UnityPoint Health Pekin
Department of Pathology
Pekin, IL 61554

Effective Date: 08/07/18
Date Reviewed/ Date Revised: 08/07/18

STA Compact Max Start Up Operating Procedure

STA Compact Max

I. PRINCIPLE

The STA Compact Max® system is designed to perform in vitro analyses for diagnosis and monitoring of pathologies linked to hemostasis. STA Compact Max® allows the performance of chronometric analyses (measurement of coagulation time), colorimetric analyses or immunological analyses on plasma samples.

A. Chronometry measurement principle:
The principle consists in measuring the variations of the ball oscillation amplitude through inductive sensors. The ball has a pendular movement obtained by two curved rail tracks in the cuvettes and an alternate electro-magnetic field created by two independent coils. The oscillation amplitude decreases when the environment viscosity increases.

B. Photometry measurement principle:
The detection of chromogenic assays on the STA Compact Max® is based on the absorbance (optical density: O.D) of monochromatic (405 nm or 540 nm) light passing through the cuvette as a chromogenic reaction takes place.

II. CLINICAL SIGNIFICANCE:

See individual procedures for clinical significance.

III. POLICY SCOPE:

The scope of this policy applies to all Laboratory staff that prepares or performs testing on laboratory specimens at UnityPoint Health Pekin.

IV. SPECIMEN TYPE:

A. 2.7 mL or 1.8 mL blue top tube. Mix nine parts of freshly collected blood with one part of 0.11 mol/L (3.2%) sodium citrate anticoagulant. Invert the tube gently three or four times immediately after venipuncture to ensure proper mixing of blood an anticoagulant.
   1. If blood is drawn from an indwelling catheter, the line should be flushed with 5.0 mL saline and the first 5 mL of blood or six dead space volumes of the catheter discarded.

B. Samples received from patients who have hematocrit values above 55% must have the volume of citrate in the blue top tube adjusted.
   1. May show prolonged time.
   2. The higher the hematocrit, the less plasma will be present.
   3. To obtain proper plasma to anticoagulant ratio for a 2.7 ml blue top tube use this formula:

$$\frac{100 - \text{Patient Hct}}{595 - \text{Patient Hct}} \times 2.7 = \text{volume of sodium Citrate required for unit of blood drawn}$$

4. Blood must be drawn in a syringe then added to the tube because these is no vacuum in the tube
5. The 2.7 mL blue top tube contains 0.3 mL of citrate.
6. Calculations for HCT product the following:

HCT	AMT OF ANTICOAGULANT NEEDED	AMT REMOVED
56	0.22	0.08
58	0.21	0.09
60	0.20	0.10
62	0.19	0.11
64	0.18	0.12
66	0.17	0.13
68	0.16	0.14
70	0.15	0.15

7. Aseptically remove 0.08 to 0.15 ml of citrate anti0coagulant to produce tubes for a wide range of HCT.
8. Notify phlebotomist that this tube can only be used for a specified patient.
9. Adjustment to anticoagulant in the 1.8 ml (pediatric) draw tubes is not advised. If needed, recalculate the above formula using 1.8 instead of 2.7.

C. Specimens that are clotted, collected in the wrong tube, have visible hemolysis or have less than a 90% fill or >10% overfill should be rejected.
D. It is unacceptable to combine the contents from separate underfilled sodium citrate tubes.

V. HANDLING CONDITIONS:

A. The whole blood specimen is checked for clot formation by gentle inversion and observation.
B. Centrifuge the capped blood specimen as soon as possible after collection for 2 minutes at 7200 RPM (3500 x g) in the Stat Spin Express 3 or S/P® Brand Stat-60.
   a. Testing requires platelet-poor plasma (platelet count $<10x10^9$/L).
   b. The plasma may remain on the packed cells if testing immediately or separated if freezing.
   c. To separate plasma, use a plastic transfer pipette; remove the plasma to a properly labeled polypropylene plastic tube until ready to test.
C. If testing is not complete within acceptable time for specimen stability (see below), the plasma must be removed to a properly labeled polypropylene plastic tube and frozen. A frost-free freezer should not be used. Frozen plasma samples must be rapidly thawed at 37°C and tested immediately after thawing. If testing is delayed, the samples may be held as stated in the storage and stability table.
D. Once removed from the analyzer, caps must be removed if additional testing is ordered. Tubes from completed coagulation testing are stored at room temperature.

