Methodist Health Services Corporation
& UnityPoint Health Methodist
Department of Pathology
Peoria, IL 61636

Effective: February 6, 2017
Revised: April 11, 2017

Stago STA CompactMax Start-up Operating Procedure

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. SPECIMEN TYPE:

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. A syringe or evacuated tubes (blue top) may be used with caution for collection. If multiple specimens are collected, the coagulation sample should be the second or third tube collected. 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 or used for other laboratory tests. The citrate concentration must be adjusted in patients who have hematocrit values above 55%. Specimens that are clotted, collected in the wrong tube, have visible hemolysis or have less that a 90% fill should be rejected.

IV. HANDLING CONDITIONS:

The whole blood specimen is checked for clot formation by gently inversion and observation. Centrifuge the capped blood specimen as soon as possible after collection for 5, Min at 4000RPM or at a speed and time required to produce platelet-poor plasma (platelet count $<10x10^9$/L). The plasma may remain on the packed cells if testing

immediately or separated if freezing. To separate plasma, use a plastic transfer pipette; remove the plasma to a polypropylene/ plastic tube until ready to test. If testing is not complete within 24 hours, the plasma must be removed to a polypropylene/ plastic tube and frozen. A frost-free freezer should not be used. Frozen plasma samples must be rapidly thawed at 37°C while gently mixing and tested immediately after thawing. If testing is delayed, the sample may be held for 24 hours at room temperature. Specimens should be stored on board the analyzer or at room temperature after testing. Once removed from the analyzer, caps must be removed if additional testing is ordered.

V. 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 VWF&VIII Analysis	4 hr.	Unacceptable	Unacceptable	4 hr.	4 hr.	2 wk	6 mo
FIBRINOGEN	4 hr.	Unacceptable	Unacceptable	4 hr.	4 hr.	2 wk	6 mo
OTHER	4 hr.		Unacceptable	4 hr.	4 hr.	Depends on the analyte.	

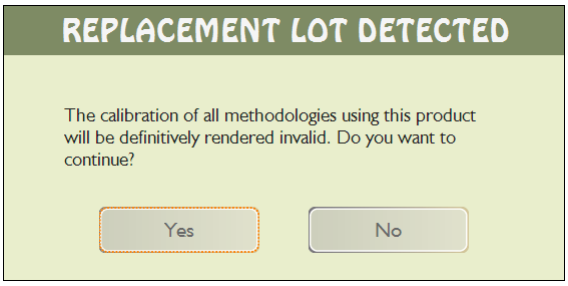
IV. REAGENT

Reagent	**Reconstitution**	**Reconstitution Time**	**Stir Bar**	**Stability Onboard**	**Stability** (2-8 °C)	**Reducer**
(PT) Neoplastine CI Plus, 5ml	**Diluent (Provided)**	30 minutes @ RT	**yes**	48 hours	8 days	**Yes**
(APTT)PTT-Automate 5	**5ml Water**	30 minutes @ RT, then **Vortex**	no	24 hours	7 days	no
(Fibrinogen) Fibrinogen 5	**5ml Water**	30 minutes @ RT	no	120 hours (5 days)	14 days	no
(D-Dimer) Liatest D-DI	Ready to Use	15 minutes @ RT	no	360 hours (15 days)	n/a	**Yes**
Liquid Anti-Xa 4ml	Ready to Use	30 minutes @ RT	no	168 hours (7 days)	3 months	**Yes**
(APTT) CaCL2 0.025M	Ready to Use	30 minutes @ RT	no	72 hours (3 days)	n/a	no
(Fibrinogen) 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	1ml Water	30 minutes @ RT	no	8 hours	n/a	no
Liatest Control N+P	1ml Water	30 minutes @ RT	no	8 hours	n/a	No

A. Prepare reagents: Follow instructions specified in each test procedure or on the chart above.

B. Product Loading:

1. Click  or click Products, then Loading products
2. Scan the vial barcode label with the barcode reader.
3. If necessary, edit the volume and stability.
4. If the product has been transferred into a microcup, check the Microvolume box.
5. Place the vial in a position corresponding to its diameter in the area of the drawer specified in each test procedure.
6. If the product requires stirring, place the vial in a stirring position.
7. The LED adjacent to the vial position lights up and a beep sounds.
8. The product appears in the Products on board table.
9. If a new lot number is detected, the following message is displayed:



10. To proceed with barcode reading, click Yes, scan the sheet in front of the barcode reader then click Validate.
11. Click  to close the product drawer.

