Local Contact Information

Siemens Healthcare
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Telephone: +1 914-631-8000
siemens.com/healthcare

Siemens Healthcare Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens.com/healthcare

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siemens.com/healthcare

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Specific Circumstances Require Specific Testing

The INNOVANCE DTI Assay delivers the reliability your lab needs to confidently test for dabigatran.

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Confidently test for dabigatran at a moment's notice with the specific and stable INNOVANCE DTI Assay.

Dabigatran is a direct thrombin inhibitor that belongs to the group of direct oral anticoagulants (DOAC). While routine monitoring of dabigatran with laboratory diagnostics is not recommended, testing can be necessary in certain emergency and preoperative situations as well as special patient populations.

Because testing can occur in urgent or emergency situations, labs require an assay that can be used immediately when needed, without labor-intensive, time-consuming preparation. And because dabigatran is not routinely and frequently tested, the components of the dabigatran assay must be sufficiently stable after opening to be used economically, with minimal waste.

In addition, many existing assays employ a diluted thrombin time test method, which may lack specificity in the assessment of dabigatran concentration. This is potentially due to the fact that clot formation, the end point of coagulation assays, can be influenced by many factors, including the concentration of fibrinogen, fibrinogen (or fibrin) degradation products, abnormal concentrations of physiologic plasma constituents, or the presence of drugs.[1]

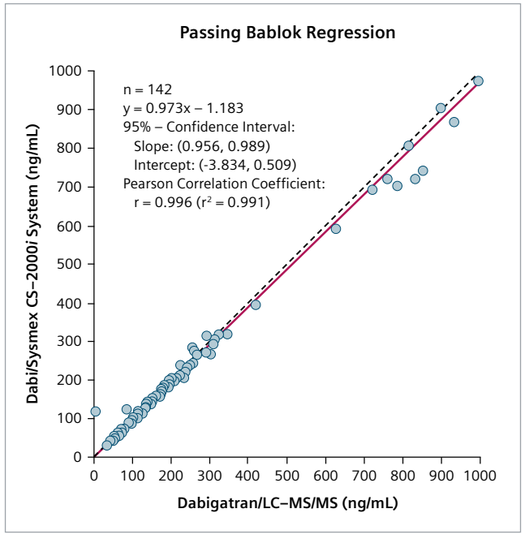
Specific, Timely, and Economical Dabigatran Testing

The INNOVANCE® DTI Assay from Siemens Healthcare is an automated chromogenic assay for dabigatran that combines high specificity and a broad measuring range of 20–500 ng/mL* so you can be confident in your dabigatran results. Liquid, ready-to-use diluent and substrate, as well as one-step reagent reconstitution minimize preparation time and allow easy integration of the assay into laboratory workflows, with minimal involvement of lab personnel. Extended onboard stability (24 or 54 hours, depending on the analyzer used) allows testing to occur immediately when needed, even in emergency situations.

Performance that Matters

The INNOVANCE DTI Assay is an automated chromogenic assay for the quantitative determination of direct thrombin inhibitors in citrated human plasma. Assay results show a strong correlation to liquid chromatography tandem-mass spectrometry (LC-MS/MS), as shown in Figure 1. Running on the BCS® XP System and Sysmex® CS Systems,† the INNOVANCE DTI Assay exhibits high correlation between systems and provides excellent lot-to-lot consistency.