VI. STORAGE AND STABILITY:

Assay	Store As Whole Blood			Processed and Plasma Aliquoted			
	Room Temp	Refrigerated	Frozen	Room Temp	Refrigerated	Frozen -20°C	Frozen -70°C
PT	Up to 24 hr.	Unacceptable	Unacceptable	Up to 24 hr.	Unacceptable	2 wk	12 mo
APTT	Up to 4 hr.	4 hrs	Unacceptable	4 hr.	4 hr.	2 wk	12 mo
APTT for Heparin	1 hr.	Unacceptable	Unacceptable	1 hr.	Unacceptable	2 wk	6 mo
D-Dimer	Up to 4 hr.	Unacceptable	Unacceptable	8 hr.	Unacceptable	4 wk	12 mo

VII. REAGENT

A. Onboard Product Status
   1. Through Test Panel (Main Menu) under Product, select Product Status
   2. Product Status lists all Onboard reagents with total volume and expiration date and time.
   3. Determine what products need to be loaded onto the instrument based on expired products, soon to be expired products, and products with low volumes
      a. The Stability End column will list the Time and Date the product will expire onboard the analyzer
      b. If a product is soon to be expired the date and time on the will be in red
      c. If a product is expired, instead of a date and time, it will say Complete.
      d. Also if a product is expired or empty, the LED adjacent to the vial position will be blinking

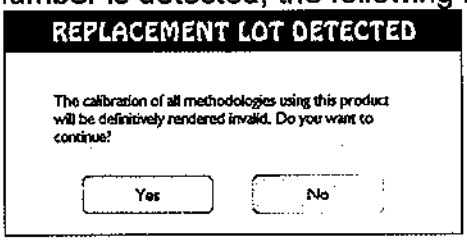
Reagent	Reconstitution	Reconstitution Time	Stir Bar	Stability Onboard	Stability (2-8 °C)	Reducer
(PT) Neoplastine CI Plus	**Diluent (Provided)**	30 minutes @ RT	**yes**	48 hours	8 days	**Yes**
(APTT) PTT-Automate	**5ml Water**	30 minutes @ RT, then **Vortex**	no	24 hours	7 days	no

5						
(APTT) CaCL2 0.025M	Ready to Use	30 minutes @ RT	no	72 hours (3 days)	n/a	no
(D-Dimer) Liatest D-DI Kit	Ready to Use	15 minutes @ RT	no	360 hours (15 days)	n/a	**Yes**
(D-Dimer) Owren-Koller	Ready to Use	30 minutes @ RT	no	72 hours (3 days)	n/a	no
Desorb U	Ready to Use	None	no	120 hours (5 days)	n/a	**Yes**
Quality Control Reagent	**Reconstitution**	**Reconstitution Time**	**Stir Bar**	**Stability Onboard**	**Stability** (2-8 °C)	**Reducer**
Coag Control N+ABN Plus	2ml Water	30 minutes @ RT	no	24 hours	n/a	no
Liatest Control N+P	1ml Water	30 minutes @ RT	no	8 hours	n/a	No

B. Prepare reagents: Follow instructions specified in each test procedure.

C. Product Loading and Removing:

1. Click  or click Products, then Loading Products. The product drawer will open.
2. Loading Reagent
   a. Scan the vial barcode label with the barcode reader.
   b. If necessary, edit the volume and stability.
   c. If the reagent has been transferred into a microcup, check the Micro Volume box.
   d. Place the vial in a position corresponding to its diameter in the area of the drawer specified in each test procedure.
   e. If the product requires stirring, place the vial in a stirring position indicated by orange arrows around position.
   f. The LED adjacent to the vial position lights up and a beep sounds.
   g. The product appears in the Products onboard table.
   h. If a new lot number is detected, the following message is displayed:



i. To proceed with barcode reading, click Yes, scan the sheet in front of the barcode reader then click Validate.