The laboratory must 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**; Ccheck product status→After morning run, perform daily maintenance (do not run QC again)→ **9:000AM** Make up new QC and any reagents needed→**9:30 AM** Run QC→3:30 PM Run QC and check reagent status→**9:00 PM** make up QC and make any reagents needed→**9:30 PM run QC →3:30 AM run QC**

B. Quality control for a methodology 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 the period defined in the METHODOLOGIES screens. That period cannot exceed 24 hours

C. Quality controls can also be run on operator's request from these 2 screens:
1. Screen Quality control - Methodologies list
2. Screen of quality control results for a selected level.

D. Quality controls are run in single or in duplicate depending on the determination chosen for the sample.

E. If upon running quality controls (automatically or on request), the quality control is not in the product drawer (absent or present but with incorrect volume or stability) and if the last quality control was run less than 24 hours ago, then the STA Compact Max® does not run the control. The analyzer proceeds with the analyses for the related methodology and all patient results for the related methodology are given with the alarm: "Quality control: out of range or not done". In the same case, with a period exceeding 24 hours, the sample pipetting for the related methodology is blocked.

F. As soon as quality control results are completed, they are compared to the range of acceptable results, if they are outside the defined range, the analyzer automatically reruns the controls in duplicate.

G. Running a quality control manually:
1. Click  or click Quality control in the System Menu
2. Select the checkboxes for all methodologies for which a quality control is to be run and click 
3. Type the access code (cq) and click confirm
4. A yellow triangle  is displayed on the right of the methodology abbreviation for the requested controls (controls in progress)
5. From the Analysis status window, check the products onboard
6. To run a quality control level by level, double click on the test line then select the level to be run
7. Click Start

H. Changing the threshold values (range) for a quality control:
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 recommendations for a laboratory that performs more than 200 tests a day. It should be adapted to suit the test volume of the laboratory.

1. **Daily**
   Cleaning the piercing needle (10 min), if equipped with a Cap-piercing needle*
2. **Daily or weekly**
   a. Clean the touchscreen
   b. Dry the product drawer
3. **Weekly**
   a. Clean the washing wells and purge the needles*

b. Clean the suction tip
c. Save Methodologies and System parameters
d. Shut down and restart the analyzer
e. Cleaning the air filters - vacuum
f. Replace the air filters
g. Clean the incubation and measurement cells
h. Check the Peltier reservoir
i. Clean sample and product drawer

Weekly maintenance should be performed on the analyzer that is currently running for the week.

4. **Monthly**
   a. Replacement of the syringe Teflon tip and O-ring*
5. **Every 100,000 piercings***
   a. Replace the piercing needle, if equipped with a Cap-piercing needle

For detailed maintenance procedures/instructions, please refer to the Sta Compact Max training manual section 11: maintenance or on-line manual.

