Hemostasis Innovation is Here.

HEMOSIL®
LIQUID ANTI-XA

Measuring heparin, apixaban, and rivaroxaban: simple, fast, 24/7

werfen

Measuring heparin and direct Xa inhibitors

Unfractionated and low molecular weight heparin

Heparin is a highly sulfated polysaccharide characterized by a wide molecular weight range and potent anticoagulant activity. It exists either as unfractionated heparin (UFH) or as depolymerized low molecular weight heparin (LMWH). UFH and LMWH have a rapid anticoagulant effect and are used in the prevention and treatment of venous thromboembolism and acute coronary syndrome.

UFH and LMWH anticoagulant activity occurs when a complex with antithrombin (AT) is formed, potentiating its anticoagulant activity up to 1,000-fold. UFH acts through both FIIa and FXa inhibition, while LMWH is a more efficient catalyst for FXa inhibition.

Laboratory monitoring is extremely important in assessing the appropriate level of anticoagulation in patients.

Anti-Xa testing is used to measure UFH and LMWH and helps improve the quality of care and the patient experience while reducing costs when compared with activated partial thromboplastin time (APTT) testing.[1-7]

The advantages include:

- Direct measurement of heparin activity
- Fewer tests and dosage changes
- Faster time to achieve therapeutic levels

Direct Xa inhibitors

Direct oral anticoagulants (DOACs), such as apixaban and rivaroxaban, do not require routine monitoring. However, measurement of apixaban and rivaroxaban concentrations is recommended by the International Society of Thrombosis and Hemostasis Subcommittee on Control of Anticoagulation in certain clinical scenarios, including:[8]

- Bleeding episodes
- Perioperative management
- Suspicion of overdose

Chromogenic anti-Xa assays are recommended for the measurement of rivaroxaban and apixaban levels.[9]

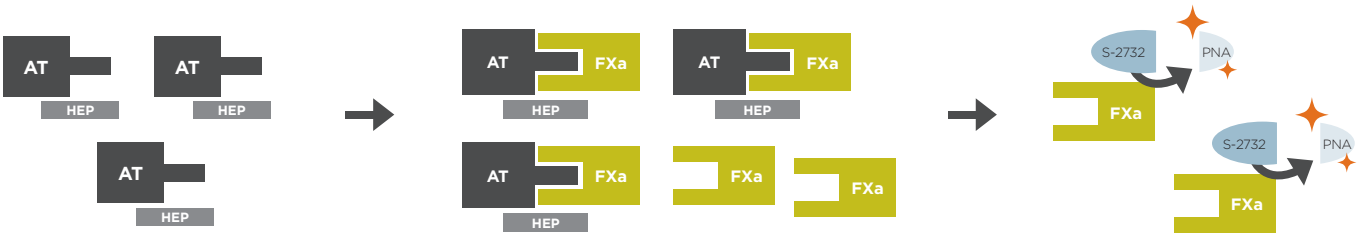
Promoting effective prophylaxis and treatment for patients on heparin

One calibration curve for UFH and LMWH

HemosIL Liquid Anti-Xa is optimized for testing UFH and LMWH with a single calibration curve, saving time and resources by eliminating the need to set up and prepare multiple calibration curves for each heparin type.

HemosIL Liquid Anti-Xa one-stage, universal heparin assay

With the one-stage HemosIL Liquid Anti-Xa assay, heparin is measured as a complex, using only the AT present in the sample (no excess AT is added). FXa is then added to the sample in excess, along with a chromogenic substrate (S-2732). Two competing reactions occur simultaneously, as depicted below.



Heparin/AT complex | **Heparin/AT complex inhibits FXa** | **Substrate hydrolysis by residual FXa releases para-nitroaniline (PNA)**

The resulting absorbance is inversely proportional to the heparin concentration in the plasma.

Greater efficiency and simplicity

With its ready-to-use format and wide linear range, HemosIL Liquid Anti-Xa provides results with greater efficiency in less time. Innovative and simple, the HemosIL Liquid Anti-Xa kit, along with HemosIL Heparin Calibrators and HemosIL UF and LMW Heparin Controls, requires only one calibration curve for the determination of both UFH and LMWH activity over a wide linear range.

