Subject	Attachments
Stago Satellite Prothrombin (Specific to Arden Hills, Bloomington, Apple Valley, Inver Grove, Brooklyn Center, Como, Coon Rapids, 401 HSC, Maplewood, St. Paul, White Bear Lake, Woodbury)	☐ Yes ☒ No
Key words Coagulation, INR, PT, Satellite	**Number** **GHI-PC-CLINIC LAB-PROCEDURES-Stago Satellite Prothrombin v. 04-2019**
Category Provision of Care (PC)	**Effective Date** **See Electronic File**
Manual Coagulation	**Last Review Date** **See Electronic File**
Issued By Clinic Laboratory Administration	**Next Review Date** **See Electronic File**
Applicable Clinic Laboratory Staff using the STA Satellite Analyzer	**Origination Date** **October, 2017**
	Retired Date
Level of Complexity **Moderate**	**Contact** Regional Clinic Laboratories Supervisors
Review Responsibility Regional Clinic Laboratories Supervisors	**Approval Date** **See Electronic File**
APPROVAL(S) Laboratory Medical Director	

Stago Satellite Prothrombin

Purpose

To provide instruction for the performance of the prothrombin time (PT) test on the Stago Satellite.

Principle

STA®-Neoplastin CI PLUS is used for Prothrombin times on the STA ® Satellite. A mixture of thromboplastin is added to citrated plasma and the time of clot formation is determined. The STA® Satellite is a fully automated coagulation instrument, which uses an electromagnetic mechanical clot detection system. The oscillation of a steel ball within the cuvette with the thromboplastin and plasma is monitored by the STA® Satellite. When the oscillation of the steel ball is stopped by clot formation, this registers the time in seconds.

The ISI value of a given thromboplastin is determined by performing PT's on normal plasmas and Coumadin treated patient plasmas with the given thromboplastin and the WHO reference thromboplastin. The slope of this regression curve of the matched pairs is the ISI for the thromboplastin. (The ISI of the WHO reference thromboplastin is 1.0, however this may not be the ISI of your lot of Neoplastin, that information is found in the package insert for that given reagent.)

The prothrombin time is a basic coagulation screening test for the assessment of congenital and acquired deficiencies of the extrinsic pathway (factors II, V, VII, X). The prothrombin time can be prolonged in certain clinical states, i.e. warfarin therapy, intestinal reabsorption disorders, liver failure, fibrinolysis and DIC.

The prothrombin time is also used to monitor warfarin therapy because of its sensitivity to variations in the concentration of the Vitamin-K dependent factors II, VII , IX and X. Because of the variations in the prothrombin time results with different thromboplastins and instruments, it is recommended that the prothrombin time results be converted to an INR. The INR corresponds to the value of the ratio of the patient's PT and the geometric mean PT of the normal reference population raised to the ISI (International Sensitivity Index) power.

Specimen

- Collect 2.7 mL of whole blood in a 3 mL tube of 3.2% Sodium Citrate Plasma (light blue-top tube) filled to fill line on the tube.
- If using a butterfly for collection, use a blue top tube to clear the line of air before collecting the sodium citrate tube.
- At minimum, tube must be 90% full to be used for testing. (Within 10% of the etched line)

Specimen stability

- Specimens are stable unspun and capped for 24 hours at room temperature.
- DO NOT refrigerate.
- If testing is delayed due to an instrument failure, batch and send specimens to Regions hospital for testing.
- If testing will not be completed within 24 hours, freeze an aliquot of plasma at -20° C.

Unacceptable Specimens

- Samples that do not meet the minimum draw requirement
- Samples exceeding maximum draw requirement
- Clotted samples
- Hemolyzed samples

Specimen processing

1. Centrifuge the blood specimen to obtain platelet poor plasma, as previously assessed per centrifuge, as soon as possible after collection.
2. Visually check the specimen for a HCT >55% or < 20% by estimating if the proportion of red blood cells to total blood drawn is greater than 55 % or less than 20%.

- If HCT visually appears < 55% and > 20% proceed with testing.
- If HCT suspected to be >55% or < 20% thoroughly remix sample, perform testing on Sysmex. Multiply Sysmex **HCT** result by 1.1.

