Adventist HealthCare

TRAINING UPDATE

Lab Location:	SGMC and WOMC	**Date Distributed:**	4/1/25
Department:	Coagulation	**Due Date:**	4/15/25
		Implementation:	**4/1/25**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
AHC.HG 1023 Stago Compact Max Operating Instructions **STA Compact Max Maintenance Log (AG.F652)**
Description of change(s):
Updated weekly maintenance to include changing the syringe tip and O ring.

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

AHC.HG 1023 Stago Compact Max Operating Instructions

Copy of version 2.0 (approved and current)

Last Approval or Periodic Review Completed	3/31/2025
Next Periodic Review Needed On or Before	3/31/2027
Effective Date	3/31/2025

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Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	3/31/2025	2.0	 Nicolas Cacciabeve	
Approval	Core lab approvals	3/31/2025	2.0	 Robert SanLuis	
Periodic review	Lab Service director	9/18/2024	1.0	 Robert SanLuis	
Approval	Lab Director	10/19/2022	1.0	Nicolas Cacciabeve	
Approval	Core lab approvals	10/19/2022	1.0	 Robert SanLuis	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.0	Approved and Current	Major revision	3/28/2025	3/31/2025	Indefinite
1.0	Retired	Initial version	10/18/2022	10/19/2022	3/31/2025

Non-Technical SOP

Title	**STA Compact Max Operating Instructions**
Prepared by	Ashkan Chini Date:
Owner	Robert SanLuis Date:

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:	

TABLE OF CONTENTS

1. PURPOSE

This procedure outlines how to effectively operate the STA Compact Max.

2. SCOPE

This procedure applies to all technologists working with the STA Compact Max 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).
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 to reconstitute Neoplastine.
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.	To open the Product drawer: Test Panel – Products – Loading Products – Reagent drawer opens – Scan the vial barcode and load.
7.	• 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.
8.	To close the product drawer, click on the green arrow. **Note**: The Owren-Koller buffer is the only reagent that is not loaded on the reagent drawer. It is loaded in sample drawer.

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.	To open the Sample drawer: Test Panel – Patient Analysis – Loading Samples – use the Mode tap on the bottom right to change from Auto to Manual if needed – Check Urgent for Stat samples and check the Micro Volume for micro cups – Scan the sample and load.
3.	To close the product drawer, click on the green arrow.

5.3 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.

5.4 Daily Maintenance

Purpose: To check the temperature and system status by following these steps:
Test Panel – System – System Status

1. Make sure the Level Detection is Enabled for Needles 1, 2, and 3.
2. Document the temperature of the following on STA Compact Max Maintenance Log:
    - Needle 3
    - Measurement Plate
    - Product Drawer on
3. 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.

5.5 Weekly Maintenance

1. Data backup
2. Soak the washing wells and purge the needles
3. Perform a shut down
4. Decontaminate stir bars
5. Replace Syringe Tip/Syringe.

Data Backup

Step	Action
1.	The instrument must be in a standby mode.
2.	Test Panel – System – User Maintenance – Save – Check Export ONLY. **Note:** Never check Import.
3.	Insert the flash drive – Select **Continue** – Select **Browse** – Select **USB Disk** – Click **OK**.

	It will take a few minutes to save. When message "**Write Finished**" appears, take out the flash drive and click on X to go back to the previous page.

Soak the washing wells and purge the needles

Step	Action
1.	The instrument must be in a standby mode.
2.	Test Panel – System – User Maintenance – Maintenance – Needle Purge – Select any Needle and click on Open drawer – Raise the front panel – Soak the Washing Wells with 10% bleach for 10 minutes and then perform Needle Purge; while waiting perform the following: 1. Clean sample and product drawers and measurement plate with a damp wipe 2. Clean measurement and incubation wells with cotton swab moistened in 20 % ethanol (only). Remove any debris. 3. Clean suction tip with warm water. Inspect for cracks and replace if needed. Needle purge: Lower the front panel – Select one needle at a time and then click on Purge. When purging is done, select Quit and then click on the green arrow.

