Hemostasis Innovation is Here.

HEMOSIL®
LIQUID ANTI-XA

Monitoring heparin therapy and measuring direct Xa inhibitors: Simple, fast, 24/7



werfen

Monitoring heparin and measuring 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 thrombosis 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 to assess the appropriate level of anticoagulation in patients. Anti-Xa is utilized for UFH and LMWH with Xa.

Anti-Xa testing for monitoring UFH helps improve quality of care and patient experience while reducing costs when compared to APTT testing.[1] The advantages include:

- Higher precision
- Fewer tests and dosage changes[1-6]
- Faster time to achieve therapeutic levels[2-7]

Direct Xa inhibitors

Direct oral anticoagulants (DOAC), such as rivaroxaban and apixaban, do not require routine monitoring. However, there are specific instances when an understanding of the DOAC concentration in a patient sample may be useful.

Clinical scenarios where DOAC measurement may be warranted[8,9]

- Bleeding
- Before surgery or an invasive procedure when the patient has taken the drug in the previous 24 hours, or longer if creatinine clearance (CrCl) is <50 mL/min
- Identification of subtherapeutic or supratherapeutic levels in patients taking other drugs that are known to significantly affect pharmacokinetics
- Identification of subtherapeutic or supratherapeutic levels in patients at the extremes of body weight
- Patients with deteriorating renal function
- Perioperative management
- Reversal of anticoagulation
- Suspicion of overdose
- Assessment of compliance in patients suffering thrombotic events while on treatment

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

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 accurate 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
- Drug-specific calibrators and controls for measurement of rivaroxaban and apixaban

Calibrators	Controls
• Tri-level calibrator traceable to World Health Organization standards for UFH and LMWH • Predetermined heparin concentrations: 0.0, 0.8, and 2.0 IU/mL	• Bi-level assayed low and high • Values near therapeutic ranges

Promoting effective management for patients taking DOAC therapy

High-performance automated solution for rivaroxaban and apixaban testing

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

Superior linearity

- Rivaroxaban (20–1000 ng/mL)
- Apixaban (15–1000 ng/mL)

Excellent sensitivity

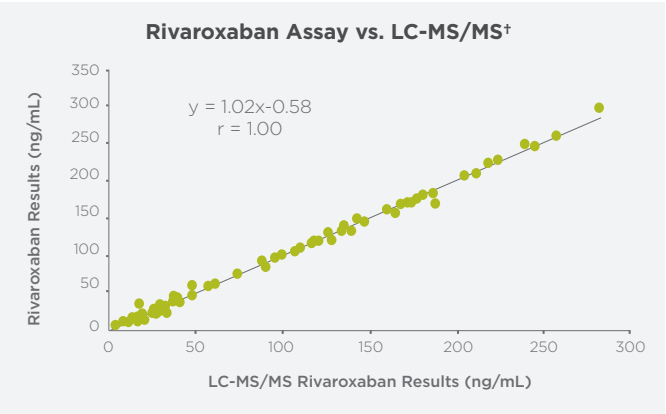
- Rivaroxaban (LoQ:20 ng/mL, LoD:10 ng/mL)
- Apixaban (LoQ:10 ng/mL, LoD:6 ng/mL)

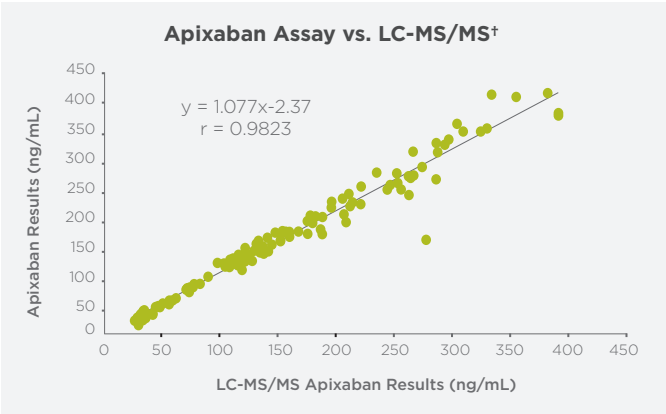
Analytical performance on ACL TOP® Testing Systems

Fully validated and automated on ACL TOP Family and ACL TOP Family 50 Series Hemostasis Testing Systems, the HemosIL Liquid Anti-Xa assay offers reduced interference for superior efficiency.

	Liquid Anti-Xa			
	Apixaban		Rivaroxaban	
Linearity	15–1000 ng/mL		20–1000 ng/mL	
Imprecision	Low control High control	**CV% (total)** 4.0 1.9	Low control High control	**CV% (total)** 4.4 2.2
Interference Hemoglobin Bilirubin Triglycerides	≤300 mg/dL ≤25 mg/dL ≤1156 mg/dL		≤550 mg/dL ≤40 mg/dL ≤1151 mg/dL	
Onboard Stability on ACL TOP Family Testing 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.

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.

The data, below, demonstrate excellent recovery for all heparin preparations tested on ACL TOP Testing systems.

		Heparin recoveries on ACL TOP Testing systems		
Heparin type	**Target values (IU/mL)**	**Calibration with LMWH**	**Calibration with UFH**	**Calibration with Heparin Calibrators**
Fragmin (dalteparin sodium)	0.40 0.80 2.00	0.40 0.77 1.80	0.42 0.80 1.83	0.44 0.78 1.83
Innohep (tinzaparin sodium)	0.40 0.80 2.00	0.40 0.77 1.83	0.46 0.83 1.87	0.44 0.81 1.87
Lovenox (enoxaparin sodium)	0.40 0.80 2.00	0.39 0.83 1.87	0.42 0.86 1.92	0.39 0.84 1.97
LMWH standard	0.40 0.80 2.00	0.40 0.84 1.93	0.43 0.84 1.97	0.40 0.87 1.97
UFH standard	0.40 0.80 2.00	0.42 0.77 1.93	0.44 0.80 1.97	0.42 0.77 1.97

In addition to the three brands of LMWH above, Heparin Calibrators can be used with Fraxiparine (nadroparin calcium) and with UFH, including Calciparin and Leo synthetic heparins. Arixtra (fondaparinux) and Orgaran (danaparoid) have not been standardized against LMWH; Heparin Calibrators can be used upon establishment of a local conversion factor.*

*Data on file.

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

Product	Part Number	Kit Configuration
Liquid Anti-Xa*	0020302600	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)	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**	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**	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)

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

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