    - If HCT result is <20%, append by free text "Low Hematocrit may affect result"

    - If HCT result is >55%, collection in a special tube adjusted for volume is required
        - If patient has a standing order for high hematocrit and a special tube was collected, perform testing on the special tube.
        - If no previous history and no standing order for special tube:
            - Cancel test
            - Notify care team
            - Contact patient to return for recollection
            - Contact St. Paul lab for further instruction

Reagents

Desorb

Preparation:

1. Remove cap and discard rubber stopper
2. Install Maxi Reducer
3. Replace cap
4. Document open date, revised expiration date and tech code on vial

Stability:

- Unopened: Until manufacturer expiration date when stored at 2-8°C
- Opened: 14 days stored on the instrument

STA-Neoplastine CI Plus

Preparation:

1. Pour liquid from Reagent Vial 2 into Reagent Vial 1 and tap gently
2. Allow to stand 30 minutes at room temperature – **DO NOT mix before 30 minute incubation**
3. Gently **invert** to mix
4. Document open date, revised expiration date and tech code on the vial
5. Add stir bar to the vial
6. Tilt vial and add maxi reducer careful not to set on top of stir bar

Stability:

- Unopened: Until manufacturer expiration date when stored at 2-8°C
- Reconstituted: 4 days when stored on the instrument

STA- Coag Control Normal and Abnormal

Preparation:

1. Reconstitute each vial of control with 2ml of Reagent Grade water
2. Allow to stand at room temperature for 30 minutes - **DO NOT swirl before 30 minute incubation**
3. Gently **swirl** vial before use
4. Document open date and time, revised expiration date and tech code on the vial

Stability:

- Unopened: Until manufacturer expiration date when stored at 2-8°C
- Reconstituted: 36 hours stored on instrument. (Deviates from package insert -See stability study documentation in labadmin drive).

Quality control

- Normal and abnormal quality control testing is performed every 8 hours each day of patient testing per procedure.
- Results interface into LIS.
- Verify results are within acceptable range.

If controls are out of acceptable range, refer to section V. Corrective action when a control fails to perform as expected

NOTE: Controls must be acceptable prior to reporting patient test results.

SATELLITE QUICK GUIDE

Procedure

NOTES:

- **Instrument to remain on, only shutdown for weekly maintenance.**
- **Press any key to "wake" instrument from save mode (dark screen)**
- **DO NOT open cover without instrument permission**
- **Press ESC to toggle between Main menu and TEST PANEL screen**
- **Blinking red light in front of probe indicates instrument is running – keep clear of probe**

I. Start up

On main menu screen:

1. Select STATUS<ENTER>
2. Use ↑↓to select System <ENTER>
    a. Review and document temperatures in LIS.
    b. Check number of cuvettes
    c. Check volume of wash solution
    d. Press ESC
    e. "Quit" is highlighted <ENTER>
    f. ESC to return to main menu
3. Select C (calibration/control)
    a. Use ↑↓to select Calibration <ENTER>
    b. PT+ highlighted <ENTER>
    c. Geo Mean is listed as Reference Time – document in LIS.
    d. ISI is located at the bottom right on the screen – document in LIS.
    e. ESC – Options
    f. "Quit" is highlighted <ENTER>
    g. ESC – return to TEST PANEL SCREEN

II. Reagent loading

Prepare reagents as instructed.
Reagents in large vials are loaded in carousel position 1,5,9 and/or 13.
Reagents placed in positions 1-11 on carousel allows viewing of all reagents on one screen.

- Desorb – Position 1 – it is required in this position for weekly maintenance – add maxi reducer
- Neoplastine – incubate at room temperature 30 minutes - Swirl the reagent vial gently to obtain a homogeneous suspension, add stir bar, tilt and add maxi reducer
- Controls - incubate at room temperature 30 minutes – swirl to mix

NOTE: reagents containing stir bars must not be directly adjacent to one another on the carousel.

A. Load by vial

On TEST PANEL screen

1. Select F2 Products: vial
2. Open cover when prompted
3. Press any key
4. Use ↑↓ to select position – when highlighted - <ENTER>
5. Selected position will be at bottom of screen
6. Carousel will rotate the selected position to be in front of the barcode reader
7. Place product in carousel with the barcode facing the reader <ENTER>
    - Use insert for controls
    - Product information will display across bottom of screen
8. Confirm volume <ENTER> (adjust as needed)
9. Confirm stability <ENTER> (adjust as needed)
    a) QC stability is 36 hours per internal stability study.
    b) Satellite will expire QC at 24hrs, to work around this the QC vials should be removed and then placed back on the carousel, update the stability to 12 hours (This will allow us to use the same QC vials for the full 36 hours). The volume should also be manually updated to reflect the remaining volume in the vial (ex: 1.8).
10. Repeat for all reagents loaded
11. Close cover
12. ESC - Quit