3. Removing product
   a. Remove the product from its position in the product drawer
   b. The red LED light adjacent to the vial will turn off and the product will be removed from the list of onboard products.
4. Click  to close the product drawer.
5. Determining
   a. Go to the "Product Status" screen (Products -> Product Status)

Strictly comply with the instructions provided by the manufacturer in the product and reagent documentation. Poor preparation of the reagent with respect to reconstitution volume, stabilization time, stirring, the presence of bubbles, or the omission or inappropriate presence of a magnetic stir bar may lead to incorrect results.

The ISI value of the thromboplastin used to determine the prothrombin time must be the one indicated on the insert for the STA product.

The ISI must be verified for each lot change, software update or intervention.

Follow the instructions specified in each test procedure.

V. QUALITY CONTROL

A. Daily QC Schedule for the N and Abn Plus controls: Check product status→After morning run, perform daily maintenance.
   1. Quality control for PT and APTT is automatically run when the STA Compact Max® has to perform an analysis using that methodology and when the time since the last control exceeds 8 hours. The time period is defined in the METHODOLOGIES screens
   2. 09:00- 09:30 Make up new QC and any reagents needed
   3. 09:30-10:00 Load QC material and Manually run QC
      a. Reconstituted Coag Control Plus N+ABN is stable onboard the Sta Compact Max for 24 hours
   4. 17:30-18:00 Manually run QC if sample are not being run01:30-02:00Manually run QC if sample are not being run
   5. QC will automatically run when testing switches to a new vial of reagent.

B. Liatest D Dimer Control N and P schedule:
   1. Liatest controls must be tested at least every 8 hours of testing and for each vial of reagent for the respective measurement range to ensure that the system if functioning properly
   2. QC will be run every 6 hours manually by the tech. This is to ensure there is no point that the QC is expired when testing needs to be done, and to minimize QC material used.

3. 09:00-09:30 - Make up new QC and any reagents needed
   a. 09:30-10:00 - Load and manually run QC and check results
   b. 15:30-16:00 - Manually run QC and check results

   21:00-21:30make up new Liatest D dimer controls
   c. 21:30-22:00 - Load and manually run QC and check results
   d. 03:30-04:00 - Manually run QC and check results

C. Quality controls can be run manually by the operator from 2 screens:
   1. Quality control screen – list of available tests to be performed.
   2. The quality control screen results for a selected level. This can be accessed by double clicking on the desired test and enables the operator to run a single quality control level of a test by clicking Start.

D. The STA Compact Max® will run patient samples with QC out/not done if the last QC run was performed with the last 24 hours and the QC products are unavailable (either not on board, or on board but out of stability/sufficient volume).
   1. The analyzer proceeds with the analyses for the related methodology and all patient results for the related methodology are given the alarm: "Quality control: out of range or not done".
   2. With a period exceeding 24 hours, the sample pipetting for the related methodology is blocked.

E. As soon as quality control results are completed, they are compared to the range of acceptable results. If the quality control results fall outside of that range an error message is generated stating that QC is out and a dark blue triangle ◥ will be displayed instead of green ◥
   1. To view the QC results, Click the Levy-Jennings icon or click the Quality Controls menu on the Test Panel screen. Double click the desired test. Results can be viewed on a Levy-Jennings graph of in table form.
      a. Results can also be viewed in CoagExpert.
         1. Click the CoagExpert icon at the
         2. Under Quality Control, Click Current Values
   2. When viewing the QC Levy-Jennings graph, if a QC result is out of limits, the analyzer software will prompt the user to do one of three things:
      a. Accept the Controls:
         - This will plot the point, but any results will be flagged with the Alarm Code: "Quality control: out of range or not done"
      b. Rerun:
         - This action will repeat the controls
      c. Postpone:
         - This allows the tech to Troubleshoot and then run the QC again
   3. Do not run patients samples or turn out patient results until the QC is within Acceptable limits.
   4. If a patient sample is run with either QC out of range or not done, the result with be flagged with an alarm, "Quality control: out of range or not done".

a. Do not report patient samples until the QC is in range.

