Features and Technical Description
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Overview

Extending Standardization Beyond the Analytical Phase
The complete line of ACL TOP Family 50 Series Hemostasis Testing Systems offers unprecedented pre-analytical quality assurance, risk-management and accreditation benefits. Automated pre-analytical sample integrity checks identify under-filled sample tubes, abnormal sample aspiration potentially caused by clots, and assay-specific interference from Hemolysis, Icterus, Lipemia (HIL). Additionally, the systems offer lab accreditation tools to facilitate regulatory compliance and enhance efficiency in the lab. ACL TOP Family 50 Series systems deliver quality and efficiency for medium- to high-volume labs, including those with fully integrated systems.

ACL TOP Family 50 Series systems are optimized to operate with a comprehensive panel of HemosIL assays. Together, they are a complete disease-state management solution.

All ACL TOP Family 50 Series systems save time and resources through a single, standardized platform, providing:
- **Same results**—standardized quality management
- **Same reagents and consumables**—optimized inventory management
- **Same features and usability**—simplified training and enhanced quality of results
- **Same powerful and intuitive software**—ease of use
- **Same assay-specific sample checks**
- **Same advanced lab accreditation support tools**

For High-Volume Labs
ACL TOP 750
User-friendly with high throughput for routine analysis in laboratories with the heaviest workloads.

ACL TOP 750 CTS
Added safety in routine, high-volume and specialty labs with Closed-Tube Sampling (CTS).

ACL TOP 750 LAS
Connects to laboratory automation tracks and HemoCell® Specialized Lab Automation work cells for maximum flexibility and efficiency.

For Medium- to High-Volume Labs
ACL TOP 550 CTS
Highly automated testing processes in routine, medium- to high-volume and specialty labs.

For Medium-Volume Labs
ACL TOP 350 CTS
Most compact analyzer for routine or specialty testing for medium-volume labs. A perfect complement to the ACL TOP 750 CTS or ACL TOP 550 CTS system.
Intelligent Testing for Efficiency, Simplicity and Quality
The most advanced automation and quality management features to enhance lab efficiency and patient care.

Analyzer Automation
- Automated tube-fill-height check
- Validated test-specific interfering substance checks for Hemolysis, Icterus and Lipemia (HIL)
- Barcoded reagents
- Continuous onboard reagent stability monitoring
- Automatic Quality Control (QC) frequency execution
- Rerun and reflex testing capabilities
- Fully automated reporting of factor assays with Parallelism
- Auto-verification and uploading of results
- Closed-Tube Sampling (CTS models only) via cap-piercing
- Comprehensive audit trail and automated audit-trail reports

Laboratory Automation
- Follows CLSI Guidelines (AUTO 1–5) for true Point-of-Reference sampling
- Open system compatible with most Laboratory Automation Track systems
- Eliminates need for costly and slow robotic interface

Continuous Operation
- Continuous loading and unloading of samples and reagents via racks with no system interruption
- Uninterrupted cuvette loading
- Uninterrupted waste disposal

Fast Turnaround
- Up to 360 PT tests/hour
- PT from standby in ~3 minutes
- Samples loaded on any rack, in any position, at any time, including STAT

Simple Maintenance
- Daily maintenance, ordered by user and performed by system, in <5 minutes
- “Maintenance overdue” notifications to alert user
- Remote instrument diagnostics and troubleshooting via web interface in real time* (optional)

*Not available in all regions.
Advanced Features

Additionally, ACL TOP Family 50 Series systems provide a variety of control and visibility features for enhanced performance and superior accuracy and efficiency—ensuring ultimate testing confidence.

Clot Signature Curves
- Available for patient samples, QC and calibrations
- Illustrate reaction readings within a cuvette, for analysis of abnormal results
- Unique to optical-based detection systems

State-of-the-Art Factor Assay Testing
- Multi-point calibration with direct dilution
- One calibration for entire linear range
- Dual calibration algorithms, including polynomial math models
- Zero calibration point for highest accuracy at very low factor activity
- Automatic multiple dilutions for sample Factor Parallelism
- Graphical display and multiple data checks enhance identification of factor inhibitors

Advanced Optical System
- Wavelengths optimized for minimal interferences from known contaminants (Figures 1–2)
- Multiple- and independent-reading channels
- Simultaneous reading of multiple wavelengths
- Clot curve outputs for independent verification and validation of results

Figure 1: Reads at 671 nm, outside the range of optical interferences for several key and routine assays

Figure 2: HIL readings plotted with defined threshold levels (red lines)
Technical Description

Analytical Measurement
The entire testing process is fully automated on ACL TOP Family 50 Series systems, with onboard QC and maintenance, enhancing performance and productivity. Results are provided for both direct hemostasis measurements and calculated parameters for the following test types:
- Coagulometric
- Chromogenic
- Immunologic

Coagulometric Measurements
Coagulometric clot detection is used to measure and record the amount of time required for a plasma specimen to clot. The technique assesses coagulation endpoints by measuring change in optical density.

Chromogenic Measurements
Chromogenic tests use the colorimetric principle of measuring absorbance of light from the solution in a cuvette. The amount of light that reaches the photodetector is converted into an electrical signal that is proportional to enzyme activity.

Immunologic Measurements
Immunologic measurement is used to directly measure and record the concentration of an analyte in a sample (not its activity) by measuring the change in optical density. The immunologic method relies on the formation of antigen-antibody complexes.

For additional details, please refer to the ACL TOP Family 50 Series Operators Manual.
Hardware
ACL TOP Family 50 Series systems are designed to offer ultimate efficiency and effectiveness in the low- to high-volume Hemostasis laboratory.

Hardware is divided into two modules:
1. **Control Module (CM)**
   - PC-based processor with Windows operating system. Used by the operator to interact with the system.

2. **Analytical Module (AM)**
   - Composed of seven areas: cuvette-loading, sample, cuvette shuttle, reagent, optical reading unit, cuvette waste, and external rinse and clean solutions.

On ACL TOP 550 CTS/ACL TOP 350 CTS systems, the AM contains components equivalent to those of ACL TOP 750 CTS, in a smaller footprint.
Cuvette Loading
For all ACL TOP Family 50 Series systems, the cuvette-loading area is on the left side of the analyzer. The cuvette, composed of polystyrene, is uniquely designed. Four individual cuvettes form a cuvette strip. Ten strips are linked together to form a cuvette clip. Ten clips are packaged together as a cuvette block (Figures 3–5). The block is packaged to facilitate entry into the cuvette-loading area. The area accommodates two blocks at a time for a total of 800 onboard cuvettes.

The cuvette clips are loaded vertically to save space. When a clip advances to the front, it is moved to a horizontal position. The cuvette shuttle then grips one strip from the clip and transports it for use. The cuvettes are used for sample predilutions or analysis. The cuvette-loading area is accessible at all times to the operator. This allows cuvette loading anytime the system is idle or operating. The system will alert the user when the cuvettes are running low and when the loader is empty.

Sample Area
The sample area is located to the right of the cuvette-loading area. This area contains the sample probe (plus cap-piercing on the CTS models) with a dedicated rinse bath, rack positions for samples and diluents, and cuvette strip holders for dilutions and incubation. Visible through the tinted plexiglass safety cover on the front of the analyzer, the sample area is maintained at ambient temperature. ACL TOP 350 CTS/550 CTS systems have a tinted plexiglass cover that protects both the sample and reagent areas.

The safety panel is monitored using sensors to ensure the cover remains closed during sample processing. This area accommodates sample racks and diluent racks.
Sample Area by Model

<table>
<thead>
<tr>
<th>Sample Area by Model</th>
<th>Sample Racks</th>
<th>Diluent Racks</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACL TOP 750/750 CTS</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>ACL TOP 750 LAS</td>
<td>9</td>
<td>2</td>
</tr>
<tr>
<td>ACL TOP 550 CTS</td>
<td>8</td>
<td>0*</td>
</tr>
<tr>
<td>ACL TOP 350 CTS</td>
<td>4</td>
<td>0*</td>
</tr>
</tbody>
</table>

Samples are loaded in racks onboard the system. Each rack holds ten samples, for up to 120 onboard samples. The racks contain barcode identification. The system alerts the user if a specimen ID in a rack position cannot be identified. The racks also contain spring clips that can accommodate sample tubes of varying sizes. In addition to processing in direct tubes, samples may be processed in cups or pour-off tubes. Adapters are available for processing in aliquot tubes on the 750 models. The diluent racks in this area are located to the right of the sample racks. Each rack can hold a sample diluent, calibrator, quality control or cleaning material (Figure 6).

* Diluent racks are accessible by sample probe.
** Individual user configurations may differ.
Any sample or diluent position can be accessed by simply pressing a button below the desired location on the analyzer. This activates the barcode reader, which positions itself accordingly. The barcode reader traverses the front of the system along with a rigid curtain. The curtain ensures safety and maintains the area at the optimal temperature during analysis. When the reader is positioned, a rack can be inserted while the sample barcodes are read.

Once a rack (Figures 7–8) is placed in position and the system has accessed it, the front-panel LED for the location turns orange. The orange LED is an indication that the rack is locked and inaccessible. The rack remains locked until the system discontinues use of that rack. When sample racks are not in use, the LED turns green, indicating rack accessibility. Note: LEDs may turn green even when samples are not completely processed on that rack. To optimize scheduling efficiency, racks can go from accessible to inaccessible without completion of all samples on that rack. Screen graphics are used to indicate when samples in racks have not been processed.

When the LED turns green and screen graphics indicate completion, the rack can be removed and replaced with a new rack of samples to be processed. The front keypad panel LED turns orange when any rack is being used and green when racks are accessible.

Materials in the sample area are aspirated using the sample probe. The probe incorporates a sensor that recognizes the presence of liquids and stops at the optimized liquid level. A Teflon tube connects the probe to a syringe pump capable of delivering 4–250 µL. Samples and materials are aspirated and dispensed into a cuvette. The cuvette strips are held in the sample area in two regions. One, for dilutions, is maintained at ambient air temperature, while the other, for incubations, is heated to 37°C. The ambient area holds up to 14 cuvette strips (eight for ACL TOP 550 CTS; four for ACL TOP 350 CTS), while the incubated area holds eight (four for ACL TOP 550 CTS; four for ACL TOP 350 CTS).
Closed-Tube Sampling (CTS models only)
The CTS probe is a specially designed unit comprising a piercer and a sample probe, located within
the piercer (Figures 9–11). The sample arm CTS probe has a foot to hold the sample tube in place,
allowing cap-piercing. The piercer remains in the cap long enough to allow the probe to move down
and into the tube to aspirate material. Following aspiration and dispensation of material into a
cuvette, the CTS sample arm moves to the wash station and performs a deep wash of the CTS probe.
Pressurized air is released through the piercer/probe to blow out any material that might remain
after a wash or rinse. Labeled CTS racks are used for cap-piercing. They are distinguished with a blue
plastic handle sleeve. The CTS mode can be enabled/disabled in the global definitions. With the CTS
mode enabled, the instrument accepts both CTS racks and Open-Tube racks. With the CTS mode
disabled, the instrument does not accept CTS racks. In the disabled mode, the instrument runs
uncapped tubes and sample cups on open-tube racks only. The CTS feature is available on ACL TOP
750 CTS/550 CTS/350 CTS models only.
**Tube-Fill-Height Detection**
Tube-fill-height may be detected during the first aspiration of a primary sample tube, if this feature is enabled. The level of fill within a tube is determined and the results compared to user-defined calibrated, lowest-acceptable fill level. Calibration of this feature is simple and required for open (uncapped), closed (capped) or sample tubes that are presented to the ACL TOP 750 LAS System from an automation track. A tube-fill-height calibration module guides the user through the calibration process. The total calibration time is <1 minute for each tube type. One tube type may be calibrated for this feature for open or closed tubes when front loaded (loaded into sample racks) or up to nine tube types for LAS tracks.

**Cuvette Shuttle**
The cuvette shuttle has a unique, highly efficient design for moving cuvette strips through the system. The shuttle runs along the back of the analyzer behind the sample and reagent areas. The shuttle grips the desired cuvette strip, retracts it into its 37°C heated chamber, moves to the next desired position and places the cuvette strip. The shuttle has access to all cuvette areas, at all times, and can therefore move cuvettes to any position. The system utilizes one shuttle for all cuvette transportation.

**Reagent Area**
The reagent area is located to the right of the sample area (Figure 12). This area contains heated reagent probes with a corresponding rinse bath and is visible through the tinted plexiglass safety panel. In addition, this area contains rack positions for reagents and diluents, eight cuvette strip incubators and the Optical Read Units (ORUs). The reagent cooling area is maintained at approximately 15°C. The safety panel is monitored and locked during reagent aspiration.

**Reagent Area by Model**

<table>
<thead>
<tr>
<th>Model</th>
<th>Reagent Arms</th>
<th>Sample Arms</th>
<th>Reagent Racks</th>
<th>Diluent Racks</th>
<th>Optical Reading Channels</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACL TOP 750/750 CTS</td>
<td>2</td>
<td>1</td>
<td>6</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>ACL TOP 750 LAS</td>
<td>2</td>
<td>2*</td>
<td>6</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>ACL TOP 550 CTS</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>ACL TOP 350 CTS</td>
<td>1**</td>
<td>1**</td>
<td>3</td>
<td>1</td>
<td>8</td>
</tr>
</tbody>
</table>

*Added sample arm for direct-from-LAS-track sampling.
**Reagent and sample probes are integrated onto one arm.
The reagents are loaded in racks onboard the system. Each reagent rack holds six reagent vials, and the reagent area accommodates up to 36 reagents (based on instrument model). All racks contain barcode identification. The system alerts the user if a reagent vial label cannot be identified or if the lot number is incorrect. The first two positions in each reagent rack have stirring capability; therefore, the system can accommodate up to 12 vials requiring reagent stirring. These positions can also be utilized for unstirred reagents.

On all ACL TOP 750 models, the reagent rack area is divided into two regions. One region is for “start” reagents, the other for “intermediate” reagents. On ACL TOP 550 CTS/350 CTS systems, there is only one reagent arm, and it does not require specific placement for start or intermediate reagents. When required, intermediate reagents are added first to the sample in the cuvette before addition of start reagent. They are then mixed and incubated with the sample. The reagent area contains eight incubator positions (four for ACL TOP 350 CTS/550 CTS systems) to hold cuvette strips for dispensation and incubation of intermediate reagents.

Start reagents initiate the final reaction and are dispensed when the cuvette strip is loaded into one of the ORUs. For example, in the APTT test, the intermediate reagent is APTT and the start reagent is calcium chloride. On all ACL TOP 750 models, Reagent Rack positions 1–4 are utilized for intermediate reagents and positions 3–6 are for start reagents. Positions 3 and 4 are crossover positions that can be utilized for either reagent type. Incubators and ORUs are maintained at 37°C.

*Individual user configurations may differ.
The diluent rack in this area is located to the left of the reagent racks. Each rack can hold eight materials, including a reagent diluent, deficient plasma or intermediate reagent. This area, like the reagent rack area, is maintained at approximately 15° C. Any of the reagent or diluent rack positions can be accessed by pressing a button below the desired location on the analyzer. This activates the barcode reader, which traverses the front of the system along with a rigid curtain. The curtain maintains the area at the optimal temperature during analysis. The barcode is read during rack insertion. Positioning the reader beside the rack minimizes stray light impacting the barcode reading. Once a rack is latched into position, the LED for the location turns green. After the barcode homes itself (in 30 seconds) or is positioned in another location, the appropriate reagent probe for the rack location checks the volume in each vial in the rack. The Barcode Reader Home icon (Figures 13–14) is present on the touchscreen monitor of all ACL TOP Family 50 Series models. The Barcode Reader Home button is also located on the body of the analyzer for ACL TOP 350 CTS/550 CTS systems.
Figure 16: Restriction Map display on ACL TOP 750/750 CTS systems

Figure 17: Restriction Map displays sample and reagent loading on ACL TOP 750 LAS systems
Figure 18: Restriction Map displays sample and reagent loading on ACL TOP 550 CTS systems.

Figure 19: Restriction Map displays sample and reagent loading on ACL TOP 350 CTS systems.
Optical Read Unit (ORU)
The uniquely designed ORU provides fast and effective assay reaction readings. ACL TOP Family 50 Series systems have 2–4 ORUs, depending on the model. Each ORU has four optical-reading channels and accommodates one cuvette strip; thus, 8–6 reactions can be read simultaneously. The optic design in the ORU allows each cuvette to be read simultaneously at two wavelengths: 671 nm and 405 nm. The sophisticated software then determines which reading to utilize based on the test definition. Simultaneous readings allow a mix of assays to be processed within a cuvette strip at different wavelengths. This results in minimal cuvette wastage and enhances throughput. An additional wavelength 535 nm is also present and is utilized exclusively for determining the presence of interfering substances. The 535 nm wavelength is not used for analytical determinations.

Waste Systems
The used cuvettes are deposited into the cuvette waste drawer (on the right side of the analyzer or in an external bin on ACL TOP 350 CTS systems) containing a disposable liner, capable of holding up to 800 cuvettes (Figures 20–21). The drawer is monitored for volume, and the operator is alerted visually and audibly when the drawer is nearly full (not available on ACL TOP 350 CTS systems). The drawer can be removed and emptied at any time during operation without affecting test processing. The liquid waste from the sample and reagent rinse baths is collected in an external waste container. The external waste container utilizes a level sensor that alerts the operator visually and audibly when it is nearly full (not available on ACL TOP 350 CTS systems). The operator can empty the container at any time during operation without affecting test processing.
System Rinse and Clean
The right side of the analyzer holds System Rinse and Clean bottles (Figure 22). The Rinse is used for cleaning the probes between aspirations and is packaged in a 4 L bottle. The Clean solution is a weak acidic solution used to prevent carryover between reagent and sample aspirations for particular tests; it is automatically aspirated and utilized based on the testing in process. It is packaged in a 500 mL bottle. Sensors monitor the level of liquid in the bottles and alert the operator visually and audibly when the containers are running low.
Main System Features

ACL TOP Family 50 Series software was designed to complement the Analytical Module hardware. The program for all models operates on a Windows platform.

Reagent Management
ACL TOP Family 50 Series systems provide a completely automated reagent tracking system (Figures 23–25). When reagents are loaded and barcodes read, the system takes complete control. First, it performs an initial volume measurement. If the measurement differs by 30% or is placed in a different rack position, the vial is considered new and the onboard stability is reset. The system then counts down stability time from that point. When the stability time approaches zero, the operator is alerted, allowing time to prepare a new vial. If the time reaches zero, an alarm is sounded, and all testing of that vial displays with an onboard stability flag. In addition, the system monitors lot number expiration via the barcode. When a lot expires, the operator is warned.

