TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	5/13/2019
Department:	Core Lab	**Due Date:**	5/31/2019
		Implementation:	**5/21/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

STA Compact Operating Instructions SGAH.G07 v7

Description of change(s):

The QC time out error rule (in appendix C, last page of SOP) is being changed.

- **The DI Error Display will be *Check QC before releasing patient result*** (currently is "Check Coag/Liatest QC. Rerun Test")
- Patent results with this error will **NOT** be suppressed in at DI SQ connection level – no longer necessary to re-run sample if QC is acceptable
- Instructions for what to do based on QC result (acceptable vs unacceptable) are updated

This revised SOP will be implemented on May 21, 2019

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**STA Compact Operating Instructions**	
Prepared by	Julie Negado	Date: 6/19/2012
Owner	Robert SanLuis	Date: 6/19/2012

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

This procedure outlines how to effectively operate the STA Compact.

2. SCOPE

This procedure applies to all technologists working with the STA Compact instruments.

3. RESPONSIBILITY

The supervisor or designee will ensure that the technologists are properly trained in the use of this instrument.
The technologists will be responsible for operating and maintaining this instrument according to this procedure.

4. DEFINITIONS

None

5. PROCEDURE

5.1 Loading Reagents

Step	Action
1.	Any time a new reagent is loaded (except for Desorb), QC must be run. On the Coag Reagent QC Handoff Log document the date, time and the reagent placed, and indicate if QC was performed and acceptable. Record your tech code. The incoming tech for the next shift must review the log and document with their tech code. **Note**: if QC is unacceptable, corrective action must be performed and documented in accordance with the QC Program. Refer to procedure Quality Control Program (QA40).

Step	Action
2.	Lyophilized reagent must be prepared with Reagent Grade Water only. **Note**: Neoplastine must be reconstituted only with the reagent provided in a vial. Deionized water should NEVER be used.
3.	All lyophilized reagents must be allowed to sit for 30 minutes before being placed into use. Gently swirl to assure complete homogeneity.
4.	Place a stirrer into the Neoplastine Cl PLUS Reagent.
5.	Remove the rubber stopper from all containers and replace the white cap with the hole onto the reagent bottles. All reagent bottles without the white cap with the center hole must be used without any cover.
6.	There are two ways to open the Product drawer: a. From the main menu move the cursor to the loading menu and press *enter*. Then move the cursor to the products line and press *enter*. b. From the main screen "Test Panel" just press F2.
7.	Product drawer will open by moving forward.
8.	Scan the barcode on the reagent bottle to record the information of the reagent and press *enter*.
9.	The cursor stops under volume for adjusting the correct volume. If the volume stated is the same quantity as on the bottle, press *enter*.
10.	When the cursor moves to the POS area, place the reagent into the well. • Reagent bottles must be placed into the correct size well. • All reagents with stirrers must be placed into the wells with the circles around them; these indicate stirrer mechanism is attached.
11.	When loading reagents or QC material in micro volume container, press F8 to activate the micro volume mode.
12.	When all reagents are loaded, press ESC, then enter cursor under the QUIT box to exit the reagent loading menu. The loading drawer will close. **Note**: The Owren-Koller buffer is the only reagent that is not loaded on the reagent drawer. It is loaded in sample drawer.
13.	TEST STATUS SCREEN: On this screen, the reagents loaded appear together with their volumes. Margin indicates the quantity, which should remain after all assays have been run. If the read out is displayed in red, then there is insufficient volume or expired reagent.

5.2 Loading the Samples

Step	Action
1.	Visually check all samples for clots and sufficient quantity. Centrifuge for specified time and speed documented on each centrifuge for preparing platelet-poor plasma. Remove caps from hemogard tubes.