5. Blocking Methodology
   a. If a methodology cannot be run due to out of range QC or during troubleshooting for that test, the test can be blocked from running on the analyzer, while still allowing other tests to run on loaded samples
   b. Under Patient Analysis, select Block/resume methodologies
   c. Select the methodology to be blocked and click Block
   d. When testing can resume, select the methodology and click Resume.

F. Running a quality control manually:

1. Click  or click the Quality Controls menu on the Test Panel screen
2. Select the checkboxes for all methodologies for which a quality control is to be run and click  to run all levels for the selected test(s)
3. A yellow triangle is displayed on the right of the methodology abbreviation for the requested controls (controls in progress)
4. Exit the Quality Controls screen to run the selected test(s).

G. Running a one level of quality control manually:

1. Go to Quality Controls menu on the Test Panel screen
2. Double click the desired test
3. You will be on the Levy-Jennings graph for Level 1, click Next Level tab to get to Level 2
4. Click Start at the bottom of the screen for the level you want to run.

H. Changing the threshold values (range) for a quality control, when a new lot of reagent QC is received:

1. Click 
2. Double click the abbreviation for the desired test
3. Select Modify thresholds
4. Enter the new thresholds
5. Click confirm

I. Printing quality control graphics

1. Click 
2. Double click test abbreviation
3. Graphics screen displays
4. Select level
5. Click 

J. Displaying and printing the quality control table

1. Click 
2. Double click test abbreviation

3. Graphics screen displays
4. Select level
5. Click  to display table
6. Click 

K. Transmitting a quality control result:

1. Click 
2. Select test for which a quality control is to be transmitted
3. Double click on the test line
4. Select 

VI. PROCEDURE

A. MAINTENANCE

The following is a summary of Diagnostica Stago Maintenance procedures. For detailed maintenance procedures/instructions, please refer to the Sta Compact Max training manual section 9: maintenance or on-line manual. Document maintenance on the Sta Compact Max CP Maintenance Chart.

1. Daily:
    a. Cleaning the piercing needle (10 min), for Cap-piercing needle (preventive maintenance)
        i. Systems -> User Maintenance -> Rinsing ->Clean Piercing Needle
        ii. Follow onscreen instructions to wash needle with Desorb
        iii. A 5mL clear plastic tube with 5 mL of Desorb
            1. When opened, mark the Desorb with opened and expiration time and date
            2. Store Desorb in the refrigerator to be used in following cleanings
        iv. If more time is needed to clean the needle, the time can be changed. However, never clean the needle for less than 10 minutes.
        v. When prompted to wipe the cap piercing needle dry, take a Kimwipe and wipe from top to bottom only.
    b. Check temperature for Needle Number 3, Measure block, and Product drawer
        i. Systems -> System Status
    c. Record Syringe % use (Pipettor %)
        i. Systems -> System Status
2. Weekly
    a. Clean the washing wells and purge the needles
        i. Click Systems
        ii. Choose User Maintenance
        iii. Select Maintenance

iv. Select Needle Purge
v. Open drawer and fill wells with 0.37% Bleach
    1. Soak wells with bleach for 10min
    2. Other maintenance can be done at this time (steps c-e below)
    3. Close drawer and let the needles soak for the remaining time
vi. Purge each needle by selected one needle at a time and clicking "Purge"

