|  |  |
| --- | --- |
| PurposePrinciple | This procedure provides instructions forperforming the D-Dimer assay.  The specific degradation of fibrin (i.e., fibrinolysis) is the reactive mechanism  responding to the formation of fibrin. Plasmin is the fibrinolytic enzyme derived  from inactive plasminogen. Plasminogen is converted into plasmin by  plasminogen activators. The main plasminogen activators are tissue  plasminogen activator (tPA) and pro-urokinase which is activated into urokinase  (UK) by, among others, the contact system of coagulation. In the bloodstream,  plasmin is rapidly and specifically neutralized by alpha 2 – antiplasmin, thereby  restricting its fibrinogenolytic activity and localizes the fibrinolysis on the fibrin  clot. On the fibrin clot plasmin degrades fibrin into various products, (i.e., D-  Dimers). Antibodies specific for these products, which do not recognize  fibrinogen, have been developed. The presence of these various fibrin  degradation products, among which D-Dimer is the terminal product, is the  proof that the fibrinolytic system is in action in response to coagulation  activation.  When a beam of monochromatic light is allowed to transverse a suspension of microlatex particles to which specific antibodies have been attached by covalent bonding and if the wavelength of the light is much greater than the diameter of the latex particles, the light is only slightly absorbed. In the presence of the antigen being tested for, the antibody-coated latex particles agglutinate to form aggregates of a diameter greater than the wavelength of the light; more of the latter is absorbed. This increase in light absorption is a function of the antigen level present in the test sample. |

|  |  |
| --- | --- |
| Scope | This procedure is intended for Clinical Laboratory Scientist (CLS) and Medical Laboratory Technicians (MLT) who are trained and competent in performing the D-Dimer assay.  This Procedure replaces LCoM 217 Diagnostica Stago STA Compact Quality Control and LCoM 218 Diagnostica Stago STA Compact Sample Processing. |

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

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

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

|  |  |
| --- | --- |
| 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 |

|  |  |
| --- | --- |
| 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 |

|  |  |
| --- | --- |
| Equipment | * Stago 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   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |  |  |  |
| --- | --- | --- | --- |
| Reagent/s | **Description** | **Preparation** | **Stability** |
| STA® Liatest® D-Dimer:  **Reagent 1:** Tris Buffer  **Reagent 2:** Latex | Ready to use. Allow the reagent to stand at room temperature for 15 minutes. Mix gently without creating bubbles. Then, place a STA**®** mini Reducer and the perforated cap on the vial perforated plastic cap on the vial.  Write the date and initial on the vial before loading on the instrument.  Ready to use. Allow reagent to stand at room temperature for 15 minutes. Mix gently without creating bubbles. Then, place a STA**®** mini Reducer and the perforated cap on the vial perforated plastic cap on the vial.  Write the date and initial on the vial before loading on the instrument. | 15 days on the STA® - Compact®  15 days on the STA® - Compact® |
|  | 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. |
|  |  |

**Calibration/** The kit reagents are pre-calibrated: this calibration is identical for all the reagents

**Verification** 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.

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

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

D-Dimer controls have been run. If the validation controls are outside the

assayed range, The STA–R®/STA® - Compact® will not run patient samples.

Refer to LCoM 416 STA® - Compact®Calibration/Verification

|  |
| --- |
| QualityControl |

D-Dimer Controls must be ran at least once per shift using theSTA® Liatest® Control. 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.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  |  |  | | --- | --- | --- | | **Controls** | **Preparation** | **Stability** | | STA® Liatest® Control N+P | 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 D-Dimer Quality Control | | | |
| 1 | Through MAIN MENU under CALIB/CONTROL select QUALITY CONTROL and press **Enter** **⮠**. |
| **2** | Move cursor to the **D-DI** test. Select **D-DI** 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

|  |  |
| --- | --- |
| 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 **D-DI** 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.

|  |  |
| --- | --- |
| Step | Action |
| 1. | From the MAIN MENU under CALIB/CONTROL select QUALITY CONTROL, press **Enter** **⮠** . |
| 2. | Move the cursor to the **D-DI** 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. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Procedure | * Follow the steps below to run D-Dimer 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. | |

**Results**

**Reporting** **For D-Dimer DVT and D-Dimer PE:**

* + - * If the result for D-Dimer DVT or D-Dimer PE is >Vmax, report the test as >4000. Do NOT dilute.
      * If the result for D-Dimer DVT or D-Dimer PE is below 270, the result should be reported as <270

**For D-Dimer DIC:**

* + - * If the result for D-Dimer DIC is >Vmax, program the sample to be diluted 1:5
      * If the 1:5 dilution is not >Vmax, report the value
      * If the 1:5 dilution result is still >Vmax, report >20000
      * If the result for D-Dimer DVT or D-Dimer PE is below 270, the result should be reported as <270

|  |  |
| --- | --- |
| Clinical Significance | Clinical applications for this test are as follows: Disseminated Intravascular Coagulation (DIC), negative predictor for the diagnosis of a thrombotic episode (i.e., DVT, PE), efficacy of treatment for a thrombotic episode and screen for possible re-occurrence (MI), and screen for other activation states of coagulation (i.e., post-operative, cancer, cirrhosis). |
| Reference Range | |  |  | | --- | --- | | D-Dimer DVT Reference Range | <=499 ng FEU/ml | | D-Dimer PE Reference Range | Age dependent | | D-Dimer DIC Reference Range | <=499 ng FEU/ml | | D-Dimer DVT Clinical Reportable Range | 270-4,000 ng FEU/ml | | D-Dimer PE Clinical Reportable Range | 270-4,000 ng FEU/ml | | D-Dimer DIC Clinical Reportable Range | 270-20,000 ng FEU/ml | |

|  |  |  |  |
| --- | --- | --- | --- |
| Interpretation Results / Critical Values | |  |  | | --- | --- | | D-Dimer Critical Values | None | |

|  |  |
| --- | --- |
| Limitations | * Cloudy plasmas may lead to an under-estimation of the D-Dimer level. Ensure that the absorbance value at 540 nm of the plasma diluted 1:6 with STA**®** - Owren-Koller buffer is < 0.35. * An over-estimation of D-Dimer level may be seen in the following conditions; FDP concentrations greater than 15 *u*g/ml, the presence of rheumatoid factor at a level greater that 50 IU/ml, and the presence of anti-bovine albumin and/or anti-mouse antibodies in certain subjects * The STA**®** Liatest**®** D-Dimer is insensitive to the following substances: hemoglobin (up to 2 g/l); conjugated bilirubin (up to 290 mg/l); unconjugated bilirubin (up to 200 mg/l); unfractionated heparin (up to 2 IU/ml0), and LMWH (up to 2 anti-Xa IU/ml). |

|  |  |  |  |
| --- | --- | --- | --- |
| 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 | |
| LCoM 416 | STA® - Compact® Calibration/Verification | |
| 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 | |

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

|  |  |
| --- | --- |
| Document No. | Name of Documents |
|  | STA® - Compact® Reference Manual |
|  | STA® Package Inserts |

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