

NEW HEMOSIL® ACUSTAR
ADAMTS13 ACTIVITY ASSAY

Introducing the only automated, on-demand assay for Thrombotic Thrombocytopenic Purpura (TTP) diagnosis and monitoring



FOR USE ON THE
ACL AcuStar®*

HEMOSTASIS INNOVATION IS HERE. ►

 **Instrumentation
Laboratory**
A Werfen Company

On-demand testing for fast, informed clinical decisions

HemosIL AcuStar ADAMTS13 Activity assay* is **the only automated, on-demand test** to aid in the diagnosis and monitoring of TTP, with the superior analytical sensitivity of chemiluminescence technology.

HemosIL AcuStar ADAMTS13 Activity assay*: Fully automated solution for fast, informed clinical decisions

A rapid, on-demand solution with superior analytical sensitivity and unmatched simplicity for the ACL AcuStar Hemostasis testing system—improving care, quality and efficiency.

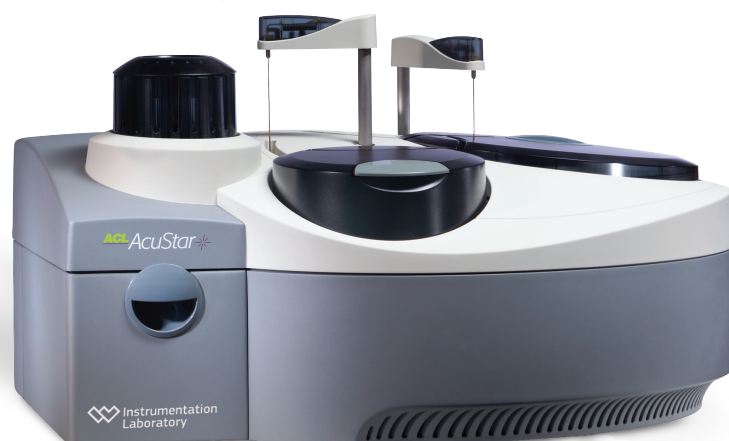
Simple, fast and always ready

- No labor-intensive or manual testing processes required
- Rapid, with first results in approximately 30 minutes
- 8-week onboard stability allows 24/7 on-demand testing

Superior analytical sensitivity with reliable chemiluminescence technology

- Extended linearity quantifies ADAMTS13 activity to 0.2%
- Traceable to World Health Organization ADAMTS13 activity 1st International Standard, ensuring result accuracy

HemosIL[®]
AcuStar ADAMTS13 Activity Assay



* Not FDA 510(k)-cleared and Health Canada licensed. Not saleable in US and Canada.

TTP and ADAMTS13 activity

TTP: Potentially deadly and difficult to diagnose¹

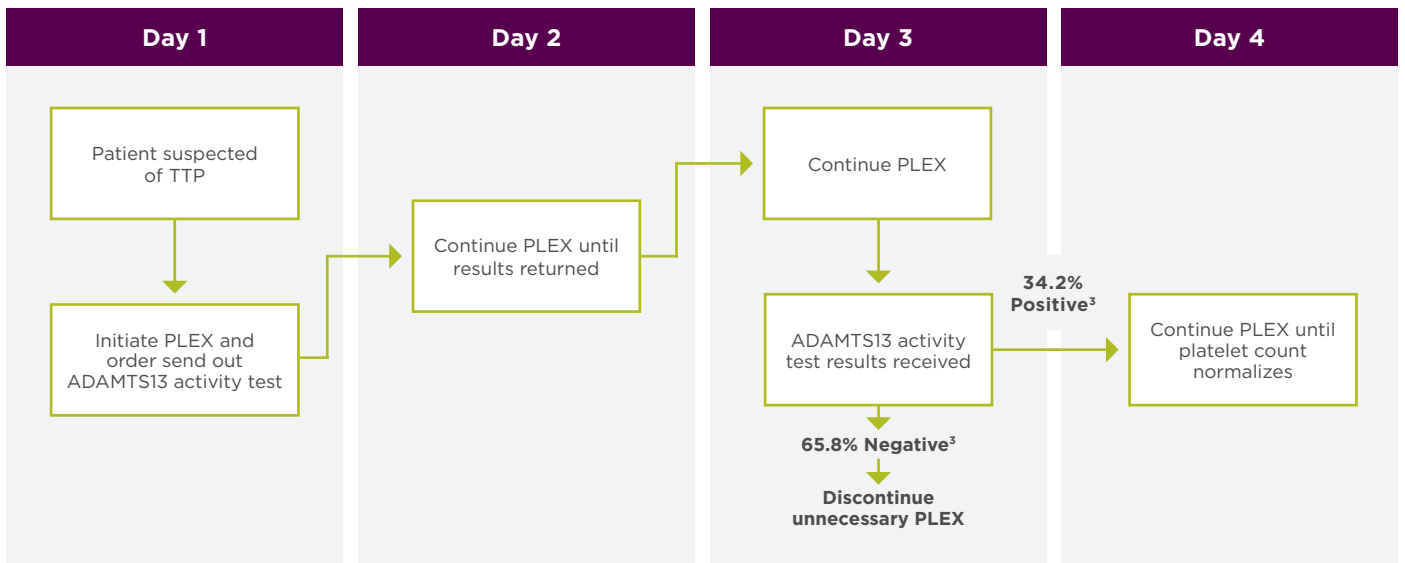
- Life-threatening disease where platelet-rich thrombi form in microvasculature due to ADAMTS13 activity deficiency (von Willebrand factor protease)
- This rare hematologic disease which requires differential diagnosis to distinguish from other thrombotic microangiopathies (TMA)
- 90% mortality rate if untreated, 10%–20% if promptly treated
- Plasma exchange (PLEX) is standard-of-care treatment—initiated immediately (recommended within 4–8 hours of presentation) in patients suspected of TTP²

