1.0 PURPOSE:

To lay down the procedure for operation and maintenance of VITEK 2 Compact identification System.

2.0 SCOPE:

This is applicable to operation and maintenance of VITEK 2 Compact identification System in Quality Control Microbiology Laboratory.

3.0 RESPOSIBILITY:

Trained Quality Control Microbiologist is responsible for operation and maintenance of VITEK 2 identification system as per procedure.

4.0 PROCEDURE:

4.1 System Overview

The VITEK 2 Compact identification system comprises of following components

4.1.1 **VITEK 2 Compact instrument**: This is the main unit which comprises of following

4.1.1.1 **User Interface Screen and Keypad** – For operation of the instrument.

4.1.1.2 **Filler Station**- Consists of fill door, fill chamber and indicator LED. At the filler Station, all of the test cards in a cassette are inoculated with the suspension contained in their corresponding test tubes.

4.1.1.3 **Cassette load and unload Station**- Consists of the load door and an indicator LED. For loading and unload cassettes into VITEK 2 Compact instrument for test card processing using this station.

4.1.1.4 **Bar Code Reader**- After the cassette is loaded in to the instrument the bar code reader located inside the Cassette load / unload station scans the information encoded on the bar code label found on each cassette and test card.

4.1.1.5 **Sealer Station**- Is located inside the cassette load/unload station, it cuts the transfer tube and seal the card.

4.1.1.6 **Test Card Incubation and Reading**- After test cards are sealed and read by the bar Code reader, the test card transport system moves the cassette into position to place each test card into a slot on a carousel of 60 card capacity where it remains throughout the incubation period. During the

incubation, the temperature is maintained at 35.5°C. As the carousel rotates, each test card moves into the reading position every 15 minutes. The reader head conveys the test card through the optics station then back to the carousel.

4.1.1.7 **Transmittance Optics**- Transmittance Optics uses visible light to directly measure Colour change. These optics measure the light transmittance for each well at the beginning and at every 15 minutes. The optics use Light Emitting Diodes (LED's) which produce light at the appropriate wave lengths, and silicon photodetectors to capture the transmitted light and the system is self-calibrating.

4.1.1.8 **Card Injection**- The card ejection function permanently removes the test cards from the carousel after their testing is completed or deleted/terminated by the user.

4.1.1.9 **Wastae Collection Station**- The ejected cards are collected in a bin at the waste collection station for removal from the instrument and disposal.

4.1.1.10 **User Interface System**- The VITEK 2 Compact User Interface System provides the means for communication between the user and the instrument.

4.1.1.11 **Key Pad and Screen**- A keypad and screen are located on the front of VITEK 2 Compact. The system sends the messages about its operation, and possible problems to the screen and keypad is used to respond to the instructions, send commands and perform other functions. The User Interface Keypad and Screen is shown in Figure 1.

4.1.1.12 **Menu System**- All of the functions used on the VITEK 2 Compact instrument through the menu system. Refer the Instrument User Manual for all the Main Menu and Sub Menus.

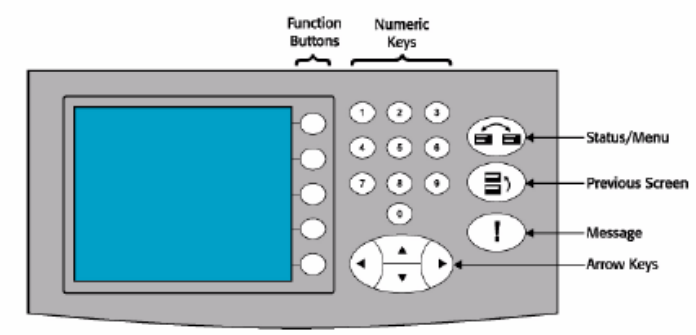


Figure 1. Interface Keypad and Screen

4.1.2 **VITEK 2 System Software**-The Vitek 2 Systems software is installed on a Workstation Computer communicates with the VITEK 2 Compact Instrument and data is transfer is bidirectional. The software compares the results with the organism database and gives identification results.

4.1.3 **Barcode Reader attached to Workstation Computer**- Used for bar coding reading of the cassette and cards into the software externally before loading into the instrument.

4.1.4 **Densicheck**- Densitometer used for reading and adjusting inoculum density for test cards.

4.1.5 **Saline Dispenser**- For dispensing the saline into polystyrene tubes for preparation of inoculum.

