STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER

PRINCIPLE

The STA–R® Evolution is a fully automated coagulation instrument that uses an electromagnetic viscosity detection system. The oscillation of a steel ball within the cuvette with the reagent and diluted plasma is monitored by the STA–R® Evolution. The viscosity increases because of the coagulation, the oscillation amplitude of the ball swing decreases. An algorithm uses these variations in oscillation amplitude to determine the clotting time in seconds.

SAFETY

Laboratory employees are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety, the safety of others and adhering to all departmental and medical center safety policies and procedures. Refer to Policy and Procedures Safety Manual Infection Control 11-085-01.

DAILY STARTUP

Print and review products available on instrument. From review, plan reconstitution for all analytes needed. All required maintenance must be performed with the frequency recommended by the manufacturer. CLS must sign the maintenance log provided.

CONTROL & REAGENT PREPARATION

STAGO COAG & LIATEST CONTROLS	Reconstitute each vial of control with exactly 1 mL of reagent grade water (See Laboratory P&P COAG.01-0040). Allow the reconstituted material to stand at room temperature (18-25°C) for 30 minutes. Then, swirl vial gently before use. All reagents should be dated and initialed before placing on instrument. Reagents are stable for 8 hours on the analyzer (15-20°C).

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REAGENTS

APTT	1. Reagent 1: PTT-Automate: Reconstitute each vial with 5.0 ml of reagent grade water (See Laboratory P&P 01-130-01). 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-R 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 STA-R.**
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 - R is 48 hours.** 2. Reagent 2: 10 ml solvent. Ready to use.
FIB	1. Reagent 1: STA-Fibrinogen: Reconstitute each vial with 5.0 ml of reagent grade water (See Laboratory P&P 01-130-01). Replace the rubber stopper and perforated plastic cap on the vial. Let sit 30 minutes at room temperature. Swirl gently. Remove the rubber stopper and place the perforated plastic cap on the bottle. Scan reagent and place the reagent into the reagent drawer (R2). **Reconstituted stability on the STA - R is 120 hours**. 2. Reagent 2: Owren-Koller buffer: Ready to use buffer. Used by the STA -R to perform dilutions of controls and patients' plasmas. Place the reagent into the reagent drawer (R0). **Stability is 120 hours on the STA – R.**

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REAGENTS, continued

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 – R mini Reducer, and place the perforated cap on the vial. Place the reagent into the reagent drawer (R1). **Reconstituted stability on the STA – R 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 – R mini Reducer, and place the perforated cap on the vial. Place the reagent into the reagent drawer, (R2). **Reconstituted stability on the STA – R is 15 days.**

LOAD REAGENTS

Loading Stago (controls and reagents) products

USING BARCODED PRODUCTS:

Step	Action
1.	• Click on the product icon. Click the “OPEN” tab. After drawer opens - tab reads “Close Drawer”.
2.	• Click the "List of Products" tab.
3.	• Product Loading Screen will be displayed.
4.	• Press “Position” button, then “type” button. This arranges products for easy assessment.
5.	• Scan bar-coded product. Volume and stability times must be edited as needed. For Micro cups click on Microcup icon or the key F8.
6.	• Place the vial in the appropriate position. R0 - Controls, calibrators, and diluents R1 - Reagents added before incubation. R2 - Start reagents (Thromboplastin, CaCl2, FBG Reagent) Note: Desorb U needed in all positions (RO, R1, & R2)

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LOAD REAGENTS, Continued

Step	Action
7.	If a new lot is detected, the following question is displayed “Do you wish to read the calibration parameters using the barcode reader?" To proceed directly with the barcode reading, click OK, pass the sheet in front of the barcode reader and then click Confirm.
8.	Load all products necessary.
9.	Click on “Close Drawer”.

USING MANUAL IDENTIFICATION:

Step	Action
1.	Open the Product Drawer.
2.	Key in the product ID as defined in Test Setup, then click ENTER.
3.	Click on the micro cup icon or the F8 key if loading micro cup.
4.	Key in lot number.
5.	Volume and stability must be edited as needed.
6.	Place vial in appropriate position.
7.	Load all products necessary following steps 2-6 above.
8.	Close drawer. Note: always run controls after loading new reagent.