Step	Action
2.	There are two ways to open the Sample drawer: a. From the main menu move the cursor to the loading menu and press *enter*. Then move the cursor to the Sample line and press *enter*. b. From the main screen "Test Panel" just press F1.
3.	The sample drawer will open towards the front of the instrument.
4.	**Auto Mode:** a. Scan barcode label. b. Immediately place sample into sample drawer, a beep indicates that the sample tube is entered properly. (Failure to place the sample within 10 seconds will result in the loss of the specimen ID entered; therefore rescanning the sample is necessary.) **Manual Mode:** a. Press ESC from the sample loading screen and choose Manual Mode, press enter after. b. For STAT samples, activate STAT mode by pressing F12. c. For micro samples, place sample into micro cups and then activate micro mode by pressing F8. d. Type sample ID, press enter, and then load the sample. e. Move the cursor to the appropriate Recorded Profile to select the profile needed. If single test is needed, move the cursor to selection and select test needed. f. Press F10 to file in memory.
5.	Once samples are loaded, press ESC, then enter on the Quit menu. The sample drawer will close.
6.	The instrument will immediately start processing the sample as soon as you exit on the test menu. Failure to start the process indicates a problem. Look for messages printed in red and investigate. (Usual causes are insufficient or expired reagent on board.) Rectify error.

5.3 Blocked Sample Pipetting

Step	Action
1.	Whenever the red message BLOCKED SAMPLE PIPETTING is printed at the bottom of the screen, the instrument will not run
2.	Go to SYSTEM menu, move the cursor down to STOP SAMPLE PIPETTING. YES. Press *enter* to change to NO. Only after corrective action is taken, press ESC and instrument will begin to run.

5.4 Resulting QC in Unity Real Time

The controls from the STA Compact are uploaded to Unity Real Time. They must be reviewed and resulted before patient results are released. Refer to the procedure Bio-Rad Unity Real Time 2.0 for details.

5.5 Daily Maintenance

Step	Action
1.	Go to STATUS and check the PRODUCTS screen and examine for the availability of sufficient quantities of reagents. Prepare all reagents that are needed to sit for 30 minutes. Add all other depleted reagents.
2.	From the main menu, press STATUS, then SYSTEM and examine the screen for the daily maintenance checks. The following temperatures must be maintained and checked in the STA Compact Maintenance log. 36.5 - 37.5°C Needle #3 36.5 - 37.5ºC Measuring Block 15 - 19°C Reagent Drawer Actual temperature is recorded by day shift, subsequent shifts verify temperatures are within range and initial the log to document.
3.	Perform Probe Wash - (See maintenance - Operational Manual)
4.	NERL Water Lot number – • Verify the lot number in use matches the one recorded on the log. • Update the Maintenance Log whenever the water lot changes.
5.	SGMC and WAH only: Soak sample needle for 10 minutes in Desorb U
6.	Delete Patient Files (can store up to 600 files) Go to main menu, select Files Press enter at “Delete Patient Files” Select F3 Select Previous days accession 3’s (cursor to start access # and end access #) Confirm selection with “YES” at prompt F10 Execute

5.6 Weekly Maintenance (See maintenance Operational Manual for Instructions)

Step	Action
1.	Clean 2 air filters.
2.	Clean washing wells with 10% bleach.
3.	Clean sample and product drawers and measurement plate with warm water and wipe dry.
4.	Clean measurement and incubation wells with cotton swab moistened in 20 % ethanol (only). Remove any debris.
5.	Clean suction tip with warm water. Inspect for cracks and replace if needed.
6.	Perform needle purge.
7.	Check liquid level in Peltier reservoir; fill with Glycol if necessary. Fluid must be 40 or greater, max 80

Step	Action
8.	Decontaminate stir bars – • Immerse bars in a vial of Desorb and soak several minutes. • Transfer bars to a vial of Reagent Grade Water and soak several minutes. • Rinse bars with Reagent Grade Water and dry carefully to remove all traces of moisture before adding them to reagent vials.
9.	SGMC and WAH only: Soak sample needle for 30 minutes in Desorb U

5.7 Monthly Maintenance (See maintenance Operational Manual for Instructions)

Step	Action
1.	Replace syringe tip and O-ring.

5.8 As Needed Maintenance (See maintenance Operational Manual for Instructions)

Step	Action
1.	Replace the air filters (air filter for rear panel and filter for optical module).
2.	Replace the cleaner solution filter

Note: Test configurations are saved as a backup by the service representative during scheduled maintenance.

