Ortho Clinical Diagnostics

Ortho's VITROS® SARS-CoV-2 Antigen Test for High-Volume Testing Receives FDA Emergency Use Authorization for New Performance, Sensitivity Data

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RARITAN, N.J., March 23, 2021 /PRNewswire/ -- Ortho Clinical Diagnostics (Nasdaq: OCDX), one of the world's largest pure-play in vitro diagnostics companies, today announced it received authorization from the U.S. Food and Drug Administration to update key claims for the VITROS® SARS-CoV-2 Antigen Test, the first high-volume SARS-CoV-2 antigen assay to receive Emergency Use Authorization (EUA) in the United States.

"Communities and laboratories across the United States continue to seek fast, reliable, simplified diagnostic solutions to help them tackle the volume of COVID-19 tests needed to aid safe reopening measures," said Chockalingam Palaniappan, PhD, chief innovation officer, Ortho Clinical Diagnostics. "Ortho Clinical Diagnostics continues to innovate to provide them with solutions—including our antigen test with new performance and sensitivity data, that enable fast, high-volume testing with accurate results."

New FDA-Emergency Use Authorized Only Claims Include:

- ***Improved Sensitivity Data***
  The VITROS® SARS-CoV-2 Antigen Test demonstrates 94.8% sensitivity for samples with a PCR cycle threshold (CT— an assessment of viral load), of less than 30.[1] Studies [2,3] have shown that samples with PCR CT values at 30 - 33 or greater carry little to no live virus, suggesting these patients may no longer be infectious. This further solidifies the test's clinical utility in identifying individuals who are in the acute stage of COVID-19 infection when the risk for viral transmission is the highest.
- ***Updated Specimen Collection Methods***
  When utilizing Ortho's antigen test, personnel at hospitals, reference labs, and other healthcare settings will now be able to use a nasal sample which is more convenient than the nasopharyngeal swab specimen collection method. Further, the authorization allows for easier and faster sample collection.[4]
- ***Additional Viral Transport Media (VTM)***
  Testing leaders will now be able to utilize three additional viral transport media (VTM) options. Designed to preserve the integrity of collected samples during transportation to laboratories, new VTM options authorized for use with the VITROS® SARS-CoV-2 Antigen Test include Saline, which is readily available and cost effective, or Phosphate Buffered Saline (PBS), Bartels FlexTrans™ transport media [Trinity Biotech], and the World Health Organization's formulation of VTM, in addition to the CDC's formulation of VTM, COPAN Universal Transport Media (UTM)®, and Hardy R99 VTM—expanding options and testing capacity for customers who use Ortho's antigen assay.

About the VITROS® SARS-CoV-2 Antigen Test

Authorized for use in the U.S. in January 2021, Ortho's VITROS® SARS-CoV-2 Antigen Test offers reliable detection of SARS-CoV-2 in patients suspected of COVID-19 by their healthcare provider within seven days of the onset of symptoms with high sensitivity and specificity. With utility for mass-scale testing and same-day results for labs, Ortho's antigen test can be processed at a rate of up to 130 tests per hour on a single analyzer, bolstering the ability of hospitals and reference labs to address testing backlogs, supply shortages, and delayed results that have undermined previous testing efforts. The VITROS® SARS-CoV-2 Antigen Test also offers a practical and cost-effective testing alternative to polymerase-chain reaction (PCR) tests, which, while highly accurate, can be expensive and require long processing times during testing surges.

This project has been funded with federal funds from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, under Contract No. 75A50120P00103.

About Ortho's VITROS® COVID-19 Testing Solutions

Ortho's SARS-CoV-2 Antigen Test is the latest addition to the company's COVID-19 solutions, which include two COVID-19 antibody tests — Total and IgG — both of which have FDA EUA and CE Mark.

Because Ortho's VITROS Systems are already installed worldwide, reporting times may be further improved because lab staff require no additional training, and the instruments are already connected to existing laboratory information systems and software. These systems are self-contained and do not require an external water source to run.

Questions from laboratories, health care providers, or government officials regarding Ortho's COVID-19 solutions can be directed to: OrthoCOVID19Test@orthoclinicaldiagnostics.com. For more information visit: https://www.orthoclinicaldiagnostics.com/global/covid19/.

The VITROS Anti-SARS-CoV-2 Total and IgG Antibody Tests and the VITROS SARS-CoV-2 Antigen Test have not been cleared or approved by the U.S Food and Drug Administration (FDA). They have been authorized by the FDA under an Emergency Use Authorization (EUA) and testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate- or high-complexity tests. The VITROS antibody tests have been authorized only for the detection of either total or IgG antibodies from SARS-CoV-2, not for any other viruses or pathogens, and results should not be used as the sole basis for diagnosis. The VITROS antigen test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of

COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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 and tools 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.

[1] Using Nasopharyngeal Swab specimen collection. Nasal Swab specimen collection demonstrated 92.3% sensitivity at cycle thresholds values of less than 30.

[2] Viral cultures for COVID-19 infectivity assessment. Systematic review. Tom Jefferson, Elizabeth Spencer, Jon Brassey, Carl Heneghan. medRxiv 2020.08.04.20167932; doi: https://doi.org/10.1101/2020.08.04.20167932.

[3] N Engl J Med 2020;382:2081-90. DOI: 10.1056/NEJMoa2008457

[4] Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing. https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

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