Beaumont HEALTH

Beaumont Laboratory
Royal Oak

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Related Documents:
RC.HM.CG.PR.002 Coagulation Tests: Reportable Limits and Normal / Therapeutic Values
RC.HM.CG.PR.007 Coagulation Correlations
RC.HM.CG.PY.001 Autoverification Policy
RC.HM.CG.PR.096 IL ACL TOP Maintenance Procedure

IL ACL TOP Operations Procedure

RC.HM.CG.PR.095.r01

IL ACL-TOP Operations Procedure

I. Principle

A. The ACL TOP instrument performs the following types of tests:

i. Coagulometric (Turbidimetric) Measurements: The principle of coagulometric (turbidimetric) clot detection is used in the system to measure and record the amount of time required for a plasma specimen to clot. This technique assesses coagulation endpoint by measuring change in optical density. Clot detection is based on the principle that light passing through a medium in which fibrinogen is converted to fibrin is absorbed by the fibrin strands. Light (405 or 671 nm) is transmitted through a sample onto a photo detector, which is positioned 180° to the source. Light absorption increases as fibrin clot formation progresses. Consequently, light transmittance through the sample continuously decreases and is measured by the photodetector. The corresponding electrical signal output from the photodetector changes according to the detected light. The signal output is processed via software through a series of algorithms to determine the clot point.

ii. Chromogenic (Absorbance) Measurements

1. Chromogenic tests can be either direct or indirect.
    a. **Direct test** – Test where the analyte of interest (e.g. protein C, plasminogen) acts directly on a specified synthetic substrate.
    b. I**ndirect test** – Test where the analyte of interest (antithrombin, plasmin inhibitor) reacts with a fixed quantity of enzyme to form inactive complexes. Under optimized test conditions, residual enzyme activity is then measured using a specific synthetic substrate.

2. In most cases, the reaction is monitored at 405 nm by the continuous release of paranitroaniline (pNA) from the synthetic substrate. The chromogenic channels use the colorimetric principle of measuring absorbance in the cuvette. An optical sensor reads light (405 nm) that passes through the cuvette. The light is absorbed by the fluid in the cuvette in direct proportion to the concentration of pNA. The amount of light reaching the photodetector is converted into an electrical signal that is proportional to the enzyme activity.

iii. Immunological Measurements: The principle of immunological measurement is used on the system to directly measure and record the amount of an analyte. This technique assesses the physical concentration of the analyte (and not its activity) by measuring change in optical density. Although similar to the turbidimetric method, the immunological method relies on the formation of antigen-antibody complexes to affect light transmission. Immunological testing of the ACL TOP uses the 405 nm or the 671 nm channels depending on the test and the reagent formulation. Both the 405 nm and the 671 nm channels use the principle of measuring absorbance in the cuvette. An optical sensor reads the light (405 nm or 671 nm) that passes through the cuvette. The light is absorbed by the fluid in the cuvette in direct proportion to the concentration of antigen-antibody complexes. The amount of light reaching the photodetector is converted into an electrical signal that is proportional or inversely proportional to the analyte concentration.

II. Specimen Collection, Storage and Preparation

A. Refer to Coagulation Tests: Specimen Collection and Handling (Non-Platelet Function Tests Only) procedure.

III. Reagent, Controls & Stability

A. Refer to individual test procedure for specific calibrator, reagent and control stability.

B. **HemosIL Cleaning Solution:** For use with ACL TOP instruments (Clean A). It contains hydrochloric acid 100 mmole/L. Store at 15-25ºC C and use by the expiration date printed on the label. It is ready for use; no reconstitution necessary.

C. **HemosIL Cleaning Agent:** for use with ACL TOP instruments (Clean B). It contains sodium hypochlorite solution with less than 5% of available chlorine. Store at 15-25ºC and use by the expiration date printed on the label. It is ready for use; no reconstitution necessary.

D. **HemosIL Rinse Solution:** for use with ACL TOP instruments. It contains surfactant and preservatives. Store at 15-25ºC and use by the expiration date printed on the label. It is ready for use; no reconstitution necessary.

IV. Maintenance

A. Refer to IL ACL Top Maintenance Procedure for Daily, Weekly, Monthly, and as needed maintenance.

V. Quality Control

A. Quality control results go directly into control files on the ACL Top.
B. Frequency of Control Use:
   i. Controls should be run at least once every 8 hours, with reagent replacement, and with a new calibration curve.

VI. Procedure

A. **Switching on the IL**
   i. To start the instrument switch on the equipment in the following order:
      1. Make sure the access cover is closed.
      2. Power on the Control Module (A Microsoft Windows PC running the ACL TOP software developed by Instrumentation Laboratory. The CM provides the User Interface and data management functionality. The CM connects to the Analytical Module and provides the high-level controls.)
      3. Power on the Analytical Module (The part of the instrument where sample processing and testing are performed. Also called the AM or the Analyzer. Using the **On/Off** switch on the right side of the analyzer.
      4. Double-click the **ACL TOP**  icon on the desktop.
      5. Log onto the ACL TOP instrument.

B. **Shutting Down the Instrument**
   i. Make sure the Analytical Module (AM) is in the READY state.
      1. Select **Instrument > Exit** in the menu bar.
      2. Select **OK** on the confirmation dialog box. The AM begins an abbreviated mechanical initialization to place the analyzer into a known safe state.
      3. At the conclusion of the mechanical initialization, turn off the AM. The switch is located on the right side of the analyzer.
      4. Shut down the Control Module according to standard Windows procedures.

C. **Emergency Stop**
   i. An *Emergency Stop* immediately terminates all operations and motion on the Analytical Module. An emergency stop can be performed when the instrument is in any state except NOT CONNECTED, even when no user is logged on.

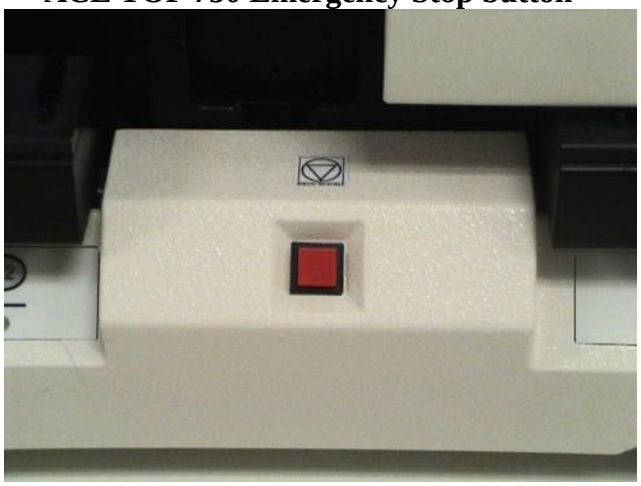
ii. ACL TOP 750 LAS: On the ACL TOP 750 LAS model, after an emergency stop has occurred and recovery is initiated, the Analytical Module notifies the Control Module of all cuvettes detected in the *LAS aspiration area*, the *LA holding area*, and in the *cuvette shuttle*. Only cuvettes in the *LAS holding area* with no previously aspirated sample are retained. Empty or partially aspirated cuvettes in the *LAS holding area*, are not restored after recovery from an emergency stop. These cuvettes are moved to the cuvette waste container. Upon recovery from an emergency stop, a primary sample tube must be reinserted onto the instrument in order to process TO DO jobs. This includes any HIL jobs that have not completed before an emergency stop if:

1. An emergency stop has occurred.
2. No aspirations have occurred from a cuvette in the *LAS holding area*, upon recovery, tests programmed in that cuvette are performed without needing to reinsert the primary sample tube onto the instrument.

iii. Performing an Emergency Stop:

a. Press the **red** Emergency Stop button on the front of the Analyzer.

ACL TOP 750 Emergency Stop button



ACL TOP 550 Emergency Stop button

D. **ACL TOP 750 LAS Controlled Stop**

i. Because the ACL TOP 750 LAS system has Auto Run always enabled, you must have the ability to stop processing samples at any time. The *LAS Controlled Stop* choice on the *Instrument* menu stops processing new samples. This is a *user-initiated* controlled stop. If selected while the instrument is in the BUSY state, it allows the tests that have already started to complete. Tests that had not started when the *LAS Controlled Stop* was initiated return to the PLACED state. When the ACL TOP 750 LAS status is STOPPED the following applies:

- **a.** New tubes from the LAS track are rejected.
- **b.** No new aspirations are performed.
- **c.** The sample tube currently in use is held at the track aspiration point.

ii. Performing a Controlled Stop

- **a.** Select **Instrument > Controlled Stop** in the menu bar.
- **b.** Select **OK** on the confirmation dialog box. If you select **Cancel** or close the confirmation dialog box without selecting **OK**, the Controlled stop request is canceled.
- **c.** After the LAS controlled stop completes, do one of the following to start a new analytical session and reactivate the Auto Run function. The instrument status will change from STOPPED to READY.
- **d.** Select **Instrument > Resume Auto Run** in the menu bar.
- **e.** Select the **Run** icon in the toolbar.
- **f.** Select **Actions > Map > Run Tests** in the menu bar.

