Hemostasis Innovation is Here.

HEMOSIL®
D-DIMER ASSAY PANEL

For the exclusion of

Deep venous thrombosis and pulmonary embolism

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

werfen

Fully automated assays for timely exclusion of VTE

HemosIL D-Dimer, HemosIL D-Dimer HS, and HemosIL D-Dimer HS 500 have been cleared by regulatory authorities for the exclusion of venous thromboembolism (VTE) in outpatients suspected of pulmonary embolism (PE) and deep venous thrombosis (DVT), in conjunction with a clinical pretest probability (PTP) assessment model. Optimized for the ACL TOP® Family and ACL TOP Family 50 Series Hemostasis testing systems, these assays are designed to accommodate various clinical or hospital laboratory needs.[1,2]

Safe and cost-effective

D-dimer testing in conjunction with a PTP assessment model:

- Is a safe and effective strategy for excluding suspected VTE
- Can reduce the need for costly imaging tests[3,4]
- Supports initiatives to reduce radiation exposure from unnecessary imaging studies

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D-Dimer Assays

HemosIL D-Dimer assays offer reliable results in minutes

Specific

- Assay kits contain a latex reagent that is a suspension of polystyrene latex particles of uniform size, coated with a monoclonal antibody highly specific for the D-dimer domain
- HemosIL D-Dimer HS and HemosIL D-Dimer HS 500 assays have demonstrated reduced false positives* with no rheumatoid factor (RF) interference up to 1,400 IU/mL

Enhanced workflow

- Fully automated on ACL TOP Family, ACL TOP Family 50 Series, and ACL Elite®/Elite Pro for optimized laboratory workflow

Rapid results

- Results in as little as 5 minutes with HemosIL D-Dimer HS and HemosIL D-Dimer HS 500
- Results in as little as 7 minutes with HemosIL D-Dimer

D-dimer in clinical practice: reducing costly and invasive tests[3]

Diagnosis of VTE, which includes PE and DVT, often begins with a clinical evaluation followed by D-dimer testing:

- Confirmatory tests generally involve imaging techniques
  - For DVT, these are proximal lower extremity or whole-leg ultrasounds
  - For PE, imaging tests are computed tomography pulmonary angiography (CTPA) or ventilation-perfusion (VQ) scans
- A substantial number of publications[1,2,4] report the use of D-dimer with a PTP assessment model as a safe, cost-effective management strategy for the evaluation of patients presenting with clinically suspected VTE
- This approach allows PE and/or DVT to be excluded in outpatients with suspected VTE who have a low or moderate PTP and a negative D-dimer, reducing the number of imaging tests required

D-dimer testing can help hospitals control costs while improving the patient experience.[4,5]

*Data on file, Werfen.

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D-Dimer HS 500

HemosIL D-Dimer HS 500 is a liquid, ready-to-use immunoassay clinically validated for the exclusion of VTE in outpatients suspected of PE and DVT, in conjunction with a clinical PTP assessment model. With excellent linearity, a low interference profile, and an automation-friendly format, HemosIL D-Dimer HS 500 is ideal for high-specificity[1] D-dimer testing measured in fibrinogen equivalent units (FEU).

Saves Time and Resources	Enhances Patient Care
• Fully automated on ACL TOP Family and ACL TOP Family 50 Series systems • Liquid, ready-to-use	• 100% negative predictive value (NPV) for the exclusion of PE and DVT • No interference from RF up to 1,400 IU/mL • No interference from hemoglobin up to 500 IU/mL

VTE management study with D-Dimer HS 500

- Performed at four hospitals on 747 samples from patients suspected of PE (n = 346) or DVT (n = 401)
- Successfully excluded PE and DVT with an NPV of 100% and sensitivity of 100% (using a cutoff value of 500 ng/mL FEU on the ACL TOP)
- Patient management based on a study-specific diagnostic algorithm involving PTP scoring
- Positive results confirmed through standard imaging techniques; negative results confirmed at a 3-month follow-up

PE Performance

	All Samples	High PTP	Low + Moderate PTP
Samples (n)	346	24	322
Sensitivity (%) (95% CI)	**100** (52/52) (93.2–100)	**100** (9/9) (66.4–100)	**100** (43/43) (91.8–100)
Specificity (%) (95% CI)	**48.3** (142/294) (42.5–54.2)	**33.3** (5/15) (11.8–61.6)	**49.1** (137/279) (43.1–55.1)
NPV (%) (95% CI)	**100** (142/142) (97.4–100)	**100** (5/5) (47.8–100)	**100** (137/137) (97.3–100)

