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| PurposePrinciple | This procedure provides instructions forperforming the Procalcitonin assay.  The assay principle combines a one-step 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  compounds 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-umbelliferone) the fluorescence of which is  measured at 450 nm. 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 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. |

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| Scope | This procedure is intended for Clinical Laboratory Scientist (CLS) and Medical Laboratory Technicians (MLT) who are trained and competent in performing the Procalcitonin assay.  Procalcitonin testing is done daily (Monday to Sunday) from 6:30 AM to10:00 PM. |

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| Specimen sources | Plasma collected on Lithium Heparin tube  For a given patient, the PCT assays must be performed on the same type of  sample tube. |

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| Specimen collection | Refer to LAMC-PPP-0189 Performing Venipuncture at KP LAMC |

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| Specimen transport | Refer to LAMC-PPP-0259 Specimen Collection, Handling, Packaging and Transportation |

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| Specimen storage | * Plasma separated from the clot can be stored at 2-8 °C in   stoppered tubes for up to 48 hours   * Frozen plasma (at -25 ± 6 °C) can be stored for 6 months |

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| Specimen rejection | Reject specimen under any of the following conditions:   * EDTA causes a decrease in the values measured, plasma collected in   EDTA should not be used (to test).   * Grossly hemolyzed samples |

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| Equipment | * bioMerieux Vidas 3 * Centrifuge |

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| Material and supplies | * 200 ul automatic pipette * Pipette tips * Vidas 3 Pipette tips * Vidas 3 Assay Dilution cups * Vidas 3 Waste Liner |
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Reagent/s PCT Reagent Kit (Refrigerate 2 to 8 °C)

1. PCT Reagent Strips
2. PCT SPRs
3. PCT Calibrators (S1 & S2)
4. PCT Kit Controls (C1 and C2)

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| Safety | All laboratory employees are expected to maintain a safe working environment  and an injury-free workplace. Laboratory employees are responsible for their own safety, and the safety of others and adhering to all departmental and medical center safety policies and procedures.   * For standard precautions and safety practices in the laboratory; see LAMC-PPP-0123, specifically, but not limited to, equipment safety, proper body   mechanics, sharps exposure and proper use of personal protective  equipment (PPE).   * For Universal Body Substance precautions, see LAMC-PPP-0128, specifically, but not limited to, exposure to body fluids. * For proper handwashing, see LAMC-PPP-0132, specifically, not limited to, proper handwashing. * For proper infection control, see LAMC-PPP-0127, specifically, but not limited to, proper use of gloves. * For proper handling of regular and infectious waste, see LAMC-PPP-0129, specifically, but not limited to, proper disposal of regular and biohazardous waste. * For proper cleaning of work area, see LAMC-PPP-0130 – Cleaning Work Areas. * For proper handling of chemicals and reagents, see the Chemical Hygiene Plan. * For proper storage and disposal of chemical hazardous waste, see LAMC-PPP-0134. |
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**Calibration**  Calibration is performed when opening a new lot of Procalcitonin reagent kit or

every 28 days.

**Before you begin Calibration:**

* + 1. **Prepare Calibrators and Kit Controls:**

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| **Description** | **Preparation** | **Stability** |
| PCT Calibrator | Reconstitute with 2 ml of distilled water. Let stand 5-10 minutes and then mix using vortex type mixer. | Stable for 8 hours at 2 - 8 °C or until the expiration date of the kit at 25 + 6 °C. 5 freeze/thaw cycles are possible. |
| PCT Controls | Reconstitute with 2 ml of distilled water. Let stand 5-10 minutes and then mix using vortex type mixer. | Stable for 8 hours at 2 - 8 °C or until the expiration date of the kit at 25 + 6 °C. 5 freeze/thaw cycles are possible. |