E. **Reagent Area**

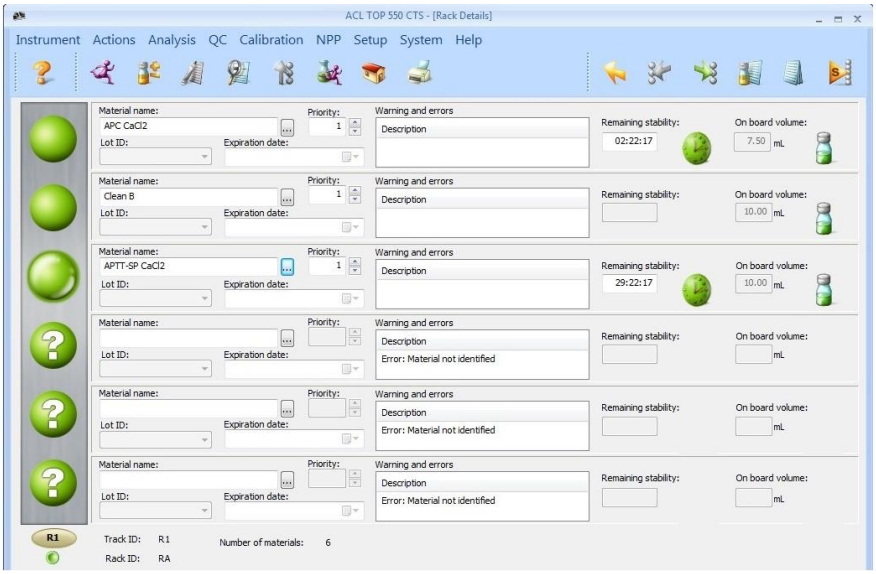
i. Each reagent rack in the Reagent Area holds up to six 20 mL or 15 mL bottles, but can also be used for the 4 mL and 10 mL bottles providing the correct adapter is inserted into the position on the rack. (See Reagent and restriction map page (9 and 10). When the rack is in use, an **amber** LED

indicates (during aspiration of material) it is locked. When the rack is no longer in use, the LED changes to **green** and the rack is accessible.

F. **Loading Non- Barcoded Reagents**

i. Select the **Reagent Area** icon, or select **Analysis > Reagent Area** in the menu bar.

ii. Insert the rack into the instrument



iii. Identify the unidentified material by selecting browse ellipsis ⋯ located next to the materials name field in the programming window.

1. There are additional tabs available for different types of testing.

iv. **CAUTION:** When loading *sample*, *diluent*, or *reagent* racks, pull the rack all the way out before loading. Pulling a rack out ***partially*** may result in incorrect identification of rack contents.

G. Colors and flags in rack loading

i. Icon Description Color

Icon	Description	Color
	NOT PLACED	Gray
	PLACED – UNIDENTIFIED	Green
	PLACED – IDENTIFIED	Green
	PLACED – WARNING	Yellow
	PLACED – ERROR	Red
	IN USE	Green
	IN USE – WARNING	Yellow
	IN USE – ERROR	Red

ii. Sample Status Color Codes:

1. **NOTE:** When the status of a sample rack is **green**, the rack can be removed. When the status changes to **amber** the sample rack is locked and cannot be removed.

Sample Status Color Codes		
Icon	Description	
	NOT PLACED	Gray
	TO DO	Light blue
	TO DO – Priority	Light blue
	PLACED – IDENTIFIED	Blue
	PLACED – Unidentified	Blue
	PLACED – Priority	Blue
	PENDING – IDENTIFIED	Orange
	PENDING - IDENTIFIED with Errors	Orange
	PENDING – Priority	Orange
	PENDING - Priority with Errors	Orange
	IN USE– IDENTIFIED	Purple
	IN USE - IDENTIFIED with Errors	Purple

iii. Reagent Remaining Stability and Reagent On-board Volume

Reagent Remaining Stability

Icon	Description	Color
	Stability OK	Green
	Stability Warning	Yellow
	Stability Alarm	Red

Reagent On-board Volume

Icon	Description	Color
	Volume OK	Green
	Volume Warning	Yellow
	Volume Alarm	Red
	On-board Waiting for Volume	

iv. Sample Area Operations Toolbar Icons

Sample Area Operations toolbar

1.  **Run Tests**. You can also select **Actions > Map > Run Tests** in the menu bar. This icon is disabled if the analyzer is running or is not READY.

2.  Open the Test Feasibility List.
3.  Open the Restriction Map.
4.  Open the **Rack Details** screen for the rack that has focus in the *Reagent Area* screen.
5.  Move the **Bar Code Reader** to its **Home Position**.
6.  **Print** a report that contains the following information:

i. Status of all inserted racks with material placed on-board.

ii. Status of on-board materials.

iii. **Note:** Useful when a maintenance activity is performed that requires the removal of material racks.

H. **Refer to Attachment A and Attachment B** for the specific calibrators, controls and reagents for each test performed on the IL ACL Top 750 LAS and 700/550 CTS.

I. **Loading Reagents, Controls and Calibrators**

i. After referring to Attachment A, load the required reagents and calibrators onto the instrument.

ii. Standards and controls use lanes D1 or D2.

iii. Use lane D1 or D2 for Factor Diluent.

iv. Push the rack until you feel it stop and click into place.

v. If the analyzer cannot recognize the barcode the Loading dialog will open.

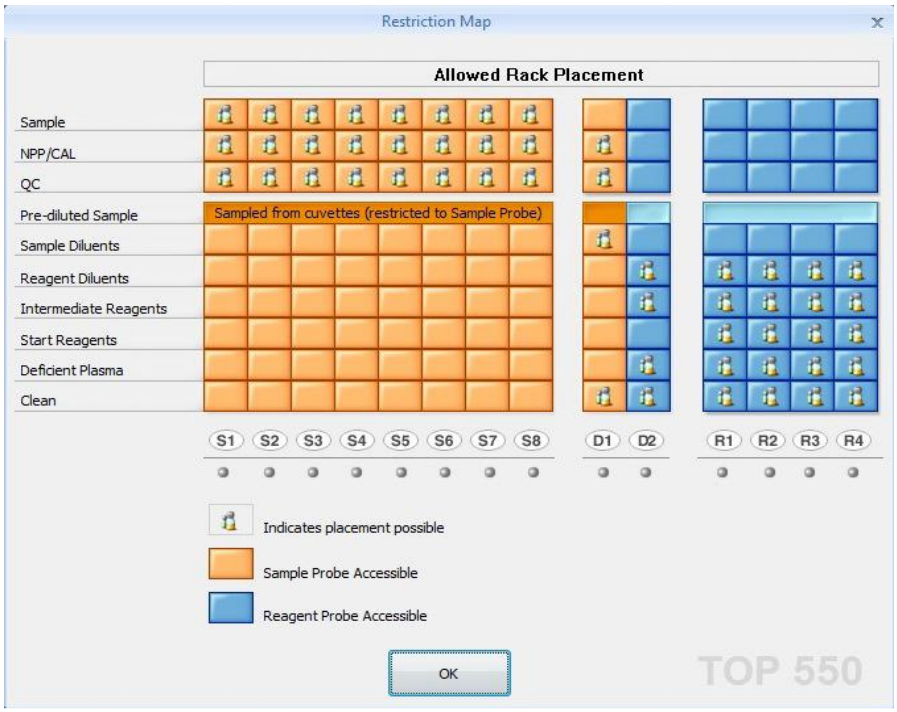
J. **Restriction Map**

i. The *Restriction Map* shows into which tracks you can insert various types of materials.

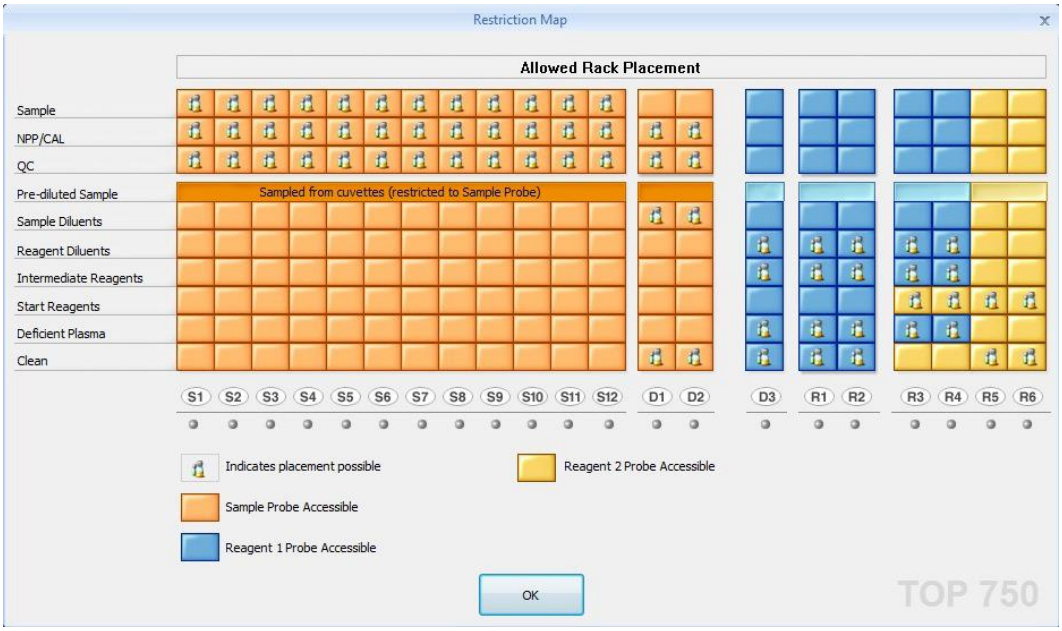
ii. I**MPORTANT – Many IL-defined tests use *Clean B diluted* as the clean material. When the *Clean B diluted* bottle is empty, the instrument performs an emergency stop, and all work in progress is lost. Hint: To avoid a loss of work, place multiple bottles of *Clean B diluted* on-board the instrument. For proper placement of all materials, see Test Feasibility**  **.**

iii. Make sure the bar code labels on sample tubes and on reagent bottles face outward in the rack so they can be read by the bar code scanner.

iv. **ACL TOP 550 CTS** – Clean materials used by the sample probe must be placed in track D1. Those used by the reagent probe must be placed in track D2 - R4.



v. **ACL TOP 750/700** – Clean materials used by the reagent probes must be placed in tracks D3- R2, R5 -R6.



