Policy Statement	Laboratory personnel are responsible for ensuring that all analyzers are operating appropriately to guarantee that testing is performed as described by the manufacturer.
Purpose	This procedure provides technical instruction for the operation of the miniVIDAS.
Scope	This procedure applies to all operating functions of the miniVIDAS analyzer.
Responsibility	It is the responsibility of all testing personnel to follow this procedure without exception.

Calibration

Master Lot Data Entry

The master lot entry (MLE) card provides a set of data with each kit of an assay that supplies the quality control ranges and, for quantitative tests, becomes the standardization curve for that lot. Upon receipt of a new kit lot, data must be entered from the MLE card before any tests in the kit are used,or the assay will not run. Enter the data via the MLE card or manually. To enter the information using the MLE card;

1. Place the card onto the plastic tray with the barcode data directed upward.
2. Insert the tray into a reagent strip section pointing the directional arrow on the card toward the instrument.
3. Select [Master Lot Menu] from the main menu.

4. Select [Read Master Lot] and specify the section containing the card. The instrument will take approximately three minutes to read the lot specific information from the MLE card.

To enter the data manually from the MLE card, select [Manual Master Lot Entry]. Enter all letters and numbers that are printed under each barcode into the analyzer. Press [ENTER] after each entry. After all entries are complete, verify that the information on the screen matches the information on the MLE card. Store the data only if the information matches. If it does not match, re-enter the barcode data. For complete instructions, refer to the Operator's Manual. The master lot data only needs to be entered once for each kit lot number.

Performance of Standards (Calibrators)

The following steps must be completed to test the standards. The performance frequency of the standards is defined by the manufacturer based on the assay. A review of *CORE 6650 Ja miniVIDAS Assay Specifications* is required to determine the number of standards required for each assay and the length of standard the validation. Recalibration over the time period the lot is in service accommodates the minor variations in assay signal throughout the shelf-life of the kit. Positive and negative controls must be run with the standards.

1. Remove one Reagent strip and one SPR for each Standard to be tested from the kit. Allow each item to reach room temperature (approximately 30 minutes). Make sure to re-seal the zip-lock on the SPR pouch after opening to prevent moisture from accumulating. All unused kit components should be returned to storage 2° to 8°C.
2. Place the Reagent Strips and SPRs on a stable surface.
3. In the space provided on the Reagent Strip label, record the appropriate Sample identification. The Standard must have an ID that begins with “S.” (*i.e.* S1, S2, etc.)
4. The Standard must be run in the first positions. The Standard should be tested in duplicate. Controls should be run in the positions immediately after the standard.
5. Pipette 100 µL of Standard into the center of the sample well of each correspondingly labeled Reagent Strip.
   NOTE: Check the Sample Wells for bubbles after pipetting the samples into the Reagent Strips. Tap gently, to remove any bubbles present.
6. Open the tray cover of each miniVIDAS section to be used. Slide the Reagent Strips into the channels.
7. Open the door of each corresponding SPR compartment and place the SPRs into the positions that correspond to the Reagent Strips. Check to make sure the color labels with the three-letter assay code on the SPRs and the Reagent Strips match.
8. Close the SPR compartment door(s) and the section tray cover(s).
9. Initiate the assay processing as directed below in the Testing Procedure section. The miniVIDAS Module will execute all steps of the sequential enzyme-linked

fluorescent immunoassay automatically. The assay will be completed in approximately 18-40 minutes.

10. After the assay is completed, discard the used SPRs and Reagent Strips into a biohazardous waste container. The instrument will inform you if the Standard **did not** meet the required definitions. (All errors are listed at the bottom of the analyzer print out.)

The Procalcitonin assay does not need to be brought to room temperature and requires a sample size of 200µL.

In the event that the standards do not produce the manufacturer's required values, the process should be completed. If the standards still do not produce the required values, contact the Technical Support hotline for assistance.

Quality Control (Assay)

Daily QC is required for each assay on the days the test is being performed. A positive and negative control must be run. The expected values for the controls are entered into the system via the MLE card. Expected values are lot dependent. Ensure that the QC samples used are from the appropriate lot. All controls should be run as described in the Testing Procedure section. If the results from the controls do not fall within these ranges, the result will be flagged as out of the preset specification value range. All errors are listed at the bottom of the analyzer print out. QC must be reviewed prior to reporting any patient result. When this occurs patient results can not be reported until the issue has been resolved. All quality control results are reviewed monthly by the laboratory director designee. This includes a review of Meditech graphs for shifts and trends.

