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|  Assay Alert |  |
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Siemens Healthineers Advances Diagnostics for Bleeding Disorder with INNOVANCE VWF Ac Assay

* Individuals with von Willebrand disease experience excessive bleeding from low levels of the von Willebrand factor protein in the blood. It is the most common inherited bleeding disorder, affecting approximately 1 percent of the population.1
* The Siemens Healthineers INNOVANCE VWF Ac assay offers VWF:GPIbM technology that mimics true von Willebrand factor function and detects variants missed by other assay technologies.
* The INNOVANCE VWF Ac assay is the only fully automated VWF:GPIbM assay currently available for sale in the U.S. and for use on a variety of hemostasis systems.

Siemens Healthineers announced today that its INNOVANCE® VWF Ac assay—the sole fully automated assay of its kind (VWF:GPIbM)—is now available to U.S. laboratories for use on the Siemens Healthineers BCS® XP System, as well as on the Sysmex® CS-2500 and CS-5100 hemostasis analyzers. Von Willebrand disease (VWD) is the most common inherited bleeding disorder, affecting approximately 1 percent of the population—and both men and women equally. Physicians diagnose VWD based on bleeding symptoms, patient history, and lab test results, including von Willebrand factor (VWF) activity.1

Until now, VWF activity assays were disadvantaged with low precision and sensitivity, and with difficulties in diagnosing certain VWF polymorphisms.1,2 To help address these deficiencies, the International Society on Thrombosis and Hemostasis (ISTH) recently published a guideline changing its recommendation for VWF activity assays from the ristocetin cofactor assay (VWF:RCo) to newer assays (VWF:GPIbM) that directly measure the platelet binding activity of VWF without the need of ristocetin.2 The Siemens Healthineers INNOVANCE VWF Ac assay is the only fully automated, commercially available VWF activity assay for laboratories in the U.S. that uses the guideline recommended VWF:GPIbM technology.

Currently deployed in many European laboratories, the assay's VWF:GPIbM technology allows for a more accurate functional assessment of VWF activity with greater precision and heightened sensitivity, and the ability to detect VWF variants that otherwise might be missed compared to other commercially available VWF assay technologies.

“After the positive experience we had using this assay in a study, we as caregivers in the U.S. are urgently waiting to use the INNOVANCE VWF Ac assay to diagnose our patients, as we believe it supports improved von Willebrand disease diagnosis and patient management—particularly now given the new recommendations from the ASH ISTH NHF WFH 2021 guidelines on the diagnosis of VWD,” said Dr. Steven Pipe, Professor of Pediatrics and Pathology from the University of Michigan, Ann Arbor.

The Siemens Healthineers INNOVANCE VWF Ac assay is a liquid, ready-to-use assay, and offers laboratorians a broad measuring range with a lower limit of quantitation compared to the VWF:RCo technology. For more information about the Siemens Healthineers INNOVANCE VWF Ac assay, please visit [siemens-healthineers.us/vwf](https://www.siemens-healthineers.com/en-us/hemostasis/innovance-assays/innovance-vwf-ac-assay).

1 Favaloro EJ. Von Willebrand disease: local diagnosis and management of a globally distributed bleeding disorder. Semin Thromb Hemost 2011; 37: 425–6.

2 James PD, Connell NT, Ameer B, Di Paola J, Eikenboom J, Giraud N, Haberichter S, Jacobs-Pratt V, Konkle B, McLintock C, McRae S, R Montgomery R, O'Donnell JS, Scappe N, Sidonio R, Flood VH, Husainat N, Kalot MA, Mustafa RA. ASH ISTH NHF WFH 2021 guidelines on the diagnosis of von Willebrand disease. Blood Adv. 2021 Jan 12;5(1):280-300.

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 **Siemens Healthineers AG** (listed in Frankfurt, Germany: SHL) pioneers breakthroughs in healthcare. For everyone. Everywhere. As a leading medical technology company headquartered in Erlangen, Germany, Siemens Healthineers and its regional companies is continuously developing its product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company’s foundation in in-vitro diagnostics, image-guided therapy, in-vivo diagnostics, and innovative cancer care. Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers’ ability to provide high-quality, efficient care. In fiscal 2021, which ended on September 30, 2021, Siemens Healthineers, which has approximately 66,000 employees worldwide, generated revenue of €18.0 billion and adjusted EBIT of €3.1 billion. Further information is available at [www.siemens-healthineers.com](http://www.siemens-healthineers.com).