K. **Calibration**

i. Calibration is performed:

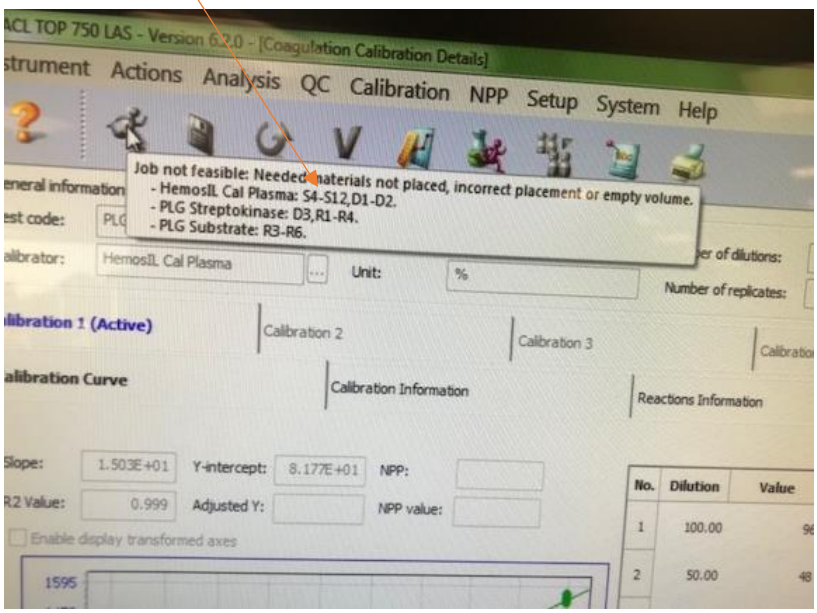
1. With a change of reagent lot numbers
2. After major parts replacement
3. To satisfy local regulatory requirements
4. Every 6 months

ii. Before performing a calibration, you must do the following:

1. Define the calibration materials.
2. In the *Test Definition* screen, define the *calibrator target value*.
3. Place all *reagents*, *diluents* and *calibrators* in the appropriate positions on the instrument. For proper placement of all materials, see test feasibility  icon.

iii. To Calibrate:

1. Always start with fresh Factor Diluent, verify all maintenance pertaining to probes and syringes is up to date, and perform the Enhance Clean for all Probes with fresh Clean B prior to calibration.
2. **Choose Setup, Material List**
3. Double-click on the appropriate calibrator to open the **Materials Definition** screen
4. Choose the **Lot Specific Information** tab and then **Enable Lot Management.**
5. Enter the calibrator lot number and expiration date
6. Select **Save** icon to store the lot number. Once the lot number is saved, **the Assign Values** icon becomes available.
7. Double click on the **Assign Values, Active lot field**.
8. Enter the calibrator value from the calibrator package insert on the ACL TOP Family. Choose OK.
9. For non-IL reagents, choose **Setup, Test list**, Select desired assay.
10. Select **Calibration, Auto dilution**, then verify or change the calibration target value if needed.
11. Load required calibrator, diluent, and reagents.
12. Select Calibration, Status, Double click desired test, then click Run  icon in toolbar.
13. If Run  icon is disabled, hover over the Run icon to display needed materials and their location to run the calibration.



iv. After calibration completes, review and validate calibration results:

1. To review calibration test results:
   - **a.** Select Calibration>Status List in the menu bar.
   - **b.** In the Calibration Status List, double-click a test code, or select a test code and select the Calibration Details icon to open the Calibration Details screen. By default, the Calibration Details screen opens displaying the VALIDATED calibration. If a test has no VALIDATED calibration, the Calibration Details screen displays Calibration 1.
   - **c.** Select the Calibration Curve tab to view the calibration curve and results for the various dilutions.
   - **d.** Select the Calibration Information tab to view calibration status information.
   - **e.** Select the Reactions Information tab to view the reaction curves for each point on the calibration curve as well as errors and warnings for specific data points.
   - **f.** Select the Tracking Information tab to view lot specific information for the materials used and a log of all comments related to the calibration.
2. To validate a calibration, select the appropriate tab (e.g., Calibration 1, 2, etc.), then select the Validate icon in the toolbar. The calibration data is stored in the system and is used to calculate calibrated results for future tests. Validation is not possible if any calibration check fails.

3. To recalculate a calibration, select the Recalculate Calibration icon. This replots the calibration curve according to the current test and material definitions. When recalculating calibration results, the system uses the calibrator lot number used during execution. If the lot number does not exist or the proper assigned values are not accessible, the recalculation fails.
4. Select the Save  icon in the toolbar to save your changes.

v. NOTES:

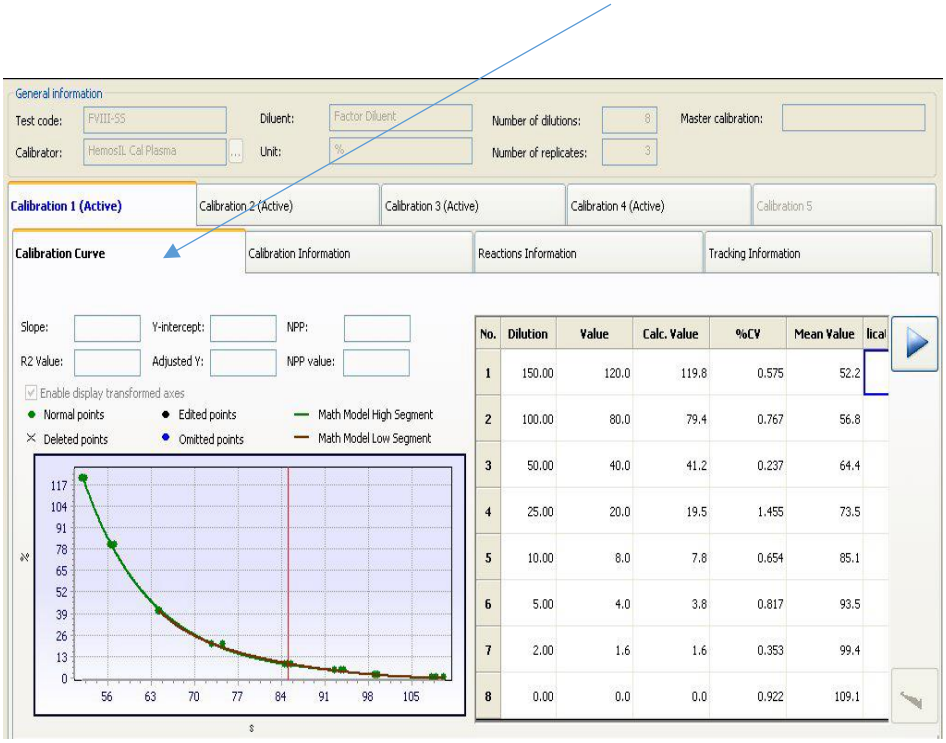
- If the calibration result has a warning and you validate the result despite the warning, that warning is not posted to the sample results. You are responsible for acknowledging the warning and ignoring it.
- FAILED calibrations may not be VALIDATED.
- A calibration becomes an alternate calibration when any of the material lots (other than the calibrator) used to generate the active calibration are no longer used on the system. When a calibration changes from *active* to *alternate*, the calibration status changes from VALIDATED to UNVALIDATED.
- The PT, APTT, TT, DRVVT assay and Activated Protein C on IL are straight line clotting time assays. No calibration is required.
- The FVIII Low and QFA low calibration curve must be validated
- All factors MD (more dilution) curves need to be calibrated.

L. **Calibration tabs**

i. The ACL TOP instrument can store the ten most recent calibrations. However, only one calibration can be validated at any time. After the 11th calibration runs, the oldest calibration is removed from the Calibration Details screen. The validated calibration cannot be removed. The tab is disabled if it contains no information. Select a *Calibration* tab to view the corresponding calibration details on the:

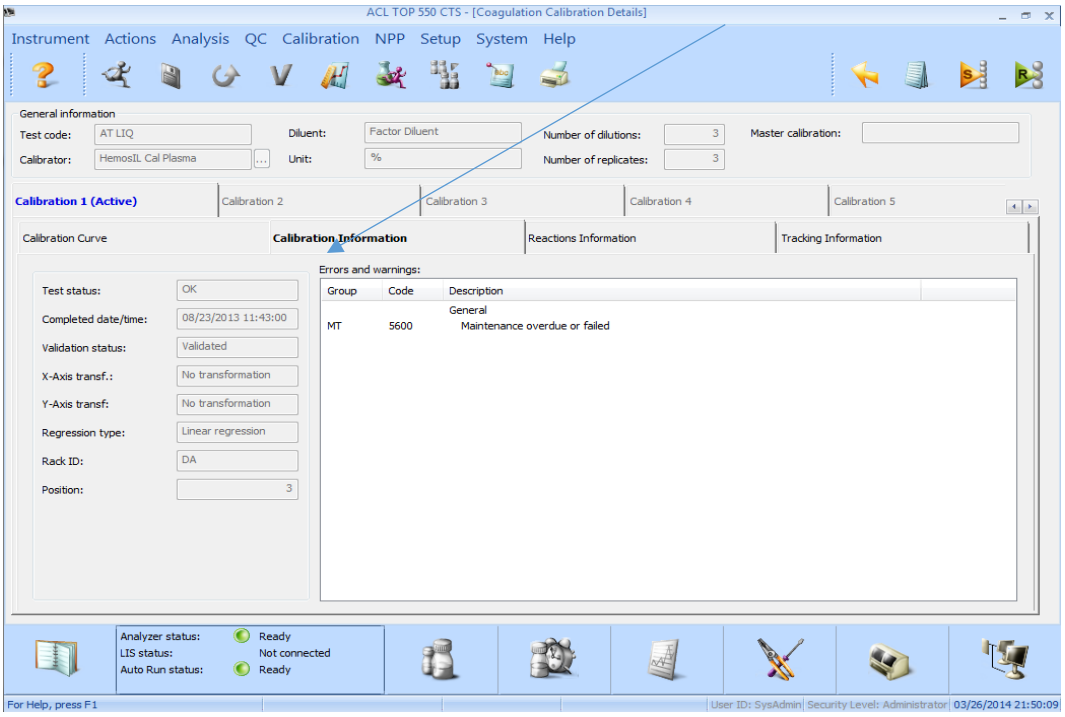
1. Calibration Curve
2. Calibration Information
3. Reaction Information
4. Tracking information tabs.

