Ortho Clinical Diagnostics

New MicroTip Partnership Assay for Coagulation Testing Launched by Ortho Clinical Diagnostics in Collaboration with Diazyme Laboratories, Inc.

April 2, 2019

D-Dimer assay now available for use on the VITROS® 5600 Integrated System and VITROS® 4600 Chemistry System

Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, in collaboration with Diazyme Laboratories, Inc. has launched its D-Dimer assay, the latest offering in Ortho's MicroTip Partnership Assay (MPA) program. The MicroTip Partnership Assay program enables Ortho to offer high-value, esoteric testing, quickly and flexibly, in step with the rapidly evolving needs of today's labs.

The D-Dimer assay detects the presence of intravascular coagulation and fibrinolysis through the measurement of the fibrin degradation product D-Dimer. According to the Centers for Disease Control and Prevention, venous thromboembolism (blood clots) cost the U.S. $10 billion a year, affecting 900,000 Americans with 100,000 deaths attributable to blood clots.[1]

> ***"Our MicroTip Partnership Assay program helps us expand our reach in delivering innovative, important new assays to our customers to help them drive value in their lab," said Jennifer Paine, chief product portfolio officer at Ortho. "Our customers can be confident in D-Dimer's performance on VITROS® Systems due to the extensive validation testing and close collaboration with Diazyme."***

The quantitative determination of the D-Dimer assay is used in the diagnosis and management of a variety of thrombosis-related clinical conditions along with other laboratory tests and imaging scans, to help rule out, diagnose, and monitor diseases and conditions that cause hypercoagulability (excessive coagulation), which yield very high concentrations of D-Dimer.

The assay will initially launch in the United States and Europe, Africa and the Middle East.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics serving the clinical laboratory and immunohematology communities. Across hospitals, hospital networks, blood banks and labs in more than 125 countries and territories, Ortho's high-quality products and services enable health care professionals to make better-informed treatment decisions. For the immunohematology community, Ortho’s blood typing products help ensure every patient receives blood that is safe, the right type and the right unit. Ortho brings sophisticated testing technologies, automation, information management and interpretation tools to clinical laboratories around the world to help them run more efficiently and effectively and improve patient care. Ortho's purpose is to improve and save lives with diagnostics, and it does that by reimagining what's possible. This is what has defined Ortho for more than 75 years, and it's what drives Ortho forward.

1. Venous Thromboembolism: Impact of Blood Clots on the United States. Centers for Disease Control and Prevention, Division of Blood Disorders, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, 2019, www.cdc.gov/ncbddd/dvt/documents/vte_impact-infogr.pdf.

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