

# 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:<sup>1</sup>

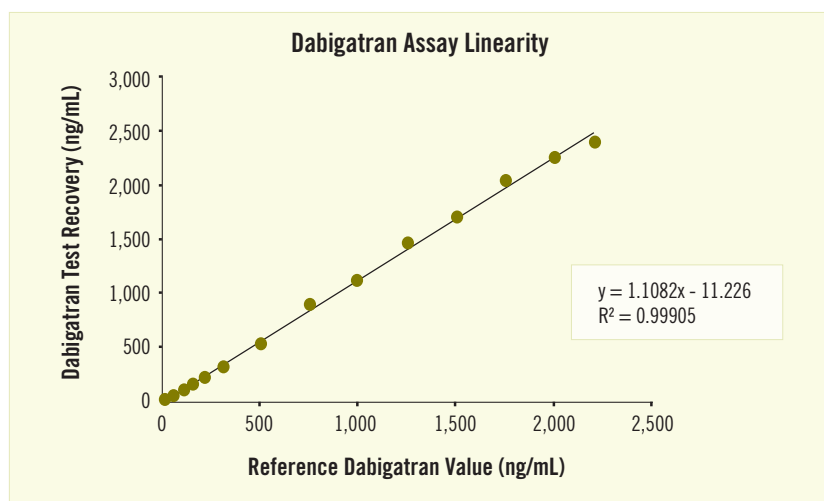
- Presents to the ER with an adverse event (e.g., thrombosis or hemorrhage)
- Requires immediate reversal of anticoagulation
- Experiences renal or liver failure
- Experiences suspected or known interaction with other drugs
- Requires verification of pre-operative drug clearance

## Performance characteristics

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

## 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 Precision (on ACL TOP® Family Hemostasis Testing Systems)

	Mean (ng/mL)	CV% (within run)	CV% (total)
Dabigatran Low Control	45	2.2	3.6
Dabigatran High Control	196	1.8	4.1

## 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)			
Component	# of Vials	Format	Vial Volume (mL)
DTI Thrombin Reagent	3	Lyo	1.0
DTI Thrombin Diluent	3	Liq	2.2
DTI Plasma Diluent	3	Lyo	2.0
Calibrators: HemosIL Dabigatran Calibrators (p/n 0020013400)			
Component	# of Vials	Format	Vial Volume (mL)
DAB Cal 1 (0 ng/mL)	5	Lyo	2.0
DAB Cal 2 (~500 ng/mL)	5	Lyo	1.0
Controls: HemosIL Dabigatran Controls (p/n 0020013500)			
Component	# of Vials	Format	Vial Volume (mL)
DAB Low Control (~50 ng/mL)	5	Lyo	1.0
DAB High Control (~250 ng/mL)	5	Lyo	1.0

Greater efficiency for improved patient care.

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.

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