b. Clean sample and product drawer with warm water and a kimwipe
c. Clean the suction tip
    i. With warm water and a kimwipe clean the suction top
    ii. Check for cracks in the rubber
    iii. The rubber tip can be removed for closer inspection
d. Clean the incubation and measurement cells with 30% Ethyl Alcohol and cotton-tip swap
    i. Add 15mL Ethyl Alchol to 35 mL DI water
    ii. Do not use the same cotton-top swab for more than 4 wells.
e. Shut down the analyzer
f. Clean the touchscreen with an alcohol pad
g. Cleaning the air filters
    i. Only clean the filters when then instrument is off
    ii. Remove the air filter from the back of the instrument and from light inside the right panel
    iii. Rinse off the dirty filters with water and allow to dry completely or vacuum
    iv. When replacing the back air filter, ensure the word "Outside" is facing out
h. Check the Peltier reservoir and fill with glycol when needed
    i. The Peltier reservoir is located in the right side panel
    ii. Ensure it is filled at least to the black line (40 mL)
i. Decontamination of stir bars
    i. Immerse the stir bars in a STA-Desorb U bottle (can be a used vial) and let them soak for at least 5 minutes with constant mixing.
    ii. Transfer stir bars to a vial of DI water and let then soak for another 5 minutes with constant mixing. Repeat with another vial of DI water.
    iii. Dry stir bars completely then place back into the storage bag.
j. Review of Quality Control Graphs by the Lead

- Weekly maintenance should be performed on the analyzer that is currently running for the week prior to being shut down

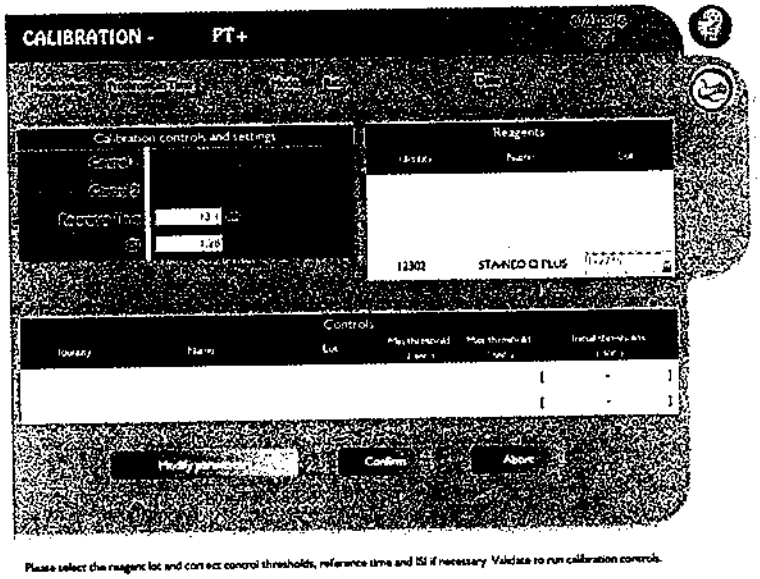
4. When Syringe reaches 25%
    a. Replacement of the syringe Teflon tip and O-ring
5. Every 100,000 piercings
    a. Replace the piercing needle.
6. Routine
    a. Replace the air filters

7. Every 6-months or with a change in lot: Instrument to Instrument Comparison
   a. Run two samples on both analyzers, ordering PT, PTT and D-Dimer under manual mode.
      i. For a lot change, only run that test.
   b. Record the results and calculate the percent difference for Protime and PTT. Calculate the difference in value for D-Dimer
   c. Guidelines: Protime ≤5% PTT ≤ 8% D-Dimer +/- 0.21 ug/mL
   d. If the value does not meet posted guidelines, repeat the run.
   e. If the repeat is outside parameters, call the hotline to request service and technical guidance.

B. Switching Analyzers
   1. One Analyzer will be run each week, while the second analyzer will remain off
   2. First, start-up the instrument that has been off
   3. Products that are Onboard the running instrument and has at least 24 hours of stability left will be transferred to the instrument that has been off the previous week.
      a. Prior to performing the weekly maintenance on the instrument that has been running, go to Product Status and print the list of products Onboard
         i. Open Product Status
         ii. Press the "prt sc" key on the key board (Print Screen)
         iii. Select the area to be printed
         iv. From the pop-up menu, select "Send to Printer"
         v. Click OK
         vi. Screen shot will print to the analyzer printer
      b. For each reagent calculate the remaining stability in whole hours rounding down
         i. If the reagent will expire in 47.5 hours, round down to 47 hours.
      c. Remove the Onboard Products and transfer them to the newly turned on analyzer, changing the volume and the stability time for each product.
   4. Perform Daily Maintenance on the analyzer that has been off for the previous week.
   5. Perform Weekly Maintenance on the Analyzer that has been running for the previous week then shut down.
   6. Each instrument must be restarted at least once a week. If an analyzer must be used for more than 7 consecutive days, then the analyzer must be restarted and weekly maintenance performed

