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| PurposePrinciple | This procedure provides instructions forperforming the Prothrombin Time assay.  A mixture of thromboplastin is added to citrated plasma and the time for clot  formation is determined. The STA-R Evolution ® is a fully automated coagulation instrument which uses an electromagnetic mechanical clot detection system. The oscillation of a steel ball within the cuvette containing the thromboplastin and plasma is monitored by the STA-R Evolution®. When the oscillation of the steel ball is slowed by clot formation, the sensor determines the time in seconds. The PT is a basic coagulation screening test for the activity of the extrinsic pathway (factors I (fibrinogen), II, V, VII, and X). |

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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 Prothrombin Time assay.  This Procedure replaces LCoM 219 STA-R Evolution Quality Control and LCoM 221 STA-R Evolution 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 can be stored at 20 + 5◦ C for 8 hours.  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 | * Stago STA-R Evolution * Centrifuge |

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| 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** | |
| Stago Neoplastine CI Plus (Reagent 1 and Reagent 2) | Transfer the entire contents of one vial of Reagent 2 into one vial of Reagent 1 of the  same lot. Let sit 30 minutes at room temperature. Swirl gently. Add a Magnetic Stir Bar to the vial, place STA**®** – Reducer and replace the perforated plastic cap. Write the date and initial on the vial before loading on the instrument. | | 48 hours on the STA-R Evolution® |

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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 a Prothrobim Time and INR

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| QualityControl |

Prothrombin 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 Qulaity 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-R Evolution® is 8 hours. | | | | |
|  | * Follow the steps below to run Prothrombin Time Quality Controls | | | |
| Step | Action |
| 1 | Click the icon |
| 2 | Click the **PT** test abbreviation |
| 3 | Click the **Control Level #** tab (#corresponds to the number of the level) |
| 4 | Click the button |
| 5 | Confirm by clicking **OK** |
| 6 | Repeat for each level |
| 7 | All control ranges are monitored automatically by the STA–R Evolution®. Control results are automatically filed in the STA–R Evolution® QC file. All results for a 24-hour period will be converted to a “mean” value at midnight. This mean is used in the statistical data and is plotted on the Levy-Jennings chart as a daily mean. Each point can be viewed on the Levy-Jennings Daily control chart by clicking on the left arrow. |

* Follow the step below to Display Daily Controls

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| Step | Action |
| 1. | Click on the  The **Daily controls** screen is displayed: |
|  | * For Quality control result >2SD, the value will be flagged ‘To Validate’. ‘To Validate’ denotes that the result must be reviewed and accepted or appropriate action taken such as repeating the quality control run. Follow the step below to validate the quality control result. | | | |
| Step | Action |
| 1 | From the **Daily Control** **screen**, **double click** on the quality control to be validated. The following options will display:   * Validate * Rerun * Delete |
| 2 | |  |  | | --- | --- | | **If…** | **Then…** | | The quality control result is acceptable | Choose ‘Validate’ | | The quality control requires repeat or rerun | Choose ‘Rerun’ | | The quality control needs to be excluded from the daily statistical data. | Choose ‘Delete’ | |

* + - * Follow the step below to print daily Quality Control results.

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| Step | Action |
| 1. | From the **Daily Control screen**, **click** on  to print daily quality control results. |

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| Procedure | * + - * Follow the steps below to run Prothrombin Time on patient samples. | | | |
| Step | Action |
| 1 | Place tubes in rack |
| 2 | Place rack(s) on tray |
| 3 | Place tray on STA-R. Tubes are automatically loaded, their barcoded labels are read, work lists are downloaded from the host computer or the predefined profile is applied according to the chosen option. Tests are automatically carried out by the analyzer. |
| 5 | **Test Panel**  Click on |
| 6 | If the instrument is unable to read the barcode, the automatic unloading of not read tubes is selected  and all tubes which are not read are automatically unloaded.  The **Manual Input of Patient ID’s** window is displayed for re-identification. |
| 7 | Enter the sample ID |
| 8 | Click on to load the rack |

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| Clinical Significance | A prolonged PT has been observed in the following clinical disease states: congenital or acquired deficiencies of Factor II, V, VII, X, or fibrinogen. The PT may also be prolonged in liver disease, treatment with vitamin K antagonists, disorders of metabolism of vitamin K, fibrinolysis, and DIC.  The PT is also used to monitor Warfarin therapy because of its sensitivity to variations in the concentration of the Vitamin-K dependent factors II, VII and X. Because of the variations in the PT results with different thromboplastin reagent and instruments, it is recommended (by the World Health Organization) that PT results be converted to an International Normalized Ratio (INR). The INR corresponds to the value of the ratio of the patient’s PT and the geometric mean PT of the normal reference population raised to the ISI (International Sensitivity Index) power. |
| Reference Range | |  |  | | --- | --- | | Prothrombin Time Reference Range | 12.0-15.4 sec | | INR Reference Range | 0.8-1.2 | | Prothrombin Time Clinical Reportable Range | 8.0-150.0 sec | | INR Clinical Reportable Range | 0.5-10.0 | |

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| Interpretation Results / Critical Values | |  |  | | --- | --- | | Prothrombin Time Critical Values | None | | INR Critical Values | >5.0 | |

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| Limitations | * + - * Many commonly administered drugs affect the results obtained in PT testing. (Example: coumadin and heparin and direct thrombin inhibitors).       * STA® - Neoplastine® CI Plus contain a specific inhibitor of heparin. The test is insensitive to unfractionated heparin levels up to 1 IU/ml and to low molecular weight heparin levels up to 1.5 anti-Xa IU/ml. |

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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-*R* Evolution Reference Manual |
|  | STA® Package Inserts |

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