TITLE: Mini Vidas Procalcitonin

PRINCIPLE / PURPOSE: The VIDAS® B•R•A•H•M•S PCT is an automated test for use on the VIDAS instruments for the determination of human procalcitonin in human serum or plasma (lithium heparinate) using the ELFA (Enzyme Linked Fluorescent Assay) technique. The VIDAS® B•R•A•H•M•S PCT is intended for use in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock.

The assay principle combines a one-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA).

The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips.

All of the assay steps are performed automatically by the instrument.

The sample is transferred into the wells containing anti-procalcitonin antibodies labeled with alkaline phosphatase (conjugate). The sample/conjugate mixture is cycled in and out of the SPR several times. This operation enables the antigen to bind with the immunoglobulins fixed to the interior wall of the SPR and the conjugate to form a sandwich. Unbound components are eliminated during washing steps.

Two detection steps are performed successively. During each step, the substrate (4-methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-methyl-ubelliferone) the fluorescence of which is measured at 450nm. The intensity of the fluorescence is proportional to the concentration of antigen present in the sample.

At the end of the assay, results are automatically calculated by the instrument in relation to two calibration curves, stored in memory, corresponding to the two detection steps. A fluorescence threshold value determines the calibration curve to be used for each sample. The results are then printed out.

SCOPE: This procedure provides instruction for Procalcitonin testing performed on the mini Vidas instrument.

SPECIMEN:

Type: Collect blood by venipuncture to obtain plasma (lithium heparinate).

For a given patient, the PCT assays must be performed on the same type of sample.

Since EDTA causes a decrease in the values measured, plasma collected in EDTA should not be used.

Centrifuge according to the tube manufacturer’s recommendations to eliminate fibrin.

The plasma separated can be stored at 2 to 8oC for 48 hours.

If longer storage is required, freeze at -25 ± 6oC for up to 6 months. The sample may undergo 3 freeze/thaw cycles.

None of the following factors have been found to significantly influence this assay: hemolysis, lipemia, or bilirubinemia.

However, it is recommended not to use samples which appear to be hemolyzed, lipemic or icteric and, if possible, to collect a new sample.

EQUIPMENT AND MATERIALS:

Equipment: Biomerieux Mini Vidas Instrument

Materials:

A. Reagents and Materials Provided

Refrigerate 2 to 8 oC - Do not freeze the reagent kit.

1. PCT Reagent Strips
2. PCT SPRs
3. PCT Calibrators (S1 and S2)
4. PCT Controls (C1 and C2)
5. MLE Barcode
6. Package Insert
7. Reagent Preparation and Storage
8. PCT Calibrators – Reconstitute with 2 ml of distilled water. Let stand 5-10 minutes, then mix. Once reconstituted, the calibrators are stable for 8 hours at 2 to 8oC, or until the expiration date on the kit at -25 ± 6oC. Freeze immediately after reconstitution. Five (5) freeze/thaw cycles are possible.
9. PCT Controls – Reconstitute with 2 ml of distilled water. Let stand 5-10 minutes, then mix. Once reconstituted, the controls are stable for 8 hours at 2 to 8oC, or until the expiration date on the kit at -25 ± 6oC Freeze immediately after reconstitution. Five (5) freeze/thaw cycles are possible.

C. Materials Required But Not Provided

1. Calibrated pipette to dispense 200 ul and 2 ml.

2. Disposable pipette tips for pipette.

3. Powderless disposable gloves.

1. MAS Omni-IMMUNE Integrated Immunoassay Controls

Preparation: Remove the required reagents and SPR's from the refrigerator. They can be used immediately. Use one PCT and one PCT SPR from the kit for each sample to be tested. Make sure the SPR pouch has been resealed after the required SPRs have been removed. Note: Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPRs.

CALIBRATION:

1. Master Lot Entry Data Entry

Before each new lot of reagents is used, specifications (or factory master calibration curve data) must be entered into the instrument using a master lot entry (MLE) barcode included on each kit. If this operation is not performed before initiating the tests, the protocol will not run. The master lot entry (MLE) only needs to be entered once for each lot.

Scan the 3D barcode on the box to enter the MLE data as needed.

1. From the main menu, select Master Lot Menu
2. Select Scan Master Lot
3. Use the barcode reader to scan the 3D barcode on the box in a downward motion
4. Once the barcode reader beeps, the MLE data will print
5. Place the printout in a sheet protector in the MiniVidas logbook
6. Calibration

Calibration, using the two calibrators provided in the kit, must be performed upon receipt of a new lot of reagents after the master lot data has been entered. Calibration should then be performed every 28 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf life of the kit.

The calibrators, identified as S1 and S2, must be tested in duplicate in the same run.