C. For Prothrombin Time (PT) when a new reagent lot is received:
   Entering or Modifying the ISI ratio and/ or the Geometric mean (reference time).
   1. Click 

2. Double Click the PT test abbreviation
3. Click Modify Parameters
4. If the user has the correct access level, they will be able to modify the parameters. If they do not have the correct access level, an error message will appear telling them they do not have the access rights to perform the task
5. Click arrow for drop down list of reagent lot



6. Click the correct lot number
7. If necessary, enter the ISI ratio value
8. If necessary, enter the value of the laboratory's Geomean (reference time) in seconds
9. Click confirm

Note: If the Geomean (reference time) is modified, it is used as the reference for the INR calculation.

The ISI value of the thromboplastin used to determine the prothrombin time must be the one indicated on the insert for the STA product. The ISI must be confirmed for each lot change, software update or intervention.

D. Load patient samples:

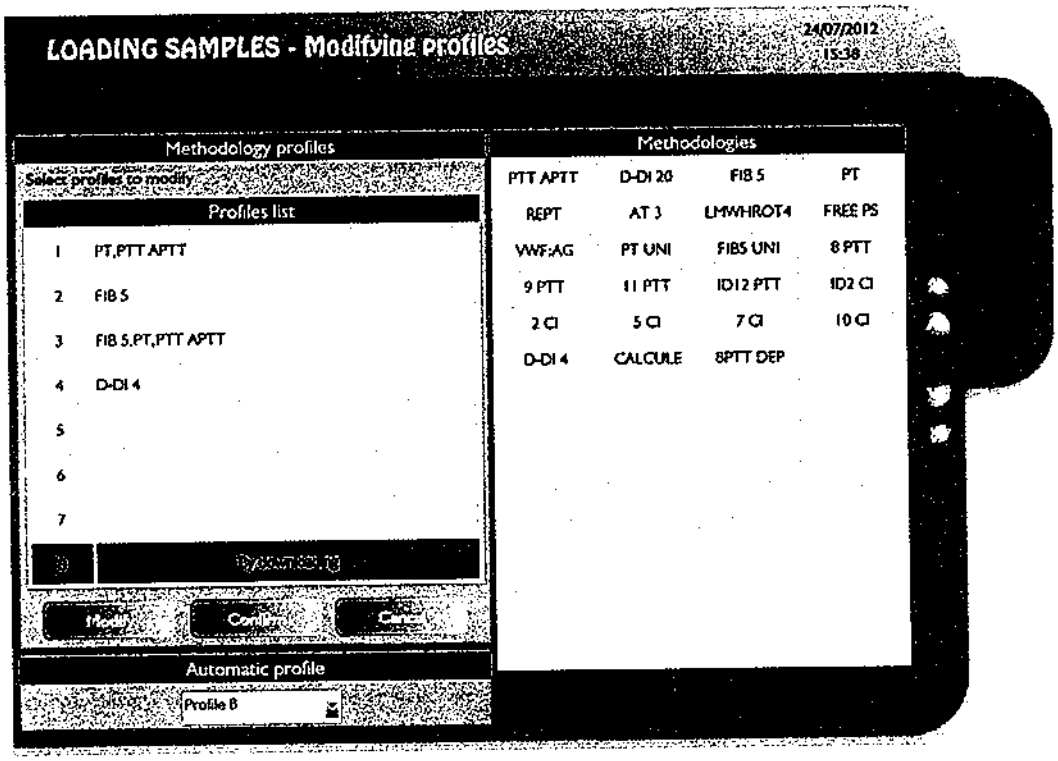
1. Click  to open the sample drawer
2. The Loading Samples screen is displayed
3. Depending on the required mode, click MANUAL MODE or AUTOMATIC MODE

a. When connected to the LIS, AUTOMATIC MODE will be selected to download the testing orders for each sample
b. MANUAL MODE will be used for downtime, competency testing and validating new reagent lots

4. Scan the tube barcode label with the barcode reader or type the sample identification and confirm with the enter key.
5. If necessary, select or unselect Micro Volume or Urgent to specify the sample type
6. Place the sample tube in the drawer within 11 seconds or the sample will have to be rescanned/retyped for loading.
7. The LED adjacent to the tube position lights up.

