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| **Coagulation Testing by ACLTOP 350 Analyzer** | *Procedure #:* | ***HC0# 200*** |
| *Version #:* | ***1.0*** |

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| **Purpose** | This procedure provides instruction for the ACL TOP system for automated use in coagulation and fibrinolysis testing in human plasma. |
| **Principle/ Clinical Significance** | The instrumentation Laboratory ACL TOP System is a fully automated, random access analyzer for specific clinical use in coagulation and fibrinolysis testing in human plasma. Results include both direct coagulation measurements and calculated parameters.  **Turbidimetric (Coagulometric) Measurement**  The principle of turbidimetric (coagulometric) clot detection is used in the system to measure and record the amount of time required for a plasma specimen to clot. This technique assesses coagulation endpoint by measuring change in optical density.  Turbidimetric (coagulometric) clot detection is based on the principle that light passing through a medium in which fibrinogen is converted to fibrin will be absorbed by the fibrin strands. Light (671nm) transmitted through the plasma sample is monitored by a sensitive photodetector positioned 180o to the incident source.  Light absorption increases as fibrin clot formation progresses. Consequently, light transmittance through the sample continuously decreases and is measured by the photodetector.  The corresponding electrical signal output from the photodetector changes according to the detected light. The signal output is processed via software through a series of algorithms to determine the clot point.  **Chromogenic Measurements**  Chromogenic tests can be either direct or indirect.   * Direct tests are those tests where the analyte of interest (e.g. protein C, plasminogen) acts directly on a specified synthetic substrate. * Indirect tests are those tests where the analyte of interest (antithrombin, plasmin inhibitor) reacts with a fixed quantity of enzyme to form inactive complexes.   Under optimized test conditions, residual enzyme activity is then measured using a specific synthetic substrate. In all cases, the reaction is monitored at 405 nm by the continuous release of paranitroaniline (pNA) from the synthetic substrate.  The chromogenic channels utilize the colorimetric principle of measuring absorbance (Delta A) in the measuring cuvette. The optical sensor reads light (405 nm) that passes through the cuvette. The light is absorbed by the fluid in the cuvette in direct proportion to the concentration of pNA. The amount of light reaching the photodetector is converted into an electrical signal that is proportional to the enzyme activity.  **Immunological Measurements**  The principle of immunological measurement is used on the system to directly measure and record the amount of an analyte. This technique assesses the physical concentration of the analyte (and not its activity) by measuring change in optical density.  The immunological method relies on the formation of antigen‐antibody complexes to affect light transmission. Immunological testing of the ACL TOP uses the 405 nm or the 671 nm channels depending on the test and the reagent formulation. The 405 nm and the 671 nm channels both utilize the principle of measuring absorbance in the cuvette. An optical sensor reads the light (405 nm or 671 nm) that passes through the cuvette. The light is absorbed by the fluid in the cuvette in direct proportion to the concentration of  antigen‐antibody complexes. The amount of light reaching the photodetector is converted into an electrical signal that is proportional or inversely proportional to the analyte concentration. |
| **Scope** | This standard operating procedure applies to all laboratory technicians, technologists and supervisory personnel of the Baltimore VA Medical Center Pathology & Laboratory Medicine Service |
| **Responsibilities** | |  |  | | --- | --- | | **Responsible Party** | **Responsibilities** | | Hematology Supervisor | * review this procedure annually and make any necessary revisions in a timely manner | | Medical Director | * review all new or substantially revised procedures, before implementation | | Staff | * read this procedure in its entirety and ask any questions before implementation * govern yourself according to the contents of this procedure after implementation | |
| **Safety Precautions** | Standard Precautions:   * Gloves * Fluid resistant laboratory coat. |
| **Specimen** | The plasma is anticoagulated by mixing one volume 3.2% sodium citrate with nine volumes of freshly drawn venous blood. The blood and anticoagulant should be mixed thoroughly immediately after drawing. Clotted specimens are unacceptable for analysis. If specimen cannot be tested within 4 hours, platelet-poor plasma should be removed from the cells and frozen (-70°C) for up to 6 months.  **Plasma separation:**   * During collection and centrifugation of the sample, hemolysis must be avoided. The breakage of red cells, whose phospholipid surfaces have thromboplastin activity, causes a change in coagulation times. Therefore, the samples should be centrifuged as soon as possible at a minimum of 2-500 g or a period long enough to obtain plasma with a platelet count less than 10,000/µL. * If a sample is to be frozen, the plasma should be double-spun (10 g) in eppendorf tubes for 60 seconds to ensure it is platelet poor (<1000/4) * Lipemic specimens should be spun in Beckman Airfuge to clear (see "Troubleshooting" section of individual tests for procedure). * Hemolysis should be avoided. Hemolysis is generally associated with traumatic venipuncture which causes falsely decreased clotting times. * If plasmas are to be stored, the recommended times and temperatures from the time of draw are:   22-24°C (room temperature) = 4 hours (aPTT),  or 2-4°C (refrigerated) 24 hours(PT/FIB)  -20°C (frozen plasma) 2 weeks  -70°C (rapidly frozen plasma) = 6 months |
