Sep 22, 2022	Wayne Chiu
In "To change the order number" section, update the good practice when changing order number (accession ID number) in Vitek 2 Software.	July 22, 2024	Oliver Li

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