UnityPoint Health
Methodist | Proctor

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Protime PTT Fibrinogen D-Dimer

Viscosity Based Clot Detection and Optical Density

Diagnostica Stago Compact Max

PTIM

PTT

FIBR

DDIMR

I. PRINCIPLE and CLINICAL SIGNIFICANCE

The Compact Max 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 test reagents and plasma is monitored by the Compact Max. When the oscillation of the steel ball is stopped by clot formation, the sensor registers the time in seconds.

Protime:

STA®-Neoplastine CI PLUS is used for Prothrombin time. A mixture of thromboplastin is added to citrated plasma and the time of clot formation is determined. 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. coumadin therapy, intestinal reabsorption disorders, liver failure, fibrinolysis and DIC.

The prothrombin time is also used to monitor coumadin therapy because of its sensitivity to variations in the concentration of the Vitamin-K dependent factors II, VII and X. Because of the variations in the prothrombin time results with different thromboplastins and instruments, the prothrombin time result is 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:

Geometric Mean = See PT Cal on Analyzer
Current Lot ISI = Package Insert or Cal page

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

Activated Partial Thromboplastin Time:

STA®-PTTA reagent is used to perform the APTT test. The APTT test involves the recalcification time of plasma in the presence of a standardized amount of platelet substitute and a specific activator. This procedure minimizes test variables by standardizing the contact activation and optimizes the concentration of platelet-like phospholipids. The time of clot formation is measured on the STA® Compact Max. The activated partial thromboplastin time (APTT) is a basic screening test for the assessment of congenital and acquired deficiencies of the intrinsic pathway (factors XII, XI, IX, VIII). It is also the test most often used to monitor unfractionated heparin therapy.

Fibrinogen:

The STA® Fibrinogen is intended for the quantitative determination of fibrinogen in plasma by the clotting method of Clauss. In the presence of an excess of thrombin, the clotting time of diluted plasma is inversely proportional to the level of plasma fibrinogen. The Compact Max detects the clot and the time is read from a stored curve. An increase of the fibrinogen level is observed in cases of diabetes, inflammatory syndromes and obesity. A decrease of the fibrinogen level is observed in DIC, fibrinolysis, thrombolytic therapy and hereditary diseases.

D-Dimer:

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.

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).

The principle of the test is as follows. 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.

I. SPECIMEN

1. Citrated blood 9:1 (blood to anticoagulant) 3.2% sodium citrate.
   No other anticoagulant is acceptable.
2. Must be Platelet Poor Plasma Centrifugation: 9 minutes at 3800 rpm.

UNACCEPTABLE SPECIMENS:

A. Samples that are short (below the Line)
B. Over filled specimens
C. Hemolyzed Samples are poor quality and should be redrawn
D. Clotted samples will have PT, PTT and Fibrinogen results that are inaccurate or unobtainable. Check for clots with applicator sticks. Specimens with fibrinogens <25mg/dl should be suspected of being serum (clotted).

SPECIMEN STORAGE

Protime:

Whole Blood- 24 hours at 18-24 °C Do not keep at 2-8° C
Plasma- 2 weeks at -20º C

PTT:

Whole Blood- 4 hours at 18-24 °C or 2 hours at 20 °C if on heparin
Plasma - 4 hours at 2-8 º C 2 weeks at -20º C

Fibrinogen:

Whole Blood- 4 hours at 18-24 °C
Plasma- 2 weeks at -20° C. Frozen plasma should be thawed once @ 37° C

D-Dimer:

Spun whole Blood- 8 hours at 18-24 °C
Plasma- 4 weeks at –20 °C. Frozen plasma should be thawed once at 37 °C for 5 min

INTERFERRING SUBSTANCES:

Special Notes Related to D-Dimer Results

1. The Liatest reagent is insensitive to:
    a. Hemoglobin less that 5.1 g/l
    b. Bilirubin less than 201 mg/l
    c. Unfractionated Heparin less than 2IU/ml
    d. Low Molecular Weight Heparin less than 2 anti-Xa IU/ml
2. Cloudy plasmas may lead to an under-estimation of the D-dimer level. Ensure that the absorbance value at 540nm of plasma-diluted 1:6 with Owren-Koller Buffer is less than 0.35.
3. Concentrations of fibrinogen degradation products greater than 15 micrograms/ml may lead to an over-estimation of the D-dimer level.
4. The presence of rheumatoid factor at a level greater than 50 IU/ml may lead to an over-estimation of the D-dimer level.
5. The presence of anti-bovine albumin and/or anti-mouse antibodies in certain subjects may lead to an over-estimation of the D-dimer level.