QUALITY CONTROL:

Two controls are included in each VIDAS® B•R•A•H•M•S PCT kit and must be tested:

* Immediately after opening a new kit or new kit lot number to ensure that reagent performance has not been altered.
* After each calibration

MAS Omni-IMMUNE Integrated Immunoassay Control

* These are external controls that may be used daily and identified as Sample ID 1 and Sample ID 3
* Ranges for these controls are located on the daily QC logsheet
* Ranges are determined within the lab using an analysis on 20 runs
* MAS Omni-IMMUNE controls are stable for 30 days once thawed and stored at 2-8 ˚C

PROCEDURE FOR RUNNING SAMPLES, CONTROLS, AND CALIBRATORS

1. Remove the VIDAS® B•R•A•H•M•S PCT reagent kit from the refrigerator.
2. Use one PCT strip and one PCT SPR for each sample, control, or calibrator to be tested. Make sure the storage pouch has been carefully resealed after the required SPRs have been removed.
3. Mix the controls and calibrators with a vortex-type mixer in order to improve result reproducibility.
4. Pipette 200 ul of sample, control, or calibrator into the sample well avoiding bubbles
5. The controls must be identified by C1 and C2 and will be tested singly. The calibrators must be identified by S1 and S2 and run in duplicate. Daily MAS controls must be identified as 1 and 3.
6. Insert the VIDAS® SPRs and strips into the positions indicated on the screen. Verify that the color labels with the assay code on the SPRs and strips match.
7. Initiate the assay processing by pressing START. The instrument performs all the assay steps automatically. The assay will be completed in approximately 20 minutes.
8. After the assay is completed, dispose of SPRs and strips into biohazardous waste.
9. Refer to daily logsheet to verify that controls are within expected ranges.
10. In the event that controls exceed acceptable limits, do not perform patient testing. Troubleshoot QC outliers by repeating with fresh control material.

EXPECTED VALUES FOR THE CONTROLS AND CALIBRATOR

The expected values for the controls (C1 and C2) and calibrator are printed from the MLE barcode. The values for the MAS Omni-IMMUNE controls are recorded on the daily logsheet for review. If the result from testing the controls and calibrator do not meet these specifications, do not report patient results.

Any outlier will be noted at the bottom of the QC printout.

INTERPRETATION & REPORTING RESULTS:

Reference Ranges:

Based on ARMC studies, the analytic measurement range of the mini Vidas Procalcitonin assay is 0.10 ng/ml to 150.00 ng/ml.

Reporting Format:

Once the assay is completed, the results are analyzed automatically by the computer using two calibration curves which are stored by the instrument, and then printed. The concentrations are expressed in ng/ml.

Results are entered into the LIS using an interface.

1. Login to Sunquest
2. Select Result Entry
3. Enter the Instrument method code
4. Select the Result button at the bottom right
5. Use the binoculars at the bottom left to enter the container ID
6. Review results and Save
7. Accept results

Result Interpretation: PCT concentrations between 0.5 and 2.0 ng/mL should be interpreted taking into account the patient’s history.

It is recommended to retest PCT within 6-24 hours if any concentrations < 2 ng/mL are obtained.

Interpretation of test results should be made taking into consideration the patient’s history, and the results of any other tests performed.

The results obtained with VIDAS® B•R•A•H•M•S PCT during a study performed on patients admitted to intensive care units are as follows:

* A concentration < 0.5 ng/mL represents a low risk of severe sepsis and/or septic shock.
* A concentration > 2 ng/mL represents a high risk of severe sepsis and/or septic shock.

Nevertheless, concentrations < 0.5 ng/mL do not exclude an infection, on account of localized infections (without systemic signs) which can be associated with such low concentrations, or a systemic infection in its initial stages (< 6 hours). Furthermore, increased procalcitonin can occur without infection.

PROCEDURE NOTES: None of the following factors have been found to significantly influence this assay but samples with visible signs should not be used: Hemolysis, lipemia, or bilirubinemia.

LIMITATIONS OF THE PROCEDURE:

Interference may be encountered with certain samples containing antibodies directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient’s history, and the results of any other tests performed.

REFERENCES:

VIDAS System package insert. Refer to the insert for the complete details of the procedure, references, and performance of the product. January 2015

MAS Omni-IMMUNE package insert. Thermo Scientific. December 2015

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|  | Signature Date | |
| Medical Director Approval –  ARMC Cancer Center ARMC Main Lab |  |  |
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HISTORY PAGE

SOP Number: COAG-716

SOP Title: miniVidas Procalcitonin Assay

Written By: Quanisha Dyson

Manual in which Hard Copy of this SOP is located: ARMC Coagulation Manual

Distribution: none

Supersedes Procedure: N/A

SOP CHANGE CONTROL

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|  | Approvals | |  | Action | In |
| Mgmt. | Date | Director | Date |  | Effect |
| Q.Dyson | 8/29/17 |  |  | Update procedure format | 8/29/17 |
|  |  |  |  |  |  |
| Q.Dyson | 1/29/18 |  |  | Updated reportable range (0.10-150 ng/ml) |  |
|  |  |  |  |  |  |
| Q.Dyson | 2/16/18 |  |  | Added information for interface result entry | 2/27/18 |
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