6. RELATED DOCUMENTS

- Prothrombin Time and INR
- Activated Partial Thromboplastin Time (APTT)
- Fibrinogen
- D-Dimer
- Platelet Poor Plasma Verification
- Quality Control Program, QA procedure
- STA Compact Maintenance Log (AG.F195)
- STA Compact Reagent Reconstitution and Handling Information (AG.F266)
- Coag Reagent QC Handoff Log (AG.F315)
- Bio-Rad Unity Real Time 2.0, Chemistry procedure

7. REFERENCES

STA – Operator's Manual, Diagnostic Stago, Inc., Version V 2.1a, June 1996.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP G001.003		
000	11/18/14	Section 5.1: add requirement to run and document QC with reagent changes Section 5.7: add saving configurations Section 6: add forms Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett H Genser	R SanLuis
1	2/12/15	Section 5.1: remove requirement to perform patient look-back Section 6: add QC Program	L Barrett	R SanLuis
2	4/9/15	Section 5.4: replace LIS with Unity Real Time, remove LIS QC codes Section 6: add Bio-Rad Unity Real Time SOP	L Barrett	R SanLuis
3	5/2/16	Section 5.5: add shift checks for temperatures, NERL water check and soak sample needle Section 5.6: add detail to match log, add stir bar decontamination Section 5.8: change frequency to as needed App B: delete LIS QC set up	L Barrett	R SanLuis
4	1/26/17	Header: add other sites Section 5.7, 5.8: remove saving configuration to disk, add note	L Barrett	R SanLuis
5	3/28/19	Section 6: remove Thrombin Time SOP Section 9: add Appendix C with QC time out error	L Barrett	R SanLuis
6	5/7/19	App C: changed display and steps for QC time out error	L Barrett H Genser	R SanLuis

9. ADDENDA AND APPENDICES

A. STA Compact Description
B. Sunquest Configuration
C. DI (Data Innovations) Actions

Appendix A

STA Compact Description

The STA Compact is an automated coagulation instrument, which performs in vitro tests, which aids in the diagnosis of coagulation abnormalities as well as assists in monitoring anticoagulant therapy. It is capable of performing clotting assays as well as photometric (chromogenic and immunological) assays on plasma.

The primary sample tubes and the dilution buffers are loaded in the sample drawer. The Positive Identification System automatically detects the position of each sample tube.

The control plasma vials, the calibration plasma vials as well as the reagent vials are loaded in the product drawer where the temperature is monitored between 15º C and 19º C by a system based on Peltier elements.

Sample plasmas, control plasmas as well as calibrator plasmas are pipetted by needle No. 1 (cap piercing needle) of the pipetting head, then they are distributed in the related cuvette in incubation position.

Reagents to be added before the first incubation are pipetted by needle No.2 of the pipetting head, then they are distributed in the related cuvette in incubation position.

Reagents to be added after the first incubation (mainly the start reagents) are pipetted by needle No.3 of the pipetting head. If a pre heating to 37º C is necessary, the reagents are moved from needle No.3 up to heating tube No.3. Then, with or without preheating, those reagents are added in the related cuvette.

A level detection system on each needle ensures accurate and precise dispensing of fluid volumes. Rinsing the interior as well as the exterior of the needles, each in its own well, minimizes carry over.

Test cuvettes are loaded onto the STA Compact® from a roll of 1,000 cuvettes. At the cuvette loading station, they are placed one-by-one in a shuttle. The shuttle is then moved to the measurement station by a system based on a pneumatic jack.

At this station, the suction head picks up the cuvette and transfers it to the incubation zone. This same head then transfers the cuvette from the incubation zone to the measurement zone then from the measurement zone to the cuvette disposal container.

The principle of the clotting-time assay is based on the increase of viscosity of the plasma being tested. The increase of viscosity is measured through the motion of a stainless steel ball that is made to effect pendular swings in the bottom of the cuvette containing the test plasma.

