



INNOVANCE D-Dimer Assay

Proven D-dimer testing for robust VTE exclusion

[siemens-healthineers.com](https://www.siemens-healthineers.com)

SIEMENS
Healthineers 

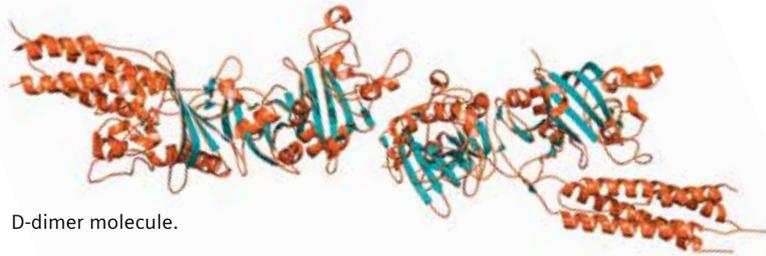
Expanding precision medicine by advancing therapy outcomes through proven D-dimer testing

D-dimer is a global indicator of coagulation activation and fibrinolysis and therefore an indirect marker of thrombotic activity. Low levels of D-dimer can be found circulating under normal physiological conditions, while pathologically elevated levels can be found in any condition associated with enhanced fibrin formation and fibrinolysis, such as venous thromboembolism, disseminated intravascular coagulopathy (DIC), cancer, surgery, pregnancy, inflammatory diseases, and others.¹ An international standard for D-dimer assays does not yet exist, which makes proven, robust reagent performance even more important.

The major diagnostic application of D-dimer testing is for the exclusion of thromboembolic events, such as deep vein thrombosis (DVT) or pulmonary embolism (PE) in conjunction with a clinical pretest probability (PTP) assessment model in outpatients suspected of VTE.^{2,3}

Speed, reliability, and linearity of test results are critical factors for efficient D-dimer testing, particularly

in high-risk clinical practice situations. In addition, efficient assessment of thrombotic events using D-dimer tests is essential in reducing hospital and laboratory costs by avoiding more expensive diagnostic methods, enabling early detection of life-threatening thrombotic complications, and avoiding unnecessary or inappropriate treatment.



The INNOVANCE D-Dimer Assay Links a broad range of clinical utility with economical testing

Applicable across a wide range of clinical conditions:

- **Exclusion of DVT and PE** in outpatients with a non-high PTP. An age-related cutoff may be applied.
- **Diagnosis and monitoring of hypercoagulable states** in patients at risk or with signs of DIC⁴, or COVID-19-associated coagulopathy.⁵
- **Exclusion of VTE in pregnancy.** Pregnancy-related reference ranges have been reported for the INNOVANCE D-Dimer Assay and showed good distinction between trimesters and from normal population.^{6,7}

Excellent clinical performance enables fast, sensitive, and specific results to support patient care throughout diagnosis, monitoring, and follow-up

- **Validated negative predictive value (NPV)** of $\geq 99\%$ enables safe rule-out of DVT/PE in outpatients suspected of VTE, using a cutoff of 0.50 mg/L FEU. This was demonstrated in studies close to real-life experience, in accordance to the CLSI guideline H59-A³ and FDA requirements.
- **Excellent precision and low lot-to-lot variability** ensure high consistency of results: $\leq 6.7\%$ CV assay precision* and between-laboratory mean variance of 8.3% CV (based on 16,936 responses of EQA participants over 6 consecutive years).⁸
- **11-minute-or-less turnaround time** ensures fast availability of results in emergencies for Siemens Healthineers-validated applications.
- **Linearity across a broad measuring range** helps reduce reruns. The 0.19–4.4 mg/L FEU measuring range[†] can be extended up to 35.20 mg/L FEU by automatic redilution, which can cover $>96\%$ of test results.⁹
- **A HAMA blocker and no interferences from rheumatoid factors** up to 1330 IU/mL help to reduce false-positive results and unnecessary diagnostic follow-up.

*Within-device/lab CV.

†0.17–4.4 mg/L FEU with BCS XP System.

INNOVANCE D-Dimer Assay: speed, linearity, and reliability for efficient testing

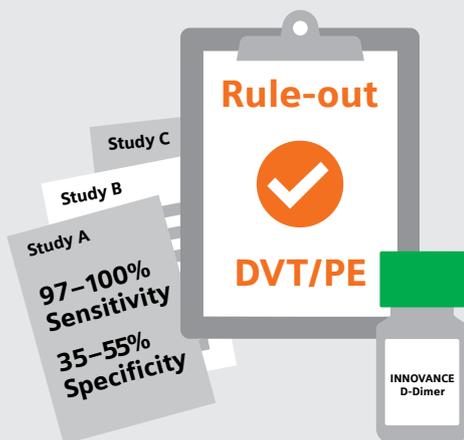
To address these needs, Siemens Healthineers engineered the INNOVANCE® D-Dimer Assay. This assay combines diagnostic efficiency with clinical utility and stable performance on platforms of different sizes, using the same cutoff across platforms. It has a fast turnaround time and seamlessly integrates into the workflow of your laboratory.

The INNOVANCE D-Dimer Assay is a proven, automated test for D-dimer testing. With its broad measuring range and controls covering normal to pathological D-dimer levels, the INNOVANCE D-Dimer Assay allows detection and monitoring of D-dimer for a variety of patient conditions. The assay provides high lot-to-lot consistency and supports improved patient management and outcomes.