- Liquid, ready-to-use
- One-stage chromogenic anti-Xa assay
- Available 24 hours/day, 7 days/week
- Single calibration curve for UFH and LMWH
- Linear up to 2.0 IU/mL for UFH and LMWH
- Measures heparin activity

Calibrators	Controls
• Tri-level calibrator traceable to World Health Organization standards for UFH and LMWH	• Bi-level assayed low and high • Values near therapeutic ranges

Promoting effective management for patients taking DOAC therapy

High-performance automated solution for apixaban and rivaroxaban testing

HemosIL Apixaban and HemosIL Rivaroxaban Calibrators and Controls, used in conjunction with HemosIL Liquid Anti-Xa, deliver an automated solution for reliable results.

Broad linearity

- Rivaroxaban (20–1,000 ng/mL)
- Apixaban (20–1,000 ng/mL)

Analytical performance

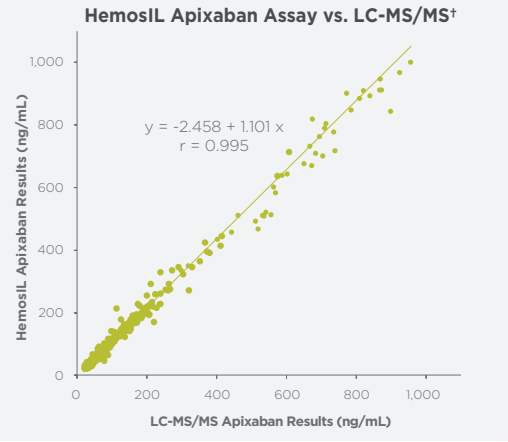
- Fully validated and automated on ACL TOP Family/50 Series/70 Series system

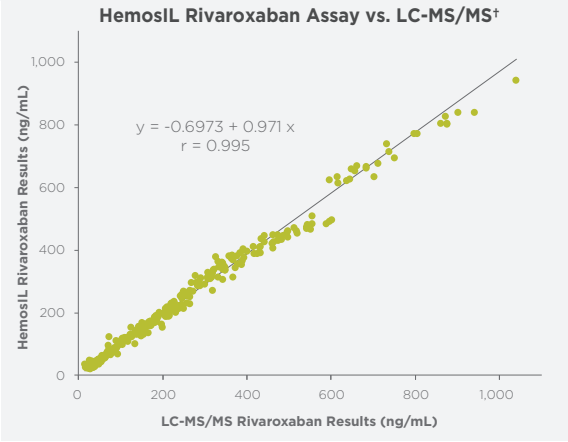
Excellent sensitivity

- Rivaroxaban (LoQ: 20 ng/mL, LoD: 8 ng/mL)
- Apixaban (LoQ: 20 ng/mL, LoD: 9 ng/mL)

	Liquid Anti-Xa			
	Apixaban		**Rivaroxaban**	
Linearity	20–1,000 ng/mL		20–1,000 ng/mL	
Precision	Low control High control	**CV% (total)** 6.4 3.3	Low control High control	**CV% (total)** 4.9 2.4
Interference Hemoglobin Bilirubin Triglycerides	≤300 mg/dL ≤25 mg/dL ≤1,150 mg/dL		≤600 mg/dL ≤40 mg/dL ≤921 mg/dL	
Onboard stability on ACL TOP Family/50 Series/70 Series systems	Liquid Anti-Xa: 4 days at 15–25° C Calibrator/Control: 8 hours at 15–25° C		Liquid Anti-Xa: 4 days at 15–25° C Calibrator/Control: 8 hours at 15–25° C	

Demonstrates excellent agreement with the “gold standard” liquid chromatography-tandem mass spectrometry (LC-MS/MS) method





†Data on file.