* + 1. **Enter MLE Data**

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| Step | Action |
| 1 | Select the  icon |
| 2 | Then select the  icon |
| 3 | The Scan MLE Barcode screen appears |
| 4 | Read the barcode on the assay box label using the barcode reader. Slowly scan the barcode from top to bottom or bottom to top  until the code has been read completely. The reader emits a beep when reading is finished.  Note: If the reader cannot read the barcode data correctly, the system will indicate an error. |

* Follow the steps to perform calibration

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| **Steps** | **Action** |
| 1 | Select **[Analyses]** from the Navigation Toolbar |
| 2 | Select the **+ ICON** next to **Calibration**. |
| 3 | Select Assay being run: PCT |
| 4 | Select the Lot Number  **NOTE:** Be sure to select Lot # of assay |
| 5 | Select Save and Close |
| 6 | Calibration test requests will appear in the calibration section of the screen. |
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| 7 | Select **[Load]** in the Action Bar. |
| 8 | The Loading work area will be displayed. |
| 9 | Remove the appropriate rack **completely** from the *VIDAS*® 3. Instrument.  Blue Segment—Sample Tubes  Purple Segment—Calibrators and Kit Controls |
| 10 | Load the calibrator and kit controls into the appropriate segment of the rack. |
| 11 | Reinsert the rack horizontally and smoothly into the instrument to avoid spills. *VIDAS*® 3 will automatically read the barcodes and  update the Sample/Reagent Loading Plan. |
| 12 | Load strips and SPR’s according to the loading plan. |
| 13 | Ensure the appropriate quantity of disposables are available. |
| 14 | Select **[Start]** in the action bar to begin the analysis. |
| 15 | The calibration values must be within the set RFV ("Relative Fluorescence Value"). If this is not the case, recalibrate using S1 and S2. |
| 16 | Do not open the rack section of the loading section if the Local Rack LED or Local Section LED is SOLID ORANGE |
| 17 | After the assay is completed, remove the SPRs and strips from the instrument. |

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| QualityControl |

Procalcitonin Controls must be ran daily using theBiorad Lypochek Specialty Controls. When Quality Control tolerance limits are

exceeded based on the QC criteria defined in LGM 2022 Quality Control (QC)

Policy, corrective action must be taken and documented before analyzing

patient samples.

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| **Description** | **Preparation** | **Stability** |
| Biorad Lypochek Specialty Controls Level 1 & 3 | Reconstitute with 2.0 ml of distilled water. Let stand 5-10 minutes and then mix. | Stable for 3 days at 2 - 8 °C |

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|  | * Follow the steps below to run Procalcitonin Quality Control | | | |
| Step | Action |
| 1 | Select **[Analyses]** from the Navigation Toolbar |
| 2 | Select the **+ ICON** next to **Quality Control.** |
| 3 | Select the Quality Control Full Name from the Full Name dropdown list (Biorad Lypochek PCT). |
| 4 | Select the Quality Control Short Name from the Short Name dropdown list (PCT1 or PCT3). |
| 5 | Select the Quality Control Lot Number from  the Lot Number dropdown list. |
| 6 | Select and highlight the Assay that need to be run: **PCT** |
| 7 | External Quality Control test requests will appear in the Quality Control section of the screen. |
| 8 | External Quality Control test requests will appear in the Quality Control section of the screen. |
| 9 | Select **[Load]** in the Action Bar. |
| 10 | The Loading work area will be displayed. |
| 11 | Load strips and SPR’s according to the loading plan. |
| 12 | Pipette 200 ul of each level of control on each PCT strip. |
| 13 | Select the Strips for the Biorad Lypochek Controls to change the pipetting mode |
| 14 | Select **[Manual]** in the action bar. The Switch pipetting modes dialog box opens. |
| 15 | Select **Switch to manual pipetting mode** to confirm or **Cancel and Close** to cancel the action. |
| 16 | The pipetting mode change is indicated in the strip display. |
| 17 | Select **[Start]** in the action bar to begin the analysis. |
| 18 | Do not open the rack section or the loading section if the Local Rack LED or Local Section LED is SOLID ORANGE |
| 19 | After the assay is completed, remove the SPRs and strips from the instrument. |

