

A validated, automated solution for rivaroxaban testing

High performance in an automated solution

Certain clinical scenarios may warrant measurement of direct oral anticoagulant (DOAC) concentration, such as rivaroxaban. HemosIL Rivaroxaban Calibrators and Controls, used in conjunction with the HemosIL Liquid Anti-Xa Assay, deliver an automated solution with excellent linearity, precision and accuracy—for reliable results that may enhance patient management decisions.

DOAC testing may be warranted when a patient taking a DOAC:¹

- Presents to the ER with an adverse event (e.g., thrombosis, hemorrhage)
- Requires immediate reversal of anticoagulation
- Experiences renal or liver failure
- Experiences suspected or known interaction with other drugs
- Requires verification of pre-operative drug clearance

Performance characteristics

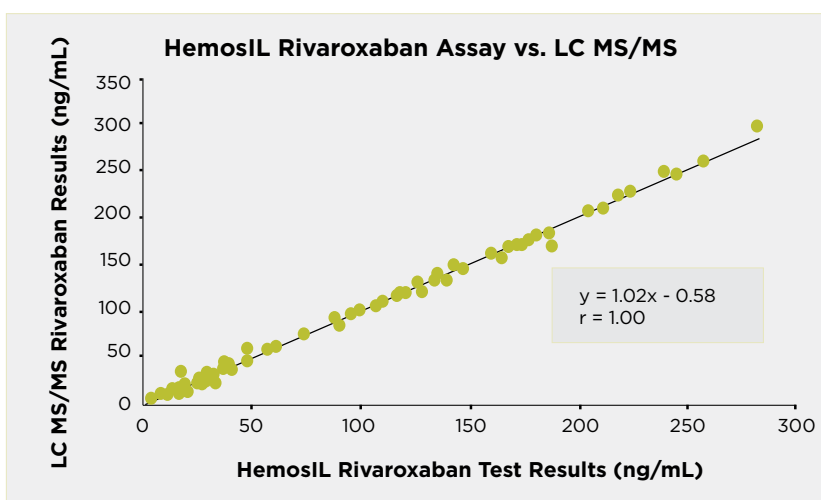
Description	Results
Linearity	20–1,000 ng/mL
Limit of Detection (LoD)	10 ng/mL
Limit of Quantitation (LoQ)	20 ng/mL
Precision (CV%)	Low Control: 4.4 (total) High Control: 2.2 (total)
Reconstituted/Opened Vial Stability (2–8° C in original vials)	Liquid Anti-Xa Assay: 1 month Rivaroxaban Calibrators: 7 days Rivaroxaban Controls: 7 days
Onboard Stability on ACL TOP® systems (original vials)	Liquid Anti-Xa Assay: 7 days at 15–25° C Rivaroxaban Calibrators: 8 hours at 15–25° C Rivaroxaban Controls: 8 hours at 15–25° C
Reconstituted Stability (–20° C in original vials)	Rivaroxaban Calibrators: 60 days Rivaroxaban Controls: 60 days



Greater efficiency for improved patient care.

Excellent agreement with Liquid Chromatography MS/MS results

The HemosIL Liquid Anti-Xa Assay, used in conjunction with HemosIL Rivaroxaban Calibrators and Controls, demonstrates excellent agreement with the “gold standard” LC MS/MS method.



Additionally, a field study compared samples from patients treated with rivaroxaban on an ACL TOP system using HemosIL Liquid Anti-Xa versus a commercially available rivaroxaban assay. Comparison data: $r = 0.97$, slope = 0.99, intercept = -27.63.

Rivaroxaban Assay Precision (on ACL TOP Hemostasis Testing Systems)

	Mean (ng/mL)	CV% (within run)	CV% (total)
Rivaroxaban Low Control	79.22	1.9	4.4
Rivaroxaban High Control	298.57	0.8	2.2

Automated on ACL TOP Hemostasis Testing Systems

HemosIL Liquid Anti-Xa Assay Kit Configuration (~115 tests/kit)

Reagents: HemosIL Liquid Anti-Xa Assay (p/n 0020302601)			
Component	# of Vials	Format	Vial Volume (mL)
FXa Reagent	5	Liq	2.5
Chromogenic Substrate	5	Liq	3.0
Calibrators: HemosIL Rivaroxaban Calibrators (p/n 0020013600)			
Component	# of Vials	Format	Vial Volume (mL)
RIV Cal 1 (0 ng/mL)	5	Lyo	1.0
RIV Cal 2 (~500 ng/mL)	5	Lyo	1.0
Controls: HemosIL Rivaroxaban Controls (p/n 0020013700)			
Component	# of Vials	Format	Vial Volume (mL)
RIV Low Control (~80 ng/mL)	5	Lyo	1.0
RIV High Control (~300 ng/mL)	5	Lyo	1.0

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

1. Pengo V, Crippa L, Falanga A, et al. Questions and answers on the use of dabigatran and perspectives on the use of other new oral anticoagulants in patients with atrial fibrillation. *Thromb Haemost.* 2011;106:868-76.