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

RUNNING CONTROLS

Controls must be run at least once per shift. When Quality Control tolerance limits are exceeded, corrective actions must be performed and recorded before analyzing patient samples. Controls must run in the same manner as the patient samples.

PT/PTT/ FIB	Coagulation Control N and ABN PLUS
D-Dimer	Liatest Control N and P
Heparin	Heparin Control Level 1 and 2

Step	Action
1.	Running 1 Test by level: • Click the Quality Control icon • Locate the test for which a control must be run • Click the test abbreviation. Background turns to blue • Click the Control Level # tab (i.e. Control Level Tab 1) • Click Run Selection icon (pointing finger). • Confirm by clicking OK • Repeat for all levels to be run
2.	Running multiple tests: • Click the Quality Control icon • Click on the uppermost test abbreviation of test to run. Background turns to blue • Hold down the ‘Ctrl” (left) key on the mouse pad, pull mouse arrow across the other tests to run all. Backgrounds turn blue. Lift “Ctrl” key. • Click the Selection icon (pointing finger). • Confirm by clicking OK

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RUNNING CONTROLS, CONTINUED

Validating, Deleting, and Rerunning QC

Step	Action
1.	Click the Quality Control icon flashing on the bottom of screen.
2.	Locate the test for which a quality control must be validated
3.	Double click the test that must be validated.
4.	A box opens up-select validate.
5.	The alarm will stop beeping.
6.	You may double click on the box again if you wish to rerun or delete that control result.

RUNNING PATIENTS

Follow the steps below to process patient samples. At the beginning of each shift, whenever preventative maintenance is done, or new reagent is put in instrument, run controls from the reagent holder work list.

Step	Action
1.	Check label to make sure barcode is readable and tube can rotate freely in rack.
2.	Place tubes in rack.
3.	Slide rack(s) on to tray.
4.	Place tray on STA-R loading station: make sure it is seated properly. Make sure automatic inquiry icon is pictured at the bottom of the test panel screen. • Racks will be loaded and barcodes read. • Tubes with no barcodes or barcodes that cannot be read are assigned an ID # (NL/# of rack/position in rack) NOTE: All fibrinogens are run in duplicate and must agree within 10% of each other.
5.	Ordering tests can be done by the following: • Using Downloading (orders will download from Cerner and tests will run automatically). • Using Automatic Profile (same tests done on all samples) • Tagging IDS and ordering individual tests on all tagged IDS. • Individual tests can be ordered by double clicking in the box of the test needed. NOTE: For detailed instruction refer to Operator's Manual - pg.19-23.

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RUNNING PATIENTS, CONTINUED

Loading STAT Rack:

Step	Action
1.	Click on STAT icon
2.	When 'READY" screen is displayed, push rack against white tooth on conveyor belt; belt will take over and push rack into star (barcode side of rack first).

Ordering/Rerunning a test Panel Screen Using the Test Box:

Step	Action
1.	Double-click the test box for the desired test window. Window will open.
2.	Choose the appropriate selection then click on “OK”

Ordering/Rerunning a Test from the Test Panel Screen using Tag Function:

Step	Action
1.	Tag the appropriate ID or IDs. (Red check mark appears in left hand box under “T”.
2.	On the Test Panel Screen, click on the Test Abbreviation (in the gray column header). A box opens.
3.	Select Add or Rerun.
4.	Confirm by clicking the OK button.
5.	The selected test has been added/rerun to all tagged samples.

Unloading Several/All Racks

Step	Action
1.	Click the Patient icon.
2.	Click the loading tab.
3.	Tag racks to be unloaded or tag all.
4.	Click Rack icon. The following message is displayed: Unload the tagged racks?
5.	Confirm by clicking OK. The icon representing the rack shows a rack icon with the word STOP in front.
6.	Release the tray by clicking on the Tray icon. The tray area on the screen turns green.
7.	The tray can then be lifted and removed from Star.
8.	When the tray is removed, the patient’s IDS are removed from the test panel screen and transferred to the archives.