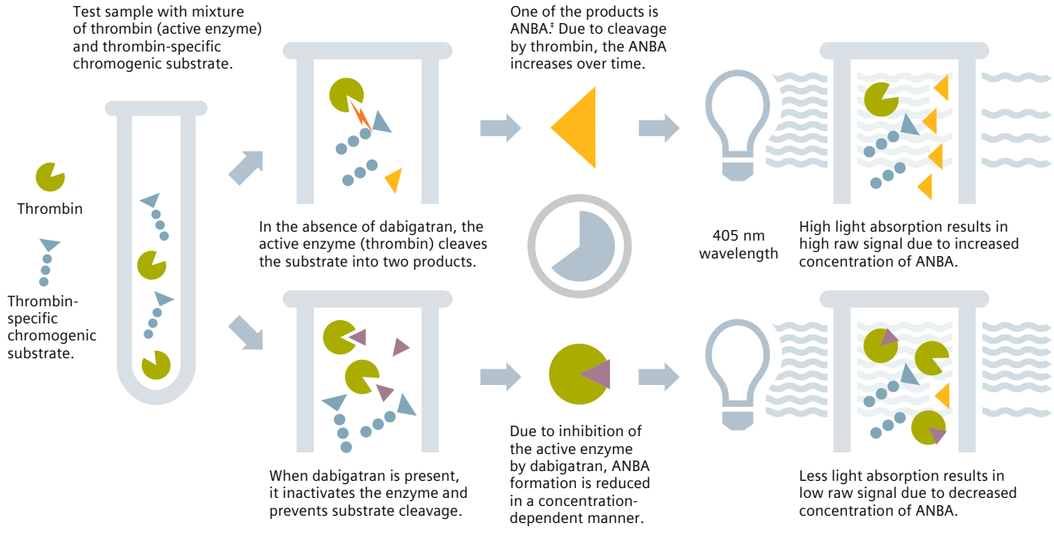
Figure 1. INNOVANCE DTI Assay Results Compared to LC-MS/MS



Increased Confidence, Not Cost

The chromogenic assay principle depicted in Figure 2 is the key technology employed by the INNOVANCE DTI Assay and delivers the high specificity needed to minimize uncertainty during testing. Due to the composition of the reagent, the assay is not influenced by the presence of therapeutic doses of unfractionated heparin (UFH) or low-molecular-weight heparin (LMWH), as shown in Table 1.

Figure 2. Chromogenic Assay Principle With and Without Dabigatran



These performance characteristics, combined with a broad measuring range, deliver an assay that consistently provides dabigatran results you can trust. With assay components that are stable for up to 8 weeks after opening (at 2-8°C), results are economical to obtain as well as specific and reliable.

Integrates Easily Into Lab Workflows

The INNOVANCE DTI Assay is easy to use and ready for testing whenever required. The assay kit includes lyophilized reagent and ready-to-use liquid substrate accompanied by a diluent, providing approximately 120 tests per kit. The ready-to-use diluent allows one-step reconstitution of the reagent with no waiting time, unlike other assays that may require up to 30 minutes or more for preparation. Controls and calibrators (available in separate kits) dissolve in water in only 15 minutes; other dabigatran controls can take up to 30 minutes.

Table 1. No Interference to the Following Levels:

Interferent	Sysmex CS-2100*i* System	BCS XP System
Bilirubin, Conjugated	24 mg/dL	40 mg/dL
Bilirubin, Unconjugated	36 mg/dL	36 mg/dL
Hemoglobin	400 mg/dL	402 mg/dL
Triglycerides	384 mg/dL	706 mg/dL
Unfractionated Heparin	14.3 IU/mL	8 IU/mL
Low-molecular-weight Heparin	17.5 IU/mL	15 IU/mL

Provide Reliable, Timely Dabigatran Testing

The INNOVANCE DTI Assay provides specific, reliable dabigatran results you can trust and is available for use with no waiting time and minimal preparation. Its extended onboard stability allows testing to occur when needed, and the long-term, once opened stability of its components makes the assay cost-effective, with minimal waste. Get the reliable, timely dabigatran testing you need. Contact your Siemens representative today for more information.

*Extensible up to 1000 ng/mL by sample predilution.
†Available on the Sysmex CS-2000*i*, CS-2100*i*, CS-2500, and CS-5100 Systems.
‡5-amino-2-nitro-benzoic acid.

1. Lind S, Boyle ME, Fisher S, Ishimoto J, Trujillo T, Kiser, T. Comparison of the aPTT with alternative tests for monitoring direct thrombin inhibitors in Patient samples. Am J Clin Pathol. 2014;141:665-674.