

# Ortho Clinical Diagnostics

## FDA Clears ORTHO™ Sera ID-MTS for Use on the ORTHO VISION® Analyzer

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Fully automated technology from Ortho Clinical Diagnostics aids in extended antigen phenotyping and helps to ensure delivery of safe blood to transfusion patients



Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, today announced that **ORTHO™ Sera** a suite of extended antigen phenotyping, has been cleared by the U.S. Food and Drug Administration for use on the ORTHO VISION® Analyzer.

During pre-transfusion testing, lab professionals routinely encounter complex patient samples that require extended antigen typing. These patients have developed atypical antibodies to blood group antigens and require additional testing to find compatible blood.<sup>1</sup> ORTHO Sera's extended phenotype testing covers more than 99 percent of the most commonly tested blood group antigens, providing support for patients with unexpected antibodies.

***"It is critically important for lab professionals to deliver the right results for complex and chronically transfused patients," said Bob Stowers, head of Ortho's transfusion medicine product portfolio. "That's why we are excited to be the first to offer automated extended phenotype testing, saving time for the lab professional and giving skilled staff the ability to focus on other critical tasks in the lab, as well as to increase the lab's ability to standardize testing."***

Allowing virtually all testing to be done on one platform, ORTHO Sera expands the testing menu on the ORTHO VISION Analyzer, driving greater value and efficiency for customers and delivering results in a maximum of 20 minutes. With end-to-end full automation on the ORTHO VISION Analyzer, ORTHO Sera minimizes the potential for human error, improving safety, and provides consistent, reliable results while freeing up lab professionals to focus on value-added tasks.

ORTHO Sera's antisera additive approach allows extended phenotyping to be personalized according to patient needs, which reduces waste and enhances efficiency. Decreased hands-on manipulation of tests helps to eliminate time-consuming, non-value-added activities and potential for error. The 13 ORTHO Sera reagents available in the U.S. on the ORTHO VISION Analyzer include Anti-Fy<sup>a</sup>, Anti-Fy<sup>b</sup>, Anti-Jk<sup>a</sup>, Anti-Jk<sup>b</sup>, Anti-S, Anti-s, Anti-K, Anti-K (IAT), Anti-D (DVI), Anti-P1, Anti-Le<sup>a</sup>, Anti-Le<sup>b</sup> and Anti-N.

### 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. Hamilton JR, Common and Frequently Encountered Antibodies, Transfusion and Apheresis Science 2009, 40, 189-194

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