4.2 Operation of VITEK 2 Compact Instrument

4.2.1 Connect the instrument to the power supply through the UPS. Ensure the instrument is connected to Workstation Computer. Switch ON the main power supply.

4.2.2 Turn the VITEK 2 Compact power switch located on the right side of the instrument to the ON position.

4.2.3 After turning on, the screen displays the VITEK 2 Compact logo followed by Instrument Name, Initialization Process bar and other information as shown in Figure 2.

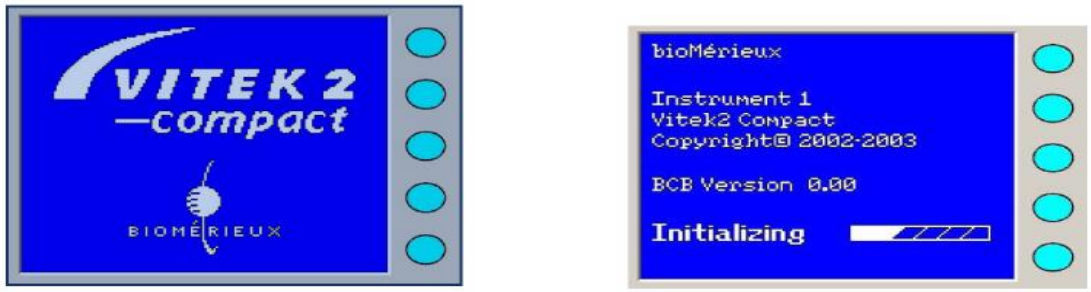


Figure 2. Initialization Screens

4.2.4 Once initialization is complete the status screen displays the filler, loader, instrument name, error messages if and the current time as in Figure 3.

Figure 3. Status Screen in Idle Condition

4.2.5 Simultaneously turn on the Workstation Computer as described in 4.5 and prepare test requirements as per SOP.

4.2.6 Allow the instrument to achieve the optimum temperature of 35.5 ± 1.0°C.

4.2.7 Filling:

4.2.7.1 When the display reads **Filler: Idle, Start Fill** the instrument is ready to fill cycle.

4.2.7.2 Open the filler door, load the cassette to the filler, close the filler door and press the **Start Fill** key shown on the upper-right side of the screen to start the fill cycle.

4.2.7.3 The screen displays **Filler: Filling** when the filling process has started. The **Filling in process** indicator displays to indicate filling (Figure 4)

Figure 4. Filling –in-progress indicator

4.2.7.4 Once the filling cycle is complete, the screen displays **Filler: Complete** and instrument gives audible and/or blinking alert and fill indicator's blue LED blinks. The door interlock is disabled and door can be opened. Make sure not to open loader door while filling is going on.

4.2.7.5 After completion of filling, open the filler door and remove the cassette and cassette can be loaded to the loader within 10 minutes.

4.2.7.6 When the **Filler: Not Ready** indicator displays, the instrument cannot start the filling cycle, because either the filler is not ready or there is fault condition in the Filler or the in the instrument.

4.2.8 Loading

4.2.8.1 When there is no status in the **Loader** field, the loader is not ready to load a cassette and the loader door is locked.

4.2.8.2 After completion of filling cycle is complete, open the filler door and remove the cassettethe Loader status displays **Loader: Transfer** and the loader door is unlocked.

4.2.8.3 Remove the cassette from the filler and while keeping the filler door in open condition, open the loader door and load the cassette.

4.2.8.4 A maximum of 10 minutes is allowed to transfer the cassette. After this time period, the system no longer accepts the cards. This countdown is visible in the upper-right corner of the screen.

4.2.8.5 After loading the card close the door and the loader starts in the following sequence and the appropriate message is displayed

- **Loader: Reading Bar Code** message indicates the instrument is processing the cassette and checking the readability of all bar codes. If the reading is success, the instrument provides alert and unique alert if the cassette setup has non-correctable errors.

- **Loader: Sealing** message indicates that the instrument successfully read the bar codes, and the instrument continues to process the card for sealing.
- **Loader: Loading card** message indicates the completion of sealing and loading of cards to the carousel.
- **Loader: Remove** message indicates that the instrument has finished processing the cards in the cassette and cassette is ready for removal

4.2.9 Removing Ejected Test Cards

4.2.9.1 Open the Waste collection station door.

4.2.9.2 Remove the Waste Collection Bin from the station by pulling front edge of the bin.

4.2.9.3 Dispose the test cards as per decontamination and disposal procedures.

4.2.9.4 Slide the Waste Collection Bin back into place.

4.2.9.5 Close the Waste Collection Station Door.

4.2.9.6 The waste collection bin level is displayed by  icon at the right side bottom corner of the screen and when waste collection bin is not present,  icon will be displayed.