Lot Verification

Upon receipt of a new lot or a new shipment of the existing lot, verification must be performed to ensure that the assay performance has remained unimpaired throughout shipping and storage. To complete this verification standards and QC should be performed. In addition to this, the current controls should be run as patients using the new lot kit contents. A previous known patient sample should also be run to validate the new lot with a patient sample matrix. Lots are deemed okay for use if the standard and QC parameters are achieved, the current lot results are within the defined range, and the known patient sample result is confirmed.

Quality Control (Instrument)

Quality Control VIDAS (QCV) is an automated test for use on the miniVIDAS system to detect abnormal operation of the miniVIDAS instrument pipette mechanisms and optical systems. The test corresponds to successive aspirations/dilutions of fluorescent substrate (4-Methyl-umbelliferone) solutions, which are standardized and have varying

levels of concentration. The aspirations are performed at different speeds to check pump aspiration capability.

The results obtained at the end of the test correspond to the TV1 ratio of the fluorescence readings, for checking the correct operation of the pipette mechanism, and to the fluorescence reading (Read 3) for checking the optical system. The values obtained must be within the defined acceptable range.

QCV Materials should be tested like patient samples. See the Testing Procedure section below. After the test is completed, analyze the results. Circle all "TV1" and "Reading 3" results. Acceptable range for TV1: each position must be $\geq$ 6.3. If the result of a particular position is outside the range, two new VIDAS QCV strips must be tested successively in that position. If, in two out of three cases, the TV1 ratio is out of range, take the section off line and call BioMerieux. Acceptable range for reading 3 (R3): each position must be $\geq$ 4100 RFU. An anomaly should be suspected if at least one position produces a value for reading 3 < 4100 RFU. In this case, take the instrument offline and call BioMerieux. Once interpretation of results has been validated, dispose of the used SPRs and strips into a biohazard bag.
QCV testing must be completed once a month. Document the testing on *CORE 6650 F miniVIDAS Maintenance Log*.

Testing Procedure

1. Remove one Reagent strip and one SPR for each sample to be tested from the kit. Do not mix lot numbers. Allow each item to reach room temperature (approximately 30 minutes). Make sure to re-seal the zip-lock on the SPR pouch after opening to prevent moisture from accumulating. All unused kit components should be returned to storage 2° to 8°C.
2. Place the Reagent Strips and SPRs on a stable surface.
3. In the space provided on the Reagent Strip label, record the appropriate Sample identification. This could be the barcode number, the accession number or the worksheet cup number.
4. The Standard and or controls must be run in the first positions. Patient samples should follow in the remaining positions. If the controls have already been tested in the last 24 hours, patient samples can be placed in the first positions.
5. Pipette 100 μL of sample into the center of the sample well of each correspondingly labeled Reagent Strip.
   NOTE: Check the Sample Wells for bubbles after pipetting the samples into the Reagent Strips. Tap gently, to remove any bubbles present.
6. Open the tray cover of each miniVIDAS section to be used. Slide the Reagent Strips into the channels.
7. Open the door of each corresponding SPR compartment and place the SPRs into the positions that correspond to the Reagent Strips. Check to make sure the

color labels with the three-letter assay code on the SPRs and the Reagent Strips match.

8. Close the SPR compartment door(s) and the section tray cover(s).
9. Select [AVAILABLE] for the appropriate section.
10. Select the position number.
11. Select the appropriate sample type; [S] for standards, [C] for controls and [Sample ID] for patient samples.
12. For each strip position, scan the specimen barcode or manually enter the specimen ID.
13. Press the return button to go to the next sample. For samples in position six, press the return button an extra time.
14. Review the Section Map to ensure that all of the samples IDs were entered correctly. (If an error is discovered, press the position number and re-enter the sample ID.)
15. Press START
16. Select the user number based on your initials.
17. The miniVIDAS Module will execute all steps of the sequential enzyme-linked fluorescent immunoassay automatically. The assay will be completed in approximately 18-40 minutes.
18. After the assay is completed, discard the used SPRs and Reagent Strips into a biohazardous waste container.

The Procalcitonin assay does not need to be brought to room temperature and requires a sample size of 200µL.

