

Siemens Healthineers Launches Innovance D-Dimer 2.0 Assay to Help Clinicians Rule Out, Monitor Serious Blood-clotting Conditions

- **Blood clots affect approximately 10 million people each year worldwide**
- **D-dimer testing helps clinicians quickly assess patients during time-sensitive, emergent situations**
- **Supports exclusion of deep vein thrombosis and pulmonary embolism**

Siemens Healthineers announced today the global launch of its [Innovance D-Dimer 2.0 assay](#)¹, which is CE-marked and has received FDA 510(k) clearance. The blood test helps clinicians assess patients with suspected venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE). Blood clots affect approximately 10 million people each year worldwide² and can become dangerous when they block normal blood flow. Clots are especially dangerous when they break loose and travel to the heart, lungs, and brain and prevent oxygen from reaching vital organs³. Rapid intervention is critical to facilitate optimal patient outcomes.

“Minutes matter when clinicians are evaluating a patient for a serious blood clot,” said Martin Fuhrer, head of Specialty Laboratory Solutions for Diagnostics, Siemens Healthineers. “Our new D-dimer assay is designed to help laboratories deliver timely, high-quality results that underpin quicker, confident clinical decisions.”

What is the purpose of a D-dimer test?

D-dimer testing helps assess patients with conditions and/or complications that increase clotting activity. People face a higher risk of VTE during or shortly after immobilization, during cancer treatment, and during pregnancy or postpartum⁴.

During time-sensitive, potentially life-threatening situations, exclusion of DVT and PE helps clinicians confidently determine the next steps for their patients’ care. The Innovance D-Dimer 2.0 assay from Siemens Healthineers is intended for DVT and PE exclusion in conjunction with a clinical pretest probability (PTP) assessment model in outpatients suspected of DVT or PE. It also is used to aid in the diagnosis and monitoring of hypercoagulable conditions, including disseminated intravascular coagulation (DIC)⁵ – a

serious condition that may occur in patients suffering, for example, from sepsis, malignancy, or toxic snake bites.

How does the Innovance D-Dimer 2.0 assay support more efficient D-dimer testing?

Clinical laboratories are often asked to process urgent “STAT” orders while managing increasing test volumes and staffing constraints. The Innovance D-Dimer 2.0 assay helps laboratories achieve optimal operational efficiency through ready-to-use reagents and controls and short time to results while a high level of clinical safety supports confident patient management. Workflow-oriented features enable fast emergency department triage and timely treatment decisions. Analytical robustness and high specificity can help clinicians safely rule out patients from unnecessary imaging and follow-up procedures.

The Innovance D-Dimer 2.0 assay is part of Siemens Healthineers comprehensive coagulation portfolio for thrombotic conditions and disorders available for a variety of hemostasis systems including the [CN-3000/CN-6000 systems](#) from Siemens Healthineers. The assay is now available across many markets, with expanded availability expected in October. More information can be found [here](#).

¹ K253985. Product availability varies by country.

² International Society on Thrombosis and Haemostasis, Inc. <https://www.worldthrombosisday.org/know-thrombosis/>

³ CDC <https://www.cdc.gov/blood-clots/about/index.html>

⁴ CDC <https://www.cdc.gov/blood-clots/data-research/facts-stats/index.html>

⁵ The products/features/applications mentioned here are not commercially available in all countries and are subject to local regulations. Their future availability cannot be guaranteed. This claim is not applicable in the U.S.

A press picture is available [here](#).

Further information on the Innovance D-Dimer 2.0 assay can be found [here](#).

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