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

RUNNING PATIENTS, CONTINUED

Unloading Several/All Racks

Step	Action
1.	Click the Patient icon.
2.	Click the loading tab.
3.	Tag racks to be unloaded or tag all.
4.	Click Rack icon. The following message is displayed: Unload the tagged racks?
5.	Confirm by clicking OK. The icon representing the rack shows a rack icon with the word STOP in front.
6.	Release the tray by clicking on the Tray icon. The tray area on the screen turns green.
7.	The tray can then be lifted and removed from Star.
8.	When the tray is removed, the patient's IDS are removed from the test panel screen and transferred to the archives.

RESULTS REPORTING: PT, APTT, FBG & QUANT, D-DIMER

- Results will appear on Cerner identified by the barcode number and patient demographics.
- For the current reportable range refer to P&P 01-100-01.
- See Lab P&P 05-090-01 for procedure regarding notification of critical values.

INR VERIFICATION

The INR calculation performed by the coagulation analyzer must be verified annually. This is done by manually calculating the patient INR and comparing it with the instrument calculated INR. Both calculated INR's should match. Refer to P&P 03-050-01 for manual INR calculation procedure.

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

REPORTING GUIDELINES

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.
FBG	60-1800 mg/dL	If <60 mg/dL, report as "<60 mg/dL", this will trigger the critical pop up notification. If >1800 mg/dL, report as ">1800 mg/dL", this will trigger the critical pop up notification. **NOTE:** **A VMAX result means value is extremely low.** **A VMIN result means value is extremely high.**
D-Dimer (DVT, PE)	270-4000 ng/mL FEU	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 ">4000 ng/mL."
D-Dimer (DIC)	270-20,000 ng/mL FEU	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, program instrument to run D-DI x 5 (instrument does automatic dilutions) and if result is >VMAX, report as ">20,000 ng/mL."

IMPORTANT: **DO NOT** "Convert Results" to "Free text", just type in < or > and the value, it will default to what is in Cerner and trigger the critical notification pop up if applicable.

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

REPORTING GUIDELINES CONTINUED

Check coagulation specimen for clot before reporting results
NOTE: Specimen with grossly visible clots may have extremely low levels for fibrinogen and variably decreased levels of coagulation proteins, so that the result of the PT, aPTT, Fibrinogen and other coagulation assay will be inaccurate and unobtainable. Checking for clots may be done using an applicator sticks, visual inspection of centrifuge plasma for small clots or analysis of results (Delta Checks). Additionally, when a clot is not detected during PT and PTT testing and, where the fibrinogen is extremely low, it should be suspected that the sample is actually serum. This is important when coagulation specimens are received as centrifuged, frozen "plasma."

REFERENCE RANGE

- See Coagulation P&P COAG.01-0010 ver. 1

THERAPEUTIC RANGE PT INR

PROTIME/CLINICAL STATE
Prophylaxis - venous thromboembolism (high risk surgery)
Treatment of initial episodes of DVT or PE
Prevention of systemic embolism in-patients with atrial fibrillation (without systemic embolism), valvular heart diseases, tissue heart valves, acute myocardial infarction anterior transmural) and atrial fibrillation with systemic embolism
Mechanical prosthetic heart valves and recurrent systemic embolism

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY

SUPPLY MANAGEMENT:
Changing the cuvette roll: do this when all the cuvettes are used up in the current roll