Carousel will initialize and display TEST STATUS screen
ESC to return to TEST PANEL screen

B. Load by carousel

On TEST PANEL screen

1. Select F2 Products: vial
2. Open cover when prompted
3. Press any key
4. Load reagents with barcode facing reader
5. Close cover - Instrument will initialize carousel
6. A reagent will be highlighted
   a. verify reagent name <ENTER>
   b. verify reagent volume <ENTER>
   c. verify reagent stability <ENTER>
      a) QC stability is 36 hours per internal stability study.
      b) Satellite will expire QC at 24hrs, to work around this the QC vials should be removed and then placed back on the carousel, update the stability to 12 hours (This will allow us to use the same QC vials for the full 36 hours). The volume should also be manually updated to reflect the remaining volume in the vial (ex: 1.8).
8. press ESC

III. Quality control testing

Controls must be run prior to performing any patient testing and every 8 hours of operation

A. Running controls

On main menu screen

1. Select C (calibration/control)
2. Use ↑↓to select Quality control <Enter>
3. PT+ highlighted
4. Press F1 to Select – a letter "S" will appear to the left
5. Press F10 to confirm – run selected controls
6. A pop up window will appear: " Password" will be highlighted in blue, password is QC <ENTER>.
   - The "S" will change to a yellow rectangle
7. Press ESC to return to Test Status screen
8. Instrument will run controls
9. ESC
10. ESC – return to TEST PANEL screen

IF A CONTROL FAILS – an alarm will sound and a pop up window will appear- refer to procedure section V. Corrective action when a control fails to perform as expected. The failure must be addressed prior to continuing with testing. To silence alarm – press the space bar

B. Reviewing controls

1. ESC to return to main menu screen
2. Select C (calibration/controls).
3. Use ↑↓to select Daily control <Enter>
4. F6 to print results
   a. attach printout to worksheet
   b. document tech code

5. Press ESC two times

To review Levy Jennings graphs

1. Select C (calibration/controls).
2. Use ↑↓to select Quality control <Enter>
3. PT+ highlighted <ENTER>
4. Use F2/F3 to toggle between levels
5. ESC
6. Pop up window – "Return to result list" highlighted <ENTER>
7. ESC – return to TEST PANEL screen
8. Results interface into LIS.

IV. Patient testing- Loading samples

NOTE: Microtainer tubes must be loaded in MANUAL MODE

A. Sample loading by VIAL - MANUAL MODE - cover must remain CLOSED

On TEST PANEL screen

1. Select F1 Samples – sample loading pop up window
2. Verify MANUAL MODE – if in AUTO MODE, see below to select MANUAL MODE
3. ESC
4. Remove cap from sample tube
5. Place tube with barcode facing reader - gently press tube down to ensure it is seated at bottom of carousel
6. PT+ highlighted <ENTER>
7. F10 to validate – sample ID will move to upper box on the screen with carousel position and PT+ indicated
8. Repeat steps 4--7 for all samples to be tested
9. ESC – options
10. "Quit" highlighted <ENTER>
11. Run will start
12. End of run – results will print
13. Attach printout to worksheet and affix patient label
14. Document tech code
15. Results interface into LIS.

Loading a **microtainer tube**

1. Place a microtainer adapter on the carousel
2. Using a disposable pipette, aliquot ~ 1ml of sample into a microtainer tube and place in adapter on carousel
3. Select F8 to select microtainer tube
4. Manually enter patient L number <ENTER>
5. PT+ highlighted <ENTER>
6. Select F10 validate– sample ID will populate box on the upper screen with position and PT+
7. verify presence of a "µ" to the right of the sample carousel position

B. Sample loading by VIAL - AUTO MODE

On TEST PANEL screen

1. Select F1 Samples – sample loading pop up window will appear
2. Verify in AUTO MODE
3. ESC
4. Remove cap from sample

5. Place tube with barcode facing reader – gently press tube down to seat at bottom of carousel
6. Press any key – sample ID and position will populate lower box
7. Repeat for all samples
8. ESC
9. "Quit" highlighted <ENTER>
10. Run will begin
11. End of run – results will print
12. Attach printout to worksheet and affix patient label
13. Document tech code
14. Results interface into LIS.