4.2.10 **Instrument Shutdoun:**

4.2.10.1 Ensure all cards finish processing before beginning the shutdown procedure and VITEK-2 Systems Software is open in the Workstation Computer.

4.2.10.2 Access the **Shutdown** function using the following path: **Main Menu > Maintenance > Shutdown**.

4.2.10.3 The message **Shutdown the system? Yes / No** appears on the screen. If any cards are processing the message **Warning: Cassette processing and/or cards in incubator, Shutdown Anyway? Yes or No** appears on the screen.

4.2.10.4 Select **Yes** to shut down the instrument.

4.2.10.5 The instrument briefly displays **Shutdown in progress** during preparing for shutdown and later **Ready for shutdown** message is displayed on the screen.

4.2.10.6 Press the power switch to shut instrument OFF.

4.3 Maintenance of VITEK-2 compact Instrument :

4.3.1 Manual Temperature Check-

4.3.1.1 This procedure should be performed only when more than one hour has passed from the time of power up, more than one hour has passed after cards loaded into carousel and overall instrument status is OK.

4.3.1.2 Follow steps under **Manual Temperature Check (Optional)** as per VITEK 2 Compact Instrument User Manual.

4.3.1.3 Check the thermometer and close the user access doors when done.

4.3.2 Cleaning and Maintenance of VITEK 2 Compact Instrument

4.3.2.1 Perform the following activities as described under Chapter – Instrument Maintenance in VITEK 2 Compact Instrument User Manual.

S.No.	Activity	Frequency
1	Cleaning of Carousel	Monthly
2	Cleaning of Cassettes	Monthly
3	Cleaning of Optics	Monthly
4	Cleaning of Waste Bin	Monthly
5	Cleaning of Filler Seal	Monthly
6	Cleaning of Filler Station	Monthly
7	Cleaning of Load/Unload Station	Monthly
8	Cleaning of Instrument Exterior and User Access Doors	Monthly
9	Checking of Carousel Temperature	Daily*
10	Checking of Optics Systems Status	Daily*

* = On the days of Activity

4.3.2.2 Enter the maintenance details in Vitek 2 Maintenance Log

4.3.3 Diagnostics and Troubleshooting

4.3.3.1 During the operation of the VITEK 2 Compact Instrument problems may occur, which may be resolved.

4.3.3.2 During such times the instrument gives the error messages and the user needs to respond appropriately.

4.3.3.3 Refer Chapter 6 – Diagnostics and Troubleshooting and Appendix C of VITEK 2 Compact Instrument User Manual and resolve the errors accordingly.

4.3.3.4 On the days of instrument operation, perform Temperature check and optics self test.

4.3.4 For any other maintenance activities call bioMérieux's service engineers.

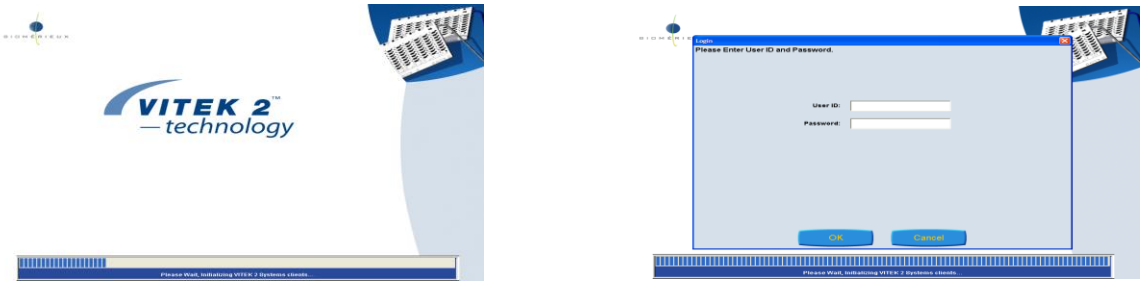
4.4 Operation of VITEK 2 Systems Software

4.4.1 Starting and Logging out VITEK 2 Systems Software

4.4.1.1 Turn on the workstation computer and log in to the Windows Operating System using the User ID and Password.

4.4.1.2 Follow the path **Start** Menu > **Programs** > **VITEK 2 Compact** > **VITEK 2 Compact** to start the application, or double click on the **VITEK 2 Compact** icon on the desktop.