Constant pendular swings of the ball are created by electromagnetic field that is applied alternately on opposite sides of the cuvette by two independent coils. The energy of the field can be varied depending on the test being performed. However, as soon as the plasma starts to clot, the viscosity of the plasma starts to increase, and this change in plasma movement affects the ball movement, slowing it down. As the viscosity increases, the oscillation amplitude of the ball wing decreases. An algorithm uses these variations in oscillation amplitude to determine the clotting time.

Principle of Photometric

The detection of chromogenic assays on the STA Compact® is based on the absorbance (optical density: OD) of monochromatic (405 nm or 540nm) light passing through the cuvette as chromogenic reaction takes place.

The diagram below depicts the principle of absorbance measurement. Incident light (I_0) entering the cuvette is partially absorbed by the reaction mixture as it passes through. The transmitted light ($I + I_p$) is measured, and converted to absorbance by the following equation:

$$A = - \log (I_1/I_0)$$

Note: decimal Logarithm

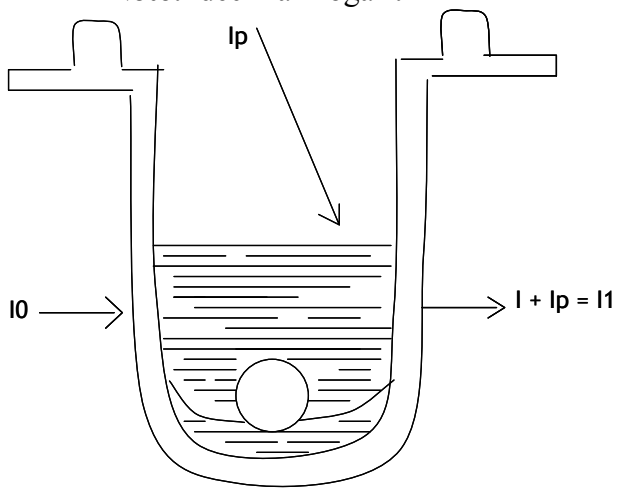


Fig. 1 - Principle of Absorbance Measurement

The effect of the stray light (I_p) is eliminated by taking two fairly close measurements of the light transmitted.

I1 = I + Ip (first measurement which includes incident light and stray light)
I2 = Ip (second measurement while blocking the incident light, corresponds to the stray light).

When I2 is subtracted from I1, the result is I, which is only the light transmitted from the incident light. Ip is assumed to remain constant between the two measurements.

Incident light is provided by a tungsten-halogen lamp, and is made monochromatic by passing through a 405nm or 540nm, interface filter. The step occurs inside the optical module. A system of fiber optics carries the monochromatic light from the optical module to the measurement heads. Another set of optical fibers carries the transmitted light from the measurement head to the photometry measurement board.

Appendix B

Sunquest Configuration

Instructions for Setting up the Instrument

1. Go to Setup ->Global options
2. Enter (Access Code)
3. Page down to page 2

Communications

- Protocol: ASTM
- Station Number: 99
- Baud Rate: 9600
- Parity: None
- Number of Data Bits: 8
- Number of Stop Bits: 1
- Number of On Error Retries: 6
- Verify Patient Data: No
- Send Sequence Number: Yes

File Acquisition

Item	Format	Name
1.	16 Characters	ID
2.	16 Characters	Nom
3.	12 Characters	PreNom
4.	6 Characters	
5.	4 Characters	info 4

ID Type: Alpha Numeric

To Transmit Data to the LIS

1. Go to Status
2. Select Online Transmission: Yes
3. Select Online Printout: Yes

To set Download

1. Go to Sample -> Loading
2. Press Enter (draw will open)
3. Esc
4. Arrow up to Auto Mode, press enter
5. Note following on screen
    a. Automode in upper right corner
    b. Under Parameters, “By Teleloading”
6. Esc
7. Quit

To associate Transmission Codes on the instrument with the upload/download codes defined in the LIS Interface

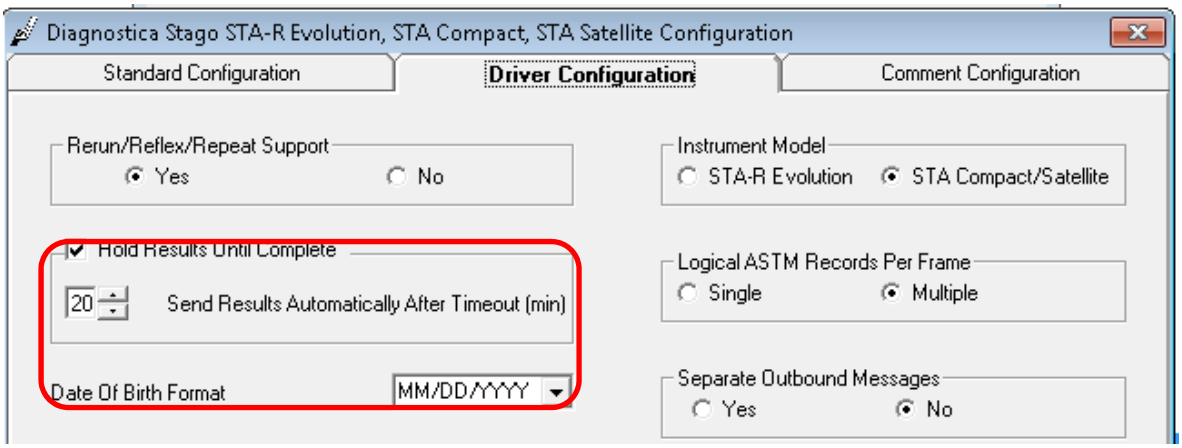
1. Go to Setup -> TESTS
2. For each test, go to page 3 of Test Setup
3. Change Transmission Test# to match your upload/download code. If the transmission code for the test is not needed, leave at the transmission code for this test to the default of 0.

Appendix C

DI (Data Innovation) Actions

A. General Information

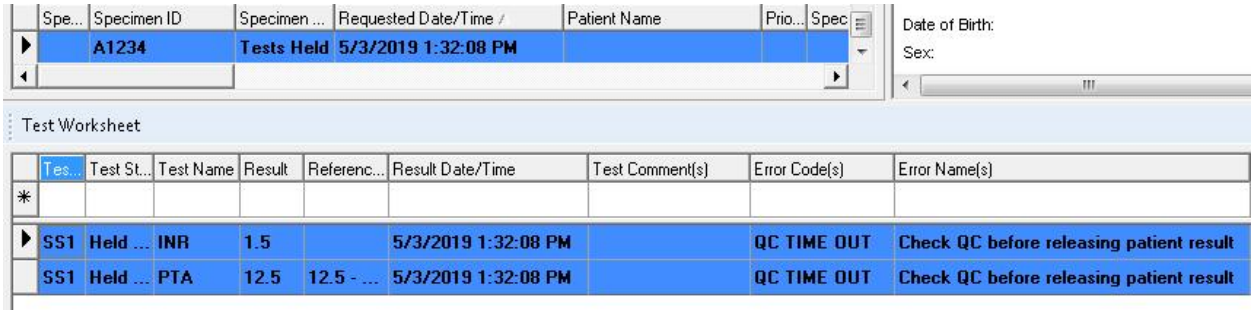
The DI Stago driver is set to collate all the coagulation tests on the same accession number until all the results have been completed within a set amount of time. For example, if the first test has been completed and the second test is still pending and the collation time has been exceeded, DI will release the first test as long as it does not have an error. This setting is at the Driver level.



B. QC Time Out Error

Review all results for QC Time Out Error

1. The Stago instrument is set to automatically run QC for each test every 4 hours.
2. DI will display a "Check QC before releasing patient result" error whenever a patient test is run and the last QC run for that test is over the 4 hour time limit. Actions:
   a. If the patient test finished first and the QC is still running, DI will hold all tests with the "Check QC before releasing patient result" error.
   b. Once the QC run is finished and if the QC results are acceptable, upload the patient test result (one with the error) from DI.
   c. If the QC is unacceptable, then reject the patient results. Troubleshoot the QC and once it is acceptable, re-run the sample. Alternatively, samples may be run on another instrument that has acceptable QC results.



Form revised 3/31/00