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| PurposePrinciple | This procedure provides instructions forperforming Fibrinogen assay.  The clotting method of Clauss is employed in the quantitative determination of  fibrinogen. In the presence of an excess of thrombin, the clotting time of diluted  plasma is inversely proportional to the level of plasma fibrinogen. The clot is  detected by the STA-R Evolution®, a fully automated coagulation instrument,  which uses an electromagnetic mechanical clot detection system. The oscillation  of a steel ball within the cuvette with the thrombin and diluted 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 time is  read from a stored curve on the STA-R Evolution®. |

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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 Fibrinogen 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** |
| STA® - Fibrinogen | Reconstitute each vial with 5.0 ml of reagent grade water. Let stand 30 minutes at room temperature. Swirl gently. Replace the perforated plastic cap on the vial.  Write the date and initial on the vial before loading on the instrument. | 5 days on the STA-R Evolution® with the perforated cap in place |
|  | STA® - Owren-Koller Buffer | Ready to use buffer. Used by the STA-R Evolution® to perform dilutions of controls and patients’ plasmas.  Write the date and initial on the vial before loading on the instrument. | 72 hours on the STA-R Evolution® |
| 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** The kit reagents are pre-calibrated: this calibration is identical for all reagents of

each lot.

Entering the data for the calibration curve: When the operator scans a new lot of

fibrinogen reagent, the STA-R Evolution® will request the operator to scan the

barcode printed on the barcode insert across the barcode reader.

* Follow the steps below to view the calibration curve:

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| **Step** | **Action** |
| **1** | Click on Calibration menu icon |
| **2** | Click **FIB TEST** (on the test abbreviation) |
| **3** | Calibration screen includes current calibration curves and product information |
| **4** | Position for two different lots of reagent are available |
| **5** | Click on the calibration icon  or calibration icon |
| **6** | Confirm by clicking on **Calibrate** |
| **7** | Select the lot # to be calibrated  (the one highlighted in green) |
| **8** | Click the Print icon |

The calibration curve will be validated for the lot being used when the two

fibrinogen control levels have been run. If the validation controls are outside the

assayed range, the STA-R Evolution® will not run fibrinogen until the controls are

validated.

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| QualityControl |

Fibrinogen 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 Fibrinogen Quality Control | | | |
| Step | Action |
| 1 | Click the icon |
| 2 | Click the **FIB** 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 Fibrinogen 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 |
| 9 | **Note:** The results >Mmax and <Mmin are prompted on raw data (sec) and FIB is reported in concentration (mg/dL or g/L). The Fibrinogen curve is an inverse curve, thus:   * On the STA-R Evolution® a result of **>Vmax** for fibrinogen means the fibrinogen value is **extremely low**. * On the STA-R Evolution® a result of **<Vmin** for fibrinogen means the fibrinogen value is **extremely high**. * It is possible to have a **>Vmax** or **<Vmin** result after the instrument does the auto redilute. |
| Clinical Significance | An increase of the fibrinogen level is observed in cases of diabetes,  inflammatory syndromes and obesity. A decrease of the fibrinogen level is  observed in DIC, fibrinolysis, thrombolytic therapy and inherited disorders.  Fibrinogen seems to be involved in the pathogenicity of thrombotic  cardiovascular events. | | | |
| Reference Range | |  |  | | --- | --- | | Fibrinogen Reference Range | 218-441 mg/dL | | Fibrinogen Clinical Reportable Range | 60-1800 mg/dL | | | | |

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| Interpretation Results / Critical Values | |  |  | | --- | --- | | Fibrinogen Critical Value | <100 mg/dL | |

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| Limitations | * In patients receiving drugs that affect the fibrinolytic system, the plasma levels of fibrinogen degradation products (FDP) may be extremely high. FDPs may inhibit both thrombin action of fibrinogen and fibrin polymerization. At normal fibrinogen concentrations, FDPs have a minimal effect on the fibrinogen assay. At fibrinogen concentrations below 150 mg/dL, FDPs greater than 130 g/mL increasingly inhibit the thrombin clotting rate assay. High levels of paraproteins may interfere with the polymerization of fibrin monomers. * The clinical use of topical bovine thrombin has led to the generation of antibodies in some patients. These antibodies may lead to artifactual prolongation of the thrombin clotting rate assay of fibrinogen. * Heparin may interfere with this assay. However, the STA® - Fibrinogen reagent contains a specific inhibitor of heparin. Any prolongation of the assay is therefore, related to a real coagulation factor deficiency of fibrinogen. * The STA® - Fibrinogen procedure is insensitive to the following substances: fibrin degradation products (up to 130 µg/mL), hirudin (up to 3 µg/mL), and heparin (up to 2 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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| Author(s) | Rosalie I. Fajardo, MS CLS(ASCP) |