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| Purpose | This procedure provides instructions for start-up and operation of the STA-Compact Max coagulation analyzers. |

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| **Principle** | The **Compact Max® system** is an in vitro diagnostic medical device that comprises a laboratory analyzer and software intended to be used in combination with disposables and reagent products.The system has been designed to perform in vitro tests for the diagnosis and monitoring of disorders related to hemostasis. It can be used to perform chronometric tests (measurement of coagulation time), colorimetric tests or immunological tests on plasma samples.Chronometry measurement principle:The principle consists in measuring changes in the oscillation amplitude of the ball inside the cuvette, using electromagnetic sensors. An algorithm uses these magnetic field changes to calculate the oscillation amplitude to precisely determine the clotting times.Photometry measurement principle:The detection principle for chromogenic or immunological analyses on the STA Compact Max**®** is based on the absorbance (optical density, O.D.) of monochromatic (405 nm or 540 nm) light passing through a cuvette as an enzymatic or immunological reaction takes place. |

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| **Scope**  | This procedure is to be performed by a trained Clinical Laboratory Scientist (CLS) or Medical Laboratory Technician (MLT). |
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| **Safety** | ***Refer to the safety manual for general safety requirements.*** |

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| **Equipment** | * STA Compact Max**®** Analyzer
* Cuvette roll
* Centrifuge
* Distilled Water
* Pipettes & tips
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| **Water Sources** | For coagulation testing the only acceptable water for rehydration of control sera, preparation of reagents and standards (Supplied by OCI): * Nerl Ultra Pure Reagent Grade Water
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| **Quality Control & Reagent Preparation** |

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| **STA® Coag Control Plus** | **Reagent 1:** STA**®** - Coag Control N, citrated normal human plasma, lyophilized.**Reagent 2:** STA**®** - Coag Control ABN, citrated abnormal human lyophilized.**Preparation:** Reconstitute each vial of Reagent 1 or 2 with exactly 2 ml of Reagent Grade water. Allow the reconstituted material to stand at room temperature (18-25 °C) for 30 minutes. Then, swirl the vial gently before use.**Storage:** The reagents in intact vials are stable until the expiration date indicated on the box label, when stored at 2-8 °C. Once reconstituted, Reagents 1 and 2 remain stable for 24 hours on the **STA** **Compact Max®** in the original vials.When Reagents 1 and 2 are ready for use, place the control vials in the R0 area of the product drawer. |
| **STA® Liatest Control** | **Reagent 1: STA**® **- Liatest**® **Control,** citrated normal human plasma, lyophilized.**Reagent 2: STA**® **- Liatest**® **Control,** citrated abnormal human plasma, lyophilized. **Preparation:** Reconstitute each vial of Reagent 1 or 2 with exactly 1 ml of distilled water. Allow the reconstituted material to stand at room temperature (18-25 °C) for 30 minutes. Then, swirl the vial gently before use.**Storage:** The reagents in intact vials are stable until the expiration date indicated on the box label, when stored at 2-8 °C. Once reconstituted, they remain stable for 8 hours on **STA Compact Max®** **.** **Do not freeze.**When the Reagents 1 and 2 are ready for use, place the control vials in the R0 area of the product drawer |
| **PT** | 1. Reagent 1: Neoplastine CI+: Transfer the **entire** contents of one vial of Reagent 2 into one vial of Reagent 1 of the same lot. Use a transfer pipette to aspirate all the remaining reagent. Let sit 30 minutes at room temperature. Swirl gently. Add a stir bar and maxi-reducer to the vial and place perforated plastic cap on the vial. Make certain the stir bar is not caught underneath the reducer. Place the vial into a stirring position in the reagent drawer (R2). **Reconstituted stability on the STA Compact Max®**  **is 48 hours.**
2. Reagent 2: 10 ml solvent. Ready to use.
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| **APTT** | 1. Reagent 1: PTT-Automate: Reconstitute each vial with 5.0 ml of reagent grade water. Let sit 30 minutes at room temperature. Mix vigorously by turning the vial upside down (5-10 times) or vortex on low for 5 seconds before loading. Remove the stopper and replace the perforated plastic cap. Place in the R1 section of the drawer.
2. **Reconstituted stability on the STA Compact Max®** **is 24 hours.**

