When accuracy is critical, trust superior sensitivity.

Fully automated on ACL TOP Family 50 Series Hemostasis Testing Systems
Superior performance for accurate DOAC testing

Direct Oral Anticoagulants (DOACs), such as dabigatran and rivaroxaban, do not require routine monitoring. However, there are instances when determining levels of these drugs may be warranted. The HemosIL DOAC Assay Panel provides superior analytical performance in a standardized and validated automated solution.

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

- Presents to the ER with an adverse event (e.g., thrombosis or 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
A complete automated solution for anticoagulation testing.
HemosIL assays are fully automated on the new ACL TOP Family 50 Series testing systems for a complete disease-state management solution designed to minimize errors and enhance quality of care. Other HemosIL anticoagulation assays include Liquid Anti-Xa, APTT and PT reagents.

A validated, automated solution for dabigatran testing

High performance in an automated solution
Certain clinical scenarios may warrant measurement of direct oral anticoagulant (DOAC) concentration, such as dabigatran. The HemosIL Direct Thrombin Inhibitor Assay, used in conjunction with HemosIL Dabigatran Calibrators and Controls, offers an automated solution with excellent linearity, precision and accuracy—for reliable results that may help improve outcomes for critically ill patients.

DOAC testing may be warranted when a patient taking a DOAC:¹
- Presents to the ER with an adverse event (e.g., thrombosis or 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

<table>
<thead>
<tr>
<th>Description</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linearity</td>
<td>20–2,000 ng/mL</td>
</tr>
<tr>
<td>Limit of Detection (LoD)</td>
<td>2 ng/mL</td>
</tr>
<tr>
<td>Limit of Quantitation (LoQ)</td>
<td>20 ng/mL</td>
</tr>
<tr>
<td>Precision (CV%)</td>
<td>Low Control: 3.6 (total)</td>
</tr>
<tr>
<td></td>
<td>High Control: 4.1 (total)</td>
</tr>
<tr>
<td>Reconstituted Stability (2–8º C)</td>
<td>Direct Thrombin Inhibitor Assay: 48 hours</td>
</tr>
<tr>
<td></td>
<td>Dabigatran Calibrators: 7 days</td>
</tr>
<tr>
<td></td>
<td>Dabigatran Controls: 7 days</td>
</tr>
<tr>
<td>Onboard Stability on ACL TOP (original vials)</td>
<td>Direct Thrombin Inhibitor Assay: 6 hours at 15º C</td>
</tr>
<tr>
<td></td>
<td>Dabigatran Calibrators: 8 hours at 15–25º C</td>
</tr>
<tr>
<td></td>
<td>Dabigatran Controls: 8 hours at 15–25º C</td>
</tr>
<tr>
<td>Reconstituted Stability (-20º C)</td>
<td>Direct Thrombin Inhibitor Assay: 30 days</td>
</tr>
<tr>
<td></td>
<td>Dabigatran Calibrators: 30 days</td>
</tr>
<tr>
<td></td>
<td>Dabigatran Controls: 30 days</td>
</tr>
</tbody>
</table>
Excellent linearity and precision

The HemosIL Direct Thrombin Inhibitor Assay, used in conjunction with HemosIL Dabigatran Calibrators and Controls, performs with consistent accuracy across a wide working range.

![Dabigatran Assay Linearity Graph]

\[ y = 1.1082x - 11.226 \]
\[ R^2 = 0.99905 \]

Dabigatran Test Recovery (ng/mL)

- 2,500
- 2,000
- 1,500
- 1,000
- 500
- 0

Reference Dabigatran Value (ng/mL)

- 3,000
- 2,500
- 2,000
- 1,500
- 1,000
- 500
- 0

Dabigatran Assay Precision (on ACL TOP® Family Hemostasis Testing Systems)

<table>
<thead>
<tr>
<th>Component</th>
<th>Mean (ng/mL)</th>
<th>CV% (within run)</th>
<th>CV% (total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dabigatran Low Control</td>
<td>45</td>
<td>2.2</td>
<td>3.6</td>
</tr>
<tr>
<td>Dabigatran High Control</td>
<td>196</td>
<td>1.8</td>
<td>4.1</td>
</tr>
</tbody>
</table>

Automated on ACL TOP Family of Hemostasis Testing Systems

HemosIL DTI Assay Kit Configuration (60 tests/kit)