DVT Performance

	All Samples	High PTP	Low + Moderate PTP
Samples (n)	401	79	322
Sensitivity (%) (95% CI)	**100** (90/90) (96–100)	**100** (45/45) (92.1–100)	**100** (45/45) (92.1–100)
Specificity (%) (95% CI)	**42.1** (131/311) (36.6–47.8)	**32.4** (11/34) (17.4–50.5)	**43.3** (120/277) (37.4–49.4)
NPV (%) (95% CI)	**100** (131/131) (97.2–100)	**100** (11/11) (71.5–100)	**100** (120/120) (97–100)

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D-Dimer HS

HemosIL D-Dimer HS offers a proven, accurate, and reliable solution for D-dimer testing utilizing D-dimer units (DDU). With linearity and an interference profile comparable to those of HemosIL D-Dimer HS 500, the HemosIL D-Dimer HS assay provides excellent sensitivity and specificity for the exclusion of VTE in outpatients suspected of PE and DVT, in conjunction with a clinical PTP assessment model.

Saves Time and Resources	Enhances Patient Care
• Fully automated on ACL TOP Family and ACL TOP Family 50 Series systems	• 100% NPV for the exclusion of PE and DVT • No interference from RF up to 1,400 IU/mL • No interference from hemoglobin up to 500 IU/mL

VTE management study with HemosIL D-Dimer HS

- Performed at four hospitals on 668 samples from patients suspected of having PE (n = 361) or DVT (n = 307)
- Successfully excluded PE and DVT with an NPV of 100% and sensitivity of 100% (using a cutoff value of 230 ng/mL DDU on the ACL TOP)
- Patient management based on a study-specific diagnostic algorithm involving PTP scoring
- Positive results confirmed through standard imaging techniques; negative results confirmed at a 3-month follow-up

PE Performance

	All Samples	High PTP	Low + Moderate PTP
Samples (n)	361	28	333
Sensitivity (%) (95% CI)	**100** (58/58) (93.8–100)	**100** (10/10) (69.2–100)	**100** (48/48) (92.6–100)
Specificity (%) (95% CI)	**35.6** (108/303) (30.2–41.3)	**16.7** (3/18) (3.6–41.4)	**36.8** (105/285) (31.2–42.7)
NPV (%) (95% CI)	**100** (108/108) (96.6–100)	**100** (3/3) (29.2–100)	**100** (105/105) (96.5–100)

DVT Performance

	All Samples	High PTP	Low + Moderate PTP
Samples (n)	307	54	253
Sensitivity (%) (95% CI)	**100** (62/62) (94.2–100)	**100** (28/28) (87.7–100)	**100** (34/34) (89.7–100)
Specificity (%) (95% CI)	**38.4** (94/245) (32.2–44.8)	**34.6** (9/26) (17.2–55.7)	**38.8** (85/219) (32.3–45.6)
NPV (%) (95% CI)	**100** (94/94) (96.2–100)	**100** (9/9) (66.4–100)	**100** (85/85) (95.8–100)

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D-Dimer

HemosIL D-Dimer provides proven, accurate, and reliable solutions for D-dimer testing.

Saves Time and Resources	Enhances Patient Care
• Fully automated on ACL TOP Family, ACL TOP Family 50 Series, and ACL Elite/Elite Pro • Uniform cutoff across Werfen Hemostasis testing systems = 230 ng/mL DDU	• Excellent NPV - 100% for PE and DVT on ACL TOP - 99.1% for PE and 100% for DVT on ACL Elite • Lower limit of the 95% confidence interval (CI) is greater than 95% for NPV of low and moderate PTP group

VTE management study with HemosIL D-Dimer

- Performed at four hospitals with samples from patients suspected of having PE and DVT
- Results below based on a cutoff value of 230 ng/mL DDU on ACL TOP and ACL Elite systems
- Patient management based on a study-specific diagnostic algorithm involving PTP scoring
- Positive results confirmed through standard imaging techniques; negative results confirmed at a 3-month follow-up

	PE Performance			DVT Performance		
ACL TOP	**All Samples**	**High PTP**	**Low + Moderate PTP**	**All Samples**	**High PTP**	**Low + Moderate PTP**
Samples (n)	330	24	306	302	53	249
Sensitivity (%) (95% CI)	**100** (50/50) (92.9–100)	**100** (7/7) (59.0–100)	**100** (43/43) (91.8–100)	**100** (59/59) (93.9–100)	**100** (27/27) (87.2–100)	**100** (32/32) (89.1–100)
Specificity (%) (95% CI)	**29.3** (82/280) (24.0–35.0)	**17.6** (3/17) (3.8–43.4)	**30.0** (79/263) (24.6–36.0)	**41.6** (101/243) (35.3–48.0)	**34.6** (9/26) (17.2–55.7)	**42.4** (92/217) (35.7–49.3)
NPV (%) (95% CI)	**100** (82/82) (95.6–100)	**100** (3/3) (29.2–100)	**100** (79/79) (95.4–100)	**100** (101/101) (96.4–100)	**100** (9/9) (66.4–100)	**100** (92/92) (96.1–100)

