Beaumont

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Document Contact: *Tamara Sabih: Medical Technologist Lead*
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Coagulation- IL ACL TOP Operations-RO

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This procedure is a guidance for the medical technologist to operate IL ACL TOP on a daily basis. Also, it provides information to trouble shoot quality controls, calibration curves when it is necessary.

II. PRINCIPLE:

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

1. **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.
2. **Chromogenic (Absorbance) Measurements**
    a. **Chromogenic tests can be either direct or indirect.**
        i. **Direct test –** Test where the analyte of interest (e.g. protein C, plasminogen) acts directly on a specified synthetic substrate.
        ii. **Indirect 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.
    b. 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.

3. **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.

III. ACRONYMS:

A. Activated Partial Thromboplastin Time (aPTT)
B. Activated Protein C resistance (APCR)
C. Analytical Module (AM)
D. Antithrombin (AT3)
E. Control Module (CM)
F. Diluted Russell's Viper Venom Time Confirm (DRVVT C)
G. Diluted Russell's Viper Venom Time Screen (DRVVT S)
H. Fibrin Split Product (FSP)
I. Hemolysis,Icteric, Lipemic (HIL)
J. Lab Test Directory (LTD)
K. Low Molecular Weight Heparin (LMWH)
L. Platelet Function Analysis (PFA)
M. Protein C (PC)
N. Protein S (PS)
O. Prothrombin Time (PT)
P. Quality Control (QC)
Q. Standard of Practice (SOP)
R. Thrombin Time (TT)
S. Unfractionated Weight Heparin (UNFH)
T. Von Willebrand Activity (VWF ACT)
U. Von Willebrand Antigen (VWFAG)

IV. PROCEDURE:

A. **Specimen Collection, Storage and Preparation:**

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

B. **Reagent, Controls & Stability:**

1. Refer to individual test procedure for specific calibrator, reagent and control stability.
2. **HemosIL Cleaning Solution**: For use with ACL TOP instruments (Clean A). It contains hydrochloric acid 100 mmole/L. Store at 15-25^{o}C C and use by the expiration date printed on the label. It is ready for use; no reconstitution necessary.
3. **HemosIL Cleaning Agen**t: for use with ACL TOP instruments (Clean B). It contains sodium hypochlorite solution with less than 5% of available chlorine. Store at 15-25^{o}C and use by the expiration date printed on the label. It is ready for use; no reconstitution necessary.
4. **HemosIL Rinse Solution:** for use with ACL TOP instruments. It contains surfactant and preservatives. Store at 15-25^{o}C and use by the expiration date printed on the label. It is ready for use; no reconstitution necessary.

C. **Maintenance:**

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

D. **Quality Control:**

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

E. **Switching ON the IL:**

1. **To start the instrument switch ON the equipment in the following order:**
   a. Make sure the access cover is closed.
   b. 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.)
   c. 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.
   d. Double-click the ACL TOP  icon on the desktop.
   e. Log onto the ACL TOP instrument.
2. **Shutting Down the Instrument**
   a. Make sure the Analytical Module (AM) is in the READY state.
      i. Select **Instrument > Exit** in the menu bar.
      ii. Select **OK** on the confirmation dialog box. The AM begins an abbreviated mechanical initialization to place the analyzer into a known safe state.
      iii. At the conclusion of the mechanical initialization, turn off the AM. The switch is located on the right side of the analyzer.

iv. Shut down the Control Module according to standard Windows procedures.

F. **Emergency Stop:** 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.

1. ACL TOP 750 LAS model, after an emergency stop has occurred and recovery is initiated, the Analytical Module notifies the CM 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:
    a. An emergency stop has occurred.
    b. 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.
2. **Performing an Emergency Stop:**
    a. Press the red Emergency Stop button on the front of the Analyzer.

G. **ACL TOP 750 LAS Controlled Stop:**

1. 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
2. **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.

