



INNOVANCE Anti-Xa assay

Anticoagulant testing, simplified

Simplify your anticoagulant testing
with one streamlined, ready-to-use
assay for heparin and DOAC testing.

siemens-healthineers.com/anti-xa

One solution for streamlined, ready-to-use anti-Xa testing

New! INNOVANCE Anti-Xa assay has now been extended to test for edoxaban.*

To monitor and manage bleeding risks, labs are asked to safeguard anticoagulant therapies such as heparin or direct oral anticoagulants (DOACs) by testing patients for a growing number of agents. This testing often requires significant time from lab staff, as multiple reagents and steps are frequently required to perform testing.

Anticoagulant testing, simplified

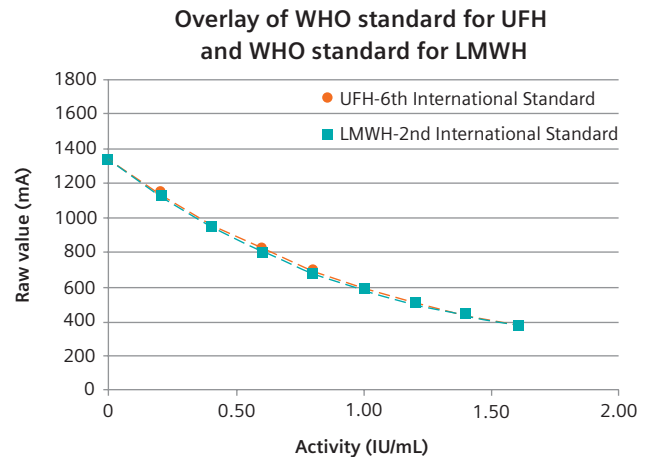
The INNOVANCE Anti-Xa assay is an automated, chromogenic assay for the quantitative determination of the activity of unfractionated heparin (UFH) and low-molecular-weight heparin (LMWH) as well as rivaroxaban*, apixaban, and edoxaban* concentrations in citrated human plasma. By combining heparin and DOAC testing into one simple and easy-to-use assay, the INNOVANCE Anti-Xa assay streamlines handling, reduces order complexity, and offers labs an economical testing outcome.

Available without the wait

The INNOVANCE Anti-Xa assay combines truly ready-to-use liquid reagent for heparin and DOAC testing, allowing 24/7 access to rapid and specific testing for anticoagulants. Unlike most other commercially available solutions, this assay requires no manual preparation or waiting time. These features not only help to control bleeding risk and balance drug dosing to prevent adverse patient outcomes, but accelerate your lab's anticoagulant testing workflow.

Why accurate DOAC assessment is imperative

Direct oral anticoagulants such as rivaroxaban, apixaban, and edoxaban are direct anti-Xa inhibitor drugs that have evolved over time because of their convenient dosing and short half-life. Though the medication usually does not require monitoring, DOAC testing is needed to properly manage individuals with bleeding conditions, emergency situations that require unplanned surgery, and relevant comorbidities (e.g., renal insufficiency).



Measured with the INNOVANCE Anti-Xa assay on the BCS XP System.

Secure and precise result interpretation

The INNOVANCE Anti-Xa assay features a universal calibrator set that employs a single calibration curve for both types of heparin (UFH and LMWH), streamlining result interpretation and eliminating the risk of evaluation on the wrong curve. The universal calibrator set is traceable to the World Health Organization (WHO) standards for UFH and LMWH, helping to ensure that laboratory personnel can confidently and accurately interpret heparin results.

In addition, the INNOVANCE Anti-Xa assay features three drug-specific standards sets for the DOACs rivaroxaban*, apixaban, and edoxaban*, allowing for accurate measurement of drug concentrations in ng/mL.

*Not available for sale in the U.S. Product availability may vary from country to country and is subject to varying regulatory requirements.

Why anti-Xa is the better choice for heparin testing

Heparin is a traditional anticoagulant drug and exists in two forms—UFH and LMWH—both of which considerably accelerate the inactivation of coagulation factor Xa by antithrombin. Clinical data shows that monitoring heparin with an anti-Xa assay has several advantages over APTT testing:¹⁻⁵

- A smoother dose-response curve
- More-stable heparin levels during therapy
- Fewer blood samples required
- Fewer dosage adjustments

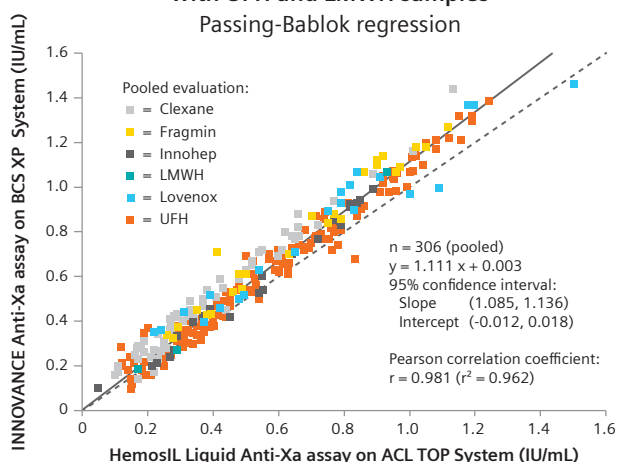
Robust performance across all parameters