Calibration Details screen – Calibration Curve tab



ii. The Calibration Curve tab contains important information to help you decide which calibration to validate. A points and lines legend appears above the curve graph.

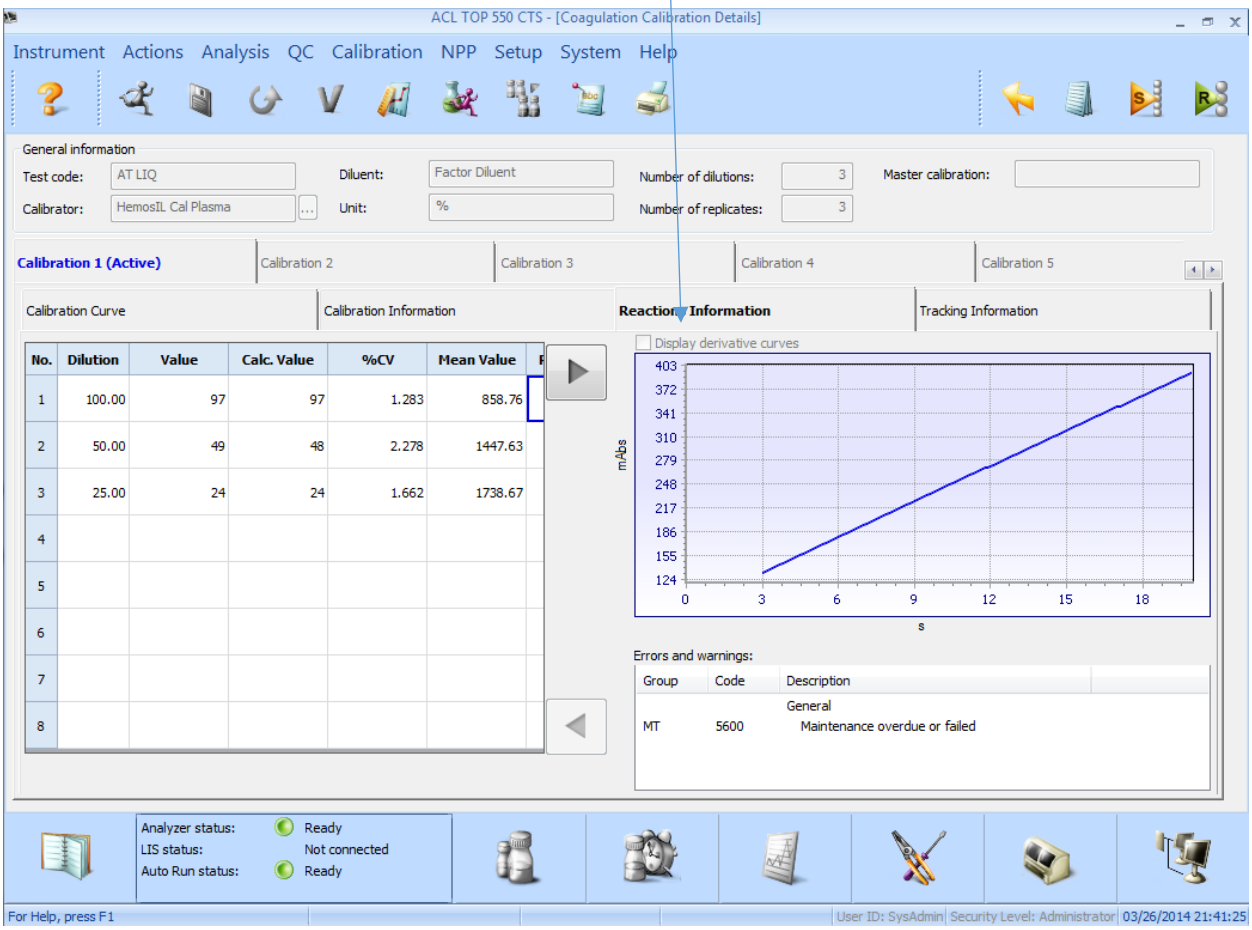
Calibration Details screen – Calibration Information tab



iii. **The Calibration Information tab** displays important status information about the calibration:

1. **Test status:** Displays OK or FAILED.
2. **Execution date/time:** Date and time the calibration was performed.
3. **Validation status:** Validation status of the calibration.
4. **Validation date/time:** Date and time the calibration was validated by the user.
5. **X-Axis trans:** Transformation method used to convert the X data into a value that produces a linear curve fit.
6. **Y-Axis trans:** Transformation method used to convert the Y data into a value that produces a linear curve fit.
7. **Regression type:** Type of regression used to plot the calibration curve.
8. **Rack ID:** Identifier of the rack where the calibration material was placed.
9. **Position:** Rack position where the calibrator was placed.

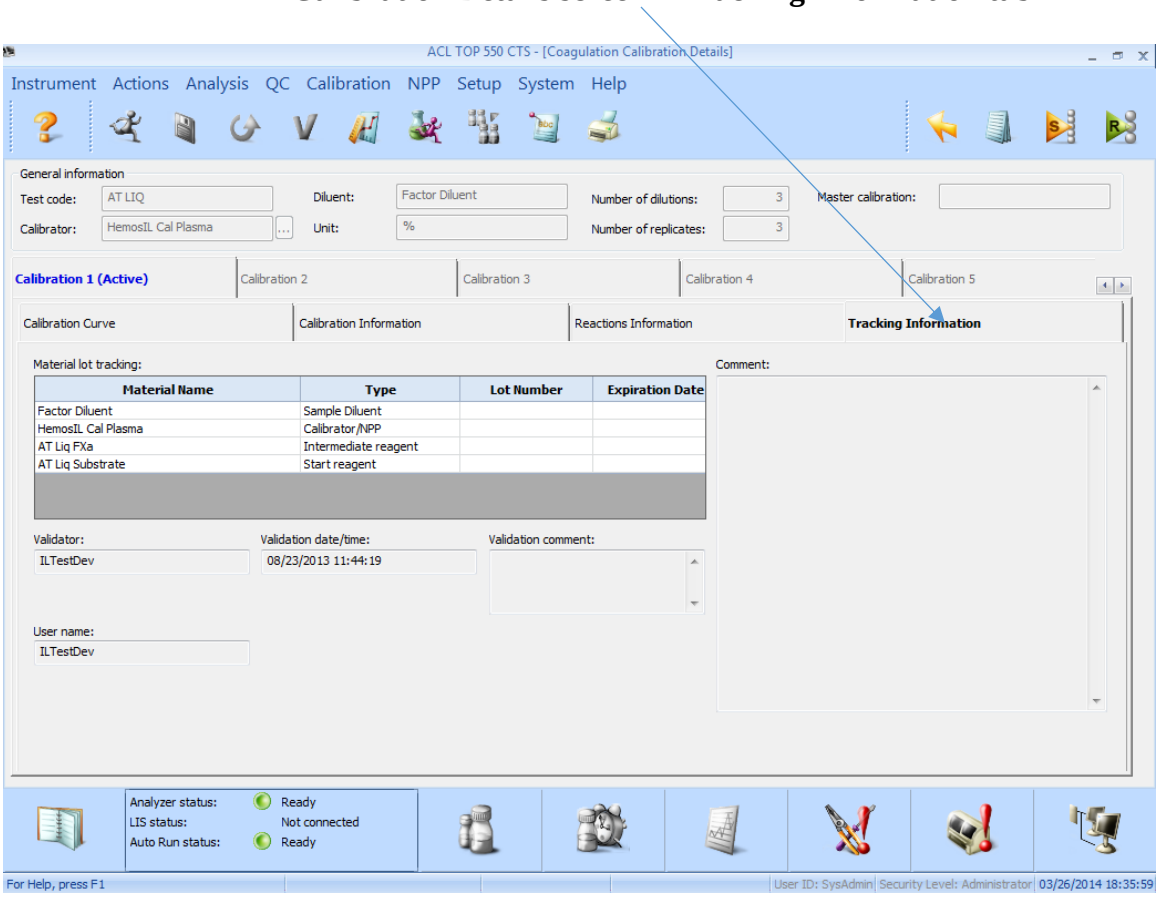
Calibration Details Screen-Reaction Information Tab



iv. The Reactions Information tab displays the following:

- **a.** Reaction curves for each point in the calibration curve.
- **b.** Errors and warnings specific to that data point. (Temperature errors and warnings are flagged only on replicates, no on the test as whole.) Displays error group, Code and Description data.
- **c.** No reaction curve is displayed for points that are manually edited.

Calibration Details screen – Tracking Information tab



2. **The *Tracking Information* tab** displays the materials used to perform the calibration.
    a. **Material lot tracking**
    b. **Material Name:** Name of the materials used to run the calibration.
    c. **Type:** types can be the following:
    d. Sample Diluent
    e. Calibration/NPP
    f. Intermediate Reagent
    g. Start Reagent
    h. Deficient Plasma
    i. **Lot Number:** Lot number of the materials used to run the calibration.
    j. **Expiration Date:** Expiration dates of the materials used to run the calibration.
    k. **Validation fields**
    l. **Validator:** The user ID who was logged in when the calibration was validated.