| **Reagents** | Reagents on the ACL TOP 350 are classified as start reagents and intermediate reagents.  **Start Reagents:**  A start reagent is a reagent that, when mixed with sample or a sample mixture, activates the reaction in the Optical Reading Unit (ORU). It is the last material added to the cuvette. Start reagents must be placed in reagent racks inserted into tracks R1 to R4 of the reagent/dilution area. Recombiplastin is an example of a start reagent (for PT testing).  **Intermediate Reagents:**  An intermediate reagent is a reagent that, when mixed with sample, activates certain constituents of the sample but is not enough to bring the reaction to the desired completion. Intermediate reagents must be placed in a diluents rack inserted into track D2 or placed in reagent racks inserted in to tracks R1 to R4. |
| **Quality Control** | * Three levels of controls are run on the ACLTOP 350 once every 8 hours that the instrument is in use. They are: * IL Normal Control (Level 1) — run for PT, FIB and aPTT * IL Abnormal Control (Level 3) — run for PT, and aPTT * Low Fibrinogen Control — run for FIB only * **Preparation & Stability:**   Reconstitute each vial (normal and abnormal) with 1.0 ml of reagent grade water.  Replace stopper and allow vial to stand for 30 minutes at room temperature. Swirl  gently before use. Reconstituted product is stable for 24 hours when kept on-board the  instrument at 15 - 25°C.   * **Running Controls:**  1. Place QC in Diluent Rack 2. Load rack in either Reagent Area or Diluent Area. 3. Go to Menu bar and choose "QC" then" Results List" from dropdown menu. Click   on "QC Statistics".   1. On Navigation Tree, select the appropriate QC to be run (only tests with check mark next to them will be run). 2. Click on the "Run" tile. 3. After controls have been run, click on the "Previous Page" tile. Select "QC" then "Results List" from the dropdown menu. Verify all QC is within acceptable range before processing patients.   **Monitoring Control Limits:**   * The Levey-Jennings chart is an extremely useful tool used to display quality control data points. It displays the mean and 2 SD lines above and below the mean. According to Gaussian statistics, the 2 SD lines indicate the area in which 95.5% of the points should fall. * The values obtained from a single lot number of control should show a relatively even distribution of points above and below the mean. * Once in approximately 20 tests, a value will fall outside the 2 SD range (usually between 2 and 3 SD). This usually occurs by chance and does not necessarily indicate an out of control situation. * Repeating the determination on that sample or reconstituting a new vial of control usually results in the value falling within expected limits. * Shifts and trends can easily be monitored by Levey-Jennings charts. Shifts are said to occur when 6 or more consecutive points fall either above or below the mean. They are usually caused by events such as a change in calibration or reference value. * A trend occurs when 6 or more values are seen to steadily increase or decrease. The trend can start on one side of the mean and continue across to the other. This is usually caused by a gradual change in a reagent, control, or instrument. |
|  | **Frequency**   * A minimum of 2 levels of control material should be analyzed at least once during each 8 hour shift, when change of reagent occurs, after performance of routine maintenance or instrument service. * An analytical run, for the purposes of quality control, is a period of time or series of measurements within which the accuracy and precision of the measuring system are expected to be stable. * The Normal and Abnormal Control are used to monitor accuracy and detect changes in the coagulation test system. |
|  | **Quality Control Rules**   * Quality control rules are designed to detect any bias or imprecision that has an impact on the quality of patient results. Although there is no requirement to use specific rules, many have been designed. Each rule detects a slightly different type of error. * A combination of several rules designed to detect both random and systematic errors will greatly improve a laboratory's quality control programs. * Ideally, a rule will not indicate an error when there is none. This would lead to a high false rejection rate of runs due to random error. It should, however, indicate a high probability for error detection due to analytical errors. * The simplest rule involves a target mean, obtained over time from multiple runs of control material, and limits around that mean.   '2s A data point is outside a control's ± 2SD limits. Additional investigation should be performed.  '3s A data point is outside a control's ± 3SD limits. This is cause for rejection of a run.  22s 2 consecutive data points exceed the same limit, the mean plus 2 SD's or the mean minus 2 SD's. This rule is applied either to 2 different control levels within the same run or to 2 consecutive results of the same material across 2 runs. In either case, it is cause for rejection of a run.  R4. The difference between 2 control values within the same run exceeds 4 SD's. This is cause for rejection of a run.  41s 4 consecutive results are greater than the mean plus 1 SD or less than the mean minus 1 SD. The results can be within 1 control material or across control materials. This is cause for rejection of a run.  10x 10 consecutive results fall on one side o f the mean. This can occur within 1 control level or across control levels. It is cause for rejection of a run.   * The '3s and **R4s** rules generally detect random error while the 22s, 41s, 10x rules and the '3s rule, when very large, detect systematic error. * Dr. James Westgard and his associates have developed an approach for using a combination of the previous rules as follows: If no control exceeds the 2 SD limit, the analytical run is considered to be in control and patient data may be reported. * The '2s rule, in this case, is used as a warning. If this is exceeded, the control data should be tested using the '3s, **22s, R4, 41s** and 10x rules. If none of these rules are violated, the run is in control. If any one of them is violated, the run is not in control and patient data cannot be reported. * Generally, if an error occurs on only one control material, the problem may be the control. If it occurs on more than one control, it is probably due to a system error, such as calibration, reagents, pipetting or optics. * All patient test results obtained in an unacceptable test run or since the last acceptable test run must be re-evaluated to determine if patient test results have been adversely affected. Once a problem has been identified, the technologist must take the action necessary to ensure the reporting of accurate and reliable test results. If a single control fails, it should be re-run using a new vial. If the second result is in, patient results can be reported. * If it is still out, the operator must consult the troubleshooting guide to determine the cause of the imprecision. In either case, both data points must be documented. * Once the problem has been identified and corrected, the patient samples and controls should be re-run. If the second run is in control, the patient results can then be reported. |
| **Calibration** | 1. The only user-calibrated parameter performed by the VAMHCS Baltimore laboratory on  the ACLTOP 350 is the PT based FIBRINOGEN.  2. This procedure is performed under the following conditions:   * At the installation of a new instrument or with major service repairs. * With a change of the thromboplastin lot number * At the request of a Beckman Coulter representative. * To follow the requirements of the appropriate regulatory agency.   3. Before running calibration, the following must be in place:   1. All maintenance must be performed up to date 2. The calibration materials and calibration units must be defined in the instrument. 3. Choose **Setup/Material List.** 4. Double-click on the HemosIL Calibration Plasma to open the **Material Definition screen.** 5. Choose **To enable Lot Management** from the **General Information** tab. 6. Choose the Lot Specific information tab and enter the Calibration Plasma lot number and expiration date. Select **Save** icon to store the lot number. Once the lot number is saved, the **Assign Values** icon becomes available. 7. Select the **Assign Values** icon. Enter the appropriate Fibrinogen target value for the appropriate PT reagent from the Calibration Plasma package insert. Press **OK**. 8. Choose the **Previous Screen** icon to exit. 9. Verify all reagents, diluents and calibrators are placed in their appropriate positions in the analyzer. 10. Recombiplastin 11. Factor Diluent 12. Calibration Plasma — place original bottle of reconstituted plasma into a diluent rack in the sample area (track D1)   4. Select **Calibration** → **Status List**.   1. Double-click on the appropriate PT test to open the **Calibration Details** screen. 2. Select the **Run** icon from the Tool Bar. 3. Select **OK** at the prompt "Do you confirm the operation?" Select **Previous Screen** icon to exit.   5. After a calibration has been completed, you can review the calibration results and manually validate the samples.   1. Select **Calibration** → **Status List**. 2. Double-click on the PT reagent in use to open the Coagulation Calibration Details screen. You can also click on the Calibration Details icon. 3. Select the Calibration 1 tab to display the most recent calibration. 4. Verify the r2 is > 0.980. 5. Choose the **Calibration Information** tab to ensure that no errors or warnings occurred. Calibration points may be omitted to improve precision, r2 values, slope, and y-intercept, at the discretion of the laboratory. 6. If the calibration is acceptable, choose the **Validate** icon to validate the calibration. 7. If the calibration is not acceptable, repeat the calibration (steps 4-5 above) |
| **Procedure** | **IMPORTANT!! The instrument uses specific racks for closed and open mode processing. Do not place closed tubes in open mode rack or sampling probe may be damaged.**  **Closed Mode:**   1. Click on "Sample Area" tile to view map of sample area. Place samples in correct Closed Mode Sample Rack (blue color on handle of rack) with barcodes facing out. 2. From toolbar, click on the "Sample Area" tile. 3. On instrument's "Track Control Panel" choose an empty or green track position (from Si to S8). Load rack by holding handle of rack and sliding rack through the guides into the instrument until an audible click is heard (the sample position on the sample area map turns dark blue). 4. If necessary, Add/Remove tests. 5. Click on "Run" tile (the sample position on the sample area map turns from dark blue to purple).   **Open Mode:**   1. Click on "Sample Area" tile to view map of sample area. 2. Choose **Open Mode** Sample Rack (black color on handle of rack). Place sample in Open Mode rack, 3. On instrument's "Track Control Panel" choose an empty or green track position (from S1 to S8). Load rack by holding handle of rack and sliding rack through the guides into the instrument until an audible click is heard (the sample position on the sample area map turns dark blue with a "?"). 