**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.

1. **Purpose:** The purpose of performing a partial thromboplastin time (PTT) assay is for the evaluation of the intrinsic and common coagulation pathways. The partial thromboplastin time (PTT) is a simple test of the intrinsic and common pathways of coagulation that requires platelet-poor plasma (<10,000 platelets/mm³). When a mixture of plasma and a phospholipid platelet substitute (Actin FSL) is recalcified, fibrin forms at a normal rate only if the factors involved in the intrinsic pathway (prekallikrein, HMW kininogen, Passovoy factor, and factors XII, XI, IX, and VIII) and in the common pathway (factors X, V prothrombin, and fibrinogen) are present in normal amounts. In the PTT, such a platelet substitute is provided in excess, and the test is thus unaffected by the relatively small number of platelets remaining in the plasma. Platelet substitutes are only “partial” thromboplastins, therefore they are incapable of activating the extrinsic pathway, which requires “complete” tissue thromboplastin (tissue factor). Thus, the PTT ``bypasses” the extrinsic pathway and is unaffected by factor VII. “Activated” PTT refers to the fact that the assay additionally employs an activator in the reagent that hastens the clotting time. The PTT is sensitive to deficiencies of factors VIII, IX, XI and XII and less so to the factors involved in the common pathway. The test yields abnormal results if the plasma level of any of the essential factors is below 15% to 30% of the normal value. The PTT thus detects many mild coagulation disorders. The PTT also is prolonged by heparin, specific inhibitors of any of the essential factors, and lupus inhibitors. As in all Stage-I tests, high levels of a single factor, most commonly factor VIII, may shorten the PTT. Thus, a short PTT may signify any of the various “hypercoagulable” stages, and high levels of any of the factors involved in the intrinsic or common pathways of coagulation may mask deficiencies of other factors. Thrombosis is the result of a process that has the potential to occlude arterial and venous blood vessels. Normally a regulatory process acts to counterbalance the hemostatic process, but thrombosis may develop whenever the dynamic balance between prothrombotic and antithrombotic processes become altered.

The Partial Thromboplastin Time (PTT) Assay quantitatively measures the overall coagulation activity of factors involved in the intrinsic and common pathways. The procedure uses Siemens CA-2500/CA-660 Reagent 0.025 M Calcium Chloride Reagent on a Siemens CA-2500/CA-660 coagulation analyzer.

Patient plasma is mixed with Actin FSL Reagent to provide optimal and uniform activation of the sample. After incubation at 37 C for **3** minutes, the reaction is initiated by the addition of 0.025 M Calcium Chloride Reagent. The endpoint is the detection of a solid gel clot by a photometric detector. The elapsed time in seconds from the combination of Reagents with a plasma sample to the detection of the gel clot is the PTT result.

1. **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.
2. **Specimen Collection**
   1. **Citrated blood 9:1 (blood to anticoagulant) with 3.2% sodium citrate.**
   2. **No other anticoagulant is acceptable.**
   3. **Centrifugation: 10 minutes at 2,500 g**
   4. **Plasma Storage: 24 hours at room temperature**
   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.**
3. **Materials, Reagents and Controls**
   1. **Actin FSL**
   2. **Siemens Citrol 1**
   3. **Siemens Citrol 3**
   4. **Calcium Chloride**
   5. **Controls are ran with each 8 hour shift or immediately following placing a new bottle of Actin FSL in service.**
4. **Preventative Maintenance**

**Daily:**

* **Shut down:** Verify that clean I is loaded on the reagent table. press shutdown Icon, select turn the main Unit OFF, press OK.

Cleaninging will take 5 minutes, wait for the IPU computer to automatically shutdown, press analyzer switch to power off, then check the trap chamber for fluid, remove any fluid if present.

* **Start Up:** Press power button on IPU computer, press enter on keyboard to select user once the screen starts up. Enter password and once logged in wait a few seconds for a green circle to appear, turn on the instrument once it appears. Once the software has started up, log into the correct user.
* **Tasks:** Select status Icon to check rinse, waste, and cuvettes. press Maint. Icon, empty cuvette trash boc and reset the counter, once the trash box is pulled out, a prompt will appear to reset. empty the waste tank, press change waste tank key, empty waste and press OK. Check/replace DI water if running low. add cuvettes to the hopper, do not fill the above red line.