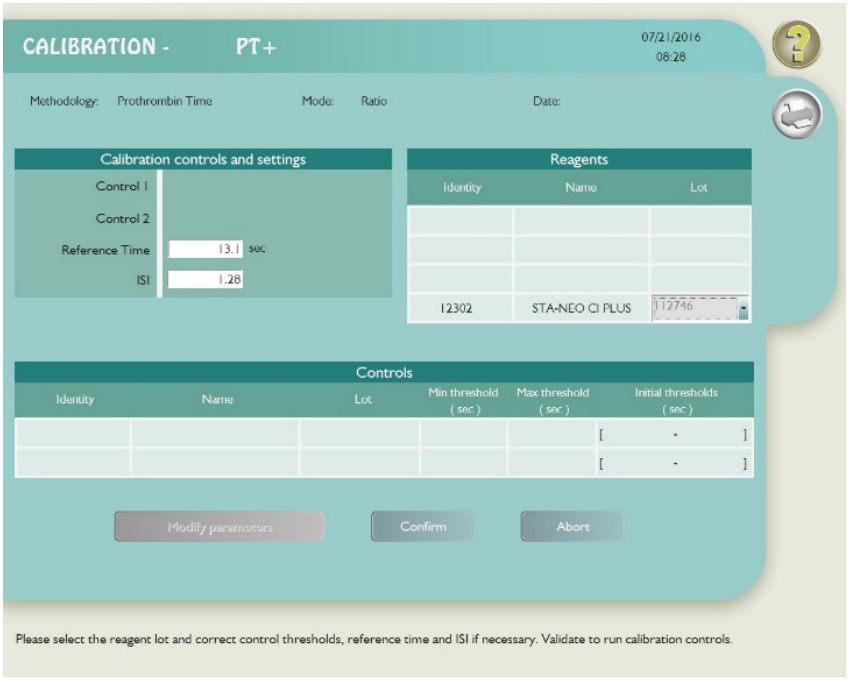
B. CALIBRATION

1. Start Calibration from Test Panel screen:
   a. Click  to access the Calibration menu
   b. Check the box next to the methodology to be calibrated
   c. Click 
   d. Type the access code and then click Confirm
   e. Select the lot to be calibrated in the Lot selection window.
   f. Lot displayed in green: the vial is present and may be used.
   g. Lot displayed in red: the vial is present but cannot be used (insufficient volume and/or stability exceeded).
   h. Lot displayed in gray: the vial is not present.
   i. Lot unknown: the vial is missing or the vial is on board but the calibration parameters have not been read.
   j. Out-of-date lots are not displayed in the list.
   k. The calibration controls are automatically run by the analyzer provided the consistency check does not lead to a blocking of the sample pipetting.
      (i.) Click 

For Prothrombin Time (PT):

Entering or Modifying the ISI ratio and/ or the reference time (geometric mean)

a. Click 
b. Double Click the PT test abbreviation
c. Click Modify Parameters
d. Enter Access code (cq), click confirm
e. Click arrow for drop down list of reagent lot



f. Click the correct lot number
g. If necessary, enter the ISI ratio value
h. If necessary, enter the value of the laboratory's reference time in seconds
i. Click confirm

Note: If the 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.

