HemosIL®

# 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 total)** | Low Control: 4.4 (total)<br>High Control: 2.2 (total) |
| **Reconstituted/Open Vial Stability**<br>(2–8° C in original vials) | **Liquid Anti-Xa Assay:** 1 month<br>**Rivaroxaban Calibrators:** 7 days<br>**Rivaroxaban Controls:** 7 days |
| **Onboard Stability on ACL TOP® systems**<br>(original vials) | **Liquid Anti-Xa Assay:** 7 days at 15–25° C<br>**Rivaroxaban Calibrators:** 8 hours at 15–25° C<br>**Rivaroxaban Controls:** 8 hours at 15–25° C |
| **Reconstituted Stability**<br>(-20° C in original vials) | **Rivaroxaban Calibrators:** 60 days<br>**Rivaroxaban Controls:** 60 days |

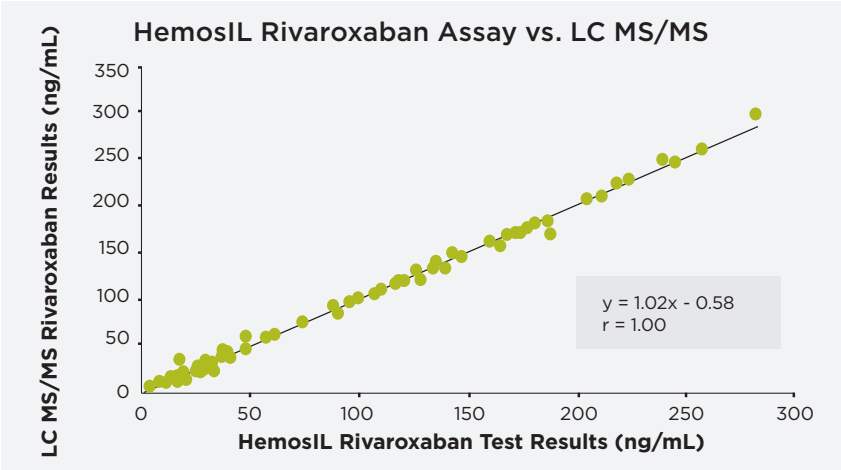
## Greater efficiency for improved patient care.

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

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## 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)

| **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 |
| **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 |
| **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 |

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;106:868-876.

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

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