HemosIL Liquid Anti-Xa and Heparin/ DOAC Calibrators/Controls

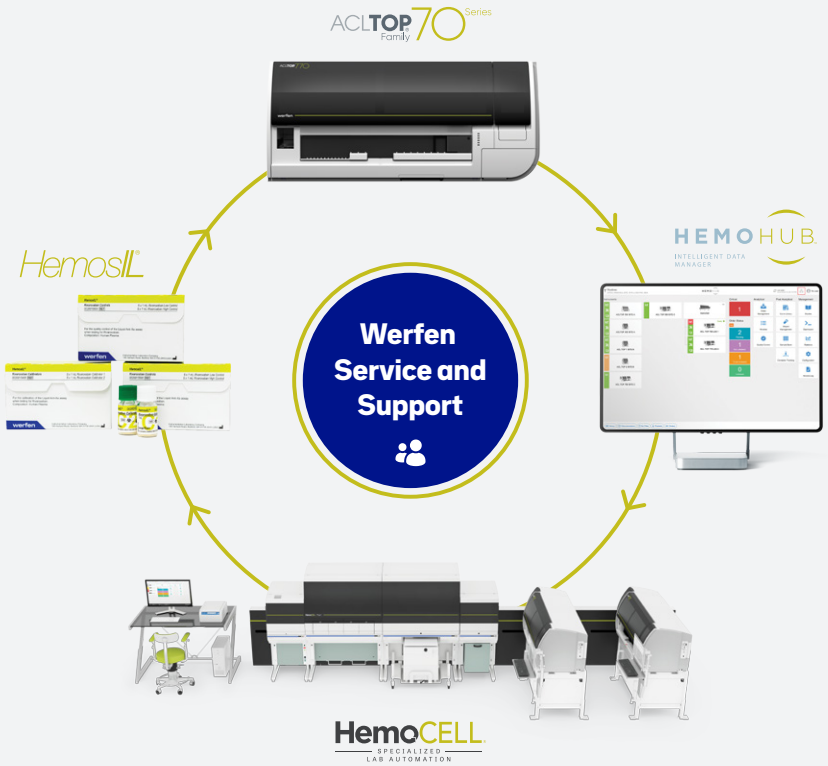
Product	Part Number	Kit Configuration
Liquid Anti-Xa‡ (for Heparin and Direct Xa Inhibitors)	0020302602	5 x 2.5 mL Factor Xa Reagent (liq) 5 x 3 mL Chromogenic Substrate (liq)
Liquid Anti-Xa‡ (for Heparin and Direct Xa Inhibitors)	0020303600	5 x 5 mL Factor Xa Reagent (liq) 5 x 6 mL Chromogenic Substrate (liq)
Liquid Anti-Xa** (for Heparin and Direct Xa Inhibitors)	0020302601	5 x 2.5 mL Factor Xa Reagent (liq) 5 x 3 mL Chromogenic Substrate (liq)
Heparin Calibrators	0020300600	3 x 1 mL Calibrator 1-3 (lyo)
UF Heparin Controls	0020300300	5 x 1 mL Low UF Heparin Control (lyo) 5 x 1 mL High UF Heparin Control (lyo)
LMW Heparin Controls	0020300200	5 x 1 mL Low LMW Heparin Control (lyo) 5 x 1 mL High LMW Heparin Control (lyo)
Rivaroxaban Calibrators‡	0020015400	5 x 1 mL Rivaroxaban Calibrator 1 (lyo) 5 x 1 mL Rivaroxaban Calibrator 2 (lyo)
Rivaroxaban Controls‡	0020015500	5 x 1 mL Rivaroxaban Low Control (lyo) 5 x 1 mL Rivaroxaban High Control (lyo)
Rivaroxaban Calibrators**	0020013600	5 x 1 mL Rivaroxaban Calibrator 1 (lyo) 5 x 1 mL Rivaroxaban Calibrator 2 (lyo)
Rivaroxaban Controls**	0020013700	5 x 1 mL Rivaroxaban Low Control (lyo) 5 x 1 mL Rivaroxaban High Control (lyo)
Apixaban Calibrators‡	0020015200	5 x 1 mL Apixaban Calibrator 1 (lyo) 5 x 1 mL Apixaban Calibrator 2 (lyo)
Apixaban Controls‡	0020015300	5 x 1 mL Apixaban Low Control (lyo) 5 x 1 mL Apixaban High Control (lyo)
Apixaban Calibrators**	0020014200	5 x 1 mL Apixaban Calibrator 1 (lyo) 5 x 1 mL Apixaban Calibrator 2 (lyo)
Apixaban Controls**	0020014300	5 x 1 mL Apixaban Low Control (lyo) 5 x 1 mL Apixaban High Control (lyo)

HemosIL®

‡FDA 510(k) cleared. Not available in all countries. I **Not FDA 510(k) cleared. Not saleable in the US.

The Complete Hemostasis Solution for your lab

- A truly standardized family of Hemostasis systems, accommodating a wide range of testing volumes and needs
- Market-leading, comprehensive panel of HemosIL reagents for routine and specialty testing[10]
- Specialized automation and data management solutions
- Award-winning service and customer support



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