Perform a Shut Down

Step	Action
1.	Test Panel – click on the Power button located on bottom left of the page.
2.	Wait for the Stago software to completely close down, then shut down the PC. Once the PC is completely off, switch off the instrument.
3.	While the instrument is turned off, perform the following before turning the instrument back on. 1. Clean 2 air filters. 2. Check liquid level in Peltier reservoir; fill with Thermo-Fluid ARCANE M25 if necessary. Fluid level must be between 40 and 80. **Note:** Do not open the Peltier reservoir when the instrument is ON.
4.	To turn the instrument on: 1. Switch on the instrument. 2. Wait for 30 seconds and then press and hold the power button, located in front of the instrument, until the PC starts. 3. Double click on "STA Compact Max" application.

Decontaminate Stir Bars

Step	Action
1.	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.

Replace Syringe Tip/Syringe

Step	Action
1.	Test Panel – System – User Maintenance – Maintenance – Replace Syringe Tip/Syringe.

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 Max Maintenance Log (AG.F652)
- Coag Reagent QC Handoff Log (AG.F315)
- Bio-Rad Unity Real Time 2.0, Chemistry procedure

7. REFERENCES

STA Compact Max – Operator's Manual, Diagnostic Stago, Inc., 05/2019.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
1	3/28/25	Section 5.5 Updated Weekly Maintenance: replace syringe/tip	M Belay	R SanLuis

9. ADDENDA AND APPENDICES

A. STA Compact Max Description
B. 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

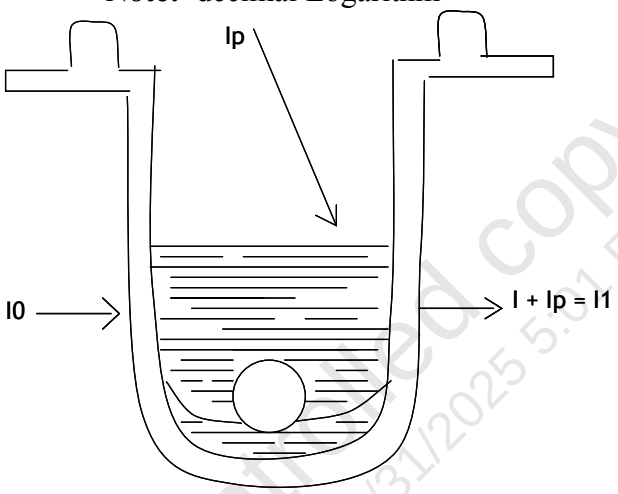


Fig. 1 - Principle of Absorbance Measurement

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.

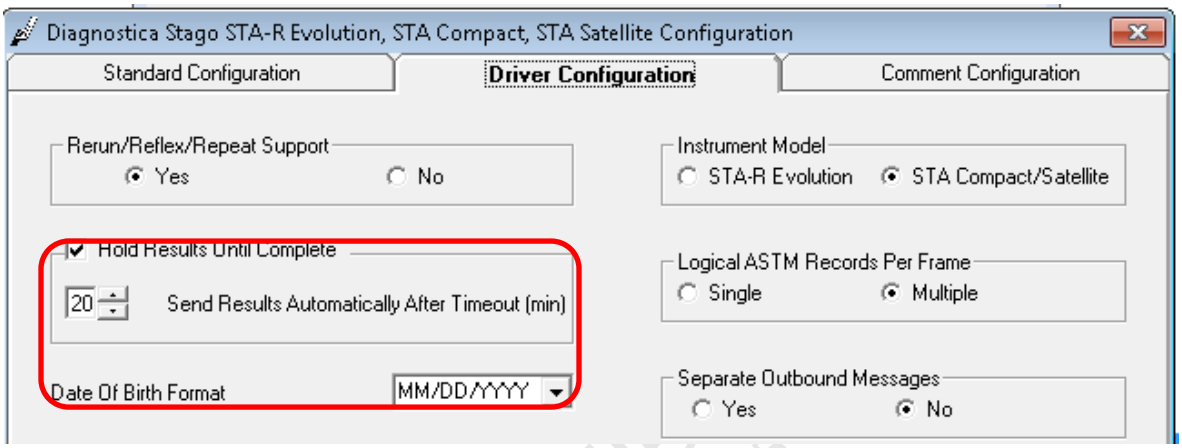
Incident light is provided by a tungsten-halogen lamp, and is made monochromatic by passing through a 405nm or 540nm, interface filter. The step occurs inside the optical module. A system of fiber optics carries the monochromatic light from the optical module to the measurement heads. Another set of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

