Case Study:

Impact of automated pre-analytical sample integrity checks on ACL TOP® Family 50 Series Hemostasis testing systems



Hospital of Legnano
Italy

Overview

Hospital and laboratory

One of the largest and most specialized hospitals in the western Lombardy region, Hospital of Legnano is a 600-bed hospital belonging to a consolidation of four National Health Care System hospitals. The ACL TOP 750 CTS system in its Hematology Laboratory performs more than 146,000 Hemostasis routine tests per year.

Study parameters and process

- More than 5,000 samples were tested during the evaluation
- Hemostasis assays included PT, APTT, AT, fibrinogen and D-dimer
- Visual inspection of all samples was performed first for Hemolysis, Icterus and Lipemia (HIL), clots and tube-fill level; visually rejected samples were documented
- Samples were then run on the ACL TOP 750 CTS system to evaluate the automatic pre-analytical sample integrity checks

Results

↓52% reduction in sample flagging rate (from 2.45 to 1.17%)

↓56% reduction in inappropriate flags

↑9% increase in detection of problematic samples

79% of samples visually identified as hemolyzed were verified as acceptable on the ACL TOP 750 CTS system

Conclusion

- The ACL TOP 750 CTS system helped identify pre-analytical errors without affecting throughput, primarily due to Hemolysis and identification of potential clots through clog detection
- Automated pre-analytical checks improved consistency beyond subjective visual inspection, leading to more timely and accurate diagnostic results



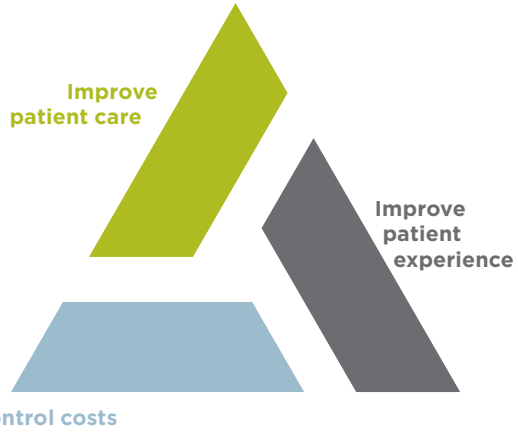
Value of automated pre-analytical sample integrity checks

Improve patient care and experience

- Improved quality and consistency of results
- Decreased sample rejection rates and reduced redraws
- More timely diagnostic results

Control costs

- Reduced pre-analytical errors
- Reduced costs associated with sample inspection, redraws and reanalysis



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TriCore Reference Laboratory System
USA

Overview

Hospital and laboratory

The TriCore Reference Laboratory System is the largest laboratory system in New Mexico, comprised of two hospital networks, 10 hospitals and a large stand-alone reference laboratory. The study was performed at two hospitals with a total of 1,082 beds: University of New Mexico Hospital and Presbyterian Hospital. ACL TOP 550 CTS systems are used in the Hematology Laboratories at both hospitals.

Study parameters and process

- During the evaluation, more than 12,000 samples were tested
- Hemostasis assays included PT, APTT, fibrinogen, anti-Xa, thrombin time and D-dimer
- Visual inspection of all samples was performed first, including detection of Hemolysis, Icterus and Lipemia (HIL), clots and fill volume; samples with a clot and/or over- or under-filled samples were rejected and not included in the study
- Hemolysis detection was performed using a Hemolysis chart, Lipemic samples were included and all Icteric samples were included but flagged
- Samples were then run on the ACL TOP 550 CTS system to evaluate the agreement of the automatic pre-analytical sample integrity checks with visual inspection

Results

↓24% reduction in sample flagging rate (from 0.74 to 0.56%)

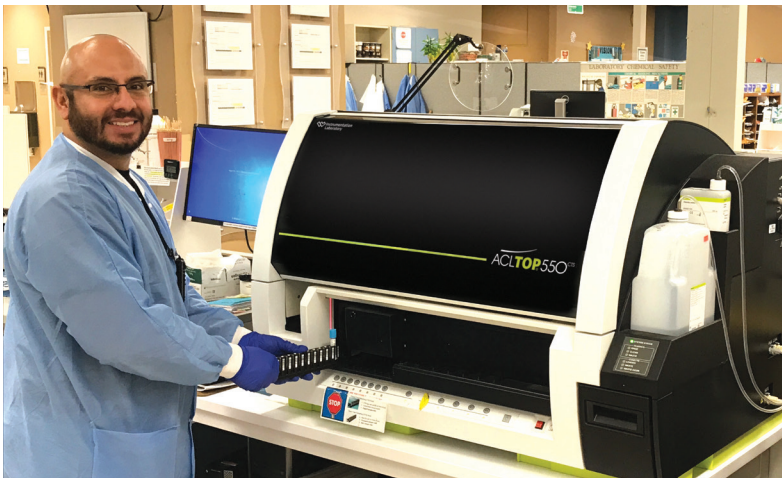
↓24% reduction in inappropriate flags

No change in detection of problematic samples

73% of samples visually identified as hemolyzed were verified as acceptable on the ACL TOP 550 CTS system

Conclusion

- Automated pre-analytical sample integrity checks on the ACL TOP 550 CTS system improved the identification of assay-specific HIL interferences, with a primary impact on Hemolysis detection
- The addition of automated sample quality assurance to augment visual inspection decreased the sample rejection rate, leading to improved efficiency



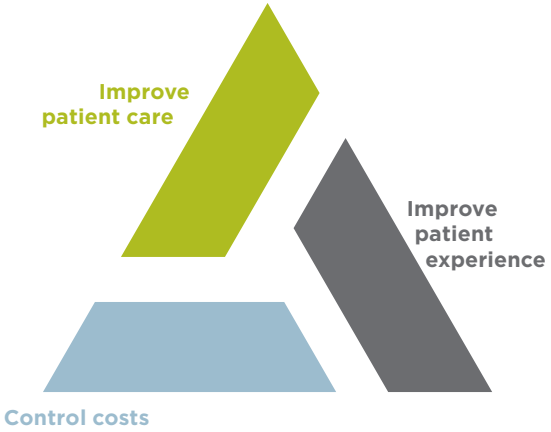
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Case Study:

Impact of automated pre-analytical sample integrity checks on ACL TOP® Family 50 Series Hemostasis testing systems



Hospital General Universitario de Alicante
Spain

Overview

Hospital and laboratory

Hospital General Universitario de Alicante, a 900-bed public health and university hospital, has the ACL TOP 750 CTS system in its Hematology Laboratory. The system performs more than 350 Hemostasis routine tests per day (77,000 tests annually).

Study parameters and process

- During the evaluation, more than 2,000 samples were tested
- Hemostasis assays included PT, APTT, TT and fibrinogen
- Visual inspection of all samples was performed first for Hemolysis, Icterus and Lipemia (HIL), clots and tube-fill level
- Visually rejected samples were documented
- Samples were then run on the ACL TOP 750 CTS system to evaluate the automatic pre-analytical sample integrity checks

Results

↓62% reduction in sample flagging rate (from 4.86 to 1.86%)

↓72% reduction in inappropriate flags

↑34% increase in detection of problematic samples

Of the 10 samples missed visually, 9 were flagged for clogs and 1 for Icterus by the ACL TOP 750 CTS system

Conclusion

- Automatic pre-analytical sample integrity checks on the ACL TOP 750 CTS system helped decrease inappropriate flags, primarily due to Hemolysis
- The instrument also assisted in the detection of samples with clogs that were missed visually



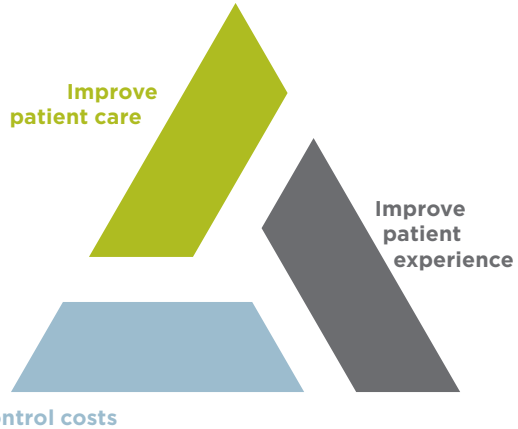
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Case Study:

Impact of automated pre-analytical sample integrity checks on ACL TOP® Family 50 Series Hemostasis testing systems



The Medical University of Gdańsk
Poland

Overview

Hospital and laboratory

One of the largest academic medical centers in Poland, the Medical University of Gdańsk includes two hospitals, totaling 1,100 beds. The Central Laboratory evaluated the ACL TOP 550 CTS system.

Study parameters and process

- More than 5,000 samples were tested during the evaluation
- Hemostasis assays included PT, APTT, fibrinogen, D-dimer, AT, factor VIII and anti-Xa
- Samples were visually inspected for Hemolysis, Icterus and Lipemia (HIL); samples with clots were excluded from the study
- Samples were then run on the ACL TOP 550 CTS system to evaluate the automatic pre-analytical sample integrity checks

Results

↓70% reduction in sample flagging rate (from 3.06 to 0.91%)

↓73% reduction in inappropriate flags

↑12% increase in detection of problematic samples

The 5 samples missed visually were flagged as Lipemic by the ACL TOP 550 CTS system

Conclusion

- Automatic pre-analytical checks on the ACL TOP 550 CTS system improved the accuracy of HIL interference detection and sample quality management, significantly reducing questionable results
- This could result in reductions in pre-analytical errors, time and costs associated with HIL inspection, and sample reanalysis



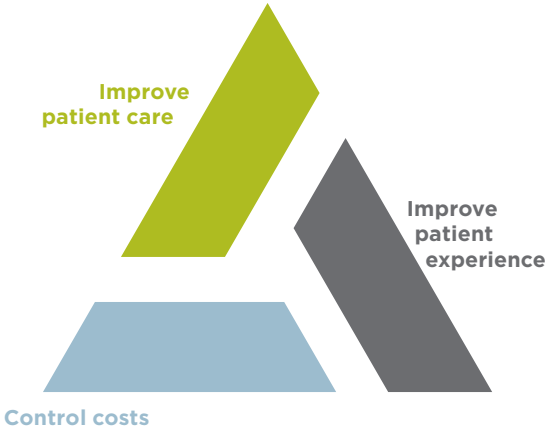
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Case Study:

Impact of automated pre-analytical sample integrity checks on ACL TOP® Family 50 Series Hemostasis testing systems



Yamagata University Hospital
Japan

Overview

Hospital and laboratory

Yamagata University Hospital is a 637-bed teaching hospital and global leader in cancer treatment. The Hemostasis Laboratory has two ACL TOP 750 CTS systems, performing approximately 3,000 tests per month.

Study parameters and process

- More than 10,000 samples were tested during the evaluation
- Hemostasis assays included PT, APTT, fibrinogen, antithrombin, FDP*, D-dimer and soluble fibrin*
- Visual inspection of all samples was performed first, including detection of Hemolysis, Icterus, and Lipemia (HIL) and clots (before and after centrifugation)
- Samples were then run on the ACL TOP 750 CTS system to evaluate the automatic pre-analytical sample integrity checks

*Not FDA 510(k)-cleared nor Health Canada-licensed. Not saleable in the United States or Canada.

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Results

↓2.7% reduction in sample flagging rate (from 0.75 to 0.73%)

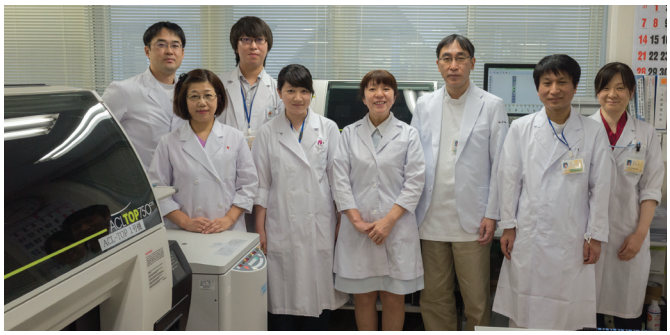
↓45% reduction in inappropriate flags

↑78% increase in detection of problematic samples

Of the 32 samples missed visually, almost half were flagged for low tube-fill height by the ACL TOP 750 CTS system



Conclusion



- Automated pre-analytical sample integrity checks with the ACL TOP 750 CTS system increased the quality inspection of the primary sample compared to visual inspection alone
- While results of both visual and automated checks were in close agreement (99.3%), the abnormal aspiration feature on the ACL TOP 750 CTS system provided a warning of a potential clot
- The primary benefit of the automated pre-analytical check was detection of low tube-fill height missed by visual inspection, and allowance of samples that passed the assay-specific Hemolysis thresholds which would have been rejected by visual methods alone
- By reducing inappropriate sample flagging, ACL TOP Family 50 Series systems have the potential to reduce costly and time-consuming patient redraw

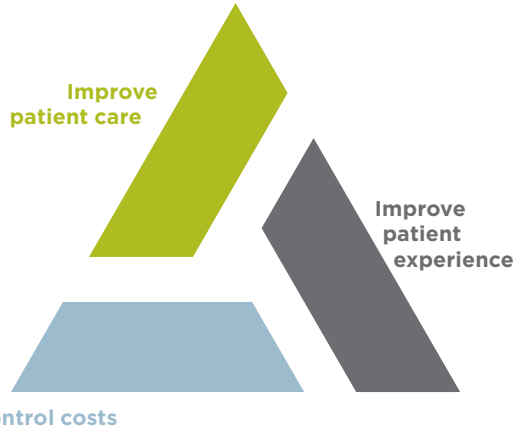
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