INNOVANCE D-Dimer Assay ordering information

Description	REF	SMN
Small kit with 150 tests	OPBP03	10445979
Large kit with 300 tests	OPBP07	10445980
Diluent kit	OPBR03	10487039
Controls kit	OPDY03	10446005



Prospective single and multicenter studies in Europe, the U.S., and Asia confirmed that the INNOVANCE D-Dimer Assay excludes DVT/PE with high sensitivity and specificity.¹⁰⁻¹⁶

Economical testing solution for any-sized lab enables access to care

- **Fully automated assay** with high correlation across systems for small to large laboratories.
- **Validated applications** for Atellica® COAG 360 and BCS® XP Systems and Sysmex® CS-2500, CS-5100, and CA-600 Systems, with excellent correlation and a common cutoff of 0.50 mg/L FEU.
- **Long once-opened and onboard stability** for efficient, 24/7 use of the assay in labs of all sizes: 4 weeks of stability after opening and system-specific onboard stability, e.g., 14 days for the Atellica COAG 360 System and 120 hours for the Sysmex CS-2500 or CS-5100 Systems.
- **Extended calibration curve stability** for reduced work in the lab. The calibration curve was shown to remain valid for up to 12 months.
- **Two assayed controls for both decision ranges:** consistently in the normal range, below the cutoff (Control 1), or above the cutoff in the pathological range (Control 2) with a precision of $\leq 3.4\%$ CV on the Atellica COAG 360 System.

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

Atellica, BCS, INNOVANCE, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc., or its affiliates. Sysmex is a registered trademark of Sysmex Corporation. All other trademarks and brands are the property of their respective owners.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

References:

1. Bates SM. D-dimer assays in diagnosis and management of thrombotic and bleeding disorders. *Semin Thromb Hemost.* 2012;38(7):673-82.
2. Lim W, Le Gal G, Bates SM, et al. American Society of Hematology 2018 guidelines for management of venous thromboembolism: diagnosis of venous thromboembolism. *Blood Adv.* 2018;2(22):3226-56.
3. CLSI. Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline. CLSI document H59-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.
4. Suzuki K, Wada H, Imai H et al. A re-evaluation of the D-dimer cut-off value for making a diagnosis according to the ISTH overt-DIC diagnostic criteria: communication from the SSC of the ISTH. *J Thromb Haemost* 2018; 16: 1442–4.
5. Goshua G, Pine AB, Meizlish ML et al. Endotheliopathy in COVID-19-associated coagulopathy: evidence from a single-centre, cross-sectional study. *Lancet Haematol* 2020; 7: e575-82
6. Khalafallah A, Morse M, Al-Barzan A-M, et al. D-Dimer levels at different stages of pregnancy in Australian women: a single centre study using two different immunoturbidimetric assays. *Thromb Res.* 2012;130(3):e171-7.
7. Kessler P, et al. The reference ranges of D-dimer levels are different in pregnant women using various D-dimer assays. *JTH.* 2011;9(suppl. 2):592.
8. CAP CGL-A 2014-2019. ECAT D-Dimer 2014-2019. (Average of 68 survey results from 16,936 participants' responses across 6 consecutive years for quantitative D-dimer with INNOVANCE D-Dimer Assay. Results reported in FEU.)
9. Data based on 63,549 sample results (uncharacterized) from laboratories in nine different countries (Germany, South Africa, Austria, Spain, and other), consecutively collected from January to July 2020.
10. Li J, Zhang F, Liang C, et al. The diagnostic efficacy of age-adjusted D-dimer cutoff value and pretest probability scores for deep venous thrombosis. *Clin Appl Thr Hem.* 2019;25:1-7.
11. Parry AP, Chang AM, Schellong SM, et al. International, multicenter evaluation of a new D-dimer assay for the exclusion of venous thromboembolism using standard and age-adjusted cut-offs. *Thromb Res.* 2018;166:63-70.
12. Farm M, Siddiqui AJ, Onelöv L, et al. Age-adjusted D-dimer cut-off leads to more efficient diagnosis of venous thromboembolism in the emergency department: a comparison of four assays. *JTH.* 2018;16:866-75.
13. Oude Elferink RFM, Loot AE, van de Klashorst CGJ, et al. Clinical evaluation of eight different D-dimer tests for the exclusion of deep venous thrombosis in primary care patients. *Scand J Clin Lab Invest.* 2015;75(3):1-9.
14. Mullier F, Vanpee D, Jamart J, et al. Comparison of five D-dimer reagents and application of an age-adjusted cut-off for the diagnosis of venous thromboembolism in emergency department. *Blood Coag Fibrinol.* 2014;25:309-15.
15. Roggenbuck L, Dörner K. Comparative evaluation of different D-dimer assays for exclusion of venous thromboembolism in a clinical routine setting. *J Lab Med.* 2008;32(3):177-81.
16. De Moerloose P, Palareti G, Aguilar C, et al. A multicenter evaluation of a new quantitative highly sensitive D-dimer assay for exclusion of venous thromboembolism. *Thromb Hemost.* 2008;100:505-12.

Siemens Healthineers Headquarters

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
siemens-healthineers.com

Published by

Siemens Healthcare Diagnostics
Products GmbH
Laboratory Diagnostics
Emil-von-Behring-Strasse 76
35041 Marburg, Germany