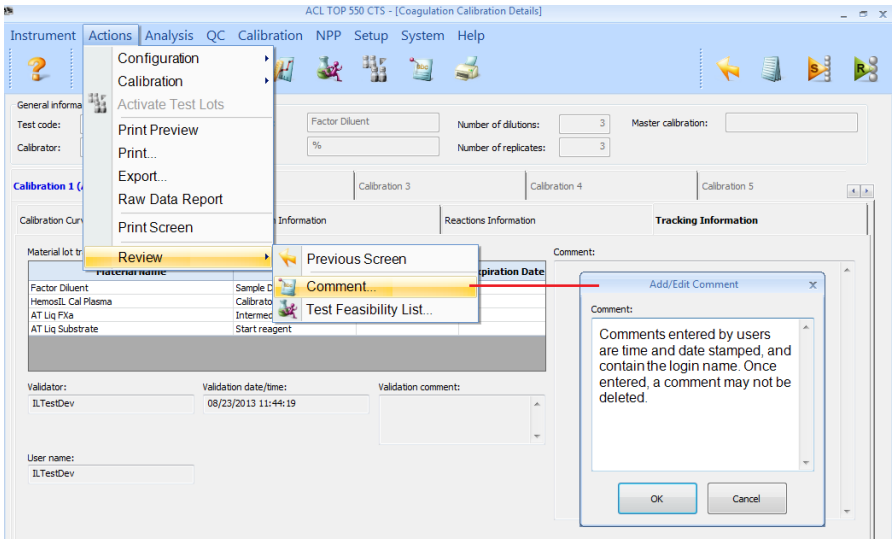
m. Validation date/time: Date and time the calibration was validated.

n. Validation comment: Optional comment entered by a user.

o. User name: User ID that was logged onto the instrument when the calibration was performed.

M. **Comments**

i. You can view and enter comments in the *Comments* field. Comments contain **Time**, **Date**, and **User ID**.



VII. Running Quality Control

A. Load reagents on to the instrument as represented in the Reagent Setup Map.

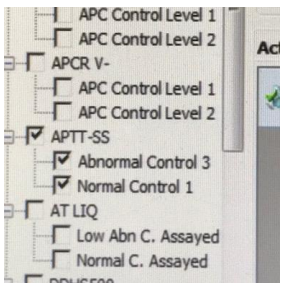
B. Load controls into the D1 or D2 diluent rack and insert them with barcodes facing out.

C. Controls can be poured into a 2 mL sample cup in the yellow rack **<u>without adapter</u>**

D. On the Menu Bar, click on QC.

E. Click on the QC Results List.

F. Double click on any test to open the QC Statistics Screen which is where the QC Navigation Tree is displayed.

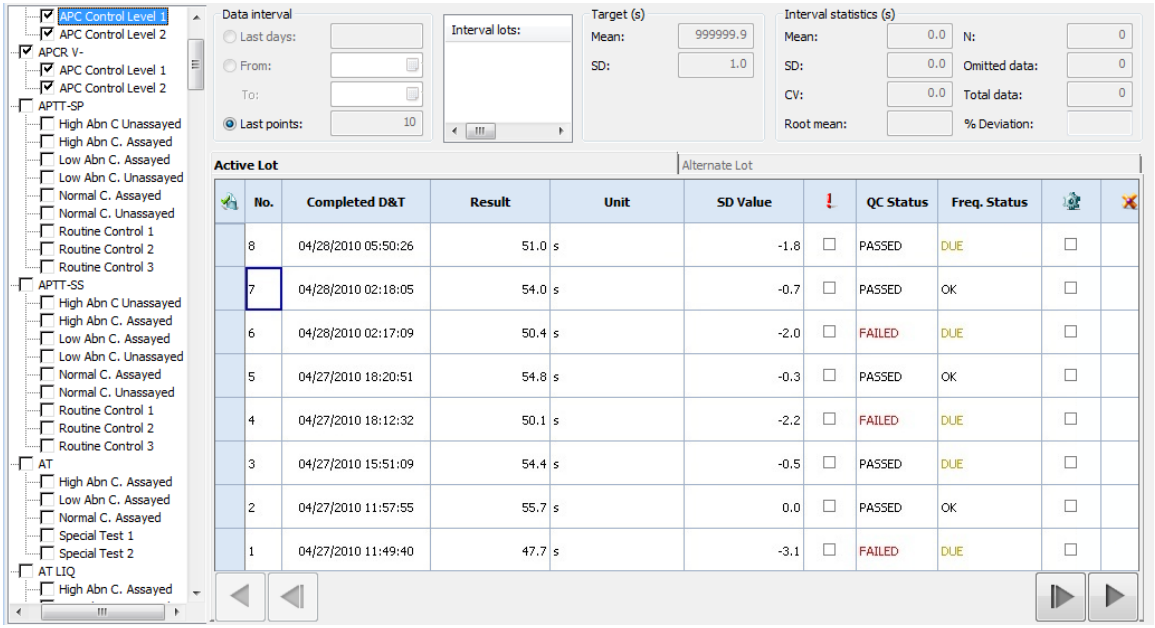


G. Select control(s) from each test listed by placing a checkmark next to that control or test. Click on the running man icon to start testing.

H. Press the Previous Screen icon to return to the QC results list where "Active" should be displayed for each control level being run.

I. When all controls are completed, the value will be displayed on this screen.

J. Again, Double click on any test to open the QC Statistics Screen.



K. Select each control to be sure it was run and that the QC value is in limits and does not show as "FAILED".

L. Patient results cannot be reported until any out of range control situation is resolved.

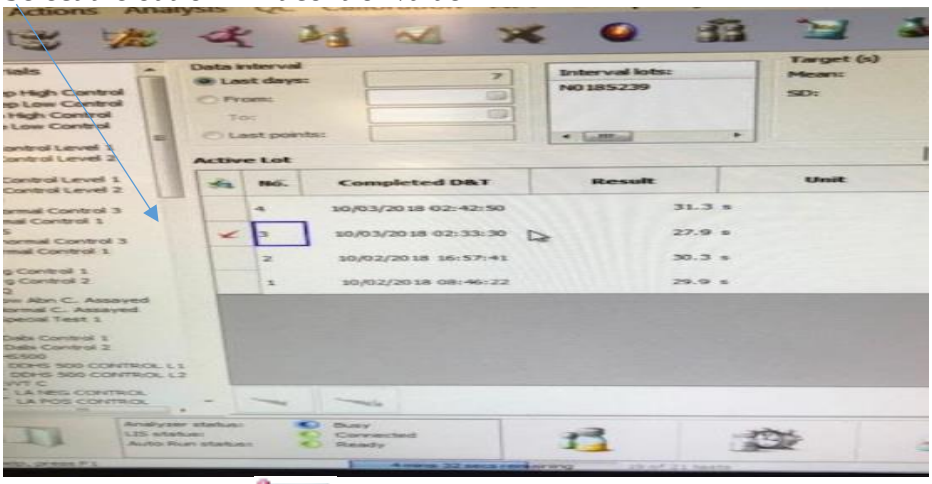
VIII. Corrective Action (controls out of limits):

A. Re-run control one time. If the new value is within control limits, proceed with patient specimens.

B. If the new value is also out-of-control, reconstitute one new vial of fresh control and retest.

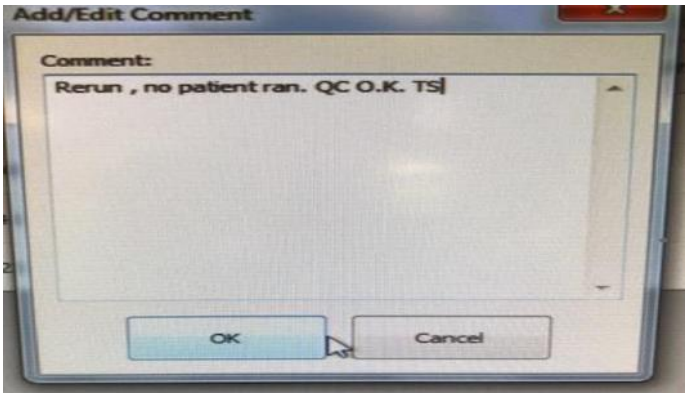
C. If fresh control value is also still out of control, check reagent stability, check analyzer function and perform troubleshooting as required. Do not run patient specimens until the problem is resolved and an acceptable value for the control material is obtained.

D. Select the out-of-limit control value



E. Click on Comment  icon

F. Enter a troubleshooting comment, action and your initials in the Add Comment dialog box.



G. Select OK to save the comment or Cancel to close the box without comment. The comment appears in this window stamped with the date and time.

H. For more details, refer to the ACL TOP Online Help.

I. Notify the supervisor/manager of problems. Document all problems and troubleshooting steps on the Coagulation Daily Communication Log.

IX. Loading Samples:

A. **Running Routine Coagulation Patient Samples**

i. Load reagents on to the instrument as represented in the Reagent Setup Map.

ii. Ensure QC has been run and is within established acceptable ranges.

iii. Place the capped samples in a **Blue CTS** sample rack with the bar code facing outwards. **Blue CTS** sample racks can only be used on 550/700 CTS instruments

iv. If you are running an uncapped sample, aliquot tube or a sample cup you MUST use the **Yellow** sample rack.
v. **NOTE:** 750 LAS does not have a cap piercer. Therefore, you cannot load samples with a cap or **Blue CTS** sample rack.
vi. **NOTE: If you run a capped sample in the Yellow sample rack, you will crash the Probe!**
vii. Press the desired "S" rack button and insert the rack into the TOP in any available rack position (labeled S1-S6 or S3-S12).
viii. The TOP will query the LIS for routine tests to run.
ix. Press the Sample List icon to see tests running and results.