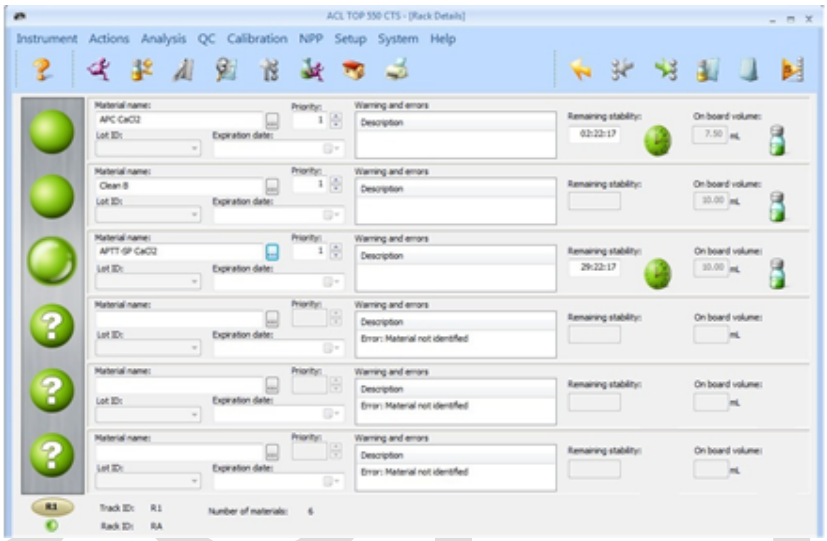
H. **Reagent Area**

1. 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. 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.

I. **Loading Non- Barcoded Reagents**

1. Select the Reagent Area icon, or select **Analysis > Reagent Area** in the menu bar.
2. Insert the rack into the instrument
3. Identify the unidentified material by selecting browse ellipsis located next to the materials name field in the programming window. There are additional tabs available for different types of testing.
4. 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.



J. **Colors and flags in rack loading**

1. 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

2. 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

3. 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	

4. Sample Area Operations Toolbar Icons

a.  **Run** this icon is disabled if the analyzer is running or is not READY.

b.  **Feasibility List**.

c.  **Restriction Map**.

d.  **Rack Details** screen for the rack that has focus in the Reagent Area screen.

e.  Move the **Bar Code Reader** to its Home Position.

f.  **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.

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

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

1. After referring to Attachment A, load the required reagents and calibrators onto the instrument.
2. Standards and controls use lanes D1 or D2.
3. Use lane D1 or D2 for Factor Diluent.

4. Push the rack until you feel it stop and click into place.
5. If the analyzer cannot recognize the barcode the Loading dialog will open.

M. **Restriction Map**

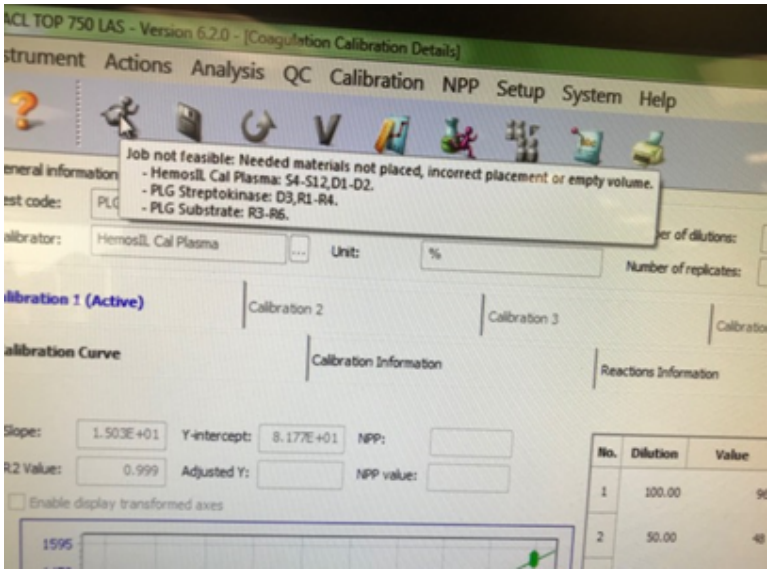
1. The Restriction Map shows into which tracks you can insert various types of materials.
2. Many IL-defined tests use Clean B diluted as the clean material. When the Clean B diluted bottle is empty, the instrument performs an emergency stop, and all work in progress is lost.
3. **Hint**: To avoid a loss of work, place multiple bottles of Clean B diluted on-board the instrument. For proper placement of all materials, see **Test Feasibility**.
4. 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.
5. **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.