ADAMTS13 activity

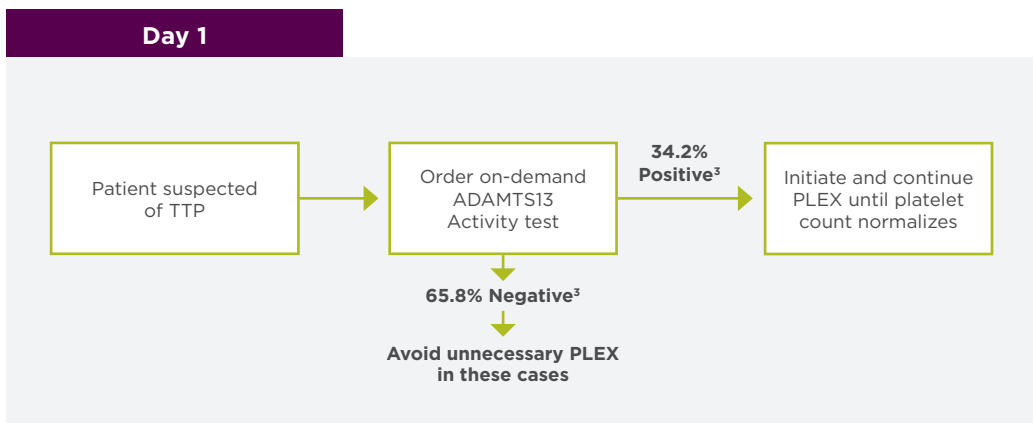
- The only biologic marker specific for TTP
- Current laboratory testing methods (e.g., ELISA, FRET) require specialty lab with turnaround times up to 3 days^{3,4}

HemosIL AcuStar ADAMTS13 Activity assay helps improve quality of patient care and efficiency when TTP is suspected