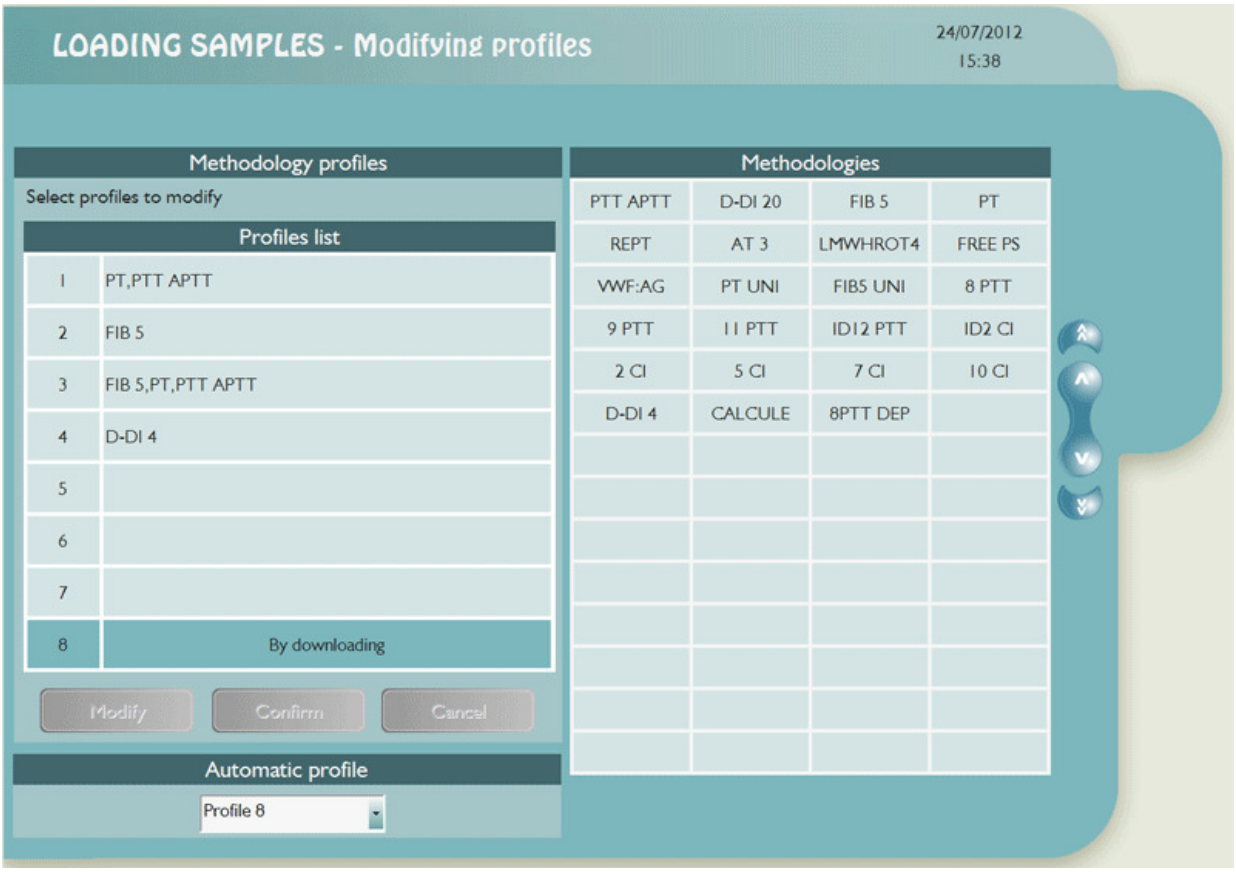
C. Load patient samples:

a. Click  to open the sample drawer
b. The Loading Samples screen is displayed

c. Depending on the required mode, click MANUAL MODE or AUTOMATIC MODE
d. Scan the tube barcode label with the barcode reader or type the sample identification and confirm with the enter key, the tube identity is displayed
e. If necessary, select or unselect Micro Volume and Urgent to specify the sample type
f. Place the sample tube in the drawer
g. The LED adjacent to the tube position lights up

D. Using Manual Mode

a. If MANUAL MODE is activated, proceed to the selection of methodologies
b. Select all the methodologies to apply to the sample or select one of the 7 defined methodology profiles. A Patient file may include up to 12 methodologies



For individual selection:

- Double-click each methodology then click Confirm.

For selection by methodology profile:

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

E. Using Automatic Mode

a. Click Change profiles
b. From the drop-down menu of the Automatic profile area, select the requested profile.
c. The selected profile is automatically applied to all the samples loaded in Automatic mode.
d. In Automatic mode, only one methodology profile is used: the Automatic profile.

Selecting a profile by Downloading The profile "by downloading" allows the operator to request the list of methodologies from the Host computer.