Reagent 2: 0.025 M CaCl2: Ready to use. Remove the rubber stopper and cap from the vial. Place in the R2 section of the drawer. **Stability is 120 hours on the Compact Max®**  |
| **D-DIMER** | 1. Reagent 1: Liatest D-Di Buffer: Ready to use. Allow the reagent to stand at room temperature for 15 minutes. Mix gently without creating bubbles. Then, remove rubber stopper, insert a **STA Compact Max®** mini Reducer, and place the perforated cap on the vial. Place the reagent into the reagent drawer (R1). **Reconstituted stability on the STA Compact Max®**  **is 15 days.**
2. Reagent 2: Latex Liatest D-Di: Ready to use. Allow reagent to stand at room temperature for 15 minutes. Mix gently without creating bubbles. Then remove stopper. Insert a STA**®-** mini Reducer and place the perforated cap on the vial. Place the reagent into the reagent drawer, (R2). **Reconstituted stability on the STA Compact Max®** **is 15 days.**
 |
| **Diluents** | 1. **STA – DESORB U** is a decontaminating solution for use with the **STA Compact Max®**. It is designed as an integral part of the STA**®** analyzer system.

**Preparation:** Install a new STA**®** - maxi Reducer and the perforated cap on a freshly opened bottle of STA**®** - Desorb U before loading it into the analyzer.NOTE: a fine white sediment may be observed in the bottom of the bottle; this has no effect on the performance of the product.**Storage:** The reagent in intact bottles is stable until the expiration date indicated on the box label, when stored at 2-8 °C and protected from light.Once opened, the STA**®** - Desorb U with STA**®** - maxi Reducer and perforated cap in place, is stable for 5 days on board **STA Compact Max®**When STA**®** - Desorb U is ready for use (with STA**®** - maxi Reducer and perforated plastic cap in place). Place one bottle in the R0, R1 and R2 areas of the product drawer1. **STA® - Owren-Koller Buffer**: is a buffer solution intended for use as a diluent for reagents and patient samples in coagulation tests.

**Preparation:** Allow the reagent to stand at room temperature (18-25 °C) for 30 minutes before use. Do not install either an STA® - Reducer or a perforated cap on the buffer bottle if the solution is to be used on analyzers of the STA® line.**Storage**After opening, it remains stable for 3 days on **STA Compact Max®**In case of partial use, the remaining solution stored at 2-8 °C in its original bottle with the cap on top, is stable, when free of any contamination, until the expiration date indicated on the bottle. |

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|  | *Refer to Attachment A: STAGO Reagent Handling Guide.* |
| **Checking****Disposables** |

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| **Step** | **Action** |
| 1 | Click  or click the Products menu on the Test Panel screen. |
| 2 | In table **Disposables**, check the number of available cuvettes and the remaining volume of washing solution |
| 3 | If necessary, load a new cuvette roll or load a bottle of washing solution *following the procedure described in the STA Compact Max® Reference Manual*  |

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| **Reagent Loading** | Loading Stago (Controls and Reagents) products **USING BARCODED PRODUCTS:**

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| **Step** | **Action** |
| 1 | Click  or click the Products menu on the Test Panel screen, then Loading Products |
| 2 | Scan the vial barcode label with either the handheld or external barcode reader |
| 3 | If necessary, correct 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.R0 - Controls, calibrators, and diluentsR1 - Reagents added before incubation.R2 - Start reagents (Thromboplastin, CaCl2, FBG Reagent)Note: Desorb U needed in all positions (R0, R1, & R2) |
| 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: To proceed with barcode reading, click Yes, scan the sheet using either the handheld or external barcode reader, then click Validate  |
| 9 | Click  to close the product drawer |

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|  | **USING MANUAL IDENTIFICATION**

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| **Step** | **Action** |
| 1 | Click  or click the Products menu on the Test Panel screen, then Loading Products |
| 2 | Enter in the product ID as defined in Test Setup under the IDENTIFIER field, then click ENTER. |
| 3 | If necessary, enter the product lot number, correct the volume and stability. |
| 4 | If the product has been transferred into a micro cup, 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.R0 - Controls, calibrators, and diluentsR1 - Reagents added before incubation.R2 - Start reagents (Thromboplastin, CaCl2, FBG Reagent)Note: Desorb U needed in all positions (R0, R1, & R2) |
| 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 | Click  to close the product drawer Note: Always run controls after loading new reagent. |

