

Ortho Clinical Diagnostics

FDA Clears VITROS® XT 7600 Integrated System from Ortho Clinical Diagnostics, Bringing Innovative New Approach to Clinical Lab Management

November 1, 2018

DIGITAL CHEMISTRY™ technology enables powerful data intelligence, operational improvements and other enhancements in the lab

Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, today announced that it has received FDA clearance for Ortho's [VITROS® XT 7600 Integrated System](#).

With this approval, Ortho introduces DIGITAL CHEMISTRY™ technology to clinical lab management in the U.S. by combining Ortho's proprietary MicroSlide technology with sophisticated digital imaging capabilities and the potential to perform two separate lab tests simultaneously. DIGITAL CHEMISTRY™ brings powerful data intelligence, operational improvements and heightened quality to the lab to help clinical laboratories keep pace with a rapidly evolving global health care environment, without requiring additional lab space.

"It's an exciting time for clinical labs, and today's clearance of Ortho's VITROS® XT 7600 System represents a fundamental improvement in the way labs can operate, now and in the future," said Jennifer Paine, Ortho's Chief Product Portfolio Officer. "VITROS® XT 7600, along with DIGITAL CHEMISTRY™, harnesses the power of our proprietary dry slide technology to deliver high-quality test results and higher throughput -- all within the lab's existing physical footprint."

The DIGITAL CHEMISTRY™ behind Ortho's VITROS® XT 7600 is based on three enabling technologies:

- **Digital imaging technology.** Advanced optics glean significantly more information from testing than before, improving performance and enabling powerful data analysis.
- **MicroSlide.** A full testing environment on a postage-stamp-sized piece of film enables precise and accurate testing.
- **Dry technology.** Unlike traditional wet chemistry systems, which require highly purified water and complex plumbing systems to operate, Ortho's proprietary dry slide technology does not require water to run. This eliminates the risk that poor water quality could impact test results.

"Ortho's MicroSlide, paired with Intellichek monitoring, allows me to sleep at night because I know the results reported by our technologists on more than 1,000 patients nightly are accurate," said Jaime Calnan, Laboratory Manager at Central Ohio Primary Care Physicians in Columbus, Ohio. "We have been an Ortho customer for more than ten years, and we welcome this new innovation."

In addition, Ortho's VITROS® XT 7600 will introduce multi-test processing¹ – the potential to offer two tests per slide instead of one -- to clinical chemistry. Multi-test processing¹ will allow the instrument to simultaneously perform tests that are frequently ordered for the same patient. This saves time and space in the lab, and increases productivity, with less patient sample required for testing, an important advantage for vulnerable patients or those with venous access issues.

The Ortho VITROS® XT 7600 Integrated System has received FDA clearance to market, and will be available for purchase in the first quarter of 2019. The product is currently available for purchase in numerous countries in Europe, the Middle East, Africa, Asia, Latin America and Canada.

About Ortho's VITROS® Systems

The VITROS® Chemistry, Immunodiagnosics and Integrated Systems from Ortho Clinical Diagnostics is a portfolio of products and patented enabling technologies which help clinical laboratories diagnose, monitor and treat disease. VITROS® Products are engineered to help clinical laboratories with organizational, operational and economic challenges.

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. Under development

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Press contact:

For media inquiries please contact

Ortho Media Relations

Ortho Clinical Diagnostics
media@orthoclinicaldiagnostics.com
(+1) 908 704 8256