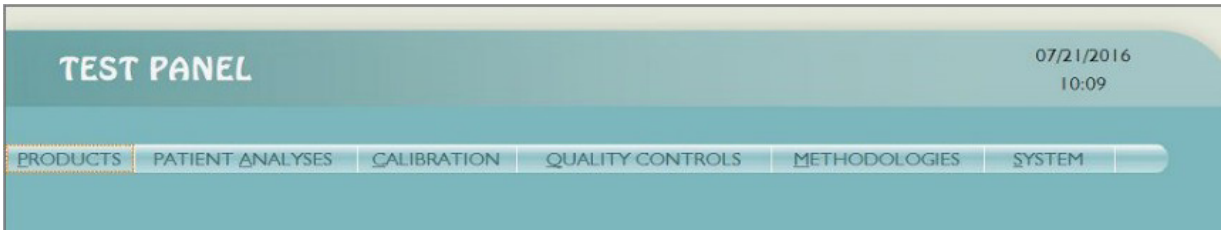
e. Click Change profiles
f. From the drop-down menu of the Automatic profile area, select profile 8, "by downloading."
g. Click 
h. Save modifications

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 and close drawer to continue.

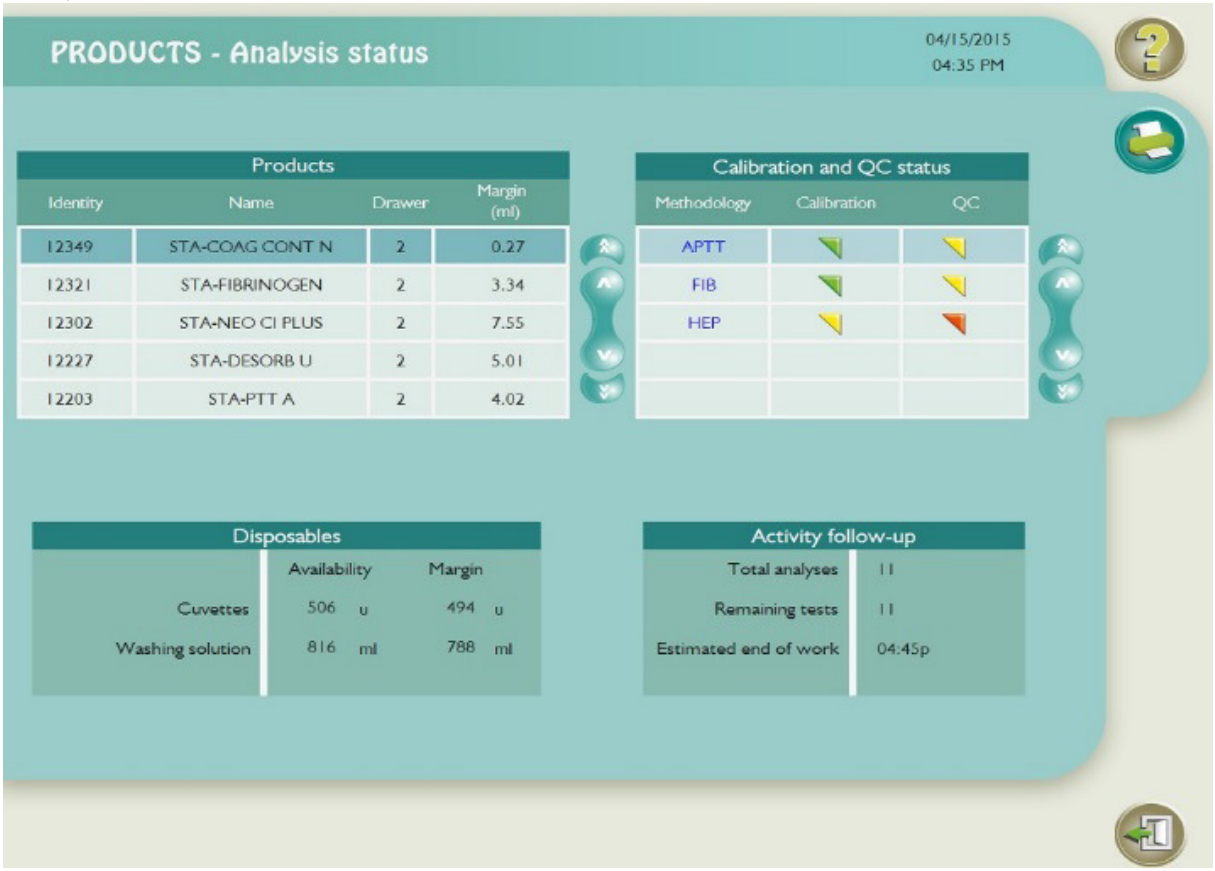
F. Analysis Status Screen

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



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) are 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:
e. Analyses executions have been stopped.
f. Do you want to reactivate them?

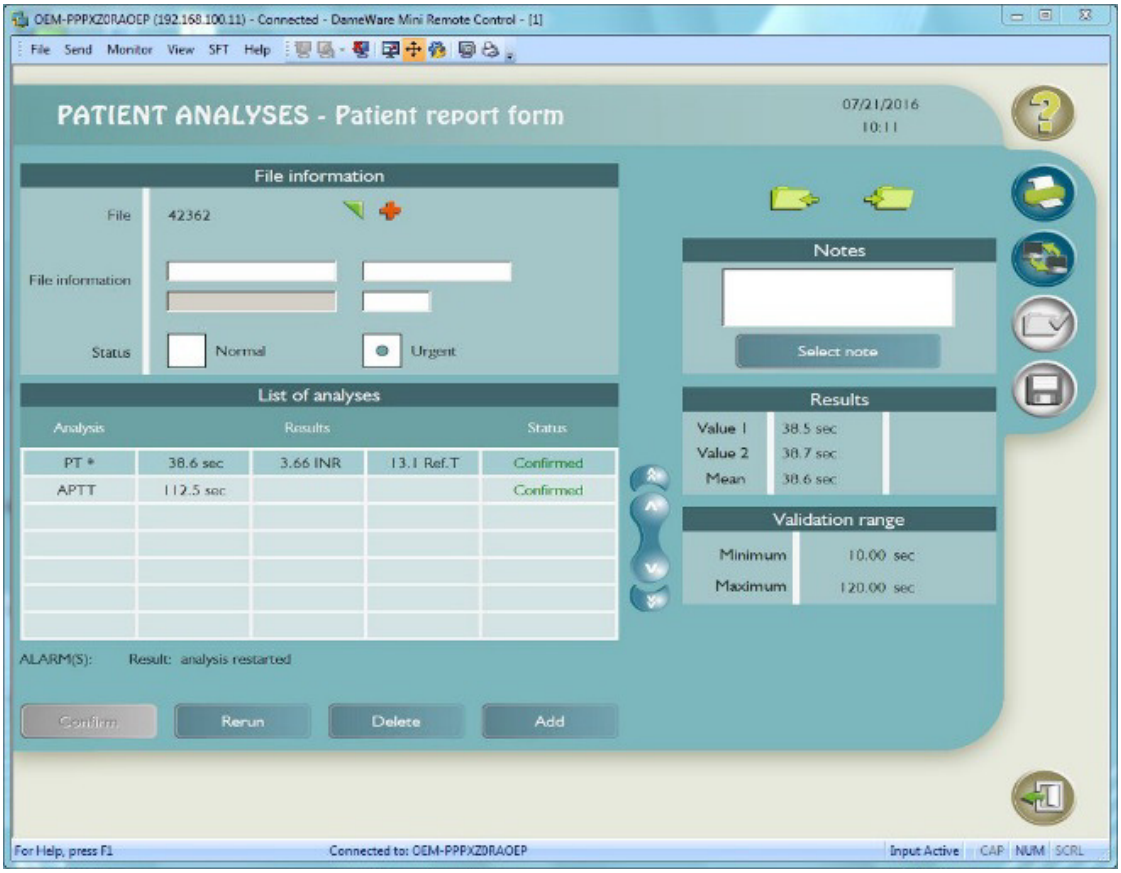
NOTE: this screen is updated every 5 minutes. [Product margins] screen displays the quantity of products available

G. Operator intervention of sample(s)

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

a. Select the desired patient to display the Patient Click menu Patient Analyses-Patient Report Form
b. Use the buttons at the bottom of the screen to select the desired action

c. Save your selection using the 



Change status to STAT

a. Select Urgent box in File information section of the Patient Report Form

VII. REPORTING RESULTS

Report results using interface/manual result entry in the LIS system.

