**Changes in Grey**

**Policy note:** The Siemens CS-2500 is to be used as the primary analyzer for Coagulation testing at Bioreach Laboratories. The Siemens CA-660 is to be used as the backup analyzer only.

**CS-2500**

* **Purpose:** The purpose of performing a prothrombin time (PT) assay is for the overall evaluation of extrinsic coagulation pathway.

The production of fibrin by means of the extrinsic and intrinsic common pathways requires tissue Innovin and factor VII, in addition to factors X and V, prothrombin, and fibrinogen. The Prothrombin Time (PT) is a basic coagulation screening test, useful in the assessment of congenital and/or acquired deficiencies of the extrinsic pathway (factors II, V, VI,I X). A prolonged PT has been observed in the following clinical states: treatment with vitamin K antagonists, hemorrhagic disease of the newborn, intestinal reabsorption disorders, liver failure (cirrhosis, hepatitis, jaundice), fibrinolysis and DIC. The INR value corresponds to the value of the ratio of the patient’s PT to that of the standard PT (geometric mean) raised to the ISI (International Sensitivity Index) power of the Innovin used.

The ISI value, which is measured against the International Reference Innovin, is provided by the manufacturer for each lot of reagent. The geometric mean is calculated from the data collected for the PT reference range.

Plasma is pre-warmed for a predetermined length of time. Innovin/Innovin, in the presence of calcium, is added to prewarmed plasma, which initiates the extrinsic pathway of coagulation. The endpoint is the detection of a clot by the electro-magnetic viscosity detector. The elapsed time in seconds from the combination of Innovin with a plasma sample to the detection of the clot is the PT result.

