HemosIL AcuStar D-Dimer Assay

REAGENT	PART NUMBER	KIT CONFIGURATION
HemosIL AcuStar D-Dimer	0009802000	1 Cartridge (100 tests) D-Dimer 1 x 1 mL D-Dimer Calibrator 1 (lyo) 1 D-Dimer Calibrator 1 barcoded tube 1 x 1 mL D-Dimer Calibrator 2 (lyo) 1 D-Dimer Calibrator 2 barcoded tube

CONTROLS	PART NUMBER	KIT CONFIGURATION
HemosIL AcuStar D-Dimer Controls	0009802100	3 x 1 mL Low D-Dimer Control (lyo) 3 D-Dimer Low Control barcoded tubes 3 x 1 mL High D-Dimer Control (lyo) 3 D-Dimer High Control barcoded tubes 3 x 1 mL D-Dimer Very High Control (lyo) 3 D-Dimer Very High Control barcoded tubes

Additional literature

- Bounameaux H, de Moerloose P, Perrier A, Reber G. Plasma Measurement of D-Dimer as Diagnostic Aid in Suspected Venous Thromboembolism: An Overview, *Thrombosis and Haemostasis.* 1994; 71 (1): 1-6.
- de Moerloose P, Reber G, Arnout J. Evaluation of a new quantitative highly sensitive D-dimer assay for the exclusion of venous thromboembolism. *J Thromb Haemost.* 2009; 7: 1590-1.
- de Moerloose P, Vanrusselt M, Reber G, Arnout J. Performance of the HemosIL D-Dimer HS assay for the exclusion of venous thromboembolism, *J Thromb Haemost.* 2005; 3: 2361-2363.
- Legnani C, Palareti G, Cosmi B, Cini M, Tosetto A, Tripodi A. Different cut-off values of quantitative D-Dimer methods to predict the risk of venous thromboembolism recurrence: a post-hoc analysis of the PROLONG study. *Haematologica.* 2008:Jun;93(6):900-907.
- Nieuwenhuizen W. A Reference Material for Harmonisation of D-Dimer Assays, *Thrombosis and Haemostasis.* 1997; 77 (5): 1031-1033.
- Perrier A, Nendaz MR, Sarasin FP, Howarth N, Bournameaux H. Cost-Effectiveness Analysis of Diagnostic Strategies for Suspected Pulmonary Embolism Including Helical Computed Tomography. *Am J Respir Crit Care Med* 2003; 167: 39-44.
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- Toh CH, Hoots WK, on behalf of the SSC on Disseminated Intravascular Coagulation of the ISTH. The scoring system of the Scientific and Standardisation Committee on Disseminated Intravascular Coagulation of the International Society of Thrombosis and Haemostasis: a 5-year overview. *J Thromb Haemost.* 2007; 5: 604-6.
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IL is passionate about bringing the most innovative solutions to Hemostasis testing. Through ACL® products, IL offers a variety of the highest- quality instruments, all complemented by a full panel of HemosIL® assays and supported by a world-class technical team. In addition to a broad Hemostasis testing offering, IL is committed to continuous enhancements through constant innovation.

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HEMOSIL® ACUSTAR

D-DIMER

FOR USE ON THE ACL AcuStar HEMOSTASIS TESTING SYSTEM



D-DIMER

Highly Sensitive, Fully Automated Chemiluminescent D-Dimer Assay

HEMOSTASIS INNOVATION IS HERE.

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Fully automated, high-performance chemiluminescent assay technology, for superior accuracy.

- Cartridge-based, ready-to-use, precalibrated assay for unmatched simplicity
- FDA-cleared as an aid in the diagnosis of Venous Thromboembolism (VTE)
- Clinically validated 500 ng/mL Fibrinogen Equivalent Units (FEU) cut-off
- Extended, eight-week onboard stability—optimal for analysis 24 hours/day, 7 days/week
- Highly sensitive, chemiluminescent immunoassay offers superior accuracy and precision
- Extremely wide linearity range and virtually no optical or Rheumatoid Factor interference

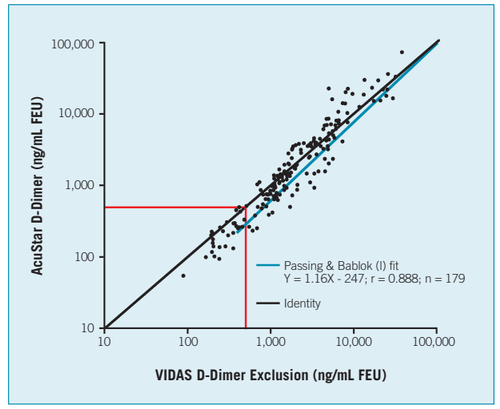
Analytical Performance Data

Linearity	Without Rerun With Rerun	54.3 – 74,000 ng/mL 54.3 – 1,110,000 ng/mL	
Imprecision		**Mean (ng/mL)**	**Total % CV**
	Low D-Dimer control	234	6.8
	Plasma sample	358	5.4
	High D-Dimer control	841	4.9
	Very High D-Dimer control	8,467	5.6
Detection Limit	6.51 ng/mL		



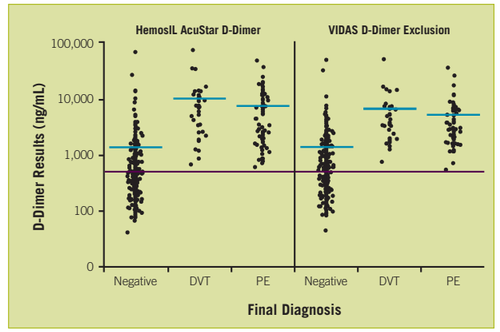
Method comparison
Excellent correlation

A comparison study, using HemosIL AcuStar D-Dimer on the automated ACL AcuStar™ vs. VIDAS D-Dimer Exclusion on the mini VIDAS, on 179 patient plasma samples, demonstrated excellent correlation and slope between the two methods.



Management study
Diagnosis of DVT and PE

A management study, using HemosIL AcuStar D-Dimer and VIDAS D-Dimer Exclusion on 344 frozen samples from patients suspected of Pulmonary Embolism (PE) or Deep Venous Thrombosis (DVT), confirmed 97 as VTE-positive (28.2% VTE frequency) and the remaining 247 as VTE-negative. The optimal cut-off on the ACL AcuStar system was determined to be 500 ng/mL FEU (purple line).



HemosIL AcuStar D-Dimer achieved:

- 100% NPV and 100% Sensitivity
- Higher specificity than VIDAS D-Dimer Exclusion

	HEMOSIL ACUSTAR D-DIMER	VIDAS D-DIMER EXCLUSION
Sensitivity (%) (95% CI)	100 (96.3 – 100)	100 (96.3 – 100)
Specificity (%) (95% CI)	55.5 (49.0 – 61.8)	42.9 (36.7 – 49.3)
NPV (%) (95% CI)	100 (97.3 – 100)	100 (96.6 – 100)