Special Notes Related to PTT Results

When monitoring heparin therapy, any release of platelet factor 4 (PF4), which is a potent inhibitor of heparin, represents a potential source of error.

II. REAGENTS

1. Neoplastine® CI Plus: Freeze-dried thromboplastin prepared from rabbit cerebral tissues. Reagent contains a specific inhibitor of heparin, thus, times obtained will not be affected by heparin at therapeutic levels. Transfer the entire contents of one vial of Reagent 2 into one vial of Reagent 1 of the same lot. Let sit 30 minutes at room temperature. Swirl gently. Add a stirring- bar to the vial and place a Reducer in the reagent and install the perforated plastic cap. Place the reagent into a stirring position in the product drawer on the Compact. Reconstituted stability on the Compact Max is 48 hours.
2. Protime Reagent 2: 10 ml solvent. Ready to use.
3. PTT-Automate ℠: The reagent is a preparation of brain phospholipids in a buffered suspension of particulate activators with added stabilizers. Reconstitute each vial with 5.0 ml of reagent grade water. Let sit 30 minutes at room temperature. Vortex gently for 10 seconds with rubber stopper on. Place 1.6ml of reagent on the Compact Max in a microtube and place the remaining reagent in the refrigerator. Stability on the Compact Max is 24 hours. Stability of the reconstituted reagent is 7 days, if refrigerated.
4. 0.025 M $CaCl_2$: Ready to use. Place 1.6 ml of $CaCl_2$ on the analyzer in a microtube. Stability is 72 hours.
5. STA®-Fibrinogen: Freeze-dried titrated human calcium thrombin (approx. 80 NIH unit/ml) containing a specific heparin inhibitor. Reconstitute each vial with 5.0 ml of

reagent grade water. Replace the perforated plastic cap on the vial. Let sit 30 minutes at room temperature. Swirl gently. Reconstituted stability on the Compact Max is 120 hours (5 days). 14 days if refrigerated. The STA® - Fibrinogen procedure is insensitive to the following substances: fibrin degradation products (up to 130 µg/mL), hirudin (up to 3 µg/mL), and heparin (up to 2 IU/mL).

6. D-Dimer Reagent 1: Tris Buffer: Ready to use. Allow the reagent to stand at room temperature for 15 minutes. Mix gently without creating bubbles. Use with the perforated cap on the vial. Reconstituted stability on the Compact Max is 15 days.
7. D-Dimer Reagent 2: Latex: Ready to use. Suspension of microlatex particles coat with two different mouse monoclonal anti-human D-Dimer antibodies. Allow reagent to stand at room temperature for 15 minutes. Mix gently without creating bubbles. Load vial with the perforate cap on. Reconstituted stability on the Compact Max is 15 days
8. Biorad Liquichek D-dimer controls: Two plasmas containing different levels of D-Dimer. Intended to be used as controls for microlatex testing. Remove QC from the Blood Bank freezer. Let sit 20 minutes at room temperature. Swirl gently. Store in microcups labeled with expiration date and time. Do not leave on the analyzer, reagent must be kept at 2-8 degrees.
9. Owren-Koller buffer: Ready to use buffer. Used by the Compact Max to perform dilutions of controls and patient samples. Place a small amount of buffer into the sample drawer. Stability is 72 hours.
10. Coag Control Plus NORM+ABN: citrated control plasmas normal and abnormal levels freeze-dried. Reconstitute each vial with 2.0 ml reagent grade water. Let sit 30 minutes at room temperature. Swirl gently. Reconstituted stability on the Compact Max is 24 hours.
11. Desorb U reagent is used by the Compact Max to clean and deproteinate the reagent probes. Stability on the Compact Max is 120 hours (5 days).
12. Wash Solution- 2500ml cleaning solution.
13. CHECK REAGENTS through TEST PANEL (MAIN MENU) under PRODUCTS, select PRODUCT STATUS. The PRODUCT STATUS screen lists all of the reagents on board, along with the total volume and expiration time. Review the list to decide which reagents need to be reconstituted for test(s) to be run. To print this screen: Press Print Screen. You may need to push the button on top of the printer to make the printout appear in the tray.
14. Reconstitute reagents and controls as needed.