* **Policy note:** Prothrombin Time measurement performed at Bioreach Laboratory are for normal patient populations only and are not intended to monitor any anticoagulant therapy
* **Procedure overview:** Please note complete test instructions and analyzer operations are contained in downloaded IFU’s and Manufacturers Operator instructions. Please refer to the most recent copy of these to ensure correct test performance.
* **Specimen Collection**
  + **Citrated blood 9:1 (blood to anticoagulant) with 3.2% sodium citrate.**
  + **No other anticoagulant is acceptable.**
  + **Centrifugation: 15 minutes at 2,500 g**
  + **Plasma Storage: 24 hours at room temperature**
  + **Do not store plasma at 2-8° C**
  + **Unacceptable Specimens: Samples that are short draws, over draws, clotted, or hemolyzed may yield incorrect results.**
  + **Any specimen not meeting specimen acceptability requirements need to be placed on the “Tests not Performed” log in the Bioreach Drive. Designated individuals on log will contact the provider to inform of the test not performed and work on recollection.**
* **Materials, Reagents and Controls**
  + **Thromborel S Reagent**
  + **Dade Innovin Reagent**
  + **Controls are ran with each 8 hour shift or immediately following placing a new bottle of Innovin in service.**
  + **See Stability log for reagent storage temperature requirement and expiration times.**
* **Preventative Maintenance**
  + **Daily Maintenance:**
    - **Shutdown**
      * **V**erify CA Clean I vial is loaded on the reagent table
      * Press Shutdown icon. Select option: Turn the Main Unit OFF
      * Press OK
      * Cleaning will take 5 minutes
      * Wait for IPU computer to automatically shut down
      * Press analyzer power switch off
      * Check the trap chamber for fluid. Remove fluid if present
    - **Startup** 
      * Press power button on IPU computer
      * Computer starts up
      * Press enter on the keyboard to select the user. (lower left side)
      * Enter user password
      * Instrument software starts up
      * select logon icon, enter password
      * press analyzer power switch on
    - **Tasks**
      * Select status icon to check rinse, waste, cuvettes
      * Press Maint. icon
      * Empty cuvette trash box. Reset trash counter
      * Empty waste tank: press Change Waste Tank Key empty waste. press ok
      * Check/replace DI water
      * Add cuvettes to the hopper. Do not fill above the red line
      * Select Manual Maintenance key: check off completed tasks
      * Press the Menu icon to view the main menu
      * Select Operations Log to initial for maintenance tasks.
      * Replace reagent and QC as needed
      * Run QC for assays
  + **Weekly Maintenance**
    - **Cleaning the Instrument**
      * Shut down the main unit and unplug the power cord
      * Wipe the instrument with a moistened paper towel with water and a neutral detergent
  + **Monthly Maintenance**
    - **Cleaning the filter (rear)**
      * Remove filters #514 and #513
      * Use a vacuum or similar tool to remove dust from the filters
      * Install the clean filters
    - **Cleaning the filter (left side)**
      * Remove filter #16A
      * Use a vacuum or similar tool to remove dust from the filter
      * Document in the Maint. Screen under Manual Maintenance
  + **As-needed Maintenance**
    - **Adjusting the 0.10 MPa pressure (range 0.10-0.11)**
      * Press Maint.
      * Press Pressure Adjustment (press more if not visible).
      * Press Power ON Pressure (If the pneumatic unit does not automatically turn on).
      * Open the cover door on left side of instrument
      * Pull the 0.10 MPa adjustment knob toward you to unlock
      * Adjust the pressure slowly
      * Once adjustment is complete, press the adjustment knob in until it locks
      * Close the cover door
      * Press OK
    - **Adjusting the 0.22 MPa pressure (range 0.22 to 0.25)**
      * Press Maint.
      * Press Pressure Adjustment
      * Press Power ON pressure
      * The 0.22 MPa adjustment knob is located on the pneumatic unit
      * loosen the fixing screw on the adjustment knob by turning the screwdriver counterclockwise
      * Adjust the pressure slowly
      * Once adjustment is complete, tighten the fixing screw while taking care not to rotate the adjustment knob
      * Press OK
* **Calibration:**  **No actual calibration of the system is necessary for PT**. However, validation of the normal range geometric mean must be confirmed with each new lot of reagent. The new ISI and geometric mean must be entered into the analyzer in order for the INR to be calculated correctly.
* Sample Processing:
  + LIS order processing
    - Place rack with barcoded sample tubes on the sampler
    - Check host connection (HC) status. HC status icon must be green or orange
    - Press Start
    - After barcode reading, confirm sample order status and progress on the Joblist screen.
  + Manual Order Processing
    - Press Order
    - Enter Rack number
    - Select tube position
    - Press Order Entry
    - Place cursor in Sample No. and input sample ID if sample does not have a barcode
    - Select assays to be analyzed
    - Press the down arrow to order the next sample
    - Press OK
    - Press Start
    - Place sample rack with tubes/cups on the sampler
    - Confirm sample order status on the Joblist
  + Reagent Table Loading
    - Press reagent icon on toolbar
    - Highlight a reagent position for removal
    - Press Change/Add
    - Lift the reagent section lid
    - Verify reagent table cover LED is solid green
    - Slide the lock lever and remove cover
    - Lift out the rack. Remove empty or expired reagents
    - Add new vial to rack with 1D barcode showing (If you add the same reagent to the same spot as the expired reagent in the rack, the new reagent will not register. Place new reagents in a new position in the rack, then it will register).
    - Load rack into the reagent table
    - replace cover and slide the lock lever
    - Close the reagent section lid
    - Press OK on screen to read barcode
    - Wait for the barcode reading to finish
    - On the reagent screen, touch the reagent position just loaded, and press Change to update date and time.
  + Prepare Samples
    - Ensure that the sample is filled to the arrow on the Na Citrate tube +/- 10%
    - Centrifuge the blood tube direction after blood collection for 15 minutes at 1500 x g to 2500 x g.
* **The International Normalized Ratio (INR)** is a derived correction factor (see formula) used to standardize PT values around the world to the World Health Organization (W.H.O.) reference Innovin. International Sensitivity Index (ISI) is the value determined by the manufacturer for a specific lot of Innovin as compared to the World Health Organization (W.H.O.) Innovin standard. It is used as an exponential power for calculating INR by the laboratory performing a PT using that specific Innovin lot number with a specific instrument.
  + Geometric Mean PT is the statistical calculation based on the reference population for PT’s in seconds for the reagent.
  + Geometric Mean PT is placed in the analyzer setting prior to introduction of the new Innovin lot.
* **Limitations:**
  + Inhibitors such as lupus anticoagulant may interfere with the prothrombin time and result for example in INRs that do not reflect the exact degree of anticoagulation.
  + Grossly Lipemic and Hemolyzed samples may affect results. Comment on report is required for grossly lipemic and hemolyzed samples (3+ to 4+).
* **Reference Ranges: PT: 9.5-12.1 seconds, INR: 0.9-1.2**
* **Critical Values: See Bioreach Critical Value policy for details**
* **PROFICIENCY TESTING:**
  + Proficiency test material will be obtained from an approved source.
  + Proficiency test material will be handled and documented in the same manner as a patient specimen.
  + The Laboratory Director will review all proficiency test results

**CA-600 Series**

**Purpose:** The purpose of performing a prothrombin time (PT) assay is for the overall evaluation of extrinsic coagulation pathway.

The production of fibrin by means of the extrinsic and intrinsic common pathways requires tissue Innovin and factor VII, in addition to factors X and V, prothrombin, and fibrinogen. The Prothrombin Time (PT) is a basic coagulation screening test, useful in the assessment of congenital and/or acquired deficiencies of the extrinsic pathway (factors II, V, VI,I X). A prolonged PT has been observed in the following clinical states: treatment with vitamin K antagonists, hemorrhagic disease of the newborn, intestinal reabsorption disorders, liver failure (cirrhosis, hepatitis, jaundice), fibrinolysis and DIC. The INR value corresponds to the value of the ratio of the patient’s PT to that of the standard PT (geometric mean) raised to the ISI (International Sensitivity Index) power of the Innovin used.