B. **Running Special Coagulation Patient Samples**

i. Load reagents on to the instrument as represented in the Reagent Setup Map.
ii. Ensure QC has been run and is within established acceptable ranges.
iii. Load the **Yellow** sample rack to run uncapped samples and aliquot tubes with the bar code facing outwards.
iv. To access the Sample Area, select the **Sample Area**  icon in the toolbar, or select **Analysis > Sample Area** in the menu bar.
v. Click a test cell on the right side of the Rack Details screen.
vi. Select the **Add/Delete Tests** icon in the toolbar to open the Tests and Profiles dialog box. Or select the **ellipsis** button that appears on the right side of the test cell.
vii. Select a **test** or profile in the Tests and Profiles window. Select **OK**.
viii. Repeat these steps for each test to run on the sample.

C. **Programming Non-Bar Coded Samples Using the Offline Rack**

i. Select the **Sample Area**  icon in the toolbar, or select **Analysis > Sample Area** in the menu bar.
ii. Double-click a position on the offline rack (located on the left side of the screen) to display the Rack Details screen.
iii. On the screen: ID each sample position with the corresponding order number in the rack. Make sure the sample in the rack matches the ID shown on the screen.
iv. Select the **Insert Rack**  icon.
v. Insert the rack into the instrument.
vi. The TOP will query the LIS for routine tests to run. The user can also select the **Add/Delete Tests** icon in the toolbar to open the Tests and Profiles dialog box. Another option is for the user to select the **ellipsis** button that appears on the right side of the test cell.
vii. Select a **test** or profile in the Tests and Profiles window. Select **OK**.

viii. 7. Select the **Run**  icon in the toolbar.

ix. NOTES:

1. If you manually identify a material placed on the offline rack (sample, diluent, or reagent) and a tube or bottle containing a bar code is on the rack, the system attempts to match the information manually entered with the information on the bar code in that position. If the bar-coded information fails to match the manually entered information, the system generates an error message.
2. If you manually identify the presence of a material (tube, bottle, or sample cup) placed on the offline rack (sample, diluent, or reagent) and, upon insertion, the bar code reader does not detect the presence of that material, an error message appears for that position that the system was expecting to detect the material's presence.
3. If you fail to manually identify the presence of a material (tube, bottle, or sample cup) placed on the offline rack (sample, diluent, or reagent) and, upon insertion, the bar code reader does detect the presence of a material, an error message appears for each detected position that the system was not expecting to detect.

X. Errors and Alarms

A. **Error Alarm Warning:** When an error is generated, the analyzer stops processing new samples and performs a controlled stop.

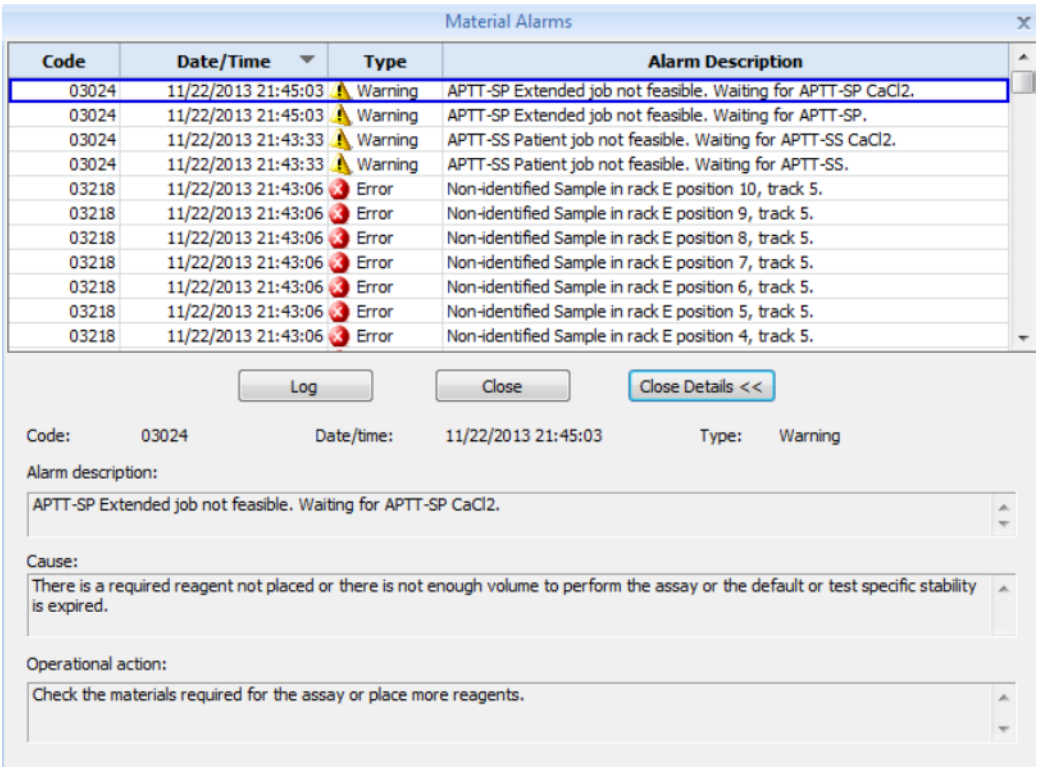
i. EXAMPLE: The Rinse fluid LED changes to red, and a red exclamation point appears on the Material Alarm Error  button on the Communication Manager (CM). In addition, the Rinse status light on the front of the Analytical Module turns red when the level of the rinse drops below 100mL.

B. **Error Data Flags:** An *Error* data flag indicates a condition has been detected, or an error limit exceeded, that will result in no test results generated. In normal conditions, samples are displayed on the screen with no flags. If a flag exists, it is displayed in capital letters, for example, CE (coagulation error), CW (coagulation warning). If a test and/or sample has multiple flags, the flag with the highest priority is displayed/printed with both capital letters underlined to indicate that there are more flags beyond what is displayed/printed. All flags and codes are listed in the Test Details screen.

C. **Accessing Alarm Messages**

i. To view an alarm message, do one of the following:

1. Select the alarm button at the bottom of the screen to open that alarm window.
2. Select **System > General Log** in the menu bar to view a list of all archived alarm messages.



3. Select the **General Log**  button on the left side of the status bar.

ii. **NOTE**: New alarm messages are displayed in bold text. When you close this window, the message text returns to normal font. The window can contain up to 200 messages. All messages that occur can be found in the General Log.

D. For more information about errors and alarms, please see the ACL TOP Family Series 50 Operator's Manual

XI. Attachments:

A. ACL TOP Family Series Reagents, Controls and Calibrations Stability.
B. ACL TOP Family Series Calibrator Chart

XII. References

A. ACL TOP Family Standard Operating Procedures, April 2017

XIII. Authorized Reviewers

A. Chair, Pathology and Laboratory Medicine
B. Medical Director, Coagulation

Attachment A: ACL TOP Family Series Reagents and Controls Chart

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
Antithrombin (Liquid)	Chromogenic Substrate	Ready to use, invert to mix before use.	Opened reagent is stable: 5 weeks at 2-8˚C in the original vial or 48 hours at 15˚C on the ACL TOP® Family instrument**. <u>Do not freeze.</u>**	(s) R3-R6
	Factor Xa Reagent			(I)D3,R1-R4
	Clean B Diluted	Dilute Cleaning Agent 1:8 with DI water (or equivalent) (1 ml Cleaning Agent + 7 ml DI water).	24 hours.	D3, R1-R2
	HemosIL Factor Diluent	Ready to use.	24 hours **(open a new bottle during calibration)**	D1-D2
QC	HemosIL Normal control assayed	Dissolve the contents of each vial of control with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 24 hours at 2-8 ˚C or 15-25 ˚C on board the ACL TOP.	D1-D2
	Low abnormal assayed			

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
Extrinsic Factor (II,V,VII,X)	HemosIL RecombiPlasTin 2G	Pipette the exact amount required (20 mL) of diluent into the vial of reagent. **DO NOT POUR** the contents of the diluent vial into the vial of RecombiPlasTin. Replace the stopper and swirl gently. Let sit for 15 to 20 minutes at 15-25˚C and invert to mix before use. **RecombiPlasTin 2G: Allow each vial of reagent and diluent to equilibrate at 15-25˚C for at least 15 minutes before reconstitution.	Stability after reconstitution: 10 days at 2-8°C, 5 days at 15-25°C in the original vial or 10 days at 15°C on the ACL TOP® Family	(s) R3-R6
	Factor-deficient plasma	Dissolve the contents of each required vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure complete reconstitution of the product. Keep at 15-25˚C for 30 minutes and invert to mix before use. Do no shake. Avoid foam formation.	Stability after reconstitution: 24 hours at 2-8˚C in the original vial or 24 hours at 15˚C on the ACL TOP® Family	D3, R1-R4
	Clean B Diluted	Dilute Cleaning Agent 1:8 with DI water (or equivalent) (1 ml Cleaning Agent + 7 ml DI water).	24 hours.	R5-R6
	Factor Diluent	Ready to use.	24 hours **(open a new bottle during calibration)**.	(D) D1-D2
QC	Normal Control assayed	Dissolve the contents of each vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 8 hours at 2-8˚C and 4 hours at 15-25˚C on board the ACL TOP.	D1-D2
	Special Test control level 2		Stability after reconstitution is 8 hours at 15-25˚C on board the ACL TOP.	

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
Intrinsic Factors (VIII,FIX,XI,XII)	SynthASil	Each vial of APTT reagent must be equilibrated at 15-25˚C for at least 15 minutes and mixed thoroughly before use.	Stability: 30 days at 2-8°C, or 10 days at 15°C on the ACL TOP® Family.	(D3, R1-R4)
	aPTT SS $CaCL_2$	Ready to use.	Opened reagent is stable 30 days at 2-30°C.	R3-R6
	Factor Deficient Plasma	Dissolve the contents of each required vial with 1 mL of DI water or equivalent.[11] Replace the stopper and swirl gently. Ensure complete reconstitution of the product. Keep at 15-25˚C for 30 minutes and invert to mix before use. Do no shake. Avoid foam formation.	Stability after reconstitution: 24 hours at 2-8˚C in the original vial or 24 hours at 15˚C on the ACL TOP® Family. **Stability for FVIII**: 24 hours at 2-8˚C in the original vial or at 15˚C on the ACL TOP® Family or 3 weeks at -20°C in the closed original vial. Frozen DP may be thawed once at 37°C and gently mixed before use. **Do no refreeze**	(D3, R1-R4)
	Factor Diluent	Ready to use.	24 hours **(open a new bottle during calibration)**.	(D) D1-D2
QC	Normal Control assayed	Dissolve the contents of each vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 8 hours at 2-8˚C and 4 hours at 15-25˚C on board the ACL TOP.	D1-D2
	Special Test Control level 2		Stability after reconstitution is 8 hours at 15-25˚C on board the ACL TOP.	

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
Factor V Leiden (APCR-V)	APC/APTT Reagent	Ready to use, mix thoroughly before use.	Opened reagent is stable 1 week at 15-25˚C, 1 month at 2-8°C in the original vial or 3 days at 15°C on the ACL TOP. Do not freeze.	(I)D3, R1-R4
	Factor V Reagent Plasma	Dissolve the contents of each required vial with 4 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure complete reconstitution of the product. Keep at 15-25˚C for 30 minutes and invert to mix before use. Do no shake. Avoid foam formation.	Stability after reconstitution is 8 hours at 15-25˚C, 24 hours at 2-8˚C, 3 months at -20˚C or below in the original vial or 3 days at 15˚C on the ACL TOP® Family. Frozen reagent should be thawed at 37˚C and gently mixed before use. Do not refreeze.	(I)D3, R1-R4
	APC/Calcium Chloride	Dissolve the contents of each required vial with 2 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure complete reconstitution of the product. Keep at 15-25˚C for 30 minutes and invert to mix before use. Do no shake. Avoid foam formation.	Stability after reconstitution is 8 hours at 15-25˚C, 5 days at 2-8˚C, 3 months at -20˚C or below in the original vial or 3 days at 15˚C on the ACL TOP® Family. Do not refreeze.	(S)R3-R6
	Calcium Chloride	Ready for use.	Opened reagent is stable 1 week at 15-25˚C, 1 month at 2-8°C in the original vial or 3 days at 15°C on the ACL TOP.	(S)R3-R6
	Clean B Diluted	Dilute Cleaning Agent 1:8 with DI water (or equivalent) (1 ml Cleaning Agent + 7 ml DI water).	24 hours.	R5-R6

QC	APC Control Plasma Level 1 & 2	Dissolve the contents of each required vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure complete reconstitution of the product. Keep at 15-25˚C for 30 minutes and invert to mix before use. Do no shake. Avoid foam formation	Stability after reconstitution is 6 hours at 2-8˚C and 15-25˚C or 3 months at -20˚C or below in the original vial. Frozen reagent should be thawed at 37˚C and gently mixed before use. Do not refreeze.	D1-D2

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
dRVVT Screen / dRVVT Confirm	dRVVT Screen	Dissolve the contents of each vial in the kit with 2 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the reagent at 15-25˚C for 30 minutes and invert to mix before use. Do not shake.	15 days at 2-8˚C or 3 days at 15˚C in their original vials on the ACL TOP® Family. For optimal stability remove reagents from the system and store them, closed, at 2-8°C in their original vials. **Do not freeze.**	(S) R3-R6
	dRVVT Confirm			
	Clean B Diluted	Dilute Cleaning Agent 1:8 with DI water (or equivalent) (1 ml Cleaning Agent + 7 ml DI water).	24 hours.	R5-R6
QC	LA Negative Control	Dissolve the contents of each vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 24 hours at 2-8˚C in the closed original vial and 24 hours at 15 ˚C on board the ACL TOP family.	D1-D2
	LA Positive Control			

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
Plasmin Inhibitor	Chromogenic Substrate	Dissolve the vial contents with 4 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure complete reconstitution. Keep at 15-25˚C for 30 minutes and mix gently before use.	Stability after reconstitution: 5 days at 2-8˚C, 3 months at -20°C in original vial, or 24 hours at 15˚C on the ACL TOP® Family.	(S) R3-R6
	Plasmin reagent	Dissolve the vial contents with 2.5 mL of **Diluted Buffer**. Replace the stopper and swirl gently. Ensure complete reconstitution. Keep the reagent at 15-25˚C for 30 minutes and mix gently before use	Stability after reconstitution: 5 days at 2-8˚C, 3 months at -20°C in original vial, or 24 hours at 15˚C on the ACL TOP® Family.	D3, R1-R4
	Buffer (**Diluted Buffer**)	Dilute the necessary quantity of the concentrated buffer 1:10 (1+9) with DI water or equivalent. Mix before use.	Buffer: Opened reagent stable until printed date kept at 2-8ºC in the original vial. **Diluted Buffer**: 24 hours at 15ºC.	D1-D2
QC	Normal Control assayed	Dissolve the contents of each vial with 1 mL of CLSI CLR water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 24 hours at 2-8˚C or 15-25˚C on board the ACL TOP.	D1-D2
	Special Test control level 2		Stability after reconstitution is 8 hours at 15-25˚C on board the ACL TOP.	

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
Plasminogen	Chromogenic Substrate	Dissolve the vial contents with **2 mL** of DI water or equivalent. Replace the stopper and swirl gently. Ensure complete reconstitution. Keep the substrate at 15-25˚C for 30 minutes and mix gently before use.	3 months at 2-8˚C in the original vial, 6 months at -20°C in original vial, or 5 days at 15˚C on the ACL TOP® Family	(S) R3-R6
	Streptokinase Reagent	Dissolve the vial contents with **2.5 mL** of DI water or equivalent. Replace the stopper and swirl gently. Ensure complete reconstitution. Keep the reagent at 15-25˚C for 30 minutes and mix gently before use		(I) D3, R1-R4
	Factor Diluent	Ready to use.	24 hours **(open a new bottle during calibration)**.	(D) D1-D2
QC	Normal Control assayed and	Dissolve the contents of each vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 24 hours at 2-8˚C or 15-25˚C on board the ACL TOP.	D1-D2
	Special Test control level 2		Stability after reconstitution is 8 hours at 15-25˚C on board the ACL TOP.	

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
Protein C (Clot)	Protein C Activator	Dissolve the contents of each required vial with **1.5 mL** DI water or equivalent. Replace the stopper and swirl gently. Ensure complete reconstitution of the product. Keep at 15-25˚C for 30 minutes and invert to mix before use. Do not shake.	15 days at 2-8˚C, or 60 days at -20˚C in the original vial.	**Not Loaded**
	Protein C Deficient Plasma	Dissolve the contents of each required vial with **1 mL** of DI water or equivalent. Replace the stopper and swirl gently. Ensure complete reconstitution of the product. Keep at 15-25˚C for 30 minutes and invert to mix before use. Do not shake.	4 hours at 15-25˚C on board the ACL Top, or 7 days at -20˚C in the original vial. *** Frozen reagent and plasma should be thawed at 37 ˚C and gently mixed before use. Do not refreeze.	D1-D2
	ProClot Diluent	Ready to use (not included in kit).	Opened reagent stable until printed date.	**Not loaded**
	Working Diluent	Add 1 parts Protein C Activator to 4.3 parts of ProClot diluent. Invert to mix.	Stability after preparation is 8 hours @ 2-8˚C.	D1-D2
	APTT-SP	Ready for use. Shake silica dispersion vigorously for 15 seconds, or vortex for 5 seconds before use.	30 days at 2-8˚C or 5 days at 15-25˚C on board the ACL Top.	(I) D3, R1-R4
	APTT-SP-$CaCl_2$	Ready for use.	30 days at 2-8˚C.	(S) R3-R6
	Factor Diluent	Ready to use.	24 hours **(open a new bottle during calibration)**.	(D) D1-D2
QC	HemosIL Normal control assayed	Dissolve the contents of each vial of control with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the	Stability after reconstitution: 24 hours at 2-8 ˚C or 15-25 ˚C on board the ACL TOP.	D1-D2

	Low Abnormal assayed	complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.		

Tests	**Reagents**	**Reconstitution**	**Stability**	**Lane on ACL Top**
Protein S Activity	Protein S reagent	Dissolve the contents of each vial with **2 mL** of DI water or equivalent. Replace the stopper and swirl gently. Make sure of the complete reconstitution of the product.	After reconstitution, 8 hours @ 15˚C on-board, 24 hours at 2-8˚C.	(I) D3, R1-R4
	Calcium Reagent	Ready to use. Invert to mix before use.	8 hours at 15˚C on-board the ACL TOP, 24 hours @ 2-8˚C.	(S) R3-R6
	Protein S deficient plasma	Dissolve the contents of each vial with **2 mL** of DI water or equivalent. Replace the stopper and swirl gently. Make sure of the complete reconstitution of the product. Keep the reagent at 15-25°C for 30 minutes and invert to mix before use. Do not shake.	6 hours at 15˚C on-board the ACL TOP.	(I) D3, R1-R4
	Clean B Diluted	Dilute Cleaning Agent 1:8 with DI water (or equivalent) (1 ml Cleaning Agent + 7 ml DI water).	24 hours.	R5-R6
	Factor Diluent	Ready to use.	24 hours **(open a new bottle during calibration)**.	(D) D1-D2
QC	Normal control assayed	Dissolve the contents of each vial of control with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at	Stability after reconstitution: 24 hours at 2-8 ˚C, 4 hours at 15-25 ˚C on board the ACL TOP.	D1-D2

	Low Abnormal assayed	15-25ºC for 30 minutes and invert to mix before use.		