15. Discard any reagents with blinking red lights. These reagents or controls are either empty or expired (complete).
16. LOAD REAGENTS through the TEST PANEL under PRODUCTS, select LOADING PRODUCTS. Or click the products icon.
    A. Select LOADING PRODUCTS
    B. Scan the product barcode.
    C. Confirm the volume is correct on the screen. [Enter]
    D. Confirm the on board stability. [Enter]
    E. Place the reagent or control in the product drawer.
    Neoplastin C plus needs to have a stir bar and a maxi reducer. The bottle should be placed in a spot with a circle.
    F. To reduce the amount of volume needed for dead space:
        1. Label a small glass tube purchased for the Compact Max
        2. Place the tube of reagent into a brass holder
        3. Press F8 for microvolume
        4. Scan the original bottle
        5. Enter the volume of reagent in your tube
        6. Enter at the expiration date
17. Load the reagent into the product drawer.

New lot of Thromboplastin:

With each new lot of thromboplastin, the operator must enter the geometric mean for Protime before the Compact Max will allow QC to be run. The Diagnostica Stago Technical Service Representative calculates this value after the side-by-side evaluation of the new and old reagents is complete.

Through the TEST PANEL, select CALIBRATION or click the calibration icon. Double click on PT. Once the PT calibration screen is displayed, select Run Controls. The cursor will be on the Reference Time field, enter the Reference Time (Geometric Mean). Click confirm. This screen also stores the ISI value, as downloaded from the reagent bar code sheet.

Check the mathematical calculation of the INR before turning out results. See New Lot Implementation Procedure.

III. INSTRUMENTATION/EQUIPMENT

Equipment	Supplies
• STA® Compact Max Analyzers • Centrifuge	• Microcups, Reagent • Pipettes • Pipette tips • STA® Reducer • Reagent Grade Water • Cuvette roll (contains 1000) • Magnetic Stir Bars • Microcuvette, specimen

IV. MAINTENANCE

Daily:

1. Record the temperatures of the Incubation well, Reading well and Product drawer on the Compact Max.
2. Perform Daily Needle Washing for Cap-piercing needle:
   A. The sample drawer must be empty when performing this procedure
   B. From the User maintenance menu, click Rinsing to display the Rinsing menu
   C. Click Clean piercing needle
   D. The pipette head assembly, gripper, and syringe pump will home.
   E. The Piercing needle – Cleaning window is displayed. Click Continue.
   F. The sample drawer will open and a message "Place a tube filled with 5mL of DESORB" appears.

Note: Take a pipette and draw out 5mL of DESORB from the 15mL bottle. Dispense this measured 5mL of DESORB into an uncapped 5mL clear plastic tube.

   G. The Piercing needle – Cleaning window appears.
   H. Check the box for Daily Maintenance. Daily Maintenance is 10 minutes.
   I. If more time is needed to clean the needle, the time can be typed into the Length of time field.

J. Click Continue to close the window and Continue again to close the drawer.
K. The cleaning cycle will start automatically once the drawer is closed.
L. If the cycle needs to be stopped, click End of cleaning.
M. When the cleaning is complete, click Continue to open the product drawer.
N. The cap piercing needle will ascend, the product drawer will open, and the needle will park itself in the product area leaving the cap piercing needle exposed.
O. Open the transparent cover and using a paper towel, wipe the cap piercing needle dry. **Wipe from top to bottom <u>ONLY.</u>**
P. Close the transparent cover and click Continue to confirm and Continue again to close the drawer.
Q. Click Continue to open the sample drawer and remove the tube of Desorb. Click Continue to close the drawer.

Weekly: Compact Max

1. Clean the Sample and Product Drawers
   A. From the Test Panel screen press F1
   B. Clean the top of the drawer with a soft cloth moistened with warm water
   C. Wipe dry
   D. Close the drawer
   E. Repeat with the Product drawer F2
2. Clean Wash Wells
   A. From TEST PANEL, under SYSTEM choose USER MAINTENANCE.
   B. From MAINTENANCE, select Needle Purge.
   C. Select Open drawer.
   D. Raise the Transparent Panel.
   E. Fill each wash well ¾ full with a 1:10 bleach solution (1m bleach + 9ml water).
   F. Lower the Panel.
   G. After 10 minutes, select Close Drawer.
   H. Proceed with Needle Purge: Select needle #1, then click Purge. Select needle #2, then click Purge. Select needle #3, then click Purge (Let pumps rest between purges)
   I. When finished, click Quit. And Confirm to return to previous screen (or continue with the rest of maintenance procedures).
3. Clean the Measurement Plate
   A. From the Test Panel, under SYSTEM choose USER MAINTENANCE.
   B. From MAINTENANCE, select PURGE needle.
   C. Raise the transparent panel.
   D. Make a 1:5 dilution of absolute alcohol.

