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| PurposePrinciple | This procedure provides instructions forperforming the Activated Partial Thromboplastin (APTT) Time assay.  APTT involves the recalcification time of plasma in the presence of a  standardized amount of platelet substitute (cephalin) and a specific activator  (silica). The time of clot formation is measured on the STA® - Compact®. The  STA® - Compact® is a fully automated coagulation instrument, which uses an  electromagnetic mechanical clot detection system. The oscillation of a steel ball  within the cuvette with the thromboplastin and plasma is monitored by the  STA® - Compact®. When the oscillation of the steel ball is slowed by clot  formation, the sensor determines the time in seconds. The APTT is a general  coagulation screening test for the activity of the intrinsic pathway (factors XII,  XI, IX, VIII, X, V, II, and fibrinogen). It is also the test most often used to  monitor heparin therapy. |

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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 Activated Partial Thromboplastin Time assay.  This Procedure replaces LCoM 217 Diagnostica Stago STA Compact Quality Control and LCoM 218 Diagnostica Stago STA Compact Sample Processing. |

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| Specimen sources | Whole Blood collected in 9:1 ratio of blood in a 3.2% (0.109M) Sodium Citrate tube |

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| Specimen collection | Refer to LPhM 200 Performing Venipuncture at KP LAMC |

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| Specimen transport | Refer to LSPM 203 Specimen Collection, Handling, Packaging and Transportation |

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| Specimen storage | Whole Blood or Plasma remain stable for 4 hours at 20 + 5◦ C.  Do not store whole blood or plasma at 2-8◦ C |

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| Specimen rejection | Reject specimen under any of the following conditions:   * Clotted * Samples collected in wrong collection tube * Short draws and over draws * Samples with visible hemolysis * Samples with unusually shortened results must be checked for clot |

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| Equipment | * STA® - Compact® * Centrifuge |
| Material and supplies | * Pipettes * Pipette tips * Cuvette Roll-1000 * Magnetic Stir Bars * STA® Reducer * Reagent Grade Water * STA – DESORB U * STA® - Cleaner Solution |

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| Reagent/s | **Description** | **Preparation** | **Stability** |
| STA® PTT A | Reconstitute each vial with 5.0 ml of distilled water. Let sit 30 minutes at room temperature. Mix vigorously by turning the vial upside down, 5-10 times or vortex on low for 5 seconds. Remove rubber stopper and replace the perforated plastic cap.  Write the date and initial on the vial before loading on the instrument. | 24 hours with the perforated cap in place on the STA® - Compact® |
|  | 0.025 M CaCl2 | Ready to use. If refrigerated, keep at room temperature for 30 minutes before use. | 72 hours on the  STA® - Compact® |

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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 LGM   8000, 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 LGM 8005, specifically, but not limited to, exposure to body fluids. * For proper handwashing, see LGM 8010, specifically, not limited to, proper handwqashing. * For proper infection control, see LGM 8004, specifically, but not limited to, proper use of gloves. * For proper handling of regular and infectious waste, see LGM 8006, specifically, but not limited to, proper disposal of regular and biohazardous waste. * For proper cleaning of work area, see LGM 8007 – 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 LGM 8012. |
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**Calibration** No calibration of the system is necessary for performing an Activated Partial

Thromboplastin Time.

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| QualityControl |

Activated Partial Thromboplastin Time Controls must be ran at least once per shift using theSTA® Control N+ABN Contol. 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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|  | |  |  |  | | --- | --- | --- | | **Controls** | **Preparation** | **Stability** | | STA® Coag Control Ⓝ+ABN | Reconstitute each vial with 1.0 ml reagent grade water. Let sit 30 minutes at room temperature. Swirl gently. Write the date and initial on the vial after reconstitution. | Reconstituted stability on the STA® - Compact® is 8 hours. | | | | |
|  | • Follow the steps below to run Activated Partial Thromboplastin Time  Quality Controls | | | |
| Step | Action |
| 1 | Through MAIN MENU under CALIB/CONTROL select QUALITY CONTROL and press **Enter** **⮠**. |
| 2 | Move cursor to the **PTT** test. Select **PTT** by pressing **F1** and then **F10**. Type in the Access Code and press **Enter** **⮠** then press **ESC** to run the QC. |
| 3 | All control ranges are monitored automatically by the STA® - Compact. The results can be found in the individual QC files. Control results are automatically filed in the STA® - Compact® QC file. All results for a 24-hour period will be converted to a “mean” value on the first run after midnight. This mean is used in the statistical data and is plotted on the Levy-Jennings chart as a daily mean. |

