Ortho Clinical Diagnostics

ORTHO OPTIX™ Reader Completes Transfusion Medicine Portfolio, Now Available in the United States and Puerto Rico

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RARITAN, N.J., June 7, 2021 /PRNewswire/ -- Ortho Clinical Diagnostics (Nasdaq: OCDX), one of the world's largest pure-play in vitro diagnostics companies, today announced its semi-automated ORTHO OPTIX™ Reader, which allows lower-volume transfusion labs to elevate their standard of patient care with the quality of results expected of an automated platform, is now available in the United States and Puerto Rico.

The analyzer received U.S. Food and Drug Administration (FDA) 510k Clearance on March 11, 2021.

When paired with the ORTHO™ Workstation, the ORTHO OPTIX™ Reader provides a complete semi-automated testing platform for transfusion labs with low- to mid-volume throughput. The ORTHO OPTIX™ Reader has been shown to deliver 99.9% concordance[1], demonstrated by the award-winning fully automated ORTHO VISION® *Swift* Platform. The concordant and high-resolution images of the ORTHO OPTIX™ Reader help to support the technologist during remote review of results from across the laboratory. It also offers larger volume labs and health care networks a way to back-up or scale up their operations without having to invest in an additional full-automation analyzer.

"Ortho is dedicated to continuous innovation and improvement that allows labs of all sizes to customize solutions to optimize their resources without compromising quality and accuracy," said Bob Stowers, Ortho's head of transfusion medicine product portfolio. "The ORTHO OPTIX™ Reader completes our transfusion medicine portfolio and offers labs the same high-quality, consistent results seen on our ORTHO VISION® *Swift* Platform with a scalable footprint, throughput and cost."

The ORTHO OPTIX™ Reader's high-resolution camera captures color, grayscale, front and back images of each test without operator intervention, which provides objective data for automated results interpretation and eliminates the subjectivity and discrepancies associated with human reading of results.

The ORTHO OPTIX™ Reader leverages the same proven ORTHO ID-MTS™ Gel card Technology as the ORTHO VISION® *Swift* Platform and a comprehensive testing menu.

When connected to the customer's laboratory information system, column grades and images can be automatically sent for long-term retention of result interpretations, therefore reducing and/or eliminating the need for manual documentation of results. The system audit log and reporting module enhances traceability and reporting capabilities to keep labs compliant with accreditations and regulations. It also utilizes best-in-class ID-MTSÔ Gel Card technology which offers a comprehensive testing menu to help standardize lab practices.

The ORTHO OPTIX™ Reader is supported by Ortho Care™, Ortho's award-winning, holistic service and support solution, and is now available across the world.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics (Nasdaq: OCDX) is one of the world's largest pure-play in vitro diagnostics (IVD) companies dedicated to transforming patient care.

More than 800,000 patients across the world are impacted by Ortho's tests each day. *Because Every Test is a Life*™, Ortho provides hospitals, hospital networks, clinical laboratories and blood banks around the world with innovative technology to ensure test results are fast, accurate, and reliable. Ortho's customized solutions enhance clinical outcomes, improve efficiency, overcome lab staffing challenges and reduce costs.

From launching the first product to determine Rh+ or Rh- blood type, developing the world's first tests for the detection of antibodies against HIV and hepatitis C, introducing patented dry-slide technology and marketing the first U.S. Food and Drug Administration-authorized high-volume antibody and antigen tests for COVID-19, Ortho has been a pioneering leader in the IVD space for over 80 years.

The company is powered by Ortho Care™, an award-winning, holistic service and support program that ensures best-in-class technical, field and remote service and inventory support to laboratories in more than 130 countries and territories around the globe.

For more information, visit Ortho's website or social media channels: LinkedIn, Twitter, Facebook and YouTube.

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[1] For direct and indirect antiglobulin testing, as determined by External Validation Testing using ID-MTS™ Gel Card Technology. The acceptance criteria for concordance for direct and indirect antiglobulin was ≥98.0% with a lower bound 95% CI of 99.87%.

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