- Single calibration curve for heparin testing that includes five levels for improved accuracy and precision
- Broad assay range of 0.10 to 1.50 IU/mL for UF and LMW heparin, extendable up to 2.25 IU/mL by sample dilution, confirming consistency of single calibration curve concept
- Quantitative measurements of rivaroxaban*, apixaban, and edoxaban* by using drug-specific calibration curves

- Measuring range for DOACs of 20–350 ng/mL, extendable up to 700 ng/mL by sample dilution
- Robust assay design that reduces susceptibility to interferences
- High lot-to-lot consistency that helps ensure consistent patient results over time

INNOVANCE Anti-Xa assay method comparison study with UFH and LMWH samples

Passing-Bablok regression



Improved outcomes for labs of any size

With its compact and ready-to-use configuration, INNOVANCE Anti-Xa assay supports improved laboratory outcomes. Applications are available for a wide range of systems, serving the needs of any-sized lab:

- Liquid reagents require no manual preparation or reconstitution, allowing staff to concentrate on high-value tasks
- Combined testing solution reduces handling, material, and ordering complexity for the lab
- Up to 36 tests per reagent vial across all systems, depending on test mix†
- Ready-to-use assay supports timely patient treatment
- Available on multiple platforms, including the BCS XP,[§] CA-660,[‡] CS-2500, CS-5100, and CN-3000/6000 Systems

INNOVANCE Anti-Xa assay method comparison studies on CS-2500 System vs. STA-Liquid Anti-Xa assay on STA Compact Max System

	Number (n)	Correlation Coefficient (r)	Regression Equation	Predicted Bias at		
				30 ng/mL	50 ng/mL	100 ng/mL
Rivaroxaban*	102	0.979	$y = 0.945x + 5.136$ ng/mL	3.5 ng/mL	2.4 ng/mL	-0.4 ng/mL
Apixaban	107	0.975	$y = 1.081x - 2.329$ ng/mL	0.1 ng/mL	1.7 ng/mL	5.8 ng/mL
Edoxaban*	103	0.994	$y = 0.996x - 2.836$ ng/mL	-3.0 ng/mL	-3.0 ng/mL	-3.2 ng/mL

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†Test capacity ranges from 22–36 tests. DOAC tests only: 22 tests per vial; heparin tests only: 36 tests per vial.

‡Heparin applications only.

§UFH/LMWH, rivaroxaban*, and apixaban applications only.

Built on a proven principle: INNOVANCE Anti-Xa assay

The INNOVANCE Anti-Xa assay builds on the proven performance of the INNOVANCE Heparin assay. It leverages the same proven components used in the INNOVANCE Heparin assay, but now also includes DOAC testing capabilities. Further, it complements the Siemens Healthineers menu of hemostasis products that deliver the performance your lab needs to overcome the most difficult testing challenges.



Contact your Siemens Healthineers representative today to simplify your anticoagulant testing with the INNOVANCE Anti-Xa assay.

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. Sustainably. As a leader in medical technology, we want to advance a world in which breakthroughs in healthcare create new possibilities with a minimal impact on our planet. By consistently bringing innovations to the market, we enable healthcare professionals to innovate personalized care, achieve operational excellence, and transform the system of care.

Our portfolio, spanning in vitro and in vivo diagnostics to image-guided therapy and cancer care, is crucial for clinical decision-making and treatment pathways. With the unique combination of our strengths in patient twinning,* precision therapy, as well as digital, data, and artificial intelligence (AI), we are well positioned to take on the greatest challenges in healthcare. We will continue to build on these strengths to help overcome the world's most threatening diseases, enable efficient operations, and expand access to care.

We are a team of more than 72,000 Healthineers in over 70 countries passionately pushing the boundaries of what is possible in healthcare to help improve the lives of people around the world.

**Personalization of diagnosis, therapy selection and monitoring, aftercare, and managing health.*

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References:

1. Vandiver JW, Vondracek TG. Antifactor Xa levels versus activated partial thromboplastin time for monitoring unfractionated heparin. *Pharmacotherapy*. 2012;32(6):546-58.
2. Vandiver JW, Vondracek TG. A comparative trial of anti-factor Xa levels versus the activated partial thromboplastin time for heparin monitoring. *Hosp Pract*. 2013;41(2):16-24.
3. Liveris A, Bello RA, Friedmann P, Duffy MA, Manwani D, Killinger JS, Rodriguez D, Weinstein S. Anti-factor Xa assay is a superior correlate of heparin dose than activated partial thromboplastin time or activated clotting time in pediatric extracorporeal membrane oxygenation. *Pediatr Crit Care Med*. 2014;15(2):e72-9.
4. Adatya S, Uriel N, Yarmohammadi H, Holley CT, Feng A, Roy SS, Reding MT, John R, Eckman P, Zantek ND. Anti-factor Xa and activated partial thromboplastin time measurements for heparin monitoring in mechanical circulatory support. *JACC Heart Fail*. 2015;3(4):314-22.
5. van Roessel S, Middeldorp S, Cheung YW, Zwinderman AH, de Pont AC. Accuracy of aPTT monitoring in critically ill patients treated with unfractionated heparin. *Neth J Med*. 2014;72(6):305-10. Free access: <http://www.njmonline.nl/getpdf.php?id=1463>

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