4.4.1.3 A Splash Screen appears when the system software initializes followed by Login Screen (Figure 5).



Splash Screen Login Screen

Figure 5.

4.4.1.4 Enter the valid user ID and password for opening the software. The main view window (Figure 6) or the last operational window appears.

Figure 6. Main Window

4.4.1.5 From the main view window, user can go to main navigational areas of the system software as detailed in following table by clicking respective icons:

View/Icon	Description
	**Manage Cassettes / Set Up Tests Post Entry** This view allows setting up tests. This view can be used to set up tests by entering information for virtual cassettes and actual cassettes and Quality Control tests.
	**View and Maintain Isolate Results** This view allows viewing and managing test results. User can view isolate summary information, detailed Biochemical information and reports can be generated and printed.
	**Maintain SRF Data** For situations where the organism identification is unclear, it will be able to maintain a supplemental react file (SRF)
	**Manage Quality Control (QC)** This view allows viewing QC isolate summary information.
	**Configuration** This view allows viewing configuration parameters. User with supervisor and above privileges can unlock and modify configuration parameters.
	**System Utilities** This view allows searching audit trail, history, archive and view archived isolate reports.

4.4.1.6 For logging out click the Login icon  on the status bar. The log widow appears. Perform the following as appropriate:

- To logout without quitting the application, click **Logout**.
- To logout and quit the application, click **Quit**.
- To return to session, click **Cancel**.

4.4.2 View and Maintain Instrument Status

4.4.2.1 Instrument Status Icon will be displayed on the status bar in different types depending on the status of the equipment as follows:

Icon	Instrument Status
	**Instrument OK Status** Icon with green square means the connection with the instrument is OK. Click to see the current instrument status.
	**Instrument Warning Status** Icon with orange triangle indicates a problem with the instrument. Click to see a description of the warning.
	**Instrument Error Status** Icon with red circle indicates an error in the instrument. Click to see a description of the error.

4.4.2.2 To view current status of the instrument, click **Instrument Status** icon on the status bar at the bottom of the screen. The alarm messages/instrument status window appears. Select Current Instrument Status tab to view the details of the instrument status. Click print to print an instrument report.

4.4.2.3 Similarly Current Alarm, Alarm History and Monthly Instrument Status can be viewed and printed.

4.4.2.4 View and Acknowledge Detected Alarms: To view and all unacknowledged alarms and acknowledge them, follow these steps.

- When and alarm is detected, click the **Instrument Status** icon to check the current alarm status.
- The alarm workspace appears and the audible alarm stops sounding.
- To acknowledge the alarm, click the check box **Acknowledge All Messages**.
- Click print to print an alarm report with the information that appears on the window.
- Refer Instrument manual Appendix C for instrument errors and respond to each error accordingly.
- Incase the alarm persist and is not possible to trouble shoot, call bioMérieux service engineer for servicing.

4.4.3 Set Up Test Cards and Cassette Information:

4.4.3.1 Printing a Blank Cassette Worksheet: Before starting the test preparation the blank cassette worksheet can be printed to fill the appropriate information during the preparations. For printing the blank cassette worksheet, go to **Set up Tests Post Entry** view and click **Print**  icon. A cassette print report appears, select **Blank Worksheet** and click **print**.

4.4.3.2 Entering Card /Organism Details in Set up Tests Post Entry Work Flow:

- From **Set up Tests Post Entry** view select the newly loaded cassette from the navigation tree (the cassette for which the details are to entered will appear in red).
- The screen displays the cassette workspace and displays the cassette ID, slot no, card type, bar code (the last four digits), Accession No, Organism, Offline test columns.
- To enter the Accession No, select the Accession No cell, and then type in the applicable accession number.
- After completion of the all the entries, save the cassette by clicking **Save**  icon. After saving the cassette colour changes to black in the navigation tree.
- Incase of Anaerobic and Cornynebacteria Indentification Card (ANC) enter Offline Test results:

Test Name	Test	Result	Definition
AERO	Aero tolerance	-	Anaerobe
		+	Aerobe
		?	Facultative
GRAM	Gram stain results	-	Anaerobe
		+	Aerobe
		?	Facultative
MORPH	Morphology	-	Anaerobe
		+	Aerobe
		?	Facultative

- If required print the cassette information by clicking **Print** and selecting **Cassette Report**.

