A validated, automated solution for dabigatran testing

High performance in an automated solution

In certain clinical scenarios, measuring the concentration of a direct oral anti-coagulant (DOAC), such as dabigatran, may be warranted. The HemosIL Direct Thrombin Inhibitor Assay,* used in conjunction with HemosIL Dabigatran Calibrators and Controls,* delivers an automated solution with excellent linearity, precision, and accuracy—for reliable results and enhanced patient management decisions.

Clinical scenarios where DOAC measurement may be warranted[1]

- Bleeding
- Before surgery or an invasive procedure when the patient has taken the drug in the previous 24 hours, or longer if creatinine clearance (CrCl) is <50 mL/min
- Identification of subtherapeutic or supratherapeutic levels in patients taking other drugs that are known to significantly affect pharmacokinetics
- Identification of subtherapeutic or supratherapeutic levels in patients at the extremes of body weight
- For patients with deteriorating renal function
- Perioperative management
- Reversal of anticoagulation
- Suspicion of overdose
- Assessment of compliance in patients suffering thrombotic events while on treatment

Performance characteristics

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

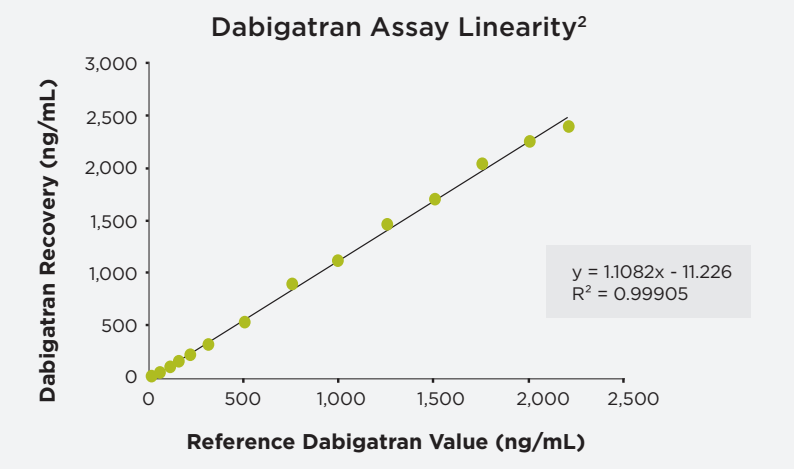


Greater efficiency for improved patient care.

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

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 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 Hemostasis Testing systems

HemosIL DTI Assay Kit Configuration (~60 tests/kit)

HemosIL Direct Thrombin Inhibitor Assay (p/n 0020302800)			
Component	**# of Vials**	**Format**	**Vial Volume (mL)**
DTI Thrombin Reagent	3	Lyo	2.0
DTI Thrombin Diluent	3	Liq	2.2
DTI Plasma Diluent	3	Lyo	2.0
HemosIL Dabigatran Calibrators (p/n 0020013400)			
Component	**# of Vials**	**Format**	**Vial Volume (mL)**
Dabigatran Cal 1 (0 ng/mL)	5	Lyo	2.0
Dabigatran Cal 2 (~500 ng/mL)	5	Lyo	1.0
HemosIL Dabigatran Controls (p/n 0020013500)			
Component	**# of Vials**	**Format**	**Vial Volume (mL)**
Dabigatran Low Control (~50 ng/mL)	5	Lyo	1.0
Dabigatran High Control (~200 ng/mL)	5	Lyo	1.0

1. Baglin T, Hillarp A, Tripodi A, Elalamry I, Buller H, Ageno W. Measuring oral direct inhibitors of thrombin and factor Xa: a recommendation from the Subcommittee on Control of Anticoagulation of the Scientific and Standardization Committee of the International Society of Thrombosis and Haemostasis. *J Thromb Haemost*. 2013;11(4):756–760.
2. Data on file, Werfen.

werfen.com

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

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