E. Dip a cotton swab in the 20% alcohol and clean each measurement well and Incubation well.
F. Clean the black panel of the measurement plate with a soft cloth moistened with warm water.
G. When finished, click Quit. And Confirm to return to previous screen.

3. Check the Level of the Peltier Reservoir.
   A. Open the right side door
   B. Check the level to make sure it is above the indicated mark.
   C. If low, shut off Compact Max using the correct procedure.
   D. Open the reservoir and fill with the cooling liquid.
   E. Turn the analyzer back on.
4. Clean and check the Suction Tip
   A. From the Test Panel, under SYSTEM choose USER MAINTENANCE.
   B. From MAINTENANCE, select REPLACE SUCTION TIP.
   C. Raise the transparent cover.
   D. Remove the cuvette disposal drawer.
   E. Gently move the arm toward the front of the analyzer. Do not move the arm using the tubing attached to the top of the arm.
   F. Gently remove the suction tip by pulling from the top.
   G. Clean the suction tip with warm water.
   H. Dry it and look for cracks by squeezing the suction tip.
   I. Replace the suction tip, which should fit snugly against the suction head.
   J. Replace the disposal drawer.
   K. When finished, click CONFIRM.
   L. Return to Previous Menu.
5. Clean Air Filters
   A. Remove the air filter on the back of the Compact Max and from the lamp
   B. Reinstall clean filters, he word exerieur should face out.
   C. Switch on the Compact Max
   D. Rinse off the dirty filters with water and allow to dry completely or vacuum.
   E. Return the filters to the Tool Box.
   F. When filters show wear, order new filters.
6. Review of Quality Control Graphs by the Lead
7. Decontaminate stir bars
   A. Immerse the bars in a vial (can be used vial) of STA-Desorb U and let them soak for 5 minutes with constant magnetic stirring.
   B. Use tweezers to transfer the bars from the Desorb to a vial of DI water and let them soak for another 5 minutes with magnetic stirring.
   C. Repeat this rinsing step with another vial of DI water
   D. Finally, remove the stir bars from the DI water and dry carefully to remove all

traces of moisture.

8. Clean Touch screen

A. Hold cursor down on blank section of screen. Wipe down screen using an alcohol pad.

Monthly: Duties

1. Print QC graphs and statistics on the first day of each month for a comprehensive review. Tolerance limits are:

PT- no greater than 5% CV and increases of 2 fold
PTT- no greater than 7% CV and increases of 2 fold
FBG- no greater than 10% CV
D-Dimer- no greater than 10% CV

Any failure in the tolerance limits should be investigated, documented and corrective action implemented.

2. Alternate O-ring and Syringe tip maintenance every other month between Stago 1 and Stago 2 Analyzer. See the Maintenance Chart and Operator Manual.

Every Six Months: Compact Max

Instrument to Instrument Comparison. Run the two samples on both Analyzers. Program Protime, PTT, FBG and D-Dimer. Record the results and calculate the percent difference. If the percent difference does not meet the posted guidelines, repeat the run. If the repeat is still outside the comparison parameters, call the hotline to request service and technical guidance. Alert the Hematology Lead of any discrepancy.

Once A Year:

Once a year, take five patient plasma samples and run them on the Hematology Analyzer (background count 0). Record the platelet count of the platelet poor plasma on the log sheet with the Instrument Comparison. Platelet poor plasma has a platelet count less than 10,000. If the Plt count is >/= 10,000, increase the time, notify the Lead and retest after the changes are made. Post any changes and notify all staff.

CALIBRATION

No calibration of the system is necessary for performing a PT or PTT if results are reported in seconds.

Calibration Verification for Fibrinogen and D-Dimer testing should occur when:

1. At the change of Lot
2. QC is out of range and no resolution is found

3. After a service call with major part changes
4. When recommended by Diagnostica Stago hotline
5. At least every 6 months

New Lot of Fibrinogen and D-Dimer

1. The pre-calibrated Fibrinogen or D-Dimer values are identical for all the vials of each lot.
2. Entering the data for the calibration curve: The database of the Compact Max monitors all reagent lot numbers. When the operator scans a new lot of fibrinogen or D-Dimer reagent, the Compact Max will request the operator to scan the bar code printed on the bar coded insert across the bar code reader.
3. The calibration curve will be checked for the lot being used when the two fibrinogen/D-Dimer control levels have been run. If the validation controls are outside the assayed range, the Compact will not run patient samples.
4. As soon as possible, verify the calibration of the new lot.