Scenario 1: Send out ADAMTS13 activity test while initiating PLEX



Scenario 2: On-demand ADAMTS13 Activity assay



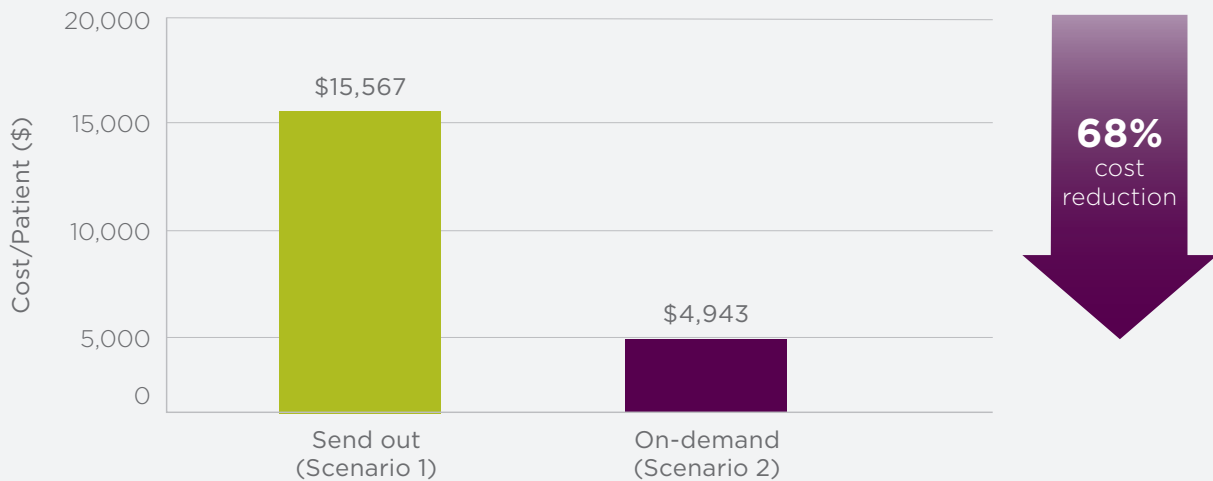
Health-economic impact of on-demand ADAMTS13 activity testing

Limitations of send out testing while initiating PLEX

- Send out ADAMTS13 activity testing can require several days for results⁴
- PLEX should only be used when necessary, due to associated increased mortality, morbidity and related costs^{3,7}
- PLEX has limited efficacy in treating other TMAs^{5,6,8}

On-demand ADAMTS13 activity testing expedites time to results for cost control and improved patient care

Total economic impact of send out vs on-demand ADAMTS13 activity testing³



Improve patient care

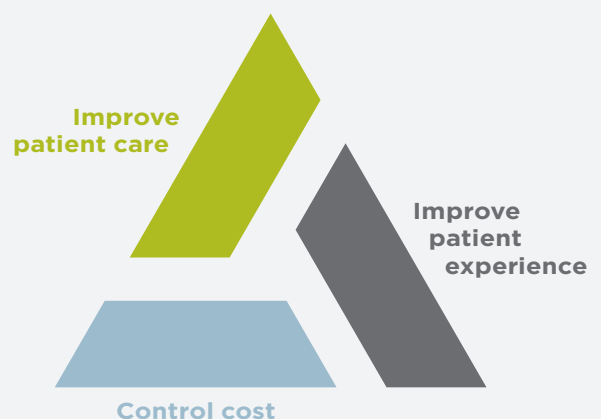
- Faster patient management decisions
- Demonstrated to reduce unnecessary PLEX procedures

Improve patient experience

- Demonstrated to reduce morbidity

Control costs

- Eliminates unnecessary PLEX procedures
- Decreases PLEX utilization



Excellent analytical performance on the ACL AcuStar system

Time-to-first result	33 min	
On-board Stability	56 days	
Linearity	0.2-150%	
Interferences	Hemoglobin	None up to 500 mg/dL
	Bilirubin	None up to 18 mg/dL
	Triglycerides	None up to 1,250 mg/dL
	Rheumatoid Factor (RF)	Presence of RF can cause underestimation
	Human Anti-Mouse Antibody (HAMA)	None up to 1 µg/mL
	von Willebrand Factor (VWF)	None up to 200 IU/dL (200%)
	Heparin (LMWH, UFH)	None up to 2 IU/mL

Method Comparison

Method comparison studies were performed on the ACL AcuStar system against both ELISA and FRET assays with clinically characterized TTP and other TMA samples. HemosIL AcuStar ADAMTS13 Activity assay demonstrated excellent correlation between methods.

N	Slope	Intercept	r	Comparative Method
105	0.975	2.617	0.943	ELISA
100	0.970	7.617	0.970	FRET

NEW HemosIL AcuStar ADAMTS13 Activity kit composition

Product	Part Number	Kit Configuration
HemosIL AcuStar ADAMTS13 Activity Assay*	0009802048	Cartridge (25 tests) Calibrator 0, 1 x 1mL (liq) Calibrator 1, 1 x 1mL (lyo) Calibrator 2, 1 x 1mL (lyo) Resuspension Buffer 1 x 1.8mL (liq)
HemosIL AcuStar VWF Controls*	0009802119	Low VWF Control 3 x 1mL Normal VWF Control 3 x 1mL

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Meet time-critical demands of TTP management

References

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