C. Sample loading by carousel – use for large batches that do not include microtainer tubes

Must be in **AUTO MODE** – If in MANUAL MODE, see below to select AUTO MODE

On TEST PANEL screen

1. Select F1 Samples – sample loading pop up window will appear
2. Verify in AUTO MODE
3. Open cover
4. Remove cap from sample
5. Place tube with barcode facing reader- gently press tube down to seat at bottom of carousel
6. Close cover
7. Carousel initialization – Reading carousel identity
8. Run will start
9. End of run – results will print
10. Attach printout to worksheet and affix patient label
11. Document tech code
12. Results interface into LIS.

D. Repeat testing

On TEST PANEL screen

1. Highlight sample to be repeated <ENTER>
2. Select F4 Delete
3. Select F10 Save – this will erase previous result
4. Select F5 Insert
5. PT+ will be highlighted <ENTER>
6. Select F10 Save
7. Select F10 Run
8. Run will start
9. End of run –results will print
10. Compare repeat result to first result- Verify within acceptable repeatability range

    The results must check within 5% on the Seconds (not the INR)

    Example: Patient seconds are 42.5 and 44.3

    Using the first result of 42.5 $\pm$ 5% = 42.5 x 0.95= 40.4

    42.5 x 1.05= 44.6

    The repeat 44.3 is within the 5% range of 40.4-44.6 and the repeat is acceptable

    Report the repeat value
11. Attach printout to worksheet and affix patient label
12. Document tech code
13. Results interface into LIS.

NOTE: **DO NOT use F3 Rerun.** This function will report a mean of the two runs and will not report actual repeat result.

E. Select MANUAL/AUTO MODE

On TEST PANEL screen

1. Select F1 Samples – sample loading pop up window will appear
2. ESC
3. ESC –options
4. ↑ to highlight MANUAL/AUTO MODE
5. <ENTER>
6. ESC
7. "Quit" highlighted <ENTER>
8. ESC to return to TEST PANEL screen

F. Performing a STAT test

Before loading sample on carousel – MANUAL MODE

1. Select F12
2. Load sample with barcode facing reader
3. The sample ID and position will populate lower box on the screen (normal tube) will change to yellow
4. PT+ highlighted <ENTER>

After sample loaded on carousel – Run **not** started

1. ↑ to select sample ID <ENTER>
2. Sample ID and position will populate lower box
3. Select F12 STAT/ROUTINE (normal tube) will change to yellow <ENTER>

After sample loaded on carousel – Run started

1. ↑ to highlight sample ID <ENTER>
2. Select F12 STAT/ROUTINE
3. F10 to validate
4. ESC

IV. Testing completed - Unloading samples and products

A. Unload samples:

On TEST PANEL screen

1. Select F1 Sample – sample loading pop up window
2. Open Cover
3. Remove samples
4. Recap and place in storage rack
5. Close cover

B. Unload product by vial:

On TEST PANEL Screen

1. Select F2 Products:vial – product loading pop up window
2. Open cover – press any key
3. Arrow ↑ to highlight product to be removed<ENTER>
4. Carousel will move product to barcode loading position
5. Remove product
6. Repeat steps 4-5 until all desired products removed
7. Close cover
8. ESC
9. ESC-Quit

Carousel will initialize – please wait

V. Corrective action when a control fails to perform as expected

An Error pop up window will display and instrument will beep

Quality control: Control out of limits for the test PT+

ESC to continue – pop up will disappear and alarm will stop

NOTE: On daily control screen, control will be Red and flagged Out of Range

1. Verify use of correct control and expiration dates
2. Verify volume and expiration dates of Desorb and Neoplastine
3. Repeat testing using same vial
   Press ESC as needed to return to main menu screen
   a. Select C (calibration/controls)
   b. Use ↑↓to select Quality control <Enter>
   Window displays : Control out of range
   c. Arrow ↑ to ACCEPT <ENTER> **(DO NOT SELECT RERUN AS FAILED DATA WILL NOT BE SAVED)**
   d. Password: CQ (super user password) <ENTER>
   e. ESC to return to main menu
   f. Repeat control testing per procedure Section III. A.
   - If results acceptable – document corrective action in LIS, record results and proceed with patient testing
   - If repeat failure – document corrective action in LIS and proceed to step 4.
4. Prepare an new vial of control
   Press ESC as needed to return to main menu screen
   a. Select C (calibration/controls)
   b. Use ↑↓to select Quality control <Enter>
   Window displays : Control out of range
   c. Arrow ↑ to ACCEPT <ENTER>
   d. Password: CQ (super user password) <ENTER>
   e. ESC to return to main menu
   f. Perform control testing per procedure Section III. A.
   - If results acceptable – document corrective action in LIS, record results and proceed with patient testing
   - If repeat failure – document corrective action in LIS and proceed to step 5.
5. Prepare a new Desorb and/or Neoplastine
   Press ESC as needed to return to main menu screen
   a. Select C (calibration/controls)
   b. Use ↑↓to select Quality control <Enter>
   Window displays : Control out of range
   c. Arrow ↑ to ACCEPT <ENTER>
   d. Password: CQ (super user password) <ENTER>
   e. ESC to return to main menu
   f. Perform control testing per procedure Section III. A.
   - If results acceptable – document corrective action in LIS, record results and proceed with patient testing
   - If repeat failure – document corrective action in LIS and proceed to step 6 .
6. Contact your laboratory supervisor.