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

N. **Calibration**: Calibration is performed with a change of reagent lot numbers, after major parts replacement, to satisfy local regulatory requirements, or every 6 months.

1. **Before performing a calibration**, you must do the following:
    a. Define the calibration materials.
    b. In the Test Definition screen, define the calibrator target value.
    c. Place all reagents, diluent and calibrators in the appropriate positions on the instrument. For proper placement of all materials, see test feasibility icon.
2. **To Calibrate:**
    a. 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.
    b. **Choose Setup, Material List**
    c. Double-click on the appropriate calibrator to open the **Materials Definition** screen
    d. **Choose the Lot Specific Information tab and then Enable Lot Management.**
    e. Enter the calibrator lot number and expiration date
    f. Select **Save** icon to store the lot number. Once the lot number is saved, **the Assign Values** icon becomes available.
    g. Double click on the **Assign Values, Active lot field**.
    h. Enter the calibrator value from the calibrator package insert on the ACL TOP Family. Choose OK.
    i. For non-IL reagents, choose **Setup, Test list**, Select desired assay.
    j. Select **Calibration, Auto dilution**, then verify or change the calibration target value if needed.
    k. Load required calibrator, diluent, and reagents.
    l. Select Calibration, Status, Double click desired test, then click Run icon in toolbar.
    m. If Run icon is disabled, hover over the Run icon to display needed materials and their location

to run the calibration



3. **After calibration completes,** to review and validate calibration results:
    a. To review calibration test results:
        i. Select Calibration>Status List in the menu bar.
        ii. 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.
        iii. Select the Calibration Curve tab to view the calibration curve and results for the various dilutions.
        iv. Select the Calibration Information tab to view calibration status information.
        v. 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.
        vi. Select the Tracking Information tab to view lot specific information for the materials used and a log of all comments related to the calibration.
    b. 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.
    c. 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.
    d. Select the Save icon in the toolbar to save your changes.
    e. 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.

f. FAILED calibrations may not be VALIDATED.

g. 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.

h. The PT, APTT, TT, DRVVT assay and Activated Protein C on IL are straight line clotting time assays. No calibration is required.

i. **The FVIII Low and Fibrinogen low calibration curve must be validated**

j. **All factors MD (more dilution) curves need to be calibrated.**

4. **Calibration tabs**

a. 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:

i. **Calibration Curve:** contains important information to help you decide which calibration to validate. A points and lines legend appears above the curve graph.

ii. **Calibration Information:** displays important status information about the calibration:

a. **Test status:** Displays OK or FAILED.

b. **Execution date/time:** Date and time the calibration was performed.

c. **Validation status:** Validation status of the calibration.

d. **Validation date/time:** Date and time the calibration was validated by the user.

e. **X-Axis trans:** Transformation method used to convert the X data into a value that produces a linear curve fit.

f. **Y-Axis trans:** Transformation method used to convert the Y data into a value that produces a linear curve fit.

g. **Regression type:** Type of regression used to plot the calibration curve.

h. **Rack ID:** Identifier of the rack where the calibration material was placed.

i. **Position:** Rack position where the calibrator was placed.

iii. **Reaction Information:** 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

iv. **Tracking information tabs**. Displays the materials used to perform the calibration.

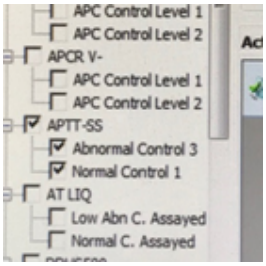
a. **Material lot tracking**

b. **Material Name:** Name of the materials used to run the calibration.

c. **Type:** types can be the following:
    i. Sample Diluent
    ii. Calibration/NPP
    iii. Intermediate Reagent
    iv. Start Reagent
    v. Deficient Plasma
d. **Lot Number:** Lot number of the materials used to run the calibration.
e. **Expiration Date:** Expiration dates of the materials used to run the calibration.
f. **Validation fields:**
    i. **Validator:** The user ID who was logged in when the calibration was validated.
    ii. **Validation date/time:** Date and time the calibration was validated.
    iii. **Validation comment:** Optional comment entered by a user.
    iv. **User name:** User ID that was logged onto the instrument when the calibration was performed.
    v. **Comments**: Can view and enter comments in the *Comments* field. Comments contain **Time**, **Date**, and **User ID**.