**Reagents: HemosIL Direct Thrombin Inhibitor Assay (p/n 0020302800)**

<table>
<thead>
<tr>
<th>Component</th>
<th># of Vials</th>
<th>Format</th>
<th>Vial Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTI Thrombin Reagent</td>
<td>3</td>
<td>Lyo</td>
<td>1.0</td>
</tr>
<tr>
<td>DTI Thrombin Diluent</td>
<td>3</td>
<td>Liq</td>
<td>2.2</td>
</tr>
<tr>
<td>DTI Plasma Diluent</td>
<td>3</td>
<td>Lyo</td>
<td>2.0</td>
</tr>
</tbody>
</table>

**Calibrators: HemosIL Dabigatran Calibrators (p/n 0020013400)**

<table>
<thead>
<tr>
<th>Component</th>
<th># of Vials</th>
<th>Format</th>
<th>Vial Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAB Cal 1 (0 ng/mL)</td>
<td>5</td>
<td>Lyo</td>
<td>2.0</td>
</tr>
<tr>
<td>DAB Cal 2 (~500 ng/mL)</td>
<td>5</td>
<td>Lyo</td>
<td>1.0</td>
</tr>
</tbody>
</table>

**Controls: HemosIL Dabigatran Controls (p/n 0020013500)**

<table>
<thead>
<tr>
<th>Component</th>
<th># of Vials</th>
<th>Format</th>
<th>Vial Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAB Low Control (~50 ng/mL)</td>
<td>5</td>
<td>Lyo</td>
<td>1.0</td>
</tr>
<tr>
<td>DAB High Control (~250 ng/mL)</td>
<td>5</td>
<td>Lyo</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Greater efficiency for improved patient care.


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For more information, contact your local IL sales representative or distributor.
High performance in an automated solution

In certain clinical scenarios, measuring the concentration of a direct oral anticoagulant (DOAC), such as apixaban, may be warranted. HemosIL Apixaban 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 and enhanced patient management decisions.

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

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

<table>
<thead>
<tr>
<th>Performance characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>Linearity</td>
</tr>
<tr>
<td>Limit of Detection (LoD)</td>
</tr>
<tr>
<td>Limit of Quantitation (LoQ)</td>
</tr>
<tr>
<td>Precision (CV%)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Reconstituted/Opened</td>
</tr>
<tr>
<td>Vial Stability</td>
</tr>
<tr>
<td>(2–8°C in original vials)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Liquid Anti-Xa Assay:</td>
</tr>
<tr>
<td>Onboard Stability on</td>
</tr>
<tr>
<td>ACL TOP® systems (original</td>
</tr>
<tr>
<td>vials)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Reconstituted Stability</td>
</tr>
<tr>
<td>(-20°C in original vials)</td>
</tr>
</tbody>
</table>

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 Apixaban Calibrators and Controls,* demonstrates excellent agreement with the “gold standard” LC MS/MS method.

Additionally, a field study compared samples from patients treated with apixaban on an ACL TOP system using HemosIL Liquid Anti-Xa versus a commercially available apixaban assay. Comparison data: $r = 0.997$, slope = 1.06, intercept = -2.53.

Apixaban Assay Precision (on ACL TOP Hemostasis Testing Systems)

<table>
<thead>
<tr>
<th>Component</th>
<th>Mean (ng/mL)</th>
<th>CV% (within run)</th>
<th>CV% (total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apixaban Low Control</td>
<td>79.6</td>
<td>2.3</td>
<td>4.0</td>
</tr>
<tr>
<td>Apixaban High Control</td>
<td>322.3</td>
<td>1.4</td>
<td>1.9</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Component</th>
<th># of Vials</th>
<th>Format</th>
<th>Vial Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FXa Reagent</td>
<td>5</td>
<td>Liq</td>
<td>2.5</td>
</tr>
<tr>
<td>Chromogenic Substrate</td>
<td>5</td>
<td>Liq</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Calibrators: HemosIL Apixaban Calibrators (p/n 0020014200)

<table>
<thead>
<tr>
<th>Component</th>
<th># of Vials</th>
<th>Format</th>
<th>Vial Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>APIX Cal 1 (0 ng/mL)</td>
<td>5</td>
<td>Lyo</td>
<td>1.0</td>
</tr>
<tr>
<td>APIX Cal 2 (~500 ng/mL)</td>
<td>5</td>
<td>Lyo</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Controls: HemosIL Apixaban Controls (p/n 0020014300)

<table>
<thead>
<tr>
<th>Component</th>
<th># of Vials</th>
<th>Format</th>
<th>Vial Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>APIX Low Control (~80 ng/mL)</td>
<td>5</td>
<td>Lyo</td>
<td>1.0</td>
</tr>
<tr>
<td>APIX High Control (~300 ng/mL)</td>
<td>5</td>
<td>Lyo</td>
<td>1.0</td>
</tr>
</tbody>
</table>

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

* Not 510(k) cleared. Not available in all countries.