Quality Control Notes:

- **Controls must be acceptable prior to reporting patient test results.**
- All QC Results should be accepted on the instrument and in EPIC Beaker.
- Document steps taken to resolve QC issues

CALCULATIONS

$$\text{INR} = \left(\frac{\textit{Patient's PT}}{\textit{Geometric Mean PT}} \right)^{\text{ISI}}$$

The INR is automatically calculated by the STA®/STA® Satellite. The ISI is furnished by the manufacturer in the package insert and is stored in the CALIBRATION page for PT (or PT+) along with the geometric mean (reference time). The Geometric Mean is determined from the normal patient study that is completed at the start of each new lot of neoplastine. This mean can be found on the New Lot documentation for the site.

REFERENCE RANGE

Reference Range	12.0-14.5 seconds	No reference range available for children < 6 months.
Critical Range	INR ≥ 5.0	Check for clots using wooden sticks
Repeat Range	INR ≥ 5.0	Check for clots using wooden sticks
Reportable Range		

Procedure Notes

<mMin	PT is low	Report PT as <10 and INR as <0.7
>mMax	PT is high	Report PT as >100 seconds and INR as >11.5
Check for clots with wooden sticks before reporting either <10 or >100 seconds. Also, check for the presence of hemolysis when reviewing an INR >5.0. Hemolyzed samples and clotted samples should be rejected.		

REPORTING RESULTS

Results interface into LIS.
Refer to EPIC Beaker result entry procedure

CHANGING PASSWORDS:

There are 4 levels of Password defined. We define passwords for level 1 and level 2. Each level defines available functions to the user.
Password for Level 1 is QC. Use this password to order QC rerun controls, re-run patient tests, delete tests.
Password for Level 2 is CQ: Use this password to change QC ranges, change reference time, cancel QC, rerun out-of-range QC, delete QC, delete patient files.

How to create or modify logins and passwords:

1. Press ESC for Main Menu
2. Go to Maintenance Menu
3. Arrow down to Users Management and press enter
4. Log in to this area with the Level 2 password (CQ) and press enter
5. Log in: We do not use a log in
6. Password; Level 1: Enter QC
7. Password, Level 2: Enter CQ
8. Password, Level 3, Level 4: Do not enter a password
9. Escape to quit

Refer to the EPIC Beaker result entry procedure

LIMITATIONS OF THE PROCEDURE

1. **Sample:** The slightest coagulation (micro-clots) will induce considerable shortening of the times measured (autocatalytic activation of all the factors) whereas extensive coagulation will prolong the clotting times because of consumption of factors and fibrinogen.

   Do not keep plasma at 2-8 °C because in this temperature range the factor VII may be activated by the kallikrein system (2).

2. **Anticoagulant:** Maintain the correct anticoagulant/blood sample volume ratio of 1:9. If there is any considerable variation in hematocrit, modify the quantity of anticoagulant accordingly.

3. **Heparins:** The STA® - Néoplastine® CI Plus test is insensitive to unfractionated heparin levels up to 1 IU/ml and to low molecular weight heparin levels up to 1.5 anti-Xa IU/ml.

4. **Thrombin Inhibitors:** Thrombin inhibitors (e.g., hirudin, argatroban...) present in the sample to be tested may lead to a prolonged prothrombin time for this sample.

Vitamin K antagonists

- Vitamin K antagonists will depress plasma levels of factors II (prothrombin), VII (proconvertin), X (Stuart factor) and IX (antihemophilic factor B).
- For the assessment of the vitamin K antagonist therapy, refer to the current recommendations.

REFERENCES

1. STA Satellite® Operator's Manual July 2016.
2. STA Satellite ® User Guide November 2011.

For additional information, please refer to the manufacturer's package inserts.

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