>Mmax result:

a. For **chronometric analyses**, raw measurement greater than the maximum time defined in the methodology screens
b. For **graphic order 2 and order 3 polynomial calibration modes**, raw measurement (sec., DO.D. or O.D./min.) greater than raw measurement obtained for the highest calibration point
c. For **immunological analyses** in kinetic 2 points with graphic order 2 or order 3 polynomial calibration modes, after redilution with parameter Redilute 1, raw measurement still out of range.

This message can and must be interpreted only after analysis of the colorimetric graph and of the raw measurement for the first point as defined in the methodology.
<Mmin result:

d. For **chronometric analyses**, raw measurement inferior to the maximum time defined in the methodology screens
e. For **graphic order 2 and order 3 polynomial calibration modes**, raw measurement (sec., DO.D. or O.D./min.) inferior to raw measurement obtained for the lowest calibration point.

This message can and must be interpreted only after analysis of the colorimetric graph and of the raw measurement for the first point as defined in the methodology.

Caution:

• Check the original tube for a clot when the PT's Mmin is <10 seconds, the APPT's Mmin is <20 seconds. If clotted specimen must be rejected and reordered according to lab policy.

• When the Mmin and Mmax flag occur a blue flag will appear on the results and they will not transmit to the LIS. Check the specimen for clots, gross hemolysis,properly spun and previous results of patient to determine the acceptability of the specimen prior to reporting. If acceptable, select the test, confirm the results, flag will turn green. You must also validate the result in Coag Expert. To validate the result in coag expert;

coag expert→workstation→dashboard→uncheck everything except "to be validated"→double click on the patient→click the validation mode button in the upper right corner→click in the box to the left of the result that needs to be validated→save.

After confirming/validating the results, they will then cross to the LIS system for resulting.

•Automatic rerun

The system performs automatic reruns when:

f. the incubation time of an analysis is exceeded
g. the result of an analysis or control is outside the defined thresholds

•Follow instructions specified in each test procedure.

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® User Guide November 2015.
C. STA Compact Max® Software version 106.08.01.00

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

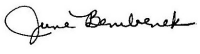
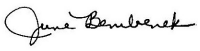
MMCI Laboratory is a CAP accredited facility, as of 7/1/11 the responsibility of new and/or substantially revised policies and procedures will be restricted the Laboratory Director whose name appears on the CLIA certificate, whose signature appears below. The biennial review will be completed by the Administrative Director.

POLICY CREATION :		
Author:	***Kim Paige, CLT***	***December 6, 2016***
Medical Director:	Elizabeth A. Bauer Marsh, M.D.	***January 29, 2017***

MEDICAL DIRECTOR		
DATE	NAME	SIGNATURE
January 29, 2017	Elizabeth A. Bauer-Marsh	Elizabeth A. Bauer Marsh MD
SECTION MEDICAL DIRECTOR		
January 20, 2017	Julia Adams, MD	Julia Adams, M.D.

REVISION HISTORY			
Rev	**Description of Change**	**Author**	**Effective Date**
0	Initial Release	Kim Paige	1/24/17
1	Changed QC protocol and added Coag Expert validation procedure to the Caution area under reporting results.	Kim Paige	3/2/17

Reviewed by

Lead	Date	Coordinator	Date	Asst. Manager	Date	Medical Director	Date
Kim Paige	1/17/17		1/29/17		1/17/17		1/20/17
Kim Paige	3/2/17		3/3/17				4/11/17