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| Procedure | * + - * Follow the steps below to run Procalcitonin on patient samples. | | | |
| Step | Action |
| 1 |  |
| 2 | Select the Accession Number in the Patient column. |
| 3 | Check the sample volume.   * + - * If the volume is at least 400 ul, load the sample in the blue segment of any sample rack.       * If the sample is less than 400 ul, pipette 200 ul the sample into the PCT strip and switch to manual pipetting mode |
| 3 | Select **[Load]** in the Action Bar. |
| 4 | The Loading work area will be displayed. |
| 6 | Remove any specimen rack **completely** from the *VIDAS*® 3. Instrument. |
| 7 | Load patient samples on the blue segment of the rack. |
| 8 | Reinsert the rack horizontally and smoothly into the instrument to avoid spills. *VIDAS*® 3 will automatically read the sample barcode and update the Sample/Reagent Loading Plan. |
| 9 | Load strips and SPR’s according to the loading plan.   * If the sample is less than 400ul, pipette 200 ul of the sample into the PCT strip * Select the specific accession number in the loading plan * Select **[Manual]** in the action bar. The Switch pipetting modes dialog box opens. * Select Switch to manual pipetting mode to confirm. |
| 10 | Ensure the appropriate quantity of disposables are available. |
| 11 | Select **[Start]** in the action bar to begin the analysis. |
| 12 | Do not open the rack section or the loading section if the Local Rack LED or Local Section LED is SOLID ORANGE |
| 13 | After the assay is completed, remove the SPRs and strips from the instrument. |

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| Clinical Significance | The VIDAS® B·R·A·H·M·S PCT (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.  VIDAS® B·R·A·H·M·S PCT™ (PCT) is also intended for use to determine:   * To aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission, using a change in PCT level over time, * To aid in decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI) – defined as community acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD)- in an inpatient setting or an emergency department, * To aid in decision making on antibiotic discontinuation for patients with   suspected confirmed sepsis. |
| Reference Range | None |

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| Interpretation Results / Critical Values | Procalcitonin testing is only intended to assess risk for progression to severe sepsis and septic shock, and for antibiotic discontinuation or adjustment in suspected or confirmed septic patients. |

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| Interferences | **None** of the following factors have been found to significantly influence this  assay:   * Hemolysis - after spiking samples with hemoglobin, up to 347 μmol/L   (monomer).   * Lipemia - after spiking samples with lipids, up to 30 g/L equivalent in   triglycerides.   * Bilirubinemia - after spiking samples with bilirubin, up to 574 μmol/L.   However, it is recommended not to use samples which appear to be  hemolyzed, lipemic or icteric and, if possible, to collect a new sample. |
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| Controlled Documents | The following non-controlled documents support this procedure. | | | |
| Document No. | Name of Documents |
| LAMC-PPP-0189 | Performing Venipuncture at KP LAMC |
| LAMC-PPP-0259 | Specimen Collection, Handling, Packaging and Transportation |
| LAMC-PPP-0026 | Quality Control (QC) Program |
| LAMC-PPP-0123 | Safety Practices |
| LAMC-PPP-0127 | Infection Control |
| LAMC-PPP-0128 | Universal Body Substance Precautions |
| LAMC-PPP-0129 | Handling of Regular and Infectious Waste |
| LAMC-PPP-0130 | Cleaning Work Areas |
| LAMC-PPP-0132 | Hand washing Policy |
| LAMC-PPP-0134 | Storage and disposal of Chemical Hazardous Waste |

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| Non-Controlled Documents | The following controlled documents support this procedure. |

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| Document No. | Name of Documents |
|  | bioMerieux Vidas 3 Operator’s Manual |
|  | Vidas 3 Basic Guide |

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| Author(s) | Rosalie I. Fajardo, MS CLS(ASCP) |