PURPOSE: To standardize quality control procedures on the Vitek 2 instrument to ensure proper functioning on a weekly basis and to ensure new shipments of Vitek 2 cards have not deteriorated during shipment.

SUPPLIES:

- ATCC organisms
- Plastic Vitek tubes and caps
- 0.45% Saline
- Sterile swabs
- DensiCHEK Plus
- Vitek 2 and supplies
- Vitek AST-N390 cards
- Vitek AST-GP67 cards
- Vitek GN, GP, NH and YST cards

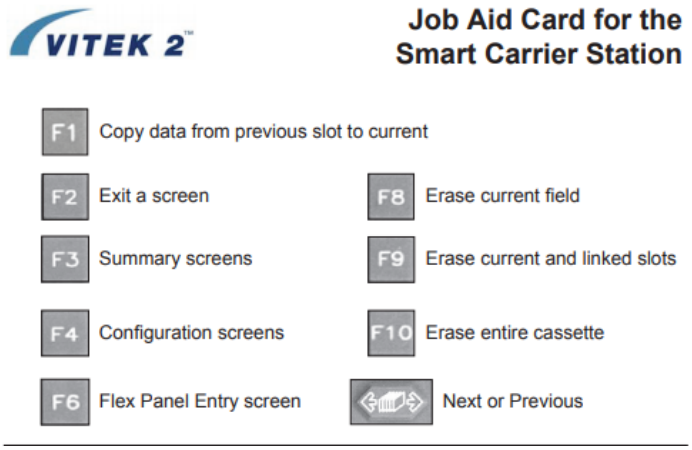
SPECIAL SAFETY PRECAUTIONS:

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

- 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. Universal precautions 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 9-5 technologist, upon receipt of new cards and after bioMerieux 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 – Vitek 2 Quality Control Results Record, with card lot number being tested, card expiry date, date of QC testing and setup technologist's initials. Place on top of the Vitek 2 to be completed the following day.
4	At the SMART CARRIER STATION (SCS): 1. Ensure that the Smart Carrier Station is on. 2. Place cassette on the Smart Carrier Station. Message appears: "Cassette has been processed. Press F1 to erase, any other key to display processed information". Press F1 to erase cassette memory. 3. Cassette ID is SCS and Tech ID is HAWK. At Bench ID, enter QC. 4. At Lab ID: use the "Vitek 2 Job Aid Card for the Smart Carrier Station" to scan the identification barcode of the QC organism you wish to place in the slot of the cassette: 