	PE Performance			DVT Performance		
ACL Elite	**All Samples**	**High PTP**	**Low + Moderate PTP**	**All Samples**	**High PTP**	**Low + Moderate PTP**
Samples (n)	331	25	306	298	54	244
Sensitivity (%) (95% CI)	**98.0** (49/50) (89.4–99.9)	**100** (8/8) (63.1–100)	**97.6** (41/42) (87.4–99.9)	**100** (61/61) (94.1–100)	**100** (29/29) (88.1–100)	**100** (32/32) (89.1–100)
Specificity (%) (95% CI)	**41.3** (116/281) (35.5–47.3)	**41.2** (7/17) (18.4–67.1)	**41.3** (109/264) (35.3–47.5)	**33.8** (80/237) (27.8–40.2)	**24.0** (6/25) (9.4–45.1)	**34.9** (74/212) (28.5–41.7)
NPV (%) (95% CI)	**99.1** (116/117) (95.3–100)	**100** (7/7) (59.0–100)	**99.1** (109/110) (95.0–100)	**100** (80/80) (95.5–100)	**100** (6/6) (54.1–100)	**100** (74/74) (95.1–100)

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D-Dimer Comparison Chart

	HemosIL D-Dimer HS 500	HemosIL D-Dimer HS	HemosIL D-Dimer
Instrument	ACL TOP Family/ACL TOP Family 50 Series		ACL TOP Family/ACL TOP Family 50 Series/ ACL Elite/Elite Pro
Technology (nm)	Latex–671		Latex–405
Units (ng/mL)	FEU	DDU	
Cutoff for VTE	500 ng/mL FEU	230 ng/mL DDU	
Calibration curve	Curve generated by instrument, 5 dilutions, 4 reps		
Detection limit (ng/mL)	203	137	69
Linearity (ng/mL)			
Without rerun	215–7,650	150–3,680	200–1,050
With rerun	215–128,000	150–69,000	200–5,250
Precision (total %)*			
Low	9.5	7.0	7.7
Cutoff	8.9	11.0	9.0
High	7.3	7.0	4.5
Interference			
Hemoglobin (mg/dL)	500	500	100
Bilirubin (mg/dL)	18	18	10
Triglycerides (mg/dL)	1,327	1,327	1,500
RF (IU/mL)	1,400	1,400	60
Onboard stability on ACL TOP Family/ACL TOP Family 50 Series (days)	7	4	2

*Representative of ACL TOP Family data only.

HemosIL D-Dimer assays—fully automated, rapid results for enhanced efficiency and improved patient care.[5,6]

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HemosIL D-Dimer HS 500 Kit

Product	Part Number	Kit Configuration
D-Dimer HS 500	0020500100	3 x 4 mL Latex Reagent (liq) 3 x 6 mL Reaction Buffer (liq) 2 x 1 mL Calibrator (lyo)
D-Dimer HS 500	0020500300	4 x 13.5 mL Latex Reagent (liq) 4 x 16 mL Reaction Buffer (liq) 1 x 1 mL Calibrator (lyo)
D-Dimer HS 500 Controls	0022550030	5 x 1 mL Level 1 D-Dimer HS 500 Control (liq) 5 x 1 mL Level 2 D-Dimer HS 500 Control (liq)

HemosIL D-Dimer HS Kit

Product	Part Number	Kit Configuration
D-Dimer HS	0020007700	3 x 2 mL Latex Reagent (lyo) 3 x 8 mL Reaction Buffer (liq) 2 x 1 mL Calibrator (lyo)
D-Dimer Controls	0022660030	5 x 1 mL Level 1 D-Dimer Control (liq) 5 x 1 mL Level 2 D-Dimer Control (liq)

HemosIL D-Dimer Kit

Product	Part Number	Kit Configuration
D-Dimer	0020008500	4 x 3 mL Latex Reagent (lyo) 4 x 9 mL Reaction Buffer (liq) 2 x 1 mL Calibrator (lyo)
D-Dimer Controls	0022660030	5 x 1 mL Level 1 D-Dimer Control (liq) 5 x 1 mL Level 2 D-Dimer Control (liq)

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