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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® - Compact®, 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® - Compact®. 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® - Compact®. |

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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 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 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-Compact * 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® - Compact®with the perforated cap in place |
|  | STA® - Owren-Koller Buffer | Ready to use buffer. Used by the STA® - Compact® 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® - Compact® |
| 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 reagent kits 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® - Compact® will request the operator to scan the

barcode printed on the barcode insert across the barcode reader. Validate

the reagent volume indicated by the analyzer. Then, place the vial in one of the

STA Compact® drawers.

* Follow the steps below to view the calibration curve:

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| **Step** | **Action** |
| **1** | Through MAIN MENU under CALIB/CONTROL select CALIBRATION and press **Enter** **⮠**. |
| **2** | Move cursor to the **FIB** press **Enter** **⮠** |
| **3** | Press **ESC** to display the Calibration curve. |

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® - Compact®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® - Compact®is 8 hours. | | | | |
|  | * Follow the steps below to run Fibrinogen Quality Control | | | |
| Step | Action |
| 1 | Through MAIN MENU under CALIB/CONTROL select QUALITY CONTROL and press **Enter** **⮠**. |
| 2 | Move cursor to the **FIB** test. Select **FIB** 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 **FIB** 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 **FIB** 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 Fibrinogen 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. | | 7 | **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® - Compact® a result of **>Vmax** for fibrinogen means the fibrinogen value is **extremely low**. * On the STA® - Compact® 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® - Compact®Reference Manual |
|  | STA® Package Inserts |

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