4. Double click on the "?". 5. Under "Sample Type" — select the appropriate specimen type (Patient, Calibrator or QC) 6. Enter Sample ID under the appropriate area then double-click on white box to the right of the Sample ID box. A "Tests and Profiles" window will open — click on desired tests then place sample in corresponding position of the Sample Rack. Repeat for all samples. 7. Click on "Insert Rack" tile. 8. On instrument's "Track Control Panel" choose an empty or green track position (from Si to S8). Load rack. 9. If necessary, Add/Remove tests. 10. Click on "Run" tile.   **Result Reporting**   * Results are interfaced directly to the US (Vista): * Access the automated result entry routine in Vista (EA — enter/verify data, auto instrument). * Choose the BCOAGULATION worklist (BCO). * Enter the accession # for the sample you wish to verify.   ***Note: certain analyzer flags will prevent results from crossing the interface. Investigate all results that do not cross the interface, as they may be in need of further action.*** |
| **Maintenance** | To maintain the ACL TOP 350 instrument in good functional condition, the following maintenance activities are to be carried out at the specified frequencies:  To perform a maintenance activity, select **System** → **Maintenance** to open the maintenance screen.  **Daily Maintenance: to be performed by the dayshift tech**  **Enhanced Clean for All Probes:**   * Fill two (2) barcoded 10mL bottles with Clean B. * Place one bottle in a reagent rack (use the silver adapter to allow the bottle to fit) then insert the rack into track R3. * Place the second full 10mL bottle of Clean B in position 1 of a diluent rack (use a red 10mL diluent adapter to allow the bottle to fit). Place the rack into track Dl. * On the Maintenance screen click the left-most column next to this activity to place a check mark there. * Select the Perform icon and the enhanced clean for all the probes is performed by the instrument. * Type the operator's initials in the box that comes up once the activity is finished. * **REMOVE THE BOTTLES OF CLEAN B ONCE THE ACTIVITY IS COMPLETED.** Clean B is corrosive and should not be left on board the instrument.   **Prepare Diluted Clean B (1 part Clean B to 7 parts deionized H20.**   * Fill the barcoded Diluted Clean B bottle to the blue line with deionized H20. * Use a graduated plastic pipette to add 2mL of Clean B to the bottle. * Place the bottle in an open position of a reagent rack and insert the rack into track R4. * On the Maintenance screen click the left-most column next to this activity to place a check mark there. * Select the Perform icon and the enhanced clean for all the probes is performed by the instrument. * Type the operator's initials in the box that comes up once the activity is finished.   **Weekly Maintenance : to be performed by the dayshift Tech**   1. **Clean Deep Wash and Clean Cup Area**  * Click the left-mast column next to this procedure to place a check mark there. * Select the Perform icon and a window is displayed with the following: "Perform the maintenance work first then press OK." * Open the cover. * Clean the deep wash and clean cup with a lint-free swab, then rinse both areas with DI- H20 to remove any debris. Leaving the filter in prevents loose debris from falling into unprotected areas. Use the filter to collect debris around the clean area. Use a maximum of 10 mL of deionized H20; more than that may cause the accumulator to overflow. * Wipe excess deionized H20 that may have splashed onto the cover or the clean cup/deep wash area with a lint-free swab. * Close the cover and select the **OK** button on the window. Enter tech initials in the pop-up window that appears. Close the window.   **b**. **Clean Cuvette Waste Drawer**   * Click the left-most column next to this activity to place a check mark there. * Select the **Perform** icon and a Maintenance Activity Execution window is displayed. * Select **OK** and another window is displayed with "Perform the maintenance work first, and then press OK." * Remove the cuvette waste drawer. * Remove the liner from the cuvette waste drawer, clean it with 10% bleach or other laboratory approved antimicrobial cleanser and replace it in the drawer; or replace the used liner with a new one. * Replace the cuvette drawer. * Select the **OK** button. |
| **Troubleshooting** | * **Results outside of analyzer range** * When a result is outside of the analyzer range, a numeric error code as well as HL or LL will be generated and result will show as FAILED. * Review the curve. If an acceptable curve is present, report the result as >249 seconds (for either PT or APTT). To view the curve, follow the steps below:  1. Select "Sample List" from toolbar. 2. The Sample List screen is divided into 2 sections. Select the patient Sample ID desired from the top section — information about that sample will show on bottom half of screen. 3. Double click on the test for which curve is desired (page will open containing all test info as well as clot curve) NOTE: If extended curve is desired, make sure the extended result is selected — an "E" will be present under the "JOB TYPE" column of the extended result. 4. Print copy of clot curve by selecting the Printer icon on the top of the page.  * If curve is unacceptable, call floor and investigate whether specimen may have been drawn from a line. Do not report an estimated result — answer test as "Possible IV contamination, redraw suggested". Refer to the "Think Quality" book for examples of acceptable and unacceptable graphs. * **Handling Lipemic/Grossly Lipemic Plasma** * The Beckman Airfuge® ultracentrifuge is located near Microbiology hood. * Fit an empty 2.4 ml plastic liner inside the metal rotor. * Draw lipemic plasma into a plastic Beckman transfer pipette (part # 343779). Insert the tip of the loaded pipette through the hole on top of the liner and into the outer chamber of the liner. * Fill the outer chamber until the plasma just overflows into the inner chamber. * Screw the metal rotor lid on tightly. * Fill the inner chamber until the plasma just touches the inside of the top of the dome. * Place the fully assembled rotor on the stator pad, then close the instrument door. * Set the TIME dial by turning past the 30 minute point, then back to the desired time of 10 minutes. * Secure the instrument door by turning the pressure regulator knob (located on top of the instrument door) clockwise, pushing down until the air pressure indicated on the PRESSURE gauge brings the rotor up to 90 kPa. * After the rotor has stopped, turn the pressure regulator knob counterclockwise until the PRESSURE gauge reading is zero. * Pipette the chylous material from the inner chamber while the rotor lid is in place, then unscrew the rotor lid. * Using a new pipette, extract the clarified plasma from the outer chamber and into 0.5 ml sample cup. \*\*BE CAREFUL NOT TO MIX ANY FATTY MATERIAL LEFT ON THE WALL OF THE INNER CHAMBER WITH THE CLARIFIED PLASMA.\*\* * Place 0.5 ml sample cup in sample rack and continue with "Open Mode" procedure section above. * **Handling Samples with Hematocrit> 55%** * A patient with HCT >55% will cause spurious coagulation results including falsely prolonged PT and APTT results and erroneous results for other calcium-dependent clotting tests due to excess anticoagulant in the plasma. * The citrate anticoagulant is distributed only in the plasma but not into the blood cells. * The amount of sodium citrate must be adjusted before re-drawing blood sample from patients with HCT>55%. * When notified by the DxH800 tech about a patient with a HCT > 55%: * Review patient Coagulation history by using the Interim Report for Select tests. Be sure to check from T (today) to T-365. * If the patient has a PT/APTT requested, hold the current tube in reserve with the comment: "HCT > 55% requires redraw. Please call lab at x5499 for further instructions." * The formula to calculate the appropriate amount of sodium citrate volume is:   **Formula:** (100 – HCT) / (595 – HCT) x Total Volume   * Prepare the Adjusted Coagulation tube using the following table:   **Amount of Anticoagulant Solution (0.5 ml) Adjustment at Different HCT for 3.2% Sodium Citrate, 2.7ML Draw**     |  |  | | --- | --- | | **HCT % Range** | **Volume of Sodium Citrate to Remove** | | 55 – 59 | 0.2 | | 60 – 64 | 0.19 | | 65 – 69 | 0.17 | | 70 – 74 | 0.15 | | 75 – 79 | 0.12 |  * **Common Data flags:**  |  |  | | --- | --- | | **Data Flag Group** | **Description** | | SE | Sampling Error | | HE | Hardware Error | | CE | Coagulation Error (measured result) | | CW | Coagulation Warning (measured result) | | QC | Quality Control flag | | HT or LT | Out of Test range High (HT) or Low (LT) | | HL or LL | Out of Linear range High (HL) or Low (LL) | | HH or LH | Out of Therapeutic range High (HH) or Low (LH) | | HN or LN | Out of Normal range High (HN) or Low (LN) | | MT | Maintenance flag | | ME | Material error/warning | | **Orange & bold result** | Outside therapeutic range | | **Purple & bold** | Outside test range | | **Red & bold** | Outside linear range/within test range | | Blue not bold | Outside normal range |   **\*\*\*Notes:**   * If the system does not give you a result (PT or APTT), NEVER assume the result is Prolonged without further investigation. Always check the sample, rerun in extended mode (if applicable) and check the sample clot curve as part of this investigation. * Results from the analyzer that have “flags” associated with them should be investigated per your local laboratory protocol prior to reporting of the result. If you are unsure of the meaning of a flag, please contact the IL Technical Support Group for assistance. * Periodically or after making system setup changes (i.e. parameter setting or lot numbers), it is recommended you exit the ACL TOP software and make a Database base backup (Start→ All Programs →ACL TOP → ACL TOP-Database Backup → and Restore). The DB Backup should then be saved to an external media such as a CD or other removable media. This will ensure you have a recent backup in the event it ever becomes needed for service. * **Technical Support/Service Information:** * Instrumentation Laboratories Technical Support Hotline (24/7)   **1-800-678-0710**   * Document all instrument troubleshooting/service and store all troubleshooting/ service records in the ACL TOP 500 analyzer Maintenance Log binder. * Important analyzer information:   ACL TOP 350 — Hematology Laboratory  **Serial #: 17030509**  ACL TOP 350 — Stat Laboratory  **Serial #: 17030507** |
| **Normal Ranges** | Normal ranges must be established for both PT and aPTT with every lot change of Recombiplastin (PT) or Synthasil (aPTT) reagent. Due to the unique patient population at the VA Medical Center, fresh specimens from at least 20 (preferably 40-50) non-AC clinic out-patients who present with PT, aPTT and Fibrinogen values within the current normal range are used to establish the new lot's normal range. These are most often found from the BNPOC (same day surgery) clinic, managed care clinics or occasionally the ED location. Once the results are captured, the MEAN, GEOMEAN, 1SD and 2SD values are calculated. From these values the 2SD range (minimum and maximum value) is determined. Note: see TOP350s onboard manual for instrument settings and file management of the normal range study.  **Current normal ranges:**  PT = 9.5— 12.6 sec.  aPTT = 26.8 — 33.7 sec.  Fibrinogen = 265 — 664 mg/dL |