O. **Running Quality Control**

1. Load reagents on to the instrument as represented in the Reagent Setup Map.
2. Load controls into the D1 or D2 diluent rack and insert them with barcodes facing out.
3. Controls can be poured into a 2 mL sample cup in the yellow rack **without adapter**
4. On the Menu Bar, click on QC.
5. Click on the QC Results List.
6. Double click on any test to open the QC Statistics Screen which is where the QC Navigation Tree is displayed.



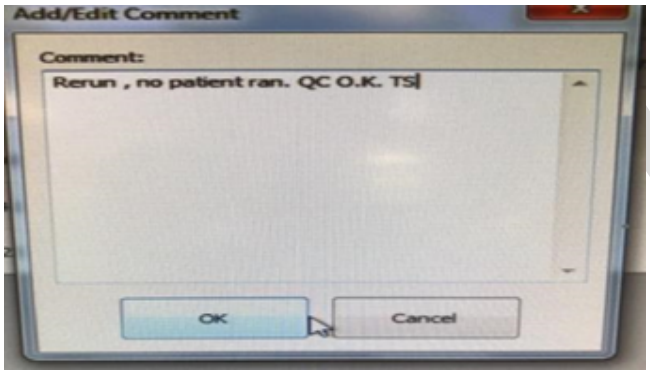
7. Select control(s) from each test listed by placing a checkmark next to that control or test. Click on the running man icon to start testing.
8. Press the Previous Screen icon to return to the QC results list where “Active” should be displayed for each control level being run.
9. When all controls are completed, the value will be displayed on this screen.
10. Again, Double click on any test to open the QC Statistics Screen
11. Select each control to be sure it was run and that the QC value is in limits and does not show as

"FAILED".

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

P. **Corrective Action** (controls out of limits):

1. Re-run control one time. If the new value is within control limits, proceed with patient specimens.
2. If the new value is also out-of-control, reconstitute one new vial of fresh control and retest.
3. 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.
4. Select the out-of-limit control value.
5. Click on Comment icon.
6. Enter a troubleshooting comment, action and your initials in the Add Comment dialog box.
7. 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. For more details, refer to the ACL TOP Online Help.
8. Notify the supervisor/manager of problems. Document all problems and troubleshooting steps on the Coagulation Daily Communication Log.



Q. **Loading Samples:**

1. **Running Routine Coagulation Patient Samples**
   a. Load reagents on to the instrument as represented in the Reagent Setup Map.
   b. Verify QC has been run and is within established acceptable ranges.
   c. 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
   d. If you are running an uncapped sample, aliquot tube or a sample cup you MUST use the **Yellow** sample rack.
   e. **NOTE:** 750 LAS does not have a cap piercer. Therefore, you cannot load samples with a cap or **Blue CTS** sample rack.
   f. **NOTE: If you run a capped sample in the Yellow sample rack, you will crash the Probe!**
   g. Press the desired "S" rack button and insert the rack into the TOP in any available rack position (labeled S1-S6 or S3-S12).

h. The TOP will query the LIS for routine test to run

i. Press the Sample List icon to see tests running and results.

2. **Running Special Coagulation Patient Samples**

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

   b. Verify QC has been run and is within established acceptable ranges.

   c. Load the **Yellow** sample rack to run uncapped samples and aliquot tubes with the bar code facing outwards.

   d. To access the Sample Area, select the **Sample Area** icon in the toolbar, or select **Analysis > Sample Area** in the menu bar.

   e. Click a test cell on the right side of the Rack Details screen.

   f. 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.

   g. Select a **test** or profile in the Tests and Profiles window. Select **OK**.

   h. Repeat these steps for each test to run on the sample.

3. **Programming Non-Bar Coded Samples Using the Off line Rack**

   a. Select the **Sample Area** icon in the toolbar, or select **Analysis > Sample Area** in the menu bar.

   b. Double-click a position on the off line rack (located on the left side of the screen) to display the Rack Details screen.

   c. 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.

   d. Select the **Insert Rack** icon.

   e. Insert the rack into the instrument.

   f. 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.

   g. Select a **test** or profile in the Tests and Profiles window. Select **OK**.

   h. Select the **Run** icon in the toolbar.

   i. **NOTES:**

      i. If you manually identify a material placed on the off line 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.