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| **Running Controls** | Controls must be run at least once per shift. 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, and error message is generated stating that QC is out and a dark blue triangle  will be displayed instead of green When Quality Control tolerance limits are exceeded, corrective actions must be performed and recorded before analyzing patient samples. Refer to *Quality Control and Quality Control Out of Range Action P&P COAG.02-0010***Running a quality control manually**

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| **Step** | **Action** |
| 1 | Click  or click the Quality Controls menu from 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) |

**Printing the daily Quality Controls**

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| **Step** | **Action** |
| 1 | Click  |
| 2 | Double click test abbreviation |
| 3 | The controls Graphic screen is displayed, select level |
| 4 | Click  |

**Displaying and printing the quality controls for a given period**

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| **Step** | **Action** |
| 1 | Click  |
| 2 | Double click test abbreviation |
| 3 | The controls Graphic screen is displayed, select level |
| 4 | Click  to display table |
| 5 | Click  |

**Transmitting a quality control result**

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| **Step** | **Action** |
| 1 | Click  |
| 2 | Double click on test for which a quality control is to be transmitted |
| 4 | Select  to transmit the individual quality control level. If more than one result is to be transmitted, this will need to be done for each level |

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| **Running Patients** | **LOADING PATIENT SAMPLES****Using Automatic profile by downloading from Cerner**

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| **Step** | **Action** |
| 1 | Click  to open the sample drawer or click on Load Samples from the Patient Analysis menu, located on the Test Panel screen |
| 2 | The Loading Samples screen is displayed |
| 3 | click Automatic profile |
| 4 | Click Change Profiles |
| 5 | From the drop-down menu of the Automatic Profile area, select profile 8, “by downloading” |
| 6 | Scan the tube barcode label with either the handheld or external barcode reader or type the sample identification and confirm with the enter key |
| 7 | If necessary, select or unselect Micro Volume to specify the sample types and Urgent to mark the sample as a stat sample |
| 8 | Place the sample tube in the drawer within 11 seconds or the sample will have to be rescanned/retyped for loading |
| 9 | The LED adjacent to the tube position will turn on |
| 10 | Click to close the drawer.  The sample pipetting starts and window **Analysis status** is displayed when all the conditions are met for all the reagents and products. |

**Using Manual Mode**

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| **Step** | **Action** |
| 1 | Click  to open the sample drawer or click on Load Samples from the Patient Analysis menu, located on the Test Panel screen |
| 2 | The Loading Samples screen is displayed |
| 3 | click MANUAL MODE |
| 4 | Select all the methodologies to apply to the sample  |
| 5 | Double-click each methodology then click Confirm |
| 6 | Scan the tube barcode label with either the handheld or external barcode reader or type the sample identification and confirm with the enter key |
| 7 | If necessary, select or unselect Micro Volume to specify the sample types and Urgent to mark the sample as a stat sample |
| 8 | Place the sample tube in the drawer within 11 seconds or the sample will have to be rescanned/retyped for loading |
| 9 | The LED adjacent to the tube position will turn on |
| 10 | Click to close the drawer.  The sample pipetting starts and window **Analysis status** is displayed when all the conditions are met for all the reagents and products. |

**Analysis Status Screen** Displays a consistency check between the workload of the STA Compact Max® and the requirements for the completion of a sample run.

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| **Step** | **Action** |
| 1 | Select the Products menu on the Test Panel screenE:\Compact Max Screen shots\CMax System Menu.JPG |
| 2 | Select Analysis Status from the drop-down menuE:\Compact Max Screen shots\Compact Max Analysis Status-forecast time.jpg |
| 3 | 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 bottom left of the screen:  |
| 4 | Depending on the situation:- Load the missing products.- Replace the products which volumes are insufficient or which stability is almost overdue.- Validate or run the required calibrations and quality controls.- Change the threshold values of the non STA® line controls and calibrators. |
| 5 | Click  |
| 6 | Message prompt will appear: “Analyses executions have been stopped. Do you want to reactivate them?”  |
| 7 | Click Yes |