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
VWF Activity	Latex Reagent	Dissolve the contents of each vial by pouring the entire contents of one vial of Buffer into one vial of Latex Reagent. Replace the stopper and swirl gently for a minimum of 20 seconds to completely dissolve the lyophilized latex. Ensure complete reconstitution of the product. It must appear as a homogenous and slightly milky suspension. Keep the reagent at 15-25˚C for 30 minutes and invert to mix before use. Do not shake.	Stability after reconstitution: 1 month at 2-8ºC in the original vial after opening, 5 days at 15°C on the ACL TOP® Family. Do not freeze.	R3-R6
	Buffer	Ready to use.	n/a	Not loaded
	Factor Diluent	Ready to use.	24 hours **(open a new bottle during calibration)**.	(D) D1-D2
QC	Normal Control assayed	Dissolve the contents of each vial with 1 mL of CLSI CLR water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 24 hours at 2-8ºC or 15-30ºC on board the ACL TOP	D1-D2
	Special Test control level 1		Stability after reconstitution is 8 hours at 15-30ºC	

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
VWF Antigen	Latex Reagent	Ready to use. Invert to mix before use.	3 months at 2-8ºC in the original vial after opening or 1 week at 15°C on the ACL TOP® Family. Do not freeze.	(S) R3-R6
	Reaction Buffer	Ready to use. Invert to mix before use.	3 months at 2-8ºC in the original vial after opening or 1 week at 15°C on the ACL TOP® Family. Do not freeze.	(I) D3, R1-R4
QC	Normal Control assayed	Dissolve the contents of each vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 24 hours at 2-8ºC or 15-30ºC on board the ACL TOP	D1-D2
	Special Test control level 2		Stability after reconstitution is 8 hours at 15-30ºC	

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
PT	HemosIL RecombiPlasTin 2G	Allow each vial of reagent and diluent to equilibrate at 15-25˚C for at least 15 minutes before reconstitution. Pipette the exact amount required 20 mL of diluent into the vial of reagent. DO NOT POUR the contents of the diluent vial into the vial of RecombiPlasTin. Replace the stopper and swirl gently. Let sit for 15 to 20 minutes at 15-25˚C and invert to mix before use.	Stability after reconstitution: 10 days at 2-8°C, 5 days at 15-25°C in the original vial or 10 days at 15°C on the ACL TOP® Family	(S) R3-R6
	Clean B Diluted	Dilute Cleaning Agent 1:8 with DI water (or equivalent) (1 ml Cleaning Agent + 7 ml DI water).	24 hours.	R5-R6
QC	Normal Control 1	Dissolve the contents of each vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 24 hours at 2-8°C or 15-30°C on board the ACL TOP.	D1-D2
	Abnormal Control 3			

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
APTT	HemosIL SynthASil APTT reagent	Ready to use. Each vial of APTT reagent must be equilibrated at 15-25˚C for at least 15 minutes and mixed thoroughly before use.	Stability after reconstitution: 30 days at 2-8°C, 10 days at 15°C on the ACL TOP® Family	R1-R4
	CaCl2	Ready to use. Each vial of APTT reagent must be equilibrated at 15-25˚C for at least 15 minutes and mixed thoroughly before use.	30 days at 2-30°C	R3-R6
QC	Normal Control 1	Dissolve the contents of each vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 24 hours at 2-8°C or 15-30°C on board the ACL TOP.	D1-D2
	Abnormal Control 3			

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
Fibrinogen	HemosIL Q.F.A. Thrombin	Allow each vial of reagent to equilibrate at 20-25˚C for **at least 15 minutes before reconstitution**. Pipette the exact amount required 2 mL of DI water or equivalent. Replace the stopper and swirl gently make sure of the complete reconstitution of the product. Let sit for 30 minutes at 20-25˚C and invert to mix before use.	Stability after reconstitution: 7 days at 2-8°C or 15-25°C on board the ACL TOP.	(S)R3-R6
	Clean B Diluted	Dilute Cleaning Agent 1:8 with DI water (or equivalent) (1 ml Cleaning Agent + 7 ml DI water).	24 hours.	R5-R6
	Factor Diluent	Ready to use.	24 hours **(open a new bottle during calibration)**.	(D) D1-D2
QC	Normal Control 1	Dissolve the contents of each vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution: 24 hours at 2-8°C or 15-30°C on board the ACL TOP.	D1-D2
	HemosIL Low Fibrinogen Control			

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
D-Dimer HS 500	Latex Reagent	Ready to use. Gently swirl several times to mix before use. Do not shake. **Avoid foam formation.** (Replace with reaction buffer.)	Opened reagent is stable 1 month at 2-8ºC in the original vial or 7 days at 15°C on the ACL TOP® Family.	R3-R6
	Reaction Buffer	Ready to use. Gently swirl several times to mix before use. Do not shake. **Avoid foam formation.** (Replace with latex reagent.)	Opened reagent is stable 1 month at 2-8ºC in the original vial or 7 days at 15°C on the ACL TOP® Family.	D3, R1-R4
	Clean B Diluted	Dilute Cleaning Agent 1:8 with DI water (or equivalent) (1 ml Cleaning Agent + 7 ml DI water).	24 hours.	R5-R6
	Factor Diluent	Ready to use.	24 hours **(open a new bottle during calibration)**.	(D) D1-D2
QC	Low D-D HS 500 Control	Controls are liquid and should be mixed by gentle inversion several times before use to assure homogeneity. Do not shake. **Avoid foam formation.**	Stability after reconstitution: 1 month at 2-8°C, 24 hours when placed continuously at 15-25°C onboard the ACL TOP® Family, 5 days when controls are on board for 1 hours each time, twice daily and the vials are returned well capped to 2-8°C between sessions.	D1-D2
	High D-D HS 500 Control			

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
Thrombin Time	Buffer	Dilute the necessary quantity of concentrated buffer 1:5 of DI water or equivalent (2mL of buffer+ 8mL DI water). Mix before use.	Discard after use.	Not Loaded
	Bovine Thrombin	Dissolve the vial contents with 8 mL of **diluted buffer.** Replace the stopper and swirl gently. Ensure complete reconstitution. Keep the reagent at 15-25˚C for 30 minutes and mix gently before use.	15 days at 2-8˚C in the original vial, or 24 hours at 15-25˚C on board the ACL TOP.	(S) R3-R6
	Clean B Diluted	Dilute Cleaning Agent 1:8 with DI water (or equivalent) (1 ml Cleaning Agent + 7 ml DI water).	24 hours.	R5-R6
QC	Normal Control 1	Dissolve the contents of each vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Ensure the complete reconstitution of the product. Keep the control at 15-25ºC for 30 minutes and invert to mix before use.	Stability after reconstitution is 24 hours at 2-8˚C or 15-25˚C on board the ACL TOP.	D1-D2
	Low Abnormal Control Assayed			

Tests	Reagents	Reconstitution	Stability	Lane on ACL Top
Liquid Anti-Xa	Chromogenic Substrate	Invert to mix before use.	Opened reagent is stable: 1 month at 2-8°C or 7 days at 15° - 25°C on-board the ACL TOP® Family in the original vial	(I) D3, R1-R4
	Factor Xa Reagent	Invert to mix before use.	Opened reagent is stable: 1 month at 2-8°C or 7 days at 15° - 25°C on-board the ACL TOP® Family in the original vial.	(S) R3-R6
	Clean B Diluted	Dilute Cleaning Agent 1:8 with DI water (or equivalent) (1 ml Cleaning Agent + 7 ml DI water).	24 hours.	R5-R6
QC	Low LMW Control and High LMW Control	Reconstitute each required vial with 1.0 mL of DI water or equivalent. Replace the stopper and keep controls at 15-25ºC for 30 minutes. Ensure the complete reconstitution of the controls. Gently swirl and invert to mix before use. Do not shake. Avoid foam formation.	Reconstituted controls are stable: 24 hours at 15-25°C on-board the ACL TOP® Family, or 48 hours at 2-8°C in the original vial.	D1-D2
	Low UNF Control and High UNF Control			

Attachment B: ACL TOP Family Series Calibrator Chart

Tests	Calibrator	Reconstitution	Stability	Lane on ACL TOP
AT PS ProC clot Q.F.A. Fibrinogen Plasminogen Plasmin Inhibitor VWF Activity VWF Antigen Intrinsic Factors Extrinsic Factors	Calibrator Plasma	Dissolve the contents of each vial with 1mL of DI water or equivalent. Replace the stopper and swirl gently. Make sure of the complete reconstitution of the product. Keep the reagent at 15-25ºC for 30 minutes and invert to mix before use. Do not shake. Avoid foam formation.	Stability after reconstitution 24 hours at 2-8ºC in the original vial for Fibrinogen, AT, PC, PS, Plasminogen, Plasmin inhibitor 8 hours at 2-8ºC in the original vial Factors.	S4-S12,D1-D2
ProC Clot	Protein C control Plasma		Stability after reconstitution is 4 hours at 15-25˚C or 7 days at -20˚C in the original vial.	
D-Dimer HS	D-Dimer Calibrator		Reconstituted calibrator is stable for 3 days at 15-25ºC, 1 month at 2-8ºC or 2 months at –20ºC in the original vial. Frozen Calibrator may be thawed at 37ºC and gently mixed before use. Do not refreeze.	
Heparin Calibrators	Heparin Calibrator (1,2,3)		Reconstituted calibrators are stable: 24 hours at 15-25°C on-board the ACL TOP® Family, or 48 hours at 2-8°C in the original vial.	

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Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: Tamara Sabih, MLS(ASCP) and Rebecca Bacarella, MLS(ASCP)	09/27/2018			
Approved by: Marc Smith, MD	10/02/2018			
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Marc Smith, MD	10/02/2018	00	New procedure for new instrumentation.	OK
Peter Millward, MD	10/01/2018			
Marc Smith, MD	1/8/2020	01	Added a note for calibration and more detailed steps Pg11 Added a notes regarding validating low curves Pg13. Added running QC in a sample cup Pg18.	OK