Appendix B

DI (Data Innovation) Actions

A. General Information

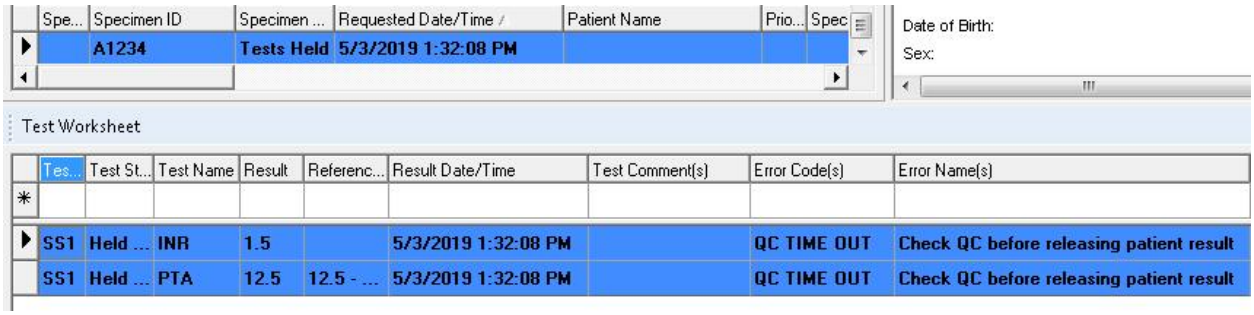
The DI Stago driver is set to collate all the coagulation tests on the same accession number until all the results have been completed within a set amount of time. For example, if the first test has been completed and the second test is still pending and the collation time has been exceeded, DI will 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.



Adventist HealthCare

STA Compact Max Maintenance Log

☐ Shady Grove Medical Center
☐ White Oak Medical Center

Month: _____ Year: _____ Instrument Serial Number: _____

Daily – day shift	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Needle # 3 36.5 - 37.5 °C																															
Measuring Block 36.5 - 37.5 °C																															
Reagent Drawer 15 – 19 °C																															
2nd shift– verify temps**																															
3rd shift – verify temps**																															
Wash Solution																															
NERL Water Lot # :																															
NERL Water Lot # : *																															
Tech Initial																															

* used only if lot # changes

** Verify Needle #3, Measuring Block and Reagent Drawer temperatures are within range, initial to indicate check

Weekly	Week 1		Week 2		Week 3		Week 4		Week 5	
	Date	Tech	Date	Tech	Date	Tech	Date	Tech	Date	Tech
Perform Data Backup										
Clean washing wells -10% bleach										
Clean drawers and measurement plate – warm H_20, wipe dry										
Clean measurement and incubation wells with 20% ethanol on cotton swab. Remove any debris.										
Clean and inspect suction tip - warm H_20										
Perform needle purge										
Check liquid level in Peltier reservoir – fill with Glycol if necessary										
Decontaminate stir bars										
Clean 2 air filters										
Performed a shut down										
Replace syringe tip and O ring										

Comment:

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review: