Case Study:

Health economics benefits of automating pre-analytical sample checks



Hospital of Legnano

Italy

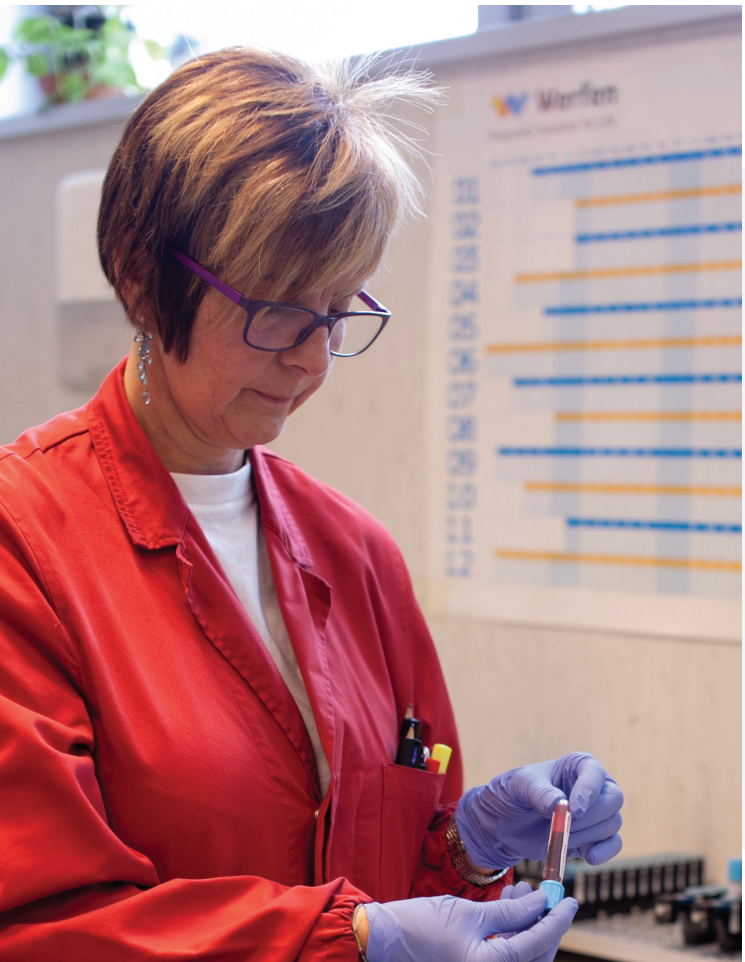
This case study highlights the impact automated pre-analytical sample quality checks on the **ACL TOP® 750 CTS Hemostasis testing system** have on laboratory quality and efficiency metrics. By extending automation and standardization to the pre-analytical phase, ACL TOP Family 50 Series systems minimize the reporting of erroneous results and reduce unnecessary redraws. This results in enhanced laboratory efficiency, improved patient care and experience, and reduced hospital costs.

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Pre-analytical challenges in Hemostasis testing

Laboratory testing provides critical information to physicians and supports 60% to 70% of all clinical decisions.[1,2] The accuracy of test results is, therefore, essential. When errors occur before, during or after the testing process, results can be compromised and ultimately have a negative impact on patient care.[1,3] Errors that occur in the pre-analytical phase of testing account for up to 75% of total laboratory errors. An estimated 26% of pre-analytical errors have detrimental effects on patient care, contributing to unnecessary tests, inappropriate treatment and increased length of hospital stay, as well as patient dissatisfaction with healthcare services.[2]

As such, laboratories around the world have been implementing procedures and innovative technologies aimed at standardizing the entire sample-testing process to prevent, detect and trace pre-analytical errors. Pre-analytical sample integrity is directly linked to the quality of the results reported, and clinicians rely heavily on accurate results to support appropriate treatment.



In Hemostasis testing, the quality of results can be compromised when under-filled sample tubes or the presence of clots interfere with PT and aPTT results and/or alter clotting factors and D-dimer levels. Hemolyzed samples, or samples with elevated levels of lipids or bilirubin, can also negatively affect the results of a number of coagulation parameters (e.g., D-dimer, chromogenic-based assays).[3] To address this, visual inspection of a sample prior to analysis is common practice in Hemostasis testing. However, it is well documented that, even with the most experienced professionals, this practice is subjective and prone to errors.[3]

The automation of sample quality checks by testing systems offers an objective solution to this challenge, along with assurance that pre-analytical issues are accurately detected and flagged. Most important, the automation of sample quality checks also prevents unnecessary sample rejection, thus reducing redraws. This positively impacts the workflow of the laboratory and the hospital at large, as well as the patient experience. Ultimately, automation of sample quality checks improves laboratory efficiency, ensures the quality of the test results, and improves patient care and satisfaction.

ACL TOP Family 50 Series Hemostasis testing systems offer automated:

Sample tube-fill check:

- Triggers warning flag if volume is too low

Test-specific interference detection:

- Measures free Hemoglobin, Icterus and Lipemia (Turbidity) in patient samples

Clog detection:

- Measures pressure changes in the sample fluidic line during aspiration

Overview

With 600 beds, Hospital of Legnano is one of the largest and most specialized in the western Lombardy region of Italy. It belongs to a consolidation of four National Health Care System hospitals in a “Hub and Spoke” structure. The Hematology Laboratory at Hospital of Legnano performs both routine and specialty Hemostasis tests (e.g., thrombophilia panel, lupus anticoagulant, von Willebrand factor). In total, they process nearly 146,000 Hemostasis routine samples annually.



Case study objectives

Primary:

- Determine the impact of **ACL TOP Family 50 Series** systems on inappropriate sample rejection during the pre-analytical phase

Secondary:

- Analyze the costs associated with pre-analytical sample rejection before and after the introduction of ACL TOP Family 50 Series systems in the lab
- Determine the impact of sample redraws on patient care before and after the introduction of ACL TOP Family 50 Series systems in the lab

Methodology

The Hematology Laboratory at Hospital of Legnano performed a three-month clinical study on the detection of potential pre-analytical issues comparing the visual inspection method to the automated sample pre-analytical checks integrated on the ACL TOP 750 CTS testing system. The system was configured using default settings, with assay-specific HIL limits provided by Werfen.

Sample analysis

During the study, 5,060 routine plasma samples were analyzed. First, samples were visually inspected by the operator, per laboratory standard procedure. Abnormalities in sample integrity were recorded for the following parameters:

- Presence of clots
- Low tube-fill volume
- Sample color due to excessive Hemolysis, Icterus and Lipemia

Samples were then classified as “rejected” due to pre-analytical issues or as “accepted,” and therefore considered suitable for analytical testing.

The entire set of samples was then tested on the ACL TOP 750 CTS system. Assays performed included:

- PT + aPTT (70% of samples)
- PT + aPTT + Fibrinogen (20%)
- PT + aPTT + Fibrinogen + D-dimer (10%)

Cost analysis

Costs associated with performing a standard Hemostasis test on a blood sample were calculated by:

- Identifying key activities performed outside and inside the laboratory (including all necessary blood draws/redraws)
- Applying the Population-of-Cost Model before and after the introduction of the ACL TOP Family 50 Series systems to calculate the cost difference

Comparison analysis

The ACL TOP 750 CTS system detected and flagged samples with pre-analytical issues. This data was then compared to data obtained using the visual inspection method.

Note: Interference levels used on ACL TOP Family 50 Series systems are analyte-specific, tested and validated by Werfen and cleared by the U.S. Food and Drug Administration (FDA).

Results

Of the 5,060 total samples analyzed, 124 were rejected using visual inspection. The ACL TOP 750 CTS system flagged 54 for pre-analytical issues (rejected). Upon further analysis, the Laboratory Manager concluded that 70 samples had been "rejected" by visual inspection, thus potentially causing unnecessary sample redraws from patients.

Of the 4,936 samples deemed acceptable by visual inspection, the ACL TOP 750 CTS system flagged five due to pre-analytical issues. Five samples were therefore considered "missed" by visual inspection **(Table 1)**. After further examination by the operator, it was determined that these samples contained micro-clots, a pre-analytical condition with the potential to adversely affect test results. In this case, visual inspection proved to be less sensitive than the automated pre-analytical checks conducted by the ACL TOP 750 CTS system.

Based on these data, the ACL TOP 750 CTS system reduced the total sample rejection rate from 2.45% to 1.17%. Additionally, 8.5% of the samples flagged by the ACL TOP 750 CTS system for pre-analytical issues were not detected by visual inspection.

The implementation of an automated analytical method to detect pre-analytical sample issues resulted in a 52% reduction in sample rejection, equivalent to 1,850 fewer sample redraws annually **(Table 2)**. Such rejections cause sample redraws, impacting laboratory and hospital workflows and operations, delaying the availability of critical test results, and negatively impacting patient care and experience.

		Visual Inspection		
		Rejected samples	**Accepted samples**	**Total**
ACL TOP 750 System	**Rejected samples**	54	5	**59**
	Accepted samples	70	4,931	**5,001**
	Total	**124**	**4,936**	**5,060**

Table 1: Comparison of visual inspection vs. sample pre-analytical checks on ACL TOP 750 CTS system.

	Annualized Data	
	# Redrawn samples	**Associated costs €**
Before **ACL TOP 750 System**	3,529	20,284
After **ACL TOP 750 System**	1,679	9,571
Difference	**1,850**	**10,713**

Table 2: Total number of samples redrawn and associated cost reductions before and after introduction of ACL TOP 750 CTS system.

Note: Cost savings associated with the automation of the pre-analytical sample checks, as well as with sample rejection rates, have been determined. Cost of compromised quality from erroneous results due to pre-analytical issues not detected by visual inspection is not included in this study.

Automating pre-analytical sample integrity checks with ACL TOP Family 50 Series systems reduced the cost of unnecessary sample redraws by 52%, representing an estimated annual savings of 10,713€. Cost calculation was based on total labor and material costs associated with redrawing blood specimens and test repetition. Additionally, overall staff time dedicated to sample quality assessment was reduced by 70%.

Overall impact of the ACL TOP 750 CTS system at Hospital of Legnano

Accuracy of pre-analytical error detection improved

- **8.5%** of samples with pre-analytical issues were not detected by visual inspection

Process efficiency

- **363** less hours per year due to sample redraws
- **70%** reduction in staff time versus visual inspection

Overall costs associated with sample redraws reduced

- **10,713€** annual savings in material and labor costs

52% reduction in sample redraws

Conclusions

ACL TOP Family 50 Series systems reduce the reporting of erroneous results and reduce unnecessary sample redraws. This results in enhanced laboratory efficiency, improved patient care and experience, and reduced hospital costs.

References

1. P Carraro, M Plebani. Errors in a stat laboratory: types and frequencies 10 years later. *Clin Chem.* 2007;Jul;53(7):1338–1342.
2. SF Green. The cost of poor blood specimen quality and errors in pre-analytical processes. *Clin Biochem.* 2013;Sep;46(13–14):1175–1179.
3. E Favaloro, D (Adcock) Funk, G Lippi. Pre-analytical variables in coagulation testing associated with diagnostic errors in hemostasis. *LabMedicine.* 2012;43:1–10.

Insights in Life Sciences (iIS) consultancy firm performed the cost analysis included in this case study.

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