INNOVANCE D-Dimer assay

Proven D-dimer testing for robust VTE exclusion

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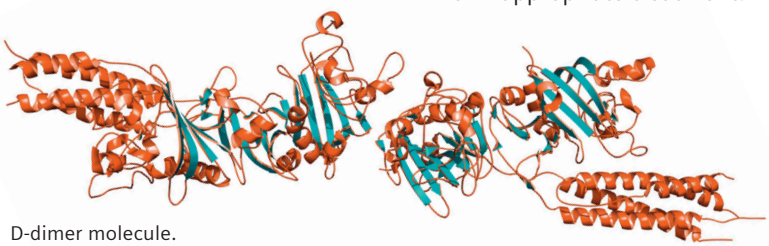
SIEMENS Healthineers

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 venous thromboembolism (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.



D-dimer molecule.

The INNOVANCE D-Dimer assay combines 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 DIC*[4] 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 ≥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 with the CLSI document H59-A[3] and FDA requirements.
- **Excellent precision and low lot-to-lot variability** ensure high consistency of results: ≤6.7% CV assay precision† and between-laboratory median variance of 8.7% 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.

**The products/features mentioned here are not commercially available in all countries. Their future availability cannot be guaranteed. Not available for sale in the U.S.*
†Within-device/lab CV.
‡0.17–4.4 mg/L FEU with BCS XP System.
Siemens Healthineers assumes responsibility for product claims only in accordance with the Instructions For Use (IFU) of the respective Siemens Healthineers product. Any changes to the product claims according to the IFU must be validated by the respective users and are their responsibility. Technical information is available at http://www.siemens.com/document-library.

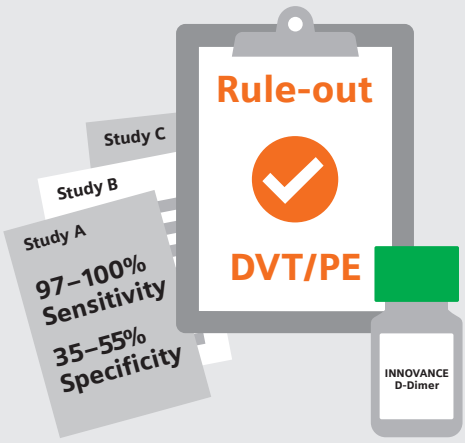
INNOVANCE D-Dimer assay: speed, linearity, and reliability for efficient testing

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.[10-17]

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® CN-3000/6000,* CS-2500/5100, and CA-660 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 ≤3.4% CV on the Atellica COAG 360 System.*

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. By constantly bringing breakthrough innovations to market, we enable healthcare professionals to deliver high-quality care, leading to the best possible outcome for patients.

Our portfolio, spanning from in-vitro and in-vivo diagnostics to image-guided therapy and innovative cancer care, is crucial for clinical decision-making and treatment pathways. With our strengths in patient twinning, precision therapy, as well as digital, data, and artificial intelligence (AI), we are well positioned to take on the biggest challenges in healthcare. We will continue to build on these strengths to help fight the world's most threatening diseases, improving the quality of outcomes, and enabling access to care.

We are a team of 66,000 highly dedicated employees across more than 70 countries passionately pushing the boundaries of what's possible in healthcare to help improve people's lives around the world.

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

Sysmex CN-3000 System refers to Automated Blood Coagulation Analyzer CN-3000. Sysmex CN-6000 System, CS-5100 System, CS-2500 System, and CA-660 System refer to Automated Blood Coagulation Analyzer CN-6000, -CS-5100, -CS-2500, and -CA-660 respectively.

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