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| **SUBJECT:** | VIDAS® B•R•A•H•M•S PCT™ | **TITLE:** | Principle and procedure for performing procalcitonin with MiniVidas |
| **EFFECTIVE DATE:** | December 2017 | **SECTION:** | Core Laboratory |
| **APPROVED:** | **POSITION RESPONSIBLE FOR REVIEW:** | Laboratory Manager or Designee |

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| **PURPOSE:** | VIDAS® B•R•A•H•M•S PCT™ (PCT) is an automated test 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 for progression to severe sepsis and septic shock, decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI), antibiotic discontinuation for patients with suspected or confirmed sepsis, and assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU. |
| **REAGENTS AND MATERIALS:**1. Reagents and Materials Provided

Refrigerate at 2-8°C (Note: Do **NOT** freeze the reagent kits)1. PCT Reagent Strips
2. PCT SPRs
3. PCT Calibrators (S1 & S2)
4. PCT Kit Controls (C1 and C2)
5. Reagent Preparation and Storage
6. PCT Calibrator – Reconstitute with 2 mL of distilled water. Wait 5-10 minutes before mixing with a vortex mixer. After reconstitution, the calibrator is stable for 8 hours at 2-8°C or until the expiration date of the kit at -25 ± 6°C. A total of five freeze/thaw cycles are possible for calibrator stability.
7. PCT Controls – Reconstitute with 2 mL of distilled water. Wait 5-10 minutes before mixing with a vortex mixer. After reconstitution, the control is stable for 8 hours at 2-8°C or until the expiration date of the kit at -25 ± 6°C. A total of five freeze/thaw cycles are possible for control stability. When reconstituting new vials of controls, they must be aliquoted into tubes containing 250µL of QC for stability.
8. Additional Materials Required:
9. Calibrated pipette to dispense 2 mL and 200 µL
10. Disposable pipette tips for pipette
11. Appropriate personal protective equipment (PPE)

**SPECIMEN COLLECTION, STORAGE AND PREPARATION**Collect human serum or plasma with Lithium Heparinate additive. For a given patient, the PCT assay must be performed on the same type of sample tube. EDTA samples are strictly prohibited from use as they can cause a decrease in the values measured. Samples containing suspended fibrin particles or erythrocyte stroma should be centrifuged before testing. Patient serum or plasma can be stored at 2-8°C for up to 48 hours; if longer storage is required, freeze at -25 ± 6°C for up to six months.**MASTER LOT ENTRY (MLE)**When using a new lot of the procalcitonin assay and before running calibrators, controls, or samples, scan the kit barcode using the instrument barcode reader. This reading will allow the VIDAS® PTC protocol data to be transferred to the instrument software for its update. Calibrator and control results reference ranges will This data should only be scanned once at the start of a new lot. **CALIBRATION**Calibration must be performed every 28 days or when a new lot of reagent is opened. The calibrators (S1 and S2) must be tested in duplicate in the same run to create an average RFV (“Relative Fluorescence Value”). The calibration values must be within the set RFV range of the current MLE lot before further testing can begin. The instrument will only be able to check the calibration values if they are identified as S1 and S2 in the status screen menu. Both standard values must be within range for the standard curve to be acceptable.**QUALITY CONTROL**Controls must be performed daily or when opening a new kit to ensure that reagent performance has not been altered. Each calibration must also be checked using these controls. The control values must be within the set RFV range of the current MLE lot before further testing can begin. The instrument will only be able to check the control values if they are identified as C1 and C2 in the status screen menu. Results cannot be validated if the controls deviate from the expected values. Samples tested in the same run must be retested.**PROCEDURE**1. Remove the required reagents from the refrigerator and allow them to sit at room temperature for 30 minutes before using.
2. Use one “PCT” strip and one “PCT” SPR for each sample, control, or calibrator to be tested.
3. The assay is identified by reading the “PCT” code on the reagent strip. The calibrators must be identified by “S1” and by “S2”, and tested in duplicate. If the controls need to be tested, they should be identified by C1 and C2 and tested singly. Patients (or controls/standards as needed) must be programed in the status menu screen prior to loading “PCT” strips and “PCT” SPRs.
4. Mix the calibrators and/or controls using a vortex-type mixer.
5. Pipette 200 µL of calibrator, control, or sample into the first well of the “PCT” strip. Visually inspect well for bubbles.
6. Insert equal number of “PCT” SPRs and “PCT” strips into their appropriate assigned position on the instrument.
7. Initiate the assay immediately. All the assay steps are performed automatically by the instrument.
8. The assay will be completed within approximately 20 minutes of initiation. After the assay is completed, remove and discard of “PCT” SPRs and “PCT” strips into a hazardous waste receptacle.

**RESULTS** Results are analyzed automatically by the computer using two calibration curves which are stored by the instrument; the concentrations are expressed in **ng/mL**. With VIDAS PC, if a result which is <0.05 ng/mL is obtained, the printed report will include the alarm “J2 > J4 & J2 – J0 < RFV threshold” and will be indicated for the RFV. This alarm, which is linked with the reading mode of the VIDAS® B•R•A•H•M•S PCT™ (PCT) technique (dual reading), does not call into question the concentration measured.As not international standard is available, VIDAS® B•R•A•H•M•S PCT™ is calibrated against an internal panel of human sera with known procalcitonin concentrations. In case of patient follow-up, it is recommended to use the same PCT assay technique.Samples with procalcitonin concentrations greater than 200 ng/mL should be retested after dilution by 1/10 (1 volume of patient sample + 9 volumes of PCT negative sample).All procalcitonin concentrations **greater than** **2 ng/mL** must be called to the appropriate personal and documented in the computer system.**INTERPREATATION OF PROCALCITONIN REFERNCE RANGES**

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| **PCT Concentration (ng/mL)** | **Interpretations** |
| PCT ≤ 0.5 ng/mL | Systemic infection (sepsis) is not likely. Local bacterial infection is possible |
| PCT > 0.5 and ≤ 2 ng/mL | Systemic infection (sepsis) is possible, but other conditions are known to elevate PCT as well |
| PCT > 2 ng/mL | Systemic infection (sepsis) is likely, unless other causes are known |
| PCT ≥ 10 ng/mL | Important systemic inflammatory response, almost exclusively due to severe bacterial sepsis or septic shock |

**LINEARITY LIMIT OF PROCALCITONIN**

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| **Analyzer** | **Linearity** |
| MiniVidas | 0.065-166 ng/mL |

**LIMITATIONS OF ASSAY**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 additional tests performed.**INTERFERENCES**None of the following factors have been found to significantly influence this assay:* Hemolysis
* Lipemia
* Bilirubinemia

However, it is recommended not to use samples which appear to be grossly hemolyzed, lipemic, or icteric and, if possible, to collect a new sample.**REFERENCE**VIDAS® B•R•A•H•M•S PCT™ (PCT) package insert. Refer to the insert for further details of the procedure, references, and performance of the product. |
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