E. Manual Mode: Downtime, competency testing and validating new reagent lots

1. If MANUAL MODE is activated, once the sample tube is placed in the drawer, proceed to the selection of methodologies
2. Select all the methodologies to apply to the sample or select one of the 7 user defined methodology profiles. A Patient file may include up to 10 methodologies



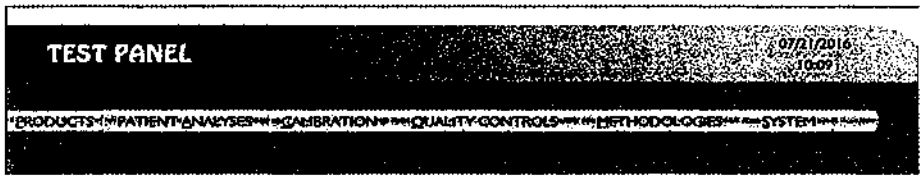
3. For individual selection:
   a. Double-click each methodology then click Confirm.
4. For selection by methodology profile:

a. From the Select methodologies window, select a methodology profile then click Confirm.
b. The sample appears in the Samples table

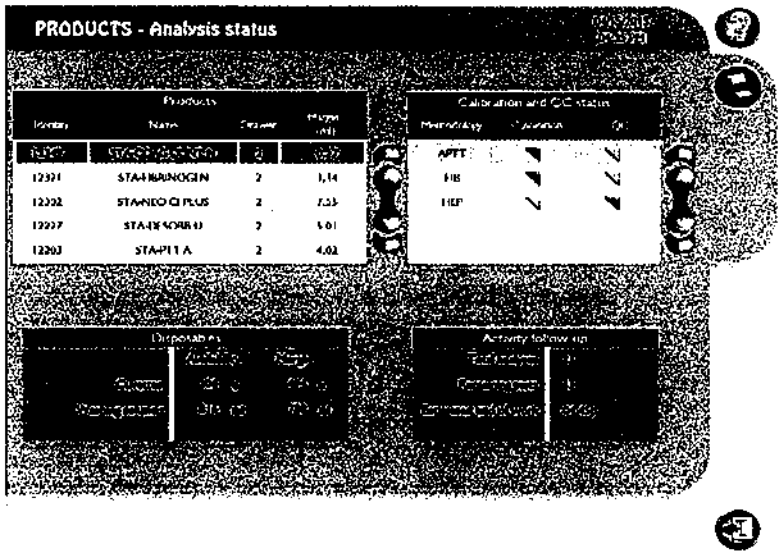
F. Automatic Mode:
1. Click Change profiles
2. From the drop-down menu of the Automatic profile area, select the requested profile.
3. The profile "by downloading" allows the operator to request the list of methodologies from the Host computer.
   a. Most often used when analyzer is connected to a LIS
   b. From the drop-down menu of the Automatic profile area, select profile 8, "by downloading."
4. The selected profile is automatically applied to all the samples loaded in Automatic mode.

G. For **STAT** specimens. If instrument is running, click block pipetting and request to open the sample drawer. You will see an open drawer request logged message. Once the instrument is finished what it is doing, the drawer will open. At this time you will enter the specimen as a STAT by selecting Urgent and close drawer to continue.