Step	Action
1.	Open the upper right door.
2.	Raise the catch holding the roll in place and catch holding the reel in place.
3.	Open the door of the cuvette loader carefully. DO NOT ALLOW TO SLAM OPEN.
4.	Remove the reel and roll by sliding each off its spindle.
5.	Discard the reel and the roll. Note: New cuvette rolls always include a reel which is connected to the roll by a film on which the cuvettes are fixed.
6.	When reading the cuvette roll bar code data, hold the bar code of the new cuvette roll in front of the product drawer bar code reader. If these 2 bar code labels are not detected by the reader, the information from both bar code labels can be entered manually.
7.	A cuvette loading window opens: showing the number of cuvettes and the code\batch of the roll that has just been loaded.
8.	Hold the new cuvette roll in such a way that the roll is on the left and reel is on the right. Lot # is facing you.
9	Slide the roll along its spindle and the reel along its spindle. Lower the catch holding the reel in place, and the catch holding the roll in place.
10	Position the film in the cuvette loader so that it is parallel to the loading racks and close the cuvette loader door. Note: Do not twist the film.
11.	Press the button located beside the reel to activate the cuvette feeder. Hold button down steadily until it stops on i's own. As it moves, check that the cuvettes correctly enter the cuvette loader without twisting sideways and continue to press the feed button until the cuvettes have reached the other side of the loader. The motor stops automatically.
12.	Click the Products icon and then the Cuvette button. The following on screen message is displayed: "Once you have replaced the Cuvette Roll, confirm quantity". Type in 1,000. Hit the green curvy arrows icon.

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

Changing the cuvette disposal bag:

Step	Action
1.	Open the front door.
2.	Remove the cuvette bin (on the extreme right).
3.	Lift the plastic bag from the metal container to close it.
4.	Remove the tie along the opening of the plastic bag.
5.	Close the plastic bag by forming a knot with the tie.
6.	Dispose of the plastic bag, observing the hospital's regulations.
7.	Take one of the plastic bags located in the box holding the cuvette rolls.
9.	Open the plastic bag and place it in the metal bin.
10.	Ensure that the bag fully spreads out at the bottom of the metal bin.
11.	Lower the plastic bag along the sides of the metal bin.
12.	Put back the metal cuvette bin into the STA-R ensuring that it is down fully in its holding place. There should be an audible click signaling the presence of the bin. Do not disrupt the function following the detection of the presence of the metal cuvette bin

Loading the cleaning solution: do this when the instrument alarms to let you know that the waste is full.

Step	Action
1.	Click the Product icon and STA-Cleaner solution button: a window is displayed with message "Remove and dispose of the Wash Bottle. CAUTION: Biohazard
2.	Open the front door. The bottle of used solution contains potentially infectious material and must be disposed of according to the hospital regulations.
3.	Gently pull out the bottle of used solution shown in blue on the screen (bottle in the center).
4.	Remove the cap of the bottle as soon as possible. Note: A symbol is used at cap level of the used solution bottle and the tubing going into this cap is red to indicate that the contents of this bottle are potentially infectious.

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

5.	Fully remove the bottle of used solution: a new window is displayed with the message “Empty then move the Cleaner Solution bottle."
6.	The empty STA-Cleaner Solution bottle becomes the new waste bottle.
7.	Gently pull out the empty bottle of STA Cleaner Solution (bottle on the extreme left).
8.	Remove the cap from the bottle as soon as possible. Avoid potential contamination by leaving the tube to hang down outside the instrument.
9.	Empty the bottle of STA-Cleaner Solution.
10.	Place the empty bottle at the front of the middle position and put the cap back on the empty bottle.
11.	Push the empty bottle back into place. There should be an audible click signaling the detection of the presence of the bottle: a new window is displayed with the message "Install a new Cleaner Solution.” Do not disrupt the function of the switch allowing the detection of the presence of the bottle of used solution.
12.	Take a new bottle of STA-Cleaner Solution.
13.	Place the new STA-Cleaner Solution in front of the empty space on the extreme left to insert the tube, and then insert tube and connect cap to bottle.
14.	Push the empty bottle to the back of its recess. There should be an audible click signaling the detection of the presence of the bottle: a new window is displayed with the message "Indicate the volume."
15.	Confirm the volume shown (2500 ml) by clicking Validate if a new bottle is used. If not, enter the remaining volume, and confirm by clicking Validate.
16.	Close the right front door.

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

PREVENTATIVE MAINTENANCE:
Refer to STA-R Evolution Reference Manual section 4 for detailed instructions.

NOTE: Quality Control must be run and be within acceptable limits after performing maintenance before patient result can be reported.

Frequency	Tasks
Daily	• Check reagent arm #3 temperature • Check measuring block temperature • Check reagent drawer • Record pipetting % of syringes #1,2 & 3 • Clean Cap Piercing Needle Daily Maintenance • Clean the Touch screen
Weekly	• Clean the main filter • Clean the washing wells with 10% bleach • Cleaning the product drawer • Clean the measurement plate • Clean the conveyor belt • Shuttle cleaning
Monthly	• Replacing the syringe teflon tips
Quarterly	• Replacing air filter • Replacing the barcode reader wheel

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

Daily Preventative Maintenance
Clean the outside and inside of Piercing Needle

Step	Action
1.	Click on the Maintenance Icon  .
2.	Click tab User Menu.
3.	Click tab Needle Washing.
4.	Click Daily to perform the recommended Daily washing time or Weekly to perform the recommended Weekly wash time.
5.	Click the Restart Analyzer Icon  .
6.	Click  following the Please Ensure Drawer is Closed and Validate message.
7.	Fill a tube with at least 5 mL DESORB. See illustration on the screen.
8.	Put the tube at position 3 in a rack.
9.	Manually load the rack (“STAT” loading). The barcode checks that the tube is in position 3 of the rack. The piercing needle moves and goes down in the tube filled with DESORB.
10.	Raise the transparent cover when the product drawer opens at the end of the washing process
11.	Dry the piercing needle with a Kim wipe from top to bottom.
12.	Close the transparent cover.
13.	Click  to validate. The product drawer closes and the rack unloads
14.	Remove the rack from the tray and validate by clicking 
15.	Click  to return to Maintenance main screen.
16.	Click  to exit the Maintenance software and return to the Operation software

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

Weekly Preventative Maintenance
Cleaning the main air filter and the optic module case filter

Step	Action
1.	Click on the Maintenance Icon  .
2.	Click the Maintenance button
3.	Open the right hand front door.
4.	Remove the main air filter. This filter is located below the instrument.
5.	Remove the coarse dirt particles from the filter using a vacuum or rinse with water and dry it**. (NOTE: The main air filter must be completely dry before installing it back to the instrument.)**
6.	Put the air filter back in place paying attention to assembly orientation: the arrow must point to the upper part of the instrument.
7.	Remove the air filter from the optic module: open the lower right-hand door and pull back on the black cover, vacuum out the dust and then replace the air filter

Cleaning the Rinsing Wells and Needles

Step	Action
1.	Click on the Maintenance Icon  .
2.	Click the Maintenance button
3.	Click the Rinse Well Tab. The "**Press the button for rinsing the wells…**" message is displayed.
4.	Click the  button. The messages "**Home position in progress…and Arm is moving towards the front of the STA-R"** are displayed for each arm
5.	Click  to close these messages. When arms 1, 2, 3 are to the front, the message **Drawer is going to open, please validate** is displayed
6.	Click  , the drawer opens and the message "**The drawer is opening, please wait…"** is displayed. When it is open, the next message **Press OK to continue** is displayed.
7.	Click  . The message "**Pour the decontaminating solution into each well**. **When you have finished please validate"** appears.
8.	Lift the transparent cover
9.	Fill each rinsing well to the ¾ level with decontaminating solution
10.	Wait 30 minutes during which you can clean the product drawer and the measurement plates.