• Follow the steps below to Rerun Out of Range Quality Control

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| Step | Action |
| 1. | **If any controls are outside the ± 2 SD range, the instrument will audibly and visually alarm.** |
| 2. | The out of range QC result will display. Press ESC to continue. |
| 3. | The Test Screen will display. |
| 4. | Through the MAIN MENU under CALIB/CONTROL select QUALITY CONTROL and press **Enter** **⮠**. |
| 5. | Move cursor to the **PTT** test. The out of range result will be displayed in blue. Press **Enter** **⮠** and then **ESC**. The following options will display: Accept, Rerun or Postpone Decision. |
| 3. | |  |  | | --- | --- | | **If…** | **Then…** | | The quality control result is acceptable | Choose ‘Accept’ | | The quality control requires repeat or rerun | Choose ‘Rerun’ | | Corrective Action will be taken at a later time. | Choose ‘Postpone Decision’ | |
| 4. | Select ‘Rerun’ and then **F10.** |
| 2. | Type your access code, then confirm with the ‘Enter’ key. |

* Follow the steps below to display and print daily Quality Control results.

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| Step | Action |
| 1. | From the MAIN MENU under CALIB/CONTROL select QUALITY CONTROL, press **Enter** **⮠** . |
| 2. | Move the cursor to the **PTT** test and press **Enter** **⮠** to view the Levy Jennings chart. |
| 3. | Press **F1** to view the results in tabular form. |
| 4. | Press **F6** and select Execute then press **Enter** **⮠** to print the individual values under current controls. |
| 5. | Press **ESC** key to exit (back to graph). |
| 6. | Press **F2** or **F3** to view other levels and continue with **F1** to view the result list. |

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| Procedure | * + - * Follow the steps below to run Activated Partial Thromboplastin Time on patient samples.  |  |  | | --- | --- | | Step | Action | | 1 | Open the sample drawer by pressing F2 from the Test Panel screen or through the MAIN MENU, under LOADING, Select Sample, press **Enter** **⮠** | | 2 | After the drawer opens, identify the sample by scanning the bar-code or manually entering the ID using the keyboard and then placing the specimen into the drawer. | | 3 | The STA® - Compact® will query the host computer and download the test(s) as well as assign the status (i.e. stat). | | 4 | As soon as the sample drawer closes, the TEST STATUS screen will appear. | | 6 | All patient results are displayed on the TEST PANEL screen and automatically transmitted to the LIS. | |

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| Clinical Significance | A prolongation of the APTT may be seen in the following deficiencies; Factors VIII, IX, XI, XII, prekallikrein and high molecular weight kininogen. It may also be abnormal in liver disease, DIC, circulating anticoagulants (such as LA, or a specific factor inhibitor) during heparin or oral anticoagulant therapy or when treated with direct thrombin inhibitors (such as hirudin, argatroban, etc). |
| Reference Range | |  |  | | --- | --- | | Activated Partial Thromboplastin Time Reference Range | 25 - 37 secs | |

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| Interpretation Results / Critical Values | |  |  | | --- | --- | | Activated Partial Thromboplastin Time Critical Values | >68 secs | |
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| Limitations | * + - * Many commonly administered drugs affect the results obtained in APTT testing (Example: coumadin and heparin).       * When monitoring heparin therapy, any release of platelet factor 4 (PF4) which is a potent inhibitor of heparin, represents a major source of error. |

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| Controlled Documents | The following non-controlled documents support this procedure. | | | |
| Document No. | Name of Documents |
| LPhM 200 | Performing Venipuncture at KP LAMC |
| LSPM 203 | Specimen Collection, Handling, Packaging and Transportation |
| LGM 2022 | Quality Control (QC) Policy |
| LGM 8000 | Safety Practices |
| LGM 8004 | Infection Control |
| LGM 8005 | Universal Body Substance Precautions |
| LGM 8006 | Handling of Regular and Infectious Waste |
| LGM 8007 | Cleaning Work Areas |
| LGM 8010 | Hand washing Policy |
| LGM 8012 | 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 |
|  | STA® - Compact® Reference Manual |
|  | STA® Package Inserts |

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