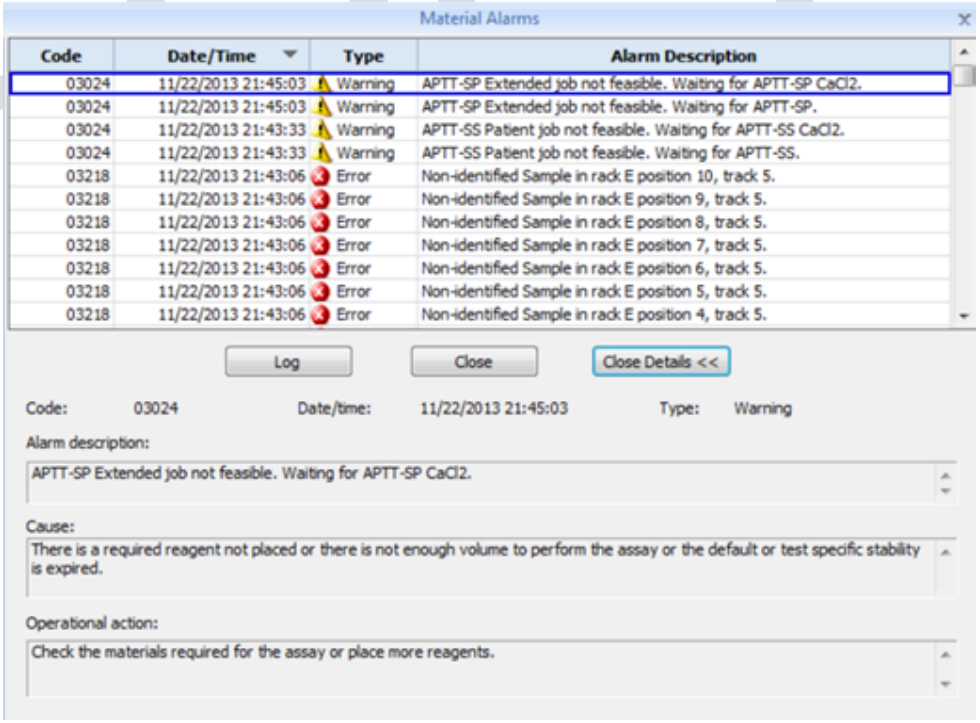
      ii. If you manually identify the presence of a material (tube, bottle, or sample cup) placed on the off line rack (sample, diluent, or reagent) and, upon insertion, the bar code reader does not detect the presence of that material, an error message appears for that position that the system was expecting to detect the material's presence.

      iii. If you fail to manually identify the presence of a material (tube, bottle, or sample cup) placed on the off line 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.

R. **Errors and Alarms**

1. **Error Alarm Warning:** When an error is generated, the analyzer stops processing new samples and performs a controlled stop.
    a. **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.
2. **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, coagulation error (CE), coagulation warning (CW). 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
3. **Accessing Alarm Messages**
    a. To view an alarm message, do one of the following:
        i. Select the alarm button at the bottom of the screen to open that alarm window.
        ii. Select **System >General Log** in the menu bar to view a list of all archived alarm messages.
        iii. Select the **General Log** button on the left side of the status bar.



    b. **NOTE**:

i. 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.

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

S. **Attachments:**

1. ACL TOP Family Series Reagents, Controls and Calibrations Stability

V. REFERENCES:

A. ACL TOP Family Standard Operating Procedures, April 2017

Attachments

ATTACHMENT A

Approval Signatures

Step Description	Approver	Date
CP Chief Medical Director	Peter Millward: Chief, Pathology Service Line	5/1/2021
Coagulation Medical Director Designee	Marc Smith: System Med Dir, Coagulation	4/30/2021
Policy and Forms Steering Committee Approval (if needed)	Tamara Sabih: Medical Technologist Lead	4/22/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	4/22/2021
System Manager	Rebecca Bacarella: Mgr Laboratory	4/22/2021
	Tamara Sabih: Medical Technologist Lead	3/2/2021

Applicability

Royal Oak