To log maintenance, select the manual maintenance key and check off tasks completed. then select the menu to view the main menu. Select operations log to initial for maintenance tasks. then replace reagents and QC as needed, now QC can be ran for assays.

**Weekly:**

* **Cleaning the instrument:** Shut down the main unit and unplug the power cord. wipe down the instrument with a moistened paper towel with water and a neutral detergent.
* **Cleaning the Rinse Tank:** Remove the cap of the rinse tank by turning counterclockwise. Use 70% isopropyl to wash the inside of the tank and float switch. Rinse the tank and float switch with distilled water. Attach the float switch and tighten the cap clockwise.

**Note:** Cleaning rinse tank does not need to be done if pre packaged ionized water is used, instead of refilling a tank regularly.

**Monthly:**

* **Clean the filter:** Remove filters (2 rear, 1 on left side), use a vacuum or similar tool to remove dust from the filters. Install the clean filters and then document cleaning in Maint. screen under manual maintenance.

**As needed:**

* **Pressure adjustment:** Press maint. and pressure adjustment, press power on pressure and then open the cover door on the left side of the instrument. pull the 0.10 MPa adjustment knob toward you to unlock, adjust the pressure slowly. Once comprelet press in the adjustment knob until it locks, close the door and press ok.
* **Vacuum adjustment:** press Maint., pressure adjustment, power on pressure, open the cover door on left side, loosent the fix nut of the bellows unit, turn knob clockwise to increase, counter clockwise to decrease. adjunct the pressure between -0.071 and -0.067. Tighten the Fixing nut and close the door, then press ok.
* **Lamp Replacement:** Turn off the power of the main unit and unplug the power cord. Wait 30 minutes for the lamp to cool down, open the lamp cover located on the right side of the instrument. Disconnect the white connector, loosen the thumb screw, remove lamp holder, and squeeze and lift the lamp retainer to remove the lamp. Install a new lamp in reverse order, reconnect the power cord and turn power ON, allow the lamp to burn in for 30 minutes before calibration.
* **Lamp Calibration:** Press Maint., then lamp calibration, then execute. Select the correct option when the lamp confirmation dialog box appears, reset the lamp counter when calibrating a new lamp, DO NOT reset when calibrating the same lamp. press OK. Enter initials in the operation log for calibrating a new lamp. Enter initials/date in mant. screen remarks field next to lamp calibration record a recalibration of the same lamp. perform QC on all Assays.
* **Clean the Sysmex Racks:** wipe racks with soft cloth with water or ethanol. Document in manual maintenance.
* **Wipe the piercer clean:** verify light shield is closed, press maint on toolbar, press wipe off piercer operation key, wait for piercer to move to position and press ok. power off main unit, open light shield, set the jig on piercer, wipe piercer with gauze moistened with distilled water. Remove jig, close the light shield, power on the main unit.

1. **Calibration:**

* **Identify the reagents:** Enter reagent and calibrator lot information in Reagent Lot Master. Refer to enter reagent information Tab in reference Quick guide book for more guidance. Load reagents, calibrator, buffer.
* **Order Calibration:** Select Order, Switch order, Holder Calib curve order. Select desired assay to be calibrated. Select change and select the correct lot number, select OK. Select the correct calibrator lot number from the list, select OK, start. To view status and progress, press the job list.

1. Assay Steps: (Insert Procedural overview here)

* **LIS order processing**
  + Once an order has been created with the LIS a barcode will be printed out and placed on a coag tube. place a rack with barcode sample tubes on the sampler. check host connection status, it must be green or orange. Press start at the top right corner. After barcode reading, confirm sample order status and progress on the job list 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 barcode. select analyze and press down arrow to order the next sample. press ok, start, place a sample rack with tubes/cups on the sampler. Confirm sampler order status on the joblist.
* **Micro mode**
  + Follow manual order processing steps, press MC column on order screen, press start, place sample rack with cups/uncapped tubes onto system.
* **Change to longer measurement time**
  + Follow manual order processing steps, press the detailed setting button, click below measurement time, select measurement time, select OK, select start.

1. **Reference Ranges:**

Range is 24.0 - 35.0 sec.

1. **PROFICIENCY TESTING:**
   1. Proficiency test material will be obtained from an approved source.
   2. Proficiency test material will be handled and documented in the same manner as a patient specimen.
   3. The Laboratory Director will review all proficiency test results