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

Cleaning the Rinsing Wells and Needles, Continued

Step	Action
11.	Click Ok. The message "**Drawer is going to close, please validate."** is displayed.
12.	Click Ok. The drawer closes and the message "**Drawer is going to close, please wait..."** is displayed. When it has been closed, the next message **"Press OK to continue."** is displayed.
13.	Click Ok. The message "**To empty the wells, please validate."** is displayed.
14.	Click Ok. The rinsing wells are emptied and the messages **"The wells are being emptied, please wait..."** and **"Press OK to continue."** are displayed.
15.	Click Ok. The message **"A circuit purge is going to be performed for each well, please validate."** Is displayed.
16.	Click Ok. Rinsing well n°1 is purged and the messages **"Please wait during the purge of the well 1."** and **"Press OK to continue."** are displayed.
17.	Click Ok. Rinsing well n°2 is purged and the messages **"Please wait during the purge of the well 2."** And **"Press OK to continue."** are displayed.
18.	Click Ok. Rinsing well n°3 is purged and the messages **"Please wait during the purge of the well 3."** And **"Press OK to continue."** are displayed.
19.	Click Ok. A window displaying the message **"The procedure was successful."** appears.
20.	Click **OK**: go back to the beginning of the procedure.
21.	Click 
22.	Click Ok
23.	Run the quality controls for the routine tests.

Cleaning Product Drawer

Step	Action
1.	Click on the Maintenance Icon  .
2.	Click the Maintenance button
3.	Lift the transparent cover.

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

Cleaning Product Drawer, Continued

Step	Action
4.	Check that no needle is left in the product drawer (in one of the positions or in one of the rinsing wells). If there is a needle, raise it and push it to the back of the analyzer.
5.	Pull the products drawer open.
6.	Clean the top with a cloth or paper towel that is slightly moistened with hot water. Wipe with a dry cloth.
7.	Push the drawer shut
8	Close the transparent cover

Cleaning Measurement Plate

1.	Click on the Maintenance Icon  .
2.	Click the **Maintenance** button.
3.	Lift the transparent cover.
4.	Remove all debris from every measurement cell and from every incubation cell.
5.	Clean every measurement cell and every incubation cell with swabs slightly moistened with ethanol (concentration between 20% and 40%).
6.	Clean the black cover for the measurement plate with a cloth or paper towel slight moistened with hot water, and then wipe it with a dry cloth. Do not use ethanol on the measurement plate.
7.	Close the transparent cover.
8.	Run the quality controls for the routine tests.

Cleaning the Conveyor belt

Step	Action
1.	Click on the Maintenance Icon  .
2.	Click the **Maintenance** button.
3.	Open the upper right door
4.	Clean both shuttle transporter belts with a cloth slightly moistened with ethanol (concentration between 20% and 40%).

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

Cleaning the Shuttles

Step	Action
1.	Clean the shuttles with ethanol (concentration between 20% and 40%); leave them to dry and put them back on the analyzer.

Purging the Needles

Step	Action
1.	Click on the Maintenance Icon  .
2.	Click the **Maintenance** button.
3.	Click the **Ndle Purge** tab. The message **"Choose a needle to purge..."** is displayed.
4.	Click the button,  the  or the button  depending on which needle is to be purged. The message: **"You have selected number x Press OK to continue."** is displayed. **x** corresponds to the needle that is to be purged.
5.	Click.  . The message **"Arm is moving towards washing wells and wells are emptied"** is displayed, the needle selected comes into position in the well, and then the extra message **"Press OK to continue."** is displayed
6.	Click.  . The messages **"P-Axis being reset..."** then **"Press OK to continue."** are displayed.
7.	Click.  . The messages **"Reservoir filling in progress..."** and then **"Press OK to continue."** Are displayed.
8.	Click.  . The message **"Circuit purge in progress. Please wait..."** is displayed. The circuit is purged and then the second message **"Press OK to continue."** is displayed.
9.	Click.  . The messages **"Home position in progress..."** and then **"Press OK to continue."** Are displayed.
10.	Click.  . The message **"The procedure was successful."** is displayed.
11.	If necessary, proceed with purging other needles.
12.	Click 