The ISI value, which is measured against the International Reference Innovin, is provided by the manufacturer for each lot of reagent. The geometric mean is calculated from the data collected for the PT reference range.

Plasma is pre-warmed for a predetermined length of time. Innovin/Innovin, in the presence of calcium, is added to prewarmed plasma, which initiates the extrinsic pathway of coagulation. The endpoint is the detection of a clot by the electro-magnetic viscosity detector. The elapsed time in seconds from the combination of Innovin with a plasma sample to the detection of the clot is the PT result.

**Procedure overview:** Please note complete test instructions and analyzer operations are contained in downloaded IFU’s and Manufacturers Operator instructions. Please refer to the most recent copy of these to ensure correct test performance.

**Specimen Collection**

1. **Citrated blood 9:1 (blood to anticoagulant) with 3.2% sodium citrate.**
2. **No other anticoagulation is acceptable.**
3. **Centrifugation: 15 minutes at 2,500 g.**
4. **Plasma Storage: 24 hours at RT**
5. **Do not store plasma at 2-8 C.**
6. **Unacceptable specimens: Samples that are short draws, over draws, clotted or hemolyzed may yield incorrect results**

**Materials, Reagents and Controls**

1. **Thromborel S reagent**
2. **Dade Innovin Reagent**

**\*\*Controls are ran with each 8 hour shift or immediately following placing a new bottle of Innovin in service.**

**Preventative Maintenance**

* **Daily Maintenance:**
  + **Clean Sample Probe**
  + **Discard Used reaction tubes**
  + **Dispose of waste**
  + **remove dw from reagent rack**
* **Weekly Maintenance**
  + **Replace Trash Box Liner**
* **Monthly Maintenance:**
  + **LED Calibration (refer to IFU Section 11.6 or quick guide pamphlet)**
* **Yearly Maintenance:**
  + **Replace rinse filter**
* **As needed maintenance:**
  + **Replace Fuse**
  + **Check Printer Paper Supply**
  + **Check and drain trap chamber**
  + **Prime rinse solution to hydraulic line**
  + **Filter inspection and cleaning**
  + **Clean Instrument**

**Calibration:**  **No actual calibration of the system is necessary for PT**. However, validation of the normal range geometric mean must be confirmed with each new lot of reagent. The new ISI and geometric mean must be entered into the analyzer in order for the INR to be calculated correctly.

Running a Sample:

* + Inspection before turning on power
    - Inspect rinse bottle (if needed replenish with DI water)
    - Inspect waste bottle
    - check power cord (check to see if the power cord is securely plugged in the socket.
    - Check connection cord
    - Check trash box
    - Check printer paper
    - Check light shield cover
  + turn on power (the switch on the left side of the instrument)
    - self check (the machine detector and cooler reach temperature)
  + Machine in ready status
  + Prepare reagents (DADE Innovin)
    - Register Reagent Volume:
      * Press [Special Menu] key on the main menu screen
      * Press [Set Reagents] key in the main menu. The reagent volume screen will display reagent level for each reagent holder
      * Press the key of the reagent holder to be registered. The reagent volume entry screen will display the numeric keys to enter reagent volume
      * Enter the reagent volume set on the reagent holder and press [Enter] key. The value entered at the cursor position will be displayed. The second line will automatically display the available reagent volume to be used for the analyses.
      * Press [Quit] key on the numeric keys. The reagent volume screen will reappear. Confirm the entered value.
      * Press [Main Menu] key on the reagent volume screen. The renew check screen is displayed. Press [Cancel] key, [FIX] key, or [Continue} key to return to the Main Menu Screen.
      * Set reaction tubes- fill up reaction tubes in rack
  + Prepare Samples
    - Ensure that the sample is filled to the arrow on the Na Citrate tube +/- 10%
    - Centrifuge the blood tube direction after blood collection for 15 minutes at 1500 x g to 2500 x g.
  + execution of analysis
    - Check the System Status display of the instrument. Make sure the the Main Menu screen displays “Ready”
    - Press [Start] key. The screen confirming the first tube’s initial position will appear
    - Press [Continue] key or [first tube] key
      * [Continue] key: starts with the reaction tube that follows the last used tube in the previous analysis.
      * [First Tube] key: Starts with the upper extreme-right tube in the right-hand reaction tube rack.
  + completion of analysis
    - When all analyses are completed the internal alarm will sound. If you want to continue analysis, when the message “Replace Rack? No!” changes to “replace rack? YES!”, then samples can be set to the next sample rack or the same sample rack.
* **The International Normalized Ratio (INR)** is a derived correction factor (see formula) used to standardize PT values around the world to the World Health Organization (W.H.O.) reference Innovin. International Sensitivity Index (ISI) is the value determined by the manufacturer for a specific lot of Innovin as compared to the World Health Organization (W.H.O.) Innovin standard. It is used as an exponential power for calculating INR by the laboratory performing a PT using that specific Innovin lot number with a specific instrument.
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