Fibrinogen Calibration Verification:

1. Find a patient with a fibrinogen between 700 – 800 mg/dl.
    A. Helpful hint: find either a labor/delivery patient or post-partum patient for a high fibrinogen.
    B. A second source for a possible high fibrinogen is a patient with a positive blood culture.
2. Run the fibrinogen test. Once this test is complete – the result should be between 700 and 800 mg/dl – add on the following dependent tests:
    A. Fib 1:15
    B. Fib 1:40
    C. Fib 1:80
    D. Fib 1:100
    E. Fib 1:160 (if available)
3. Print the test results. To print the results, select the patient on the test panel screen. Once the patient results are displayed, select [F6] to print
4. To calculate the correlation value and acceptable limits, there is a template in Microsoft Excel.
    A. Click on the Excel icon
    B. Go to Shared Drive S:
    C. Click on Hematology folder
    D. Find Calibration Template for FBG and D-Dimer Ver 08
    E. Fill out the form.
    F. Insert the STA Fibrinogen results in the Column marked STA Fibrinogen
    G. Fibrinogen Calibration Verification should be $\pm$ 20% (CAP guidelines).

H. Find the Fibrinogen Linearity Verification Template in the Hematology folder in Excel.
I. Insert the Values for the Compact results and the expected results.
J. Graph the points.
K. Acceptable Verification: R value should be 0.95-1.00 and Slope 0.90-1.10

5. If you do not have access to an excel program that will calculate linearity, fax the results to your local TSS (phone numbers are on side of Compact Max) to calculate the linearity.
6. If your Calibration Verification fails, call the hotline for solutions or to call for the service engineer. Do not run Fibrinogens until Calibration Verifications is satisfactory.

D-Dimer Calibration Verification:

1. Find a patient with a D-Dimer between 3.0 and 3.6 µg/ml FEU.
   Many patients have a positive D-Dimer, so you may need to screen several patients to find one with a suitable value.
1. Run the D-Dimer test. Once this test is complete, and the results are between 3.0 and 3.8 µg/ml FEU, add on the following dependent tests:
   A. D-Di 1:2
   B. D-Di 1:4
   C. D-Di 1:8
   D. D-Di 1:15
   E. D-Di 1:20 (optional)
2. Print the test results. To print the results, select the patient on the test panel screen. Once the patient results are displayed, select [F6] to print.
3. To calculate the linearity, (D-Dimers are performed at a 1:1 dilution)
   There is a template in Microsoft Excel.
   A. Click on the Excel icon
   B. Go to Shared Drive S:
   C. Click on Hematology folder
   D. Find Calibration Template for FBG and D-Dimer Ver 08
   E. Fill out the form.
   F. Insert the STA D-Dimer results in the Column marked STA D-Dimer
   G. D-Dimer Calibration Verification should be *Range 0.0 - 1.0 ug/mL +/- 0.15 and Range 1.0 - 4.0 ug/mL +/- 0.5*
   H. Find the D-Dimer Calibration Verification Template in the Hematology folder in Excel.
   I. Insert the Values for the Compact results and the expected results.
   J. Graph the points.
   K. Acceptable Verification is R value 0.95-1.00 and slope 0.90-1.10
4. If you do not have access to an excel program that will calculate linearity, fax the Results to your local TSS (phone numbers are on side of Compact) to calculate the

linearity.

5. If your Calibration Verification fails, call the hotline for solutions or to call for the service engineer. Do not run D-Dimers until Calibration Verifications is satisfactory.

QUALITY CONTROL

Run Quality Control material when reagents are changed and
Day Shift: Reconstitute and run a new control at 09:00
Second Shift: Run control at 17:00
Third Shift: Run control at 01:00

The analyzer is programmed to run QC after 8 hours if not ordered by a tech. The analyzer will only run QC for the test(s) that are running on the analyzer.