H. Analysis Status Screen
1. Analysis status window displays a consistency check between the workload of the STA Compact Max® (number of analyses to perform except for blocked analyses) and the requirements for the completion of a sample run.
   a. From Test Panel screen select the Products on the System Menu to access the Analysis Status screen



   b. Select Analysis Status from the drop down box



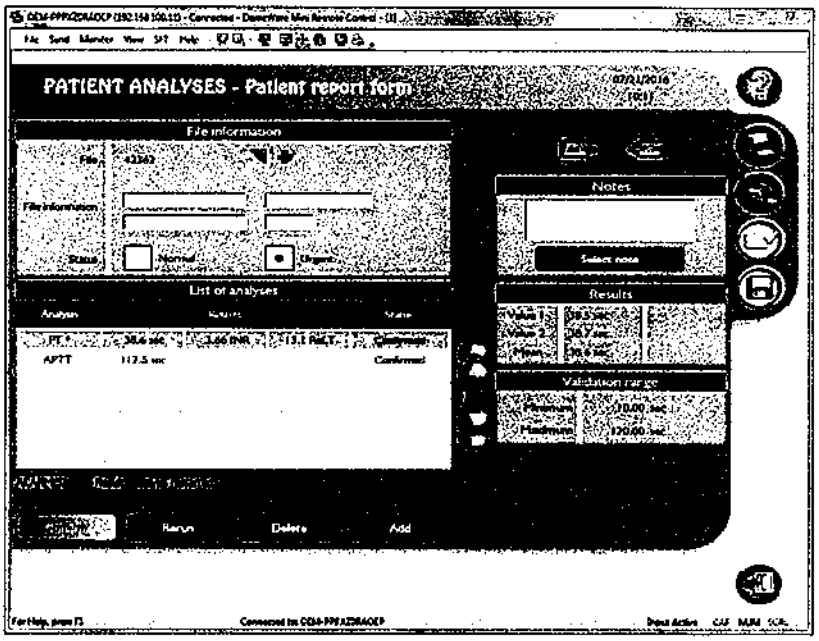
c. If after the consistency check, one of the requirements to complete the workload is not met, then all the sample pipetting (sample plasma, controls and calibrators) is blocked and the Pipetting Blocked symbol is displayed at the foot of the screen:
d. In that case, the operator can reactivate the sample pipetting for the analyses meeting all the conditions (correct calibration, quality control, volume and stability for all requested products) by clicking Yes when the following message is displayed:
   i. Analyses executions have been stopped.
   ii. Do you want to reactivate them?

NOTE: this screen is updated every 5 minutes. [Product margins] screen displays the quantity of products available

I. Operator intervention of sample(s)

1. Rerun, delete, or add a test for a patient file in the Test Panel

a. Double click the desired patient to display the Patient Files screen.
b. Use the buttons at the bottom of the screen to select the desired action
c. Save your selection using the



2. **Change status to STAT**
   - Select Urgent box in File information section of the Patient Report Form

VII. REPORTING RESULTS

A. Report results using interface/manual result entry in the LIS system.
B. See notes specified in each test procedure (PT, PTT and D-Dimer)

C. Retransmitting Results to LIS
   1. From the Patient File screen, double click the patient file to open the patient report
   2. Click the Retransmit icon
   3. Multiple files can be selected and transmitted at one time
      a. Select the files from the Patient Files screen
      b. Click the Retransmit icon, the Send Selected Files window appears
      c. Select "Include files already sent" to send all files
      d. Click Run; the sent files appear in the File processed field. Click Quit to exit.

VIII. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

See notes specified in each test procedure.

IX. REFERENCES

A. STA Compact Max® Reference Manual June 2016.
B. STA Compact Max® Reference Manual Addendum July 2017.
C. STA Compact Max® User Guide November 2015.
D. STA Compact Max® Software version 109.06.01.00

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

POLICY CREATION :

Author: Kelly Hall, Mt (ASCP) ***08/06/2018***

Medical Director: Kathryn O. Kramer, M.D. ***08/06/2018***

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
8-6-18	Kathryn O Kramer MD	
SECTION MEDICAL DIRECTOR		

Lead	Date	Coordinator	Date	Medical Director	Date

Reviewed By:

REVISION HISTORY			
Rev	Description of Change	Author	Effective Date