The system also allows multiple vials of the same reagent to be placed onboard. When this occurs, the vials are aspirated in a first-in, first-out fashion, or priority of use can be set by the operator.
Calibration

Calibration on ACL TOP Family 50 Series systems can be performed anytime, including when the system is running patient samples or being calibrated for other tests. The user has the option to set up each test for automatic calibration, (e.g., days, hours, number of tests). If this option is not used, the operator can calibrate the tests-as-needed.

The system stores the last ten calibrations for each test in a first-in, first-out order. Upon calibration completion, the system can auto-validate the curve based upon user-selectable criteria (Figure 26). If the auto-validation option is not used, the operator can manually validate the curve prior to use. The system allows validation of any of the ten available stored calibrations. Prior to validation of any curve, the operator can view the calibration and clot curves.
Quality Control (QC)
The QC program on the system features automation and implementation of Westgard Rules. The automated QC functions are similar to those for calibration, allowing QC to be performed at any time or automatically at set intervals. Automatic QC at reagent vial change is also available. The operator can set the frequency in hourly, time of day, upon any vial change or for test-count intervals. For both manual and automatic QC, barcoded QC vials can be placed on the system, eliminating the need to pour QC material into sample cups. QC can be set up and run for both an active lot and an alternate lot of material. The generated QC data can be displayed in either a table or a Levey-Jennings format, and can be viewed for a particular date range, number of points and active and alternate lot (Figures 27–28).

Figure 27: QC Rules

Figure 28: QC Levey-Jennings graph
Sample Management
Pre-analytical sample quality determinations are possible with three powerful features: tube-fill-height detection, interfering-substance detection and sample-aspiration (clog) detection. The tube-fill-height and interfering-substance detection features are enabled by the user globally and may be configured to provide the user a warning or to fail test results that exceed user-established criteria.

Optional setting to fail test results when clog or tube fill errors are detected

Tube-Fill-Height Detection
Tube-fill-height is detected during the first aspiration of a primary sample tube and warns a user when the first aspiration from a tube is below the user-calibrated lowest acceptable level. The feature may be enabled globally for specific sample-loading tracks. Testing of tube-fill-height is conducted during first sample aspiration from every tube introduced in the specific track position enabled on the ACL TOP Family 50 Series system. Flagged samples indicate the need for further user review of sample integrity and determination of appropriate actions in accordance with the established quality procedure.

Optional setting to enable tube-fill-height check per sample track position

Abnormal Sample Aspiration (Clog Detection)
The pressure profile during sample aspiration is conducted during every aspiration of plasma from the sample container. The feature compares the actual aspiration-pressure profile against a normal aspiration-pressure profile. Deviation of the actual aspiration-pressure profile may indicate that a clot is present in a sample. The clog-detection feature flags or fails the test associated with the aspiration. A flagged sample indicates the need for further review of the sample integrity and determination of appropriate actions, in accordance with the established quality procedure.
**HIL Interfering Substance Detection**

Hemoglobin, Icterus (Bilirubin) and or Lipemia (turbidity) can be measured independently for each sample on the ACL TOP Family 50 Series system. Measurements are conducted automatically when an HIL capture test is performed and has no impact on throughput, sample usage or cuvette consumption. The measurements required to perform HIL detection are determined during the data acquisition delay of the HIL capture test, and the results are applied to every test conducted on that sample.

<table>
<thead>
<tr>
<th>Current HIL Capture Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT-RP</td>
</tr>
<tr>
<td>PT-Read</td>
</tr>
<tr>
<td>Fib-RP</td>
</tr>
<tr>
<td>APTT-SS</td>
</tr>
<tr>
<td>APTT-SP</td>
</tr>
</tbody>
</table>

When an HIL Capture Test is not performed, HIL measurement can still be conducted. An HIL independent test utilizes 50 ml of plasma and one cuvette cell. HIL tests have no impact on analytical results of any test.

Rejection criteria are established for each interfering substance and by test utilizing interfering-substance threshold values. Default interfering-substance threshold values are pre-programmed, based on validated levels published in IL reagent Product Insert sheets. HIL levels may exceed threshold values for one test and be acceptable for another test from the same sample.

![Sample with no flag](image1)

![Sample with flag](image2)
Users may choose pre-validated threshold values or define their own. The interfering substance detection feature may be enabled or disabled for each interfering substance or by test. In addition, each substance may be independently configured as a warning or error (failed).

Flagged samples indicate further user review of sample integrity and determination of appropriate actions (Figures 29–31), in accordance with the laboratory’s established quality procedure.

Sample Results Management
The powerful results database enhances ease of operation. The database can hold 20,000 sample IDs, with up to 30 associated tests each. The database can, therefore, maintain 600,000 results. The IDs are entered into the database manually or, more commonly, via sample barcodes. The host interface uses dynamic download, or host query, and operates without intervention. When a rack is introduced and the barcodes read, the host is automatically queried for requests. At that point, if this operation is enabled, the system will start automatically. If the option is disabled, the operator can use the run icon on the screen to start manually.