1. Coag Control Plus NORM + ABN: After the reconstitution period, request the reagent drawer to open through the TEST PANEL under PRODUCTS, select LOADING PRODUCTS and bar code the controls. Place the controls into an appropriate hole. Reconstituted stability on the Compact Max is 24 hours.
2. Ordering manually from the Quality Control Menu runs QC. Request quality control through TEST PANEL under QUALITY CONTROL or click the QC icon. The Methodologies list window will appear. Select the check boxes of all the methodologies that need QC, then click the QC GO icon. Type the access code and then CONFIRM. A yellow triangle icon is displayed on the right of the test abbreviation for which the QC was requested.
   QC can also be ordered from the QUALITY CONTROL Result Screen: From the TEST PANEL, select QUALITY CONTROL or click the QC icon. The methodologies list window will appear. Double-click the abbreviation of the test to be run; Click the TAB of the level that must be run. Click START. Type the access code and then CONFIRM. Click the Return icon to return to Methodologies window. A yellow triangle icon is displayed on the right of the test abbreviation for which the QC was requested.
3. The Compact Max monitors all control ranges automatically. If any controls are outside the ± 2 SD range, the Compact Max will audibly and visually alarm the operator. Otherwise, the control results are automatically filed in Compact Max QC file. All results for a 24 hour period will be reduced to a "mean" value at midnight and plotted on the Levy- Jennings chart as a daily mean.
4. Accept the Results in Sunquest Result Entry
   A. Interfaced Result Mode
   B. Configuration: YDS
   C. Click Result
   D. At the cup prompt you will see 12373.
   E. 12373 is Normal Coagulation Control. Type C-YCNL and accept or add appropriate codes.

F. 12374 is Abnormal Coagulation Control. Type C-YCAB
G. 12046 is Normal D-Dimer Control. Type C-YDDN
H. 12047 is Abnormal D-Dimer Control. Type C-YDDAB
I. The results are found in order of how they finish on the analyzer.
J. If you forget what these numbers mean, look at the l=Levy Jennings graphs on the DS. Above the Lot is the control number for each Level.

5. Next, view the LEVY-JENNINGS chart. From the TEST PANEL, select QUALITY CONTROL. Double click on the test desired. This is the QC Graphics view. To print L-J chart from here click the Print icon. To view the results in a list format Press the QC Tables icon. To print QC values under the current controls, press the Print icon. Then click the Graphic QC icon to return to Graphics QC page to switch to a different level of QC.
6. When QC is out of range, all patient tests run will have the Alarm Code: QC out of range or not done. Fill out a corrective action sheet to be reviewed by the Supervisor.
7. Troubleshooting QC:
   A. When viewing the QC Levy-Jennings graph you will see the control out of range window. Fill out a corrective action sheet. The window tells you the QC results, range, test name and the level that is out of range.
   B. You have 3 decisions to choose.
      1. Accept the controls- This will plot the point
      2. Rerun- This action would repeat the controls again.
      3. Postpone- this allows you to Troubleshoot and then run the QC again.
      4. Do not turn out patient testing until the QC is within Acceptable limits.
      5. If the out of range QC is not resolved on reanalysis and an instrument problem is detected, patient test results since the last acceptable run should be re-evaluated to determine if there is a clinically significant difference in patient results.
8. Running one level of QC material:
   A. From TEST PANEL, choose QUALITY CONTROL
   B. Double click the abbreviation of the test to be run
   C. You will be on the Levy-Jennings graph for Level 1, if you need Level 2, click Next Level tab.
   D. Click START.
   E. Type the access code (CQ) and click confirm
   F. Click the Return icon to return to Methodologies window. A yellow triangle icon is displayed on the right of the test abbreviation for which the QC was requested.

PROCEDURE:

1. Load patients' samples: Access the sample drawer through the TEST PANEL under PATIENT ANALYSES, then click LOADING SAMPLES. After the drawer opens

identify the type of specimen. If the sample is a micro specimen, check the Micro Volume box (can be before or after scanning barcode). Identify the sample by bar coding or manually entering on the keyboard the patient identification number and then placing the specimen into the drawer.