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

Weekly clean the outside and inside of Piercing Needle

Step	Action
1.	Click on the Maintenance Icon  .
2.	Click tab User Menu.
3.	Click tab Needle Washing.
4.	Click Weekly to perform the recommended Weekly wash time.
5.	Click the Restart Analyzer Icon  .
6.	Click  following the Please Ensure Drawer is Closed and Validate message.
7.	Fill a tube with at least 5 mL DESORB. See illustration on the screen.
8.	Put the tube at position 3 in a rack.
9.	Manually load the rack (“STAT” loading). The barcode checks that the tube is in position 3 of the rack. The piercing needle moves and goes down in the tube filled with DESORB.
10.	Raise the transparent cover when the product drawer opens at the end of the washing process
11.	Dry the piercing needle with a Kim wipe from top to bottom.
12.	Close the transparent cover.
13.	Click  to validate. The product drawer closes and the rack unloads
14.	Remove the rack from the tray and validate by clicking 
15.	Click  to return to Maintenance main screen.
16.	Click  to exit the Maintenance software and return to the Operation software

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

Routine Shutdown

Step	Action
1.	Click the  icon, the confirmation window is displayed.
2.	Click 
3.	Wait until the software is shut down.
4.	Move the cursor to the bottom of the screen to display the taskbar.
5.	Click Start, then **Turn Off Computer...**.
6.	Click 
7.	Wait for the message **"It is now safe to turn off your computer"** is displayed.
8.	Press the screen's power supply switch.
9.	Turn the On/Off switch of the STA-R Evolution® to the Off (O) position. This switch is located on the right side of the STA-R Evolution®.
10.	Press the printer's power supply switch.

Routine Start-up

Step	Action
1.	Ensure that all the covers, doors and the product drawer of the STA-R Evolution® are shut/closed properly.
2.	Turn the printer power switch on.
3.	Turn the power switch of the STA-R Evolution® to the On (I) position. This switch is located on the bottom right side of the STA-R Evolution®.
4.	Turn the monitor power switch on.
5.	Double click the icon 
6.	The STA-R Evolution® proceeds with the checks and corrects the problems that it detects in real time (the check is displayed on the screen). The software initialization window is displayed.
7.	Click the  icon to initialize the main software application faster.

STA-R Startup and Specimen Processing for PROTIME, PTT, FIBINOGEN, & QUANTITATIVE D-DIMER, Continued

PREVENTATIVE MAINTENANCE & SUPPLY, CONTINUED

Step	Action
8.	The following message may be displayed: **"Rack Conveyor Initialization. Do you want to initialize the rack conveyor?"**: click Yes if you want all the racks and tubes on the conveyor to be re-identified, or No to avoid the conveyor being initialized. The following message is displayed: **"If you are sure that no sample was moved press Yes to cancel the Init."**, click Yes to confirm or if not, click No.

Controlled Documents

The following controlled documents support this procedure.

Reference
DIAGNOSTICA STAGO Reference Manual October2005, January 2006

Form

Author(s)

Document History Page

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.
Major	1) Added reference to reagent grade water source. 2) Remove any reference to LMWH. 3) Replaced any reference to LMS with Cerner. 4) Remove any reference to repeating any critical results. 5) Remove any reference to D-dimer results reporting protocol, P&P Office Procedures 04-555.	Julius Salomon 08/05/13			
Major	Page 7 – Removed "Coagulation Repeats/Critical Values" section. And added See Lab P&P 05-090-01 on Results Reporting section. Page 7 - Revised reporting procedure for results that's either < or > than reportable range to reflect current workflow in Cerner. Also revised reportable ranges to correctly reflect Cerner (LIS) ranges.	Julius Salomon 11/15/13			
Major	Page 7 1) added INR for PT reporting 2) added D-Dimer for DIC reporting	Julius Salomon 12/7/15			
Minor	Page 7 – added INR Verification section	Julius Salomon 10/12/16			
Minor	1. Changed the Coag Control N & ABN to Coag Control N & ABN Plus 2. Updated P&P format and Index	Marlon Esguerra 7/10/18			
Major	1. Added specimen clot check guidelines prior to reporting 2. Added step by step procedure for daily, weekly maintenance, startup and shutdown.	Marlon Esguerra 7/10/18			