STAT samples always have priority over routine samples and can be placed in any rack, in any position, without segregation. Even if STAT samples are mixed with routine samples, the system can track and process them with priority. STAT PT results are available in as little as three minutes.

During sample analysis, the system provides the estimated time to completion for all samples onboard, as well as the time to completion for each sample. Upon completion, results are available for viewing, printing or host-transmitting.

The sample results database on the system can be customized by the operator with eight views, providing flexibility to laboratory staff. The main database screen can be customized to meet the varying needs of each shift. Results in the database can be filtered using multiple criteria to select specific samples or results. In addition, samples can be selected and the results recalculated to reflect calibration or parameter updates on the system. For long-term, off-line result storage, the system provides the ability to export results into data files in various formats (e.g., PDF). These files can then be viewed using commonly available database programs on a separate computer system.
Samples with pre-analytical sample integrity warnings or errors are clearly indicated by use of user-friendly graphics, tool tips and error/warning codes (Figure 32).

Figure 32: ACL TOP Family 50 Series Sample Result screen

Audit Trail and Audit Reports
Extensive audit trails record a log of all instrument operations, including calibrations, quality control, system setup changes, maintenance activities, system operating temperature, system software updates and test parameter updates. The system will also retain a record when results are deleted and provide the user an optional comment field for any user initiated action. Operations are tagged with the time and date of the activity, as well as the operator that performed the activity, and any comments the user wishes to include.

Audit trail reports are user-configurable and can be created on-demand or automatically at set weekly or monthly intervals. Reports may be printed or exported in PDF format (Figure 33).

Figure 33: Audit Trail Report setup screen

Information included in the audit trail report:
- **Temperature report** provides detailed record system operating temperatures if operation drifts outside normal parameters
- **System changes** records changes made during software or parameter updates
- **Setup changes** records software settings altered during the audit period
- **QC report** provides current status of all quality control runs
- **Snapshot report** provides current system status and settings
- **Calibration report** provides details of all currently validated calibrations
- **Maintenance report** provide a log of all maintenance activities performed during the audit period
**Electronic Signature**
An electronic signature option is available. Electronic signatures are linked to a secondary password with an auto-expiration option.

**Factor Parallelism**
Factor assays on the system can be processed using multiple dilutions. The dilutions are automatically prepared by the system, and the results are checked for integrity, and plotted against the calibration curve. If a sample is void of factor inhibitors, the sample dilution curve and the calibration curve will appear in parallel (Figure 34). If a sample contains an inhibitor, the two curves often intersect (Figure 35). In addition to the visual representation, ACL TOP systems utilize algorithmic data checks to flag potential samples with potential inhibitors.
**Clot Curves**
ACL TOP Family 50 Series systems allow the user to view clot signature curves. Clot curves visually demonstrate the reaction readings that occur within a cuvette (*Figure 36*). They are a valuable aid for assessing results. The system will maintain the last 100,000 clot curves in its database, managed in a first-in, first-out fashion. The system allows for the export of raw data for individual reactions in text file format.

![Figure 36: Sample Result Clot Curve](image)

**Auto-Validation of Results**
ACL TOP Family 50 Series systems are ideally suited for mid- to high-volume Hemostasis labs that process hundreds of samples daily. Generally, the results of these samples fall within the normal range with no system flags. The system can automatically validate these results and automatically transmit them to the host system. This feature eliminates manual validation of results and decreases turnaround time. The criteria for auto-validation can be customized. The user selects from a list of errors and conditions for which results should not be automatically validated. In addition to patient sample results, auto-validation can also be set up for factor parallelism and calibration curves.
Lot Traceability
ACL TOP Family 50 Series systems track the lot number of materials used for all tests performed on the analyzer (Figure 37). The information is presented for Calibration, QC and Patient Data.

Parallel Lot Testing
In the Hemostasis laboratory, changes in lot numbers for controls and reagents require a crossover study in which a result comparison is run on the original and new lots. ACL TOP Family 50 Series systems facilitate this process by providing an automated system to track the original and a new lot of material for reagents, calibrators and quality controls. The reagent alternate lot allows calibration and sample processing for result evaluation. The quality controls allow a new control range to be established while the original material is processed. Once a sufficient number of control determinations have been performed, the alternate lot can be activated and thus become the primary lot.

Reflex Testing
Reflex testing is an automated method for the evaluation of an initial set of results and triggers additional testing based on evaluations of rules. The reflex-testing program provides extensive flexibility and setup options. The software permits 100 reflex logic definitions. Each of these definitions can have up to ten rules, which can utilize numeric limits or error conditions. If rules are met, additional tests can be added to the sample. Since each sample can have a maximum of 30 tests, up to 29 can be added if one test was ordered initially.
Security
The security program in the software allows each laboratory to define 100 unique users for the system. Each user can then be assigned one of four access levels: administrator, supervisor, senior operator or operator. At the administrator level, the operator can define which level has access to each submenu on the system. When users log on, they enter a unique username and password. Users can make edits to settings based on their access level. Actions performed on the analyzers are tracked by user, providing an audit trail for laboratory management (Figure 38).

System Access and Data Restrictions
The system may be configured to automatically log off users after a defined time of inactivity. Service and Specialist log-in access restricts visibility of patient demographics. Data backups may be created without patient demographics.

General Log
All system modifications, warnings and errors on the analyzers are tracked in the system logbook. This provides an automated method for the laboratory to maintain an audit trail for the analyzer and to troubleshoot. The logbook lists the date, time, user and a description of the last 40,000 entries. The log file is managed in a first-in, first-out fashion. When the logbook file is opened on the system, the user can easily sort using multiple criteria. This simplifies monitoring of the system for a certain action or time interval.

Figure 38: Advanced Security safeguards patient information from unauthorized users
<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test menu</strong></td>
<td>Clotting, chromogenic and immunologic assays</td>
</tr>
<tr>
<td><strong>System configurations</strong></td>
<td></td>
</tr>
<tr>
<td>ACL TOP 750</td>
<td>Open-tube sampling</td>
</tr>
<tr>
<td>ACL TOP 750 CTS</td>
<td>Closed-tube sampling (cap-piercing)</td>
</tr>
<tr>
<td>ACL TOP 750 LAS</td>
<td>Laboratory Automation System (off-board sampling)</td>
</tr>
<tr>
<td>ACL TOP 550 CTS</td>
<td>Compact-sized with closed-tube sampling</td>
</tr>
<tr>
<td>ACL TOP 350 CTS</td>
<td>The most compact-sized model with closed-tube sampling</td>
</tr>
<tr>
<td><strong>Continuous sample and reagent loading</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Continuous operation</strong></td>
<td>YES</td>
</tr>
<tr>
<td><strong>Samples and reagent transport system</strong></td>
<td>Racks</td>
</tr>
<tr>
<td>Samples onboard</td>
<td></td>
</tr>
<tr>
<td>ACL TOP 750</td>
<td>120</td>
</tr>
<tr>
<td>ACL TOP 750 CTS</td>
<td>120</td>
</tr>
<tr>
<td>ACL TOP 750 LAS</td>
<td>Continuous from LAS track or 90 front-loaded</td>
</tr>
<tr>
<td>ACL TOP 550 CTS</td>
<td>80</td>
</tr>
<tr>
<td>ACL TOP 350 CTS</td>
<td>40</td>
</tr>
<tr>
<td>Reagents onboard</td>
<td></td>
</tr>
<tr>
<td>ACL TOP 750</td>
<td>60 (44 refrigerated + 16 room temp)</td>
</tr>
<tr>
<td>ACL TOP 750 CTS</td>
<td>60 (44 refrigerated + 16 room temp)</td>
</tr>
<tr>
<td>ACL TOP 750 LAS</td>
<td>60 (44 refrigerated + 16 room temp)</td>
</tr>
<tr>
<td>ACL TOP 550 CTS</td>
<td>40 (refrigerated)</td>
</tr>
<tr>
<td>ACL TOP 350 CTS</td>
<td>26 (refrigerated)</td>
</tr>
<tr>
<td><strong>Reagents barcode reader</strong></td>
<td>YES (integrated)</td>
</tr>
<tr>
<td>Barcoded reagents</td>
<td>YES (barcode includes lot, expiration date and vial size)</td>
</tr>
<tr>
<td>Cuvettes onboard</td>
<td>80</td>
</tr>
<tr>
<td>Applications onboard</td>
<td>550 (250 user-programmable)</td>
</tr>
<tr>
<td>Tests/sample</td>
<td>30</td>
</tr>
<tr>
<td><strong>Throughput</strong></td>
<td></td>
</tr>
<tr>
<td>ACL TOP 750</td>
<td>PT 360 tests/hr (360 samples/hr) PT APTT 320 tests/hr (320 samples/hr) PT and APTT 330 tests/hr (165 samples/hr)</td>
</tr>
<tr>
<td>ACL TOP 750 CTS</td>
<td>PT 270 tests/hr (270 samples/hr) PT APTT 270 tests/hr (270 samples/hr) PT and APTT 260 tests/hr (130 samples/hr)</td>
</tr>
<tr>
<td>ACL TOP 550 CTS</td>
<td>PT 240 tests/hr (240 samples/hr) PT APTT 180 tests/hr (180 samples/hr) PT and APTT 180 tests/hr (90 samples/hr)</td>
</tr>
<tr>
<td>ACL TOP 350 CTS</td>
<td>PT 110 tests/hr (110 samples/hr) PT APTT 110 tests/hr (110 samples/hr) PT and APTT 110 tests/hr (55 samples/hr)</td>
</tr>
<tr>
<td>Feature</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>Sample predilution</td>
<td>YES</td>
</tr>
<tr>
<td>Calibration curve predilution</td>
<td>YES</td>
</tr>
<tr>
<td>Factor parallelism</td>
<td>YES</td>
</tr>
<tr>
<td>STAT capability</td>
<td>YES (at any time in any position)</td>
</tr>
<tr>
<td>Rerun and reflex testing</td>
<td>YES (configurable)</td>
</tr>
<tr>
<td>Reaction curves display</td>
<td>YES (derivative curves optional)</td>
</tr>
<tr>
<td>Quality Control program</td>
<td>YES (with configurable multi-rules)</td>
</tr>
<tr>
<td>Results auto-validation</td>
<td>YES</td>
</tr>
<tr>
<td>Patient samples results database</td>
<td>20,000 samples</td>
</tr>
<tr>
<td>Security system</td>
<td>YES (configurable)</td>
</tr>
<tr>
<td>Events log system</td>
<td>YES</td>
</tr>
<tr>
<td>Bidirectional interface (with host query)</td>
<td>YES</td>
</tr>
<tr>
<td>PC</td>
<td>External</td>
</tr>
<tr>
<td>Operating system</td>
<td>Windows 7</td>
</tr>
<tr>
<td>Monitor</td>
<td>17-inch color LCD touchscreen (external)</td>
</tr>
<tr>
<td>Keyboard</td>
<td>YES (external)</td>
</tr>
<tr>
<td>Mouse</td>
<td>YES (external)</td>
</tr>
<tr>
<td>Printer</td>
<td>YES (external)</td>
</tr>
<tr>
<td>User interface</td>
<td>Windows-based, powerful, easy to use</td>
</tr>
</tbody>
</table>

### Dimensions of analyzer (w x d x h)

- **ACL TOP 750**: 59 x 30 x 29 in (151 x 76 x 73 cm)
- **ACL TOP 750 CTS**: 59 x 30 x 29 in (151 x 76 x 73 cm)
- **ACL TOP 750 LAS**: 74 x 34 x 64 in (188 x 87 x 162 cm) includes integrated table
- **ACL TOP 550 CTS**: 43 x 32 x 29 in (110 x 82 x 73 cm)
- **ACL TOP 350 CTS**: 32 x 33 x 29 in (81 x 84 x 73 cm)

### Weight (of analyzer)

- **ACL TOP 750**: 356 lbs (162 kg)
- **ACL TOP 750 CTS**: 367 lbs (166 kg)
- **ACL TOP 750 LAS**: 406 lbs (184 kg)
- **ACL TOP 550 CTS**: 324 lbs (147 kg)
- **ACL TOP 350 CTS**: 200 lbs (91 kg)
Test Menu

ACL TOP Family 50 Series systems offer complete disease-state management through a comprehensive panel of HemosIL assays. The broad test menu provides flexible solutions for both routine and specialty testing. The same reagents on all ACL TOP Family 50 Series systems means true standardization throughout the lab.

### General Screening and Anticoagulant Monitoring/Testing
- **ReadiPlasTin**
- **RecombiPlasTin** 2G
- PT-Fibrinogen HS Plus
- **SynthASil**
- **SynthAFax**
- **APTT-SP**
- Q.F.A. Thrombin Fibrinogen-C
- Thrombin Time
- **Liquid Anti-Xa**
- UFH/LMWH
- Apixaban
- **Rivaroxaban**
- Direct Thrombin Inhibitor
- Dabigatran
- ProComplex
- Hepatocomplex

### D-Dimer
- D-Dimer HS 500
- D-Dimer HS
- D-Dimer
- D-Dimer 500

### Heparin-Induced Thrombocytopenia
- HIT-Ab(PF4-H)

### Antiphospholipid Syndrome
- Silica Clotting Time
- dRVVT Screen/Confirm

### Coagulation Factors
- Intrinsic Factors
- Extrinsic Factors
- FXIII Antigen

### von Willebrand Disease
- VWF:RCo
- VWF Activity
- VWF:Ag
- FVIII

### Fibrinolysis
- Plasminogen
- FDP
- Plasmin Inhibitor

### Thrombophilia
- Antithrombin
- Protein C
- ProClot
- Protein S Activity
- Free Protein S (Antigenic)
- FV Leiden (APC-R V)
- Homocysteine

*Not 510(k) cleared. Not saleable in the US.

*Liquid, ready-to-use format.

Contact your local representative for information on availability of specific products and applications in your country.
IL is passionate about bringing the most innovative solutions to Hemostasis testing. Offering a broad range of the highest quality instruments, data management solutions and a full panel of HemosIL® assays—supported by a world-class technical team—IL is committed to enhancing patient care through continuous innovation.