2. If TELELOADING is selected as the AUTO MODE profile, the Compact Max will query the host computer and download the test(s) as well as assign the status (i.e. stat).
3. To use the MANUAL MODE:
   A. Through TEST PANEL, under PATIENT ANALYSES, click LOADING SAMPLES
   B. The sample drawer will open; then click MANUAL MODE to switch modes
   C. Bar Code the sample
   D. The operator must order the test(s) from the Modifying Profiles screen, click CHANGE PROFILES. Build a test profile with the methodologies provided. Then choose the profile number you just built from the drop down box. You can create up to 7 different profiles. Profile 8 is reserved for By Downloading.
   E. When time allows, change back to Auto Mode- By Downloading for the next sample.
4. In AUTO MODE, Compact will automatically order the test(s) selected in the AUTO MODE profile. Rarely used.
5. When finished loading samples, press the Return icon, then Confirm. As soon as the sample drawer closes, the ANALYSIS STATUS screen will appear. If there is not enough reagent(s) to run the test(s), the suspect reagent(s) will appear in red with the amount of deficiency. This deficiency will BLOCK the SAMPLE PIPETTING. When this occurs, add the necessary reagent(s) to run the samples by responding N (NO) to the warning message 'NEW TESTS ARE DELAYED-REACTIVATE?' Reagents can then be loaded in the drawer. Make sure to run QC on the new reagent(s). By responding Y (YES) to the warning message 'NEW TESTS ARE DELAYED -REACTIVATE?', the instrument will continue to perform all tests for which there is sufficient reagent (i.e. while waiting for reagents to stabilize after reconstitution)
6. All patient results are displayed on the TEST PANEL screen. See the chart on the counter for an explanation of the colors and symbols.
7. For results in question that need operator intervention, access through TEST PANEL, under PATIENT ANALYSES, and click PATIENT FILES. Then double click on the sample to bring up the Patient Report Form. From here you can perform several different actions to the sample as long as it is still on board the instrument. You can view Notes about the test at the upper right of the screen.

PROCEDURAL NOTES

Procedures for Abnormal Results:

Fibrinogen results will automatically redilute and repeat if they are greater than 900 mg/dl or less than 150 mg/dl. D-Dimers will automatically be repeated with a 1:5 dilution when the results are 4.0 ug/ml.

1. Fibrinogen and D-dimers results will redilute automatically when the value is above or below the calibration curve. FBG: 1:8 when <150 mg/dl OR 1:40 when >900 mg/dl. D-Dimer: 1:5 when >4 ug/ml. When the test is done, you will not see the original result and the rediluted result will be in blue.

G. The linear range for D-dimers is 0.27-20.0 ug/ml. Results that are below the linear range have an " * " on the results and a message ALARM STA-LIATEST D- DI Result value in primary units skewed. In the File Processing screen, to the left of the D-dimer result you will see the raw data result that is below 0.27 ug/ml. These results should be reported as <0.27.

Special Notes Related to Fibrinogen Results

A >Max (seconds) for the result for Fibrinogen means the Fibrinogen value (mg/dl) is extremely low. Enter <60 mg/dl

A <Min (seconds) for the result for Fibrinogen means the Fibrinogen value (mg/dl) is extremely high. Enter > 1500 mg/dl

Special Notes Related to D-Dimer

The linear range for D-dimers is 0.27-20.0 ug/ml. Results that are below the linear range have an " * " on the results and a message ALARM STA-LIATEST

D- DI Result value in primary units skewed. In the File Processing Screen, to the left of the D-dimer result you will see the raw data result that is below 0.27 ug/ml. These results should be reported as <0.27.

Results with an "*" and the result is higher than 20 in the File Processing Screen should be reported as >20.0 ug/ml.

Special Notes Related to PTT

A congenital or acquired inhibitor may prolong the APTT

Patients receiving thrombolytic therapy will have a rapid drop in the plasma Fibrinogen level and these samples MUST be collected with an anticoagulant containing a plasmin inhibitor such as Aprotinin, Cat # 0820, to determine an accurate Fibrinogen result.

Redilution:

When the Compact Max redilutes a patient sample at a more appropriate dilution (as pre-determined in Test Set-up) the results in the TEST PANEL screen, which appear in Blue

numerals, have already been corrected by the Compact Max for the dilutional difference. The results will print with an " * " and ALARM FBG or D-DI Result: dilution changed.

Calculations:

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

Adjusting Anticoagulant for High Hematocrits
(.00185) X volume of blood to be drawn X (100 minus patient HCT)= ml of anticoagulant

When the patient hematocrit is >55%, an adjustment to the anticoagulant to blood ratio must be done. Use the formula below to determine the amount of anticoagulant needed in the tube. For Hcts below 20% there is no current data available to support adjusting the citrate concentration. Remove the amount of anticoagulant needed in the blue top and redraw the patient with a syringe and add the newly drawn blood to the tube. REMOVE THE CAP TO PLACE THE EXACT AMOUNT OF BLOOD INTO THE TUBE FROM THE SYRINGE. You cannot force blood into a tube that has had its cap removed or you will have a biohazard accident.