4.4.3.3 Entering Card/Organism Details in Virtual Cassette Work flow:

- From Set Up Tests Post Entry view, click **Maintain Virtual Cassette** icon in the left view bar.Click the **Create New Virtual Cassette** icon  . The virtual cassette work space appears.
- Select the cassette ID from the list available or read cassette bar code with bar code scanner.
- Enter the bar code for each available slot, either by using the bar code scanner or by entering bar codes manually from the keyboard.
- Enter the Accession No and in case of Anaerobic and Cornynebacteria Indentification Card (ANC) enter details as described above.
- When details for all the slots are entered, click **Save** icon.
- When the instrument processes the cards, by bar code reading, the system matches with the data entered. If the system confirms the match the instrument processes the test cards.

4.4.4 View and Maintain Results

4.4.4.1 From the main view, click **Enter Isolate View** icon  .

4.4.4.2 The View and Maintain Isolate Results Window appears. The window displays the navigation tree on the left side and the Isolate results on the right side.

4.4.4.3 The navigation tree can be configured by appropriate selections in View By and Filter By drop boxes.

4.4.4.4 To view detailed biochemical results, select a completed ID card, the detailed identification information displays in the active workspace, sorted by well number for each tested biochemical.

4.4.4.5 To print isolate result reports, click **Print** icon, select Lab Report. A detailed laboratory report gets printed.

4.4.5 Data Backup

4.4.5.1 The system is configured for automatic back up. For manual backup perform following steps.

4.4.5.2 Insert a Blank read/write CD or DVD.

4.4.5.3 Select **Start > Programs > VITEK 2 Compact > VITEK 2 Compact Backup Restore**.

4.4.5.4 If the system software is running, it will prompt to close the application before backup can begin.

4.4.5.5 Then it will prompt to log in to the application. Log in as 4.4.1 and system will verify the User ID and Password.

4.4.5.6 Select the **Backup** icon, the system will notify for stopping of all services, on confirmation the backup will begin.

4.4.5.7 If the CD has data, the system will notify and confirmation continues the backup process.

4.4.5.8 On completion of backup the workstation ejects the CD and notifies on the screen.

4.4.5.9 Select OK, the workstation automatically reboots.

4.4.6 For any other operations and if any difficulties encountered refer the VITEK 2 Compact Online Software User Manual.

4.5 Operation of DENSICHECK

4.5.1 Instrument Verification

4.5.1.1 Place the DENSICHEK on the work space and ensure it is connected to AC power supply or batteries.

4.5.1.2 Clean the outside surface of the CAlibration Standard tube with tissue paper.

4.5.1.3 Push and hold in the adjustment button located on the right-hand side of the DENSICHECK until the Calibration Standard tube has been seated at the bottom of the optical block. Release the adjustment button and rotate the Calibration Standard tube one complete revolution (360°C) within 2 seconds.

4.5.1.4 Check that the displayed McFarland value is within ± 0.10 McF of the value printed on the Calibration standard tube label.

4.5.1.5 If the McFarland value is outside this acceptable range, the DENSICHECK is ready for use.

4.5.1.6 If the McFarland value is outside the acceptable range (± 0.10 McF), verify if any dirt is present in the optical block if so clean the optical block with tissye and repeat steps 4.5.1.1 to 4.5.1.4.

4.5.1.7 If the McFarland value is still outside this acceptable range, contact the bioMerieux service engineers.

4.5.1.8 The DENSICHECK instrument should be verified using Calibration Standard at least once a month.

4.5.2 Instrument Operation

4.5.2.1 Place the DENSICHEK on the work space and ensure it is connected to AC power supply or batteries.

4.5.2.2 Place the polystyrene tube with inoculum in the optical block and rotate one complete revolution. Check the displayed McFarland (McF) value is with in the required range for the particular test card.

4.6 REPORTING:

4.6.1 In case of any deviations report to Quality Control In - Charge or his designee.

4.6.2 In case of any problems in the instrument operation, contact bioMérieux Service Engineer.

4.6.3 All the activity shall be logged in Instrument Usages Log Book

5.0 ABBREVIATIONS & DEFINITIONS:

SOP Standard Operating Procedure
QCM Quality Control Microbiology
QAD Quality Assurance Department
Rev. Revision
No. Number

6.0 REFERENCE DOCUMENTS:

SOP: Instrument Usage Log Book

VITEK 2 Compact Instrument User Manual

VITEK 2 Software User Manual

Densicheck – User Manual

7.0 ANNEXURE/ATTACHMENTS:

Annexure I: Form – 1, VITEK 2 Compact Cleaning Log

8.0 REVISION LOG:

Revision Number	Effective Date	Reference Change Control No	Reason for Revision