Daily Maintenance

Daily Maintenance on the miniVIDAS requires review of the temperatures for the SPR block and Reagent Strip Compartment. To display temperatures for SPR block and Reagent Strip Compartment follow the steps listed below.

1. Select [Status Screen] on Main Menu
2. Select [Display Temperatures]
3. A screen similar to the following appears:

Temperatures		
	Tray	SPR
A:	37.1	37.2
B:	37.1	37.1

4. Document the listed temperatures on the CORE 6650 F miniVIDAS Maintenance Log.
5. Press the [Previous Screen] key to return to the Status Menu.

Weekly Maintenance

Weekly Maintenance on the miniVIDAS includes cleaning the SPR Block and the Reagent Strip Compartment.

Required Supplies:

- Dacron swabs
- Alconox Detergent
- Foam or gauze sponge
- 10% bleach
- Distilled water
- Curved forceps

SPR Block

1. Open the SPR compartment door and tilt SPR block towards you. Moisten a Dacron swab in a detergent solution and carefully cleanse inside each SPR sleeve.
2. Moisten a foam or gauze sponge with the detergent solution. Holding the sponge with a curved forceps, swab the underside and back of the SPR block.
3. Repeat above procedure with 10% bleach. Allow the bleach to react for 10 minutes.
4. Rinse each area thoroughly with a sponge or swab moistened with distilled water.
5. Close the SPR compartment doors.

Reagent Strip Compartment

1. Pull off the panel on the front of the miniVIDAS Module below the Reagent Strip trays.
2. Manually pull the Reagent Strip trays to their outermost position.
3. Moisten a foam or gauze sponge in a detergent solution. Holding the sponge with a curved forceps, clean the metal Reagent Strip tray by sliding it along each channel. Make sure the sponge or square makes contact with the entire length of the Reagent Strip channel.
4. Remove the plastic tray that sits underneath each Reagent Strip tray by sliding it towards you.
5. Cleanse each tray with a gauze sponge moistened with the detergent solution.
6. Carefully clean the Reagent Strip compartment, compartment cover, and its surrounding external surface area with the detergent solution.
7. Clean the front of the miniVIDAS Module with the detergent solution.
8. Repeat above procedure with 10% bleach. Allow the bleach to react for 10 minutes.

9. Rinse each area thoroughly with a sponge or swab moistened with distilled water.
10. Push the Reagent Strip trays back in until they engage the tray drive mechanism. You will feel a slight resistance during the engagement.
11. Carefully replace each Reagent Strip tray. The edges of the tray must fit into the grooves on each side. The tray wire must fit into the grooves on the top of the tray. Replace the front panel.

Analytical Measurement Range (AMR)

Verification of the AMR is performed for all quantitative testing. Samples used for the AMR verification are provided by the analyzer manufacturer or an alternative vendor. All samples are matrix appropriate. Samples must include low, mid and high range. The AMR validation requires measurements of five samples of varying concentrations, minimally. The five samples are relative to one another by dilution ratios or formulation. Samples are stored and prepared according to manufacturer's instructions. AMR is performed every six months to substantiate continued accuracy of the test method. AMR verification is also performed if there are any changes in major system components. Testing is performed as described in the Testing Procedure section of this document. Each AMR sample is tested four times. (Each sample is tested twice on both analyzer section.) The results are evaluated for general acceptability. Acceptability criteria are defined by the material manufacturer. Results are plotted to visually examine outliers. The plotting of results displays the response variable plotted against the sample concentration. The plot is observed for gross deviations from linearity, misplaced points, obvious errors or evidence of instrument failure. Two or more unexplained outliers cast doubt on the testing system's performance. Troubleshooting procedures must be completed. If additional assistance is needed, contact the Technical Support line.

For the Procalcitonin assay the AUDIT® MicroCV™ Procalcitonin Linearity Set is utilized for AMR verification. Once each vial of the total set is tested, the raw data is entered via the AUDITOR™ QC Program at www.auditmicro.com. An online graph showing actual values versus predicted values for each analyte is available to print along with slope and intercept data. All documents are retained in the appropriate binder.

Supporting Documents

CORE 6650 F miniVIDAS Maintenance Log
CORE 6650 Ja miniVIDAS Assay Specifications
CORE 6650 Jb miniVIDAS Workflow
CORE 6650 Jc miniVIDAS Procalcitonin Workflow

References

Mini VIDAS Operator's Manual. 1995.