HEMOSIL®
LIQUID ANTI-XA

The first FDA-marketing authorized apixaban diagnostic test

High performance in an automated test

HemosIL Liquid Anti-Xa when used with HemosIL Apixaban Calibrators and Controls is intended to measure apixaban concentrations in patients on apixaban therapy at risk for major bleeding and those experiencing a bleeding episode, where measurement of apixaban levels could be useful to have as additional information.

Direct Xa inhibitors

- Anticoagulation for patients with venous thromboembolism (VTE) previously included heparin, heparin derivatives and/or oral vitamin K antagonists. These historical choices are associated with limitations, such as the need for infusion (UFH), subcutaneous injection (LMWH) or dietary influences (warfarin).[1]
- Direct oral anticoagulants (DOAC) are prescribed for VTE prophylaxis or treatment and for reduction of stroke or systemic embolism in patients with nonvalvular atrial fibrillation.[1] Unlike heparin, some DOACs, such as apixaban, act by directly inhibiting Factor Xa activity independent of the antithrombin (AT) present.
- DOACs do not require routine monitoring. However, measurement of apixaban concentration is recommended by the International Society of Thrombosis and Hemostasis Subcommittee on Control of Anticoagulation in certain clinical scenarios, including bleeding episodes, perioperative management and suspicion of overdose.[2]
- Chromogenic anti-Xa assays are recommended for the measurement of apixaban levels.[3,4]

Performance characteristics*

Description	Results
Linearity	20–1000 ng/mL
Limit of Detection (LoD)	9 ng/mL
Precision CV% (total)	Low Control: 5.9 High Control: 2.4
Reconstituted/Opened Vial Stability (2–8°C in original vials)	**Liquid Anti-Xa Assay:** 1 month **Apixaban Calibrators:** 7 days **Apixaban Controls:** 7 days
Onboard Stability on ACL TOP® systems (15–25°C in original vials)	**Liquid Anti-Xa Assay:** 7 days **Apixaban Calibrators:** 8 hours **Apixaban Controls:** 8 hours
Reconstituted Stability (-20°C in original vials)	**Apixaban Calibrators:** 60 days **Apixaban Controls:** 60 days



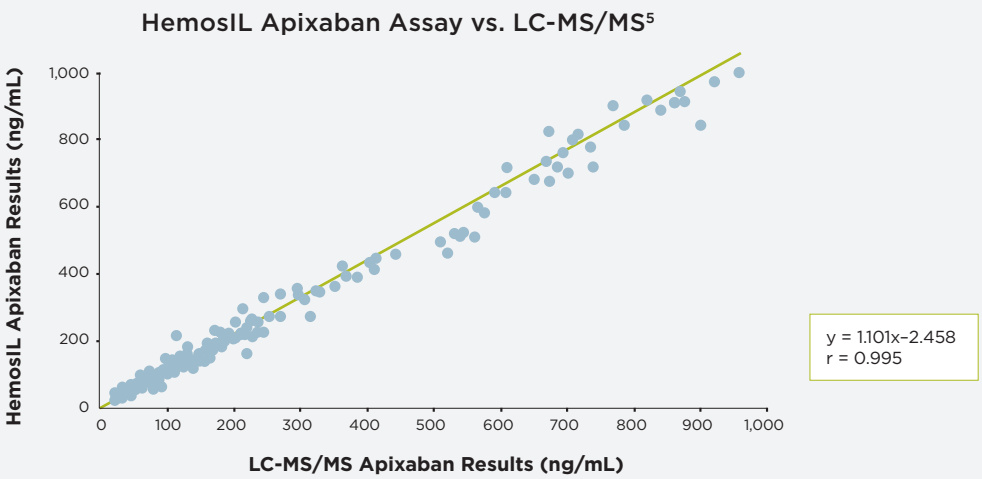
Broader testing for improved patient care.

UFH = unfractionated heparin, LMWH = low molecular weight heparin
*On ACL TOP and ACL TOP Family 50 Series Systems.

werfen

Excellent agreement with Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) results

The HemosIL Liquid Anti-Xa Assay,* used in conjunction with HemosIL Apixaban Calibrators and Controls, demonstrates excellent agreement with the LC-MS/MS method.



Apixaban Assay Precision†

	Mean (ng/mL)	CV% (within run)	CV% (total)
Apixaban Low Control	68.0	4.8	5.9
Apixaban High Control	277.0	1.6	2.4

†On ACL TOP Hemostasis Testing Systems.

HemosIL Apixaban Testing Kit Configurations

HemosIL Apixaban Calibrators (p/n 0020014200)			
Component	**# of Vials**	**Format**	**Vial Volume (mL)**
Apixaban Calibrator 1 (0 ng/mL)	5	Lyo	1.0
Apixaban Calibrator 2 (~500 ng/mL)	5	Lyo	1.0
HemosIL Apixaban Controls (p/n 0020014300)			
Apixaban Low Control (~80 ng/mL)	5	Lyo	1.0
Apixaban High Control (~300 ng/mL)	5	Lyo	1.0
HemosIL Liquid Anti-Xa Assay (p/n 0020302601)			
Factor Xa Reagent	5	Liq	2.5
Chromogenic Substrate	5	Liq	3.0

References

1. Gosselin RC, Adcock DM, Douxfils J. An update on laboratory assessment for direct oral anticoagulants (DOACs). *Int J Lab Hematol.* 2019;41 (Suppl. 1):33–39.
2. Martin K, Beyer-Westendorf J, Davidson BL, Huisman MV, Sandset PM, Moll S. Use of the direct oral anticoagulants in obese patients: guidance from the SSC of the ISTH. *J Thromb Haemost.* 2016;14:1308–1313.
3. Dale BJ, Chan NC, Eikelboom JW. Laboratory measurement of the direct oral anticoagulants. *Br J Haematol.* 2016;172(3):315–336.
4. Gosselin RC, Adcock DM, Bates SM, Douxfils J, Favaloro EJ, Gouin-Thibault I. International council for standardization in haematology (ICSH) recommendations for laboratory measurement of direct oral anticoagulants. *Thromb Haemost.* 2018;118:437–450.
5. Data on file.

werfen.com

For more information, contact your local Werfen sales representative or distributor.

ACL, ACL AcuStar, ACL Elite, ACL TOP, HemoCell, HemoHub, HemosIL, ReadiPlasTin, RecombiPlasTin, SynthAFax and SynthASil are trademarks of Instrumentation Laboratory Company and/or one of its subsidiaries or parent companies and may be registered in the United States Patent and Trademark Office and in other jurisdictions. The Werfen logo is a trademark of Werfen and may be registered in the Patent and Trademark Offices of jurisdictions throughout the world. All other product names, company names, marks, logos and symbols are trademarks of their respective owners.

©2022 Instrumentation Laboratory. All rights reserved.

APIX.SS EUROW Rev00 02/22

werfen