REFERENCE RANGES
Normal Range:
Protime: 11.7-14.2 seconds
INR: 0.89-1.13
PTT: 22.6-34.1 seconds
Fibrinogen: 200-496 mg/dl
D-Dimer: 0-0.50
Cut Off for Exclusions of DVT or PE- 0-0.50 micrograms/ml

CRITICAL VALUES:
INR: ≥4.5
PTT: ≥127 seconds
FBG: < 100 mg/dl

REPORTABLE RANGES

PT: 10-120 seconds
INR: Can change with each lot based on the ISI value. See MIQ 19 : YSTAG1 OR YSTAG2
PTT: 10-220 seconds
FBG 60-1500 mg/dl
D-Dimer 0.27-20.0 ug/ml

RESULT REPORTING

1. Click on Result Entry
2. Result Mode: Interfaced
3. Configuration: YDS PRP YDS
5. Click on Result
6. The results are set to autoverify. If any patient sample fails delta, verify or technical you will find the result in the next cup.
7. Verify results for validity and look on the DS screen for error messages before turning out these results.
8. Call and document all critical values according to the critical value policy.
9. Label the Printout if the name is not printed on the sheet. Keep printed results of Critical Values, results manually entered into Sunquest and failed technical.
10. Accept, place results in preliminary or reject.
11. When the printer has a full page of results it will automatically print. Open the sample drawer and take out the tubes that have a blinking red light. If the light is not blinking, the tube was not sampled by the analyzer due to not being received.
12. Specimens that have not been received in Sunquest will not run. Check in General Lab to see if the specimen has been received. Every once in awhile a specimen that is received will not run.

To use the MANUAL MODE:

A. Through TEST PANEL, under PATIENT ANALYSES, click LOADING SAMPLES
B. The sample drawer will open; then click MANUAL MODE to switch modes
C. Bar Code the sample
D. The operator must order the test(s) from the Modifying Profiles screen, click CHANGE PROFILES. Build a test profile with the methodologies provided. Then choose the profile number you just built from the drop down box. You can create up to 7 different profiles. Profile 8 is reserved for By Downloading.
E. When time allows, change back to Auto Mode- By Downloading for the next sample.

SUNQUEST DOWNTIME

When the computer comes back up, you may need to reschedule tests that were ordered before the computer went down.

A. Click on SMART
B. Utilities
C. Redownload
D. Contact the System Manager for more information.

When the Sunquest comes back up, you will need to result the tests in Result Entry. If the results will not flow from the DS to Sunquest, manually send them across.

A. Using the Patient Files screen, double click the file to open the Patient Report form
B. On the Patient Report form, click the Retransmit icon
C. For multiple files, select the files to be transmitted.
D. Click Retransmit icon, the Send Selected Files window appears
E. Select "Include files already sent" to send all the files
F. Click Run; the sent files appear in the File processed field. Click Quit to exit the field.
G. Result the Coagulation tests
H. Do a pending list to check for missed samples.

REFERENCES

1. Package insert for use in PT determinations, STA-Neoplastine CI PLUS®. Revised June 2015.
2. Control Plasmas for Assays of Coagulation Parameters on STA.® Analyzers. Package insert- Revised January 2015
3. STA® PTT-A®, Package insert for use in APTT determinations. Revised March 2015.
4. STA®-Fibrinogen, Quantitative Package insert– Revised March 2015
5. CaCl2 insert for use in APTT determinations. Revised May 2014.
6. Owren Kohler Buffer used in Dilution of Patient Sample. Revised May 2014.
7. D-Dimer, Quantitative Package insert- Revised August 2015.
8. Liatest Controls Package Insert – Revised March 2015.
9. STAGO STA Compact Max System Training Manual- Effective March 2, 2016.

Policy Created by: _____ Date: _____

Effective Date: September 7, 2005
Date Reviewed/ Date Revised: October 17, 2017

Medical Director Approval: _____ Date: _____

Change of Medical Director: _____ Date: _____

REVISION HISTORY			
Rev	**Description of Change**	**Author**	**Effective Date**
0	Initial Release	Cindy Schroeder	January 22, 2016
1	Updated for STAGO COMPACT MAX	Benjamin Martin	December 13, 2016
2	Updated controls, removed repeating critical results, changed platelet poor plasma check to once a year	Sheanea LaCock	October 17, 2017

Reviewed by

Lead	**Date**	**Coordinator/ Manager**	**Date**	Medical Director	**Date**
Sheanea LaCock	10/17/17				