**Reference** 1**.** ACL TOP Series Operation Manual

2. HemosIL RecombiPlasTin 2G (PN 0020002950/0020003050) package insert

3. Clinical and Laboratory Standards Institute. Collection, Transport, and Processing of

Blood Specimens for Testing Plasma-Based Coagulation and Molecular Hemostasis

Assays; Approved Guideline - Fifth Edition, CLSI Document H21-A5; Vol. 28 No. 5

4. HemosIL PT-Fibrinogen HS PLUS (PN 008469810) package insert.

5. Clinical and Laboratory Standards Institute. One Stage Prothrombin Time (PT) Test

and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline –

Second Edition, CLSI Document H47-A2;

6. Clinical and Laboratory Standards Institute. Preparation and Testing of Reagent Water

in the Clinical Laboratory; Approved Guideline. Fourth, Edition, CLSI Document C3-

A4;Vol.26 No.22

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| **Coagulation Testing by ACLTOP 350 Analyzer** | *Procedure #:* | ***HC0# 200*** |
| *Version #:* | ***1.0*** |

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| Daniel Samaila, H(ASCP) |  | |

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| **Coagulation Testing by ACLTOP 350 Analyzer** | *Procedure #:* | ***HCO# 210*** |
| *Version #:* | ***1.0*** |

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| **“I, the undersigned, do hereby certify that I have read this new/revised procedure. I understand the instructions contained within and have the opportunity for any/all of my questions to be answered by the Hematology Supervisor and/or the Medical Director. I agree to govern myself accordingly.** | | | |
| **Name:** | **Signature:** | **Date Read:** | **Comments/Notes:** |
| Ayd, Brenda |  |  |  |
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