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

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| **Step** | **Action** |
| 1 | From the Test Panel, double click the desired patient to display the Patient report form screenE:\Compact Max Screen shots\CMax Patient Report form.JPG |
| 2 | click the corresponding button at the bottom of the Patient report form screen to select the desired action |
| 3 | Save your selection using the  |

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| **Reporting Results** | * Results for PT, aPTT, aPTT Hep are AUTOVERIFIED if auto verification is “**ON**” and/or the results are within linearity and not critical.
* If Auto verification is “**OFF**” and/or result are outside linearity/critical, release results in Cerner through Accession Result Entry (ARE), instrument queue.
* Results will appear on Cerner identified by the barcode number and patient demographics.
* For the current reportable range refer to *Reference, Therapeutic and reportable Ranges P&P COAG.01-0030*
* See *Critical Value P&P Lab 05-090-01* for procedure regarding notification of critical values.
 |
| **REPORTING GUIDELINES**  |

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| Analyte | Reportable Range | Exceptions |
| PT | 0.5 – 10.0 INR (8-150 sec.) | If INR is >10 (or >150 sec.) or V>V-MAX, no value will crossover to Cerner, report as “>10.0 INR”, this will trigger the critical pop up notification. |
| APTT | 15-200 sec. | If >200 sec. or V>V-Max, no value will crossover to Cerner, report as “>200 sec”, this will trigger the critical pop up notification. |
| D-Dimer (DVT, PE) | 0.27-4.00 FEU mcg/mL | If V>VMAX, no value will crossover to Cerner. You must check the instrument to see if the result is “V>VMAX” and if so, report as “>4.00 FEU mcg/mL.” |
| D-Dimer(DIC) | 0.27-20.00 FEU mcg/mL | If V>VMAX, no value will crossover to Cerner. You must check the instrument to see if the result is “V>VMAX” and if so, report as “>20.00 FEU mcg/mL.” |

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| Preventive Maintenance | **Daily** 1. If the analyzer is equipped with the cap piercing option, clean the piercing needle (10 min)
2. Perform temperature checks of needle #3, the measurement block, and reagent drawer in the System Status menu
3. Check the syringe percentages of the 3 syringes on board in the System Statusmenu
4. Soak Needle No. 1 in Desorb for 10 mins

**Weekly** 1. Clean wash wells with fresh 0.37% active chlorine decontamination solution for 10 minutes
2. Clean drawers and measurement plate with warm H20 then wipe dry
3. Clean measurement and incubation wells with fresh 20-40% ethanol on cotton swab. Remove any debris.
4. Clean and inspect suction tip using warm water
5. Purge the needles
6. Data Backup
7. Clean 2 air filters (replace as needed)
8. Clean touch screen
9. Clean and dry the product drawer
10. Check and fill Glycol in Peltier reservoir if necessary
11. Decontaminate stir bars per package insert/instruction for use (IFU)
12. Shut down and restart the analyzer

**Monthly/as needed**1. Replace Syringe Tip and O ring
2. Replace piercing needle every 100,000 piercings

*Refer to STA Compact Max* ® *Operator’s Manual and STA Compact* *Max* ® *User Guide* for a detailed Maintenance instruction. |

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| **Non-Controlled Documents** | 1. STA Compact Max ® Operator’s Manual.
2. STA Compact Max ® User Guide.

For additional information, please refer to the manufacturer’s package inserts. |
| **Controlled Documents** | The following controlled documents support this procedure. |
|  | **Procedure** | **Number** |
|  | *Coagulation Specimen Requirements* | COAG.01-0010 |
|  | *Quality Control and Quality Control Out of Range Action* | COAG.02-0010 |
|  | *Reference, Therapeutic and Reportable Ranges* | COAG.01-0030 |
|  | *Critical Value* | LAB 05-090-01 |
|  | **Attachments** |
|  | *Attachment A: Reagent Handling Guide* |

Document History Page

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| --- | --- | --- | --- | --- | --- |
| Change type: New, Major, Minor etc. | Changes Made to SOP – describe | Name of responsible person/date | Med. Dir. Reviewed/ date | Lab Manager reviewed/ date | Date change Imp. |
| New | Instrument upgrade to Stago Compact Max | Yvette R Lingat11/8/19 |  |  | 11/20/19 |
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