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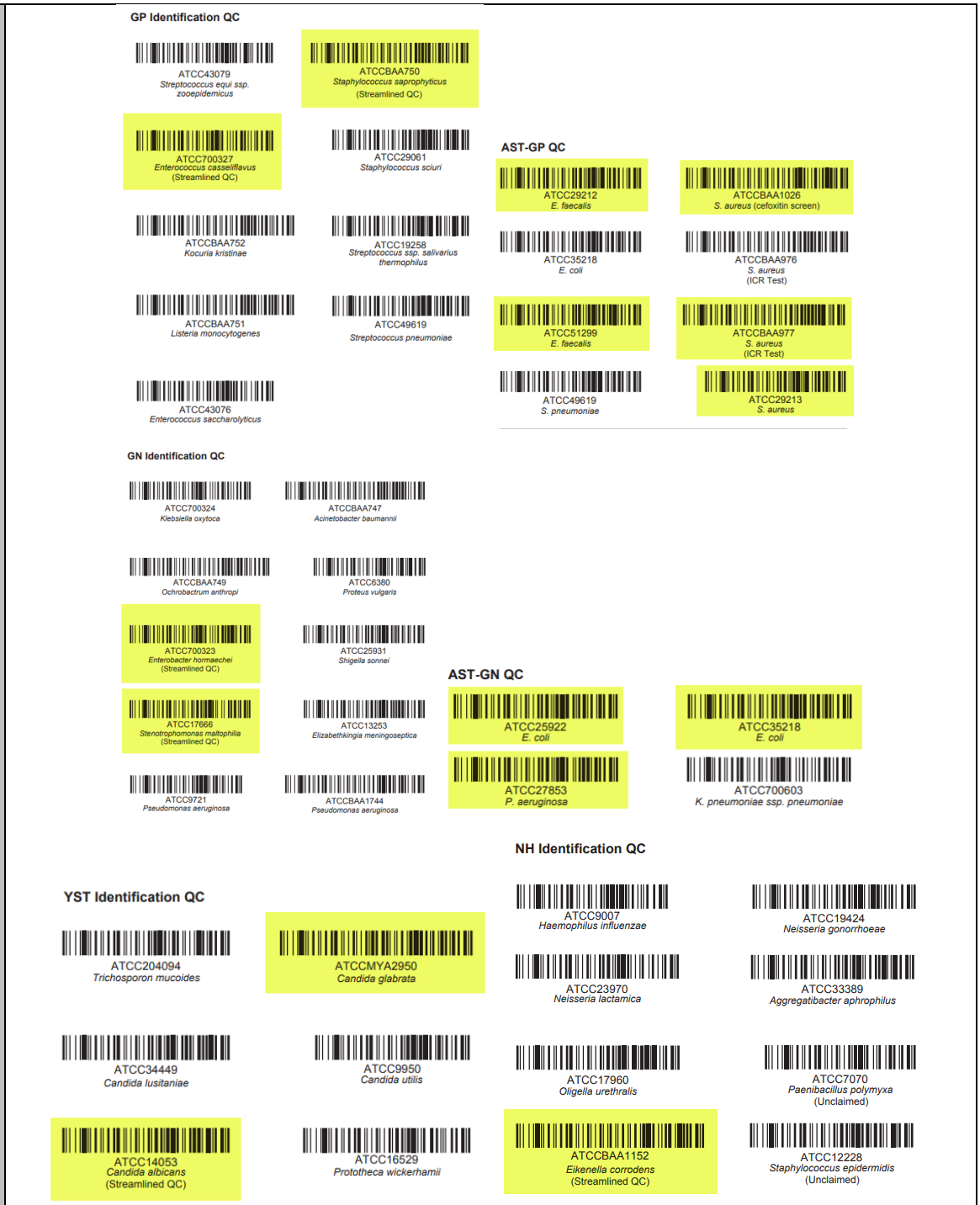
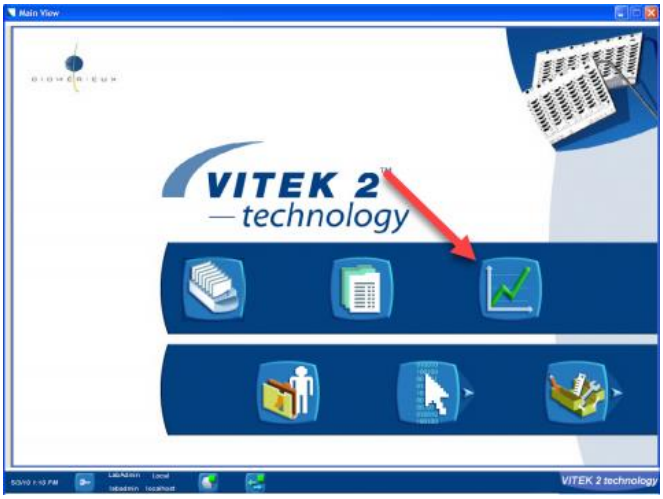
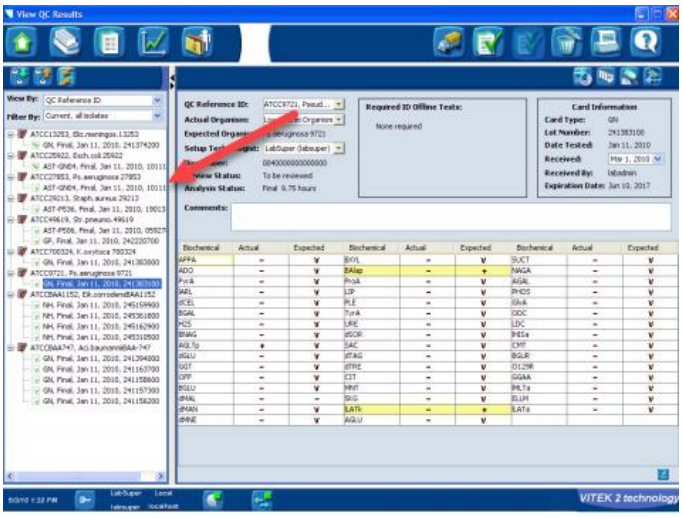


NOTE: All QC cards must use only ATCC numbers for identification to be included in the QC program. Non-ATCC numbers will appear only in the patient data program and cannot be moved to the QC program.

6	Place tube with 3 mL saline in first slot. If performing QC on ID card, scan card and place in first slot with blue stick pointing up. If performing QC on AST card, place an empty tube in the next slot, scan card and place into slot with grey stick protruding into the empty tube.
7	Select isolated colonies from the quality control organism subculture plate and inoculate tube to obtain the appropriate McFarland concentration for the card being tested.
8	Cap tube and vortex. If suspension is too heavy, dispense saline into an extra tube to use as a diluent. Do NOT dilute bacterial suspensions directly from the dispensette. If suspension is too light, add more colonies from the plate. Remove cap from tube.
9	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. Wait for the green light.
10	To avoid jams and terminated cards, check that: 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.
11	After loading the cassette, wait for the happy sound. If the Vitek 2 detects a discrepancy between data stored on the SCS and the actual location of cards in the cassette (load errors), the cassette will be returned to the Cassette Load Station and will not be processed.
12	To solve the discrepancy, place the cassette on the SCS and press any key other than F1. Press F3 to review the list of barcode numbers and card types. Check carefully that the barcode number, card type and cassette position match the F3 screen. Correct any discrepancies by using the F8 and/or F9 keys. It may be simpler to use F10 (to erase the entire cassette) and start over.
13	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.
14	Replace the cassette onto the SCS. Press any key other than F1 to display the cassette load list.
15	Make purity plates using the grey or blue stick and BA plates labelled with labels from the “QC Stickers” binder. Incubate in the air incubator.

Step	Action
Reviewing quality control on the Vitek 2 instrument	
1	All QC results must be reviewed on the Vitek 2 instrument: • From the Main view select the "Enter Quality Control View" icon to review the quality control results. 
2	QC isolates appear in the navigation tree. The results are organized by isolate groups. When an isolate is stopped for review, the icon beside the isolate represents the state of the isolate. 
3	If the icon beside the QC isolate is , all QC parameters are within range for this isolate and do not contain any deviations.
4	If the icon beside the QC isolate is , a QC parameter is out of range for this isolate and does contain deviations.

5	All QC results need to be reviewed, including results that contain deviations. Place the cursor on the QC result and select the "Review" icon to review the results. 
6	If all QC results are acceptable, complete MIC60032 – Vitek 2 Quality Control Results Record with a checkmark in "QC 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.
7	If all QC results are not acceptable, check purity plate to ensure organism was not mixed. If purity plate is pure, repeat quality control testing. If repeat QC testing is acceptable, complete MIC60032 – Vitek 2 Quality Control Results record with the date the QC was repeated in the "Repeat QC Date" column, 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.
8	If repeat QC testing is still not acceptable: • Check the QC results. Test results that were not within the expected range will be highlighted. • 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 bioMerieux to determine if issues with card exist. • Do not use card for patient isolates. • Notify the Technologist II for resolution. • Until the problem is resolved, it may be necessary to use an alternate susceptibility or identification testing method.

REFERENCES:

- Vitek 2 Software and Advance Expert System User Manual
- Vitek 2 Customer Training Course Manual
- Vitek 2 Instrument User Manual
- Vitek 2 Systems Product Information

REVISION HISTORY:

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