Ortho Clinical Diagnostics

Ortho Clinical Diagnostics Expands COVID-19 Test Offerings with Emergency Use Authorization (EUA) of Total Nucleocapsid Antibody Test

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-- Ortho's new VITROS® Anti-SARS-CoV-2 Total N test detects the individual's immune response to the COVID-19 virus and is intended to help clinicians understand if their patient had a recent or prior COVID-19 infection.

-- Ortho is the first company to have an EUA for both a quantitative IgG antibody assay targeting the spike protein and a total assay targeting the nucleocapsid protein. This new antibody test is the fifth assay to receive EUA in Ortho's COVID-19 Testing Solutions.

RARITAN, N.J., Aug. 5, 2021 /PRNewswire/ -- Ortho Clinical Diagnostics (Nasdaq: OCDX), one of the world's largest pure-play in vitro diagnostics companies, today announced its qualitative COVID-19 Total N antibody test received U.S. Food and Drug Administration EUA. This new antibody test is the fifth assay to receive EUA within Ortho's COVID-19 testing solutions. The test detects the individual's immune response or total antibodies to the COVID-19 virus and is intended to help clinicians understand if their patient had a recent or prior COVID-19 infection.

Ortho's new qualitative VITROS® Anti-SARS-CoV-2 Total N antibody test is designed to capture the nucleocapsid protein, detect total antibodies to the COVID-19 virus, and is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2. The test offers 99.2% specificity and excellent sensitivity.[1] Ortho is the first company to have an EUA for both a quantitative IgG antibody assay targeting the spike protein and a total assay targeting the nucleocapsid protein.

"Ortho's new Total N test rounds out our portfolio of accurate and scalable COVID-19 testing solutions to meet the continued need for testing in communities across the globe." said Ivan Salgo, MD, head of medical, clinical, and scientific affairs, Ortho Clinical Diagnostics. "From virus detection, to identifying individuals with an adaptive immune response to infection, and measuring antibody response, our customers can support their community's COVID-19 testing needs now and in the future."

Communities rely on their local laboratories for accurate testing and results. Ortho's COVID-19 portfolio of testing can be done on one system, allowing labs to run high-volume testing to meet the continued demand. As the pandemic continues and more testing is needed in remote areas, Ortho is uniquely positioned to support these needs with a strong foothold in more than 1,000 labs across the United States."

About Ortho's VITROS® COVID-19 Testing Solutions

Ortho's VITROS® COVID-19 Testing Solutions help labs meet the demands of the pandemic with reliable, high-throughput testing solutions that offer SARS-CoV-2 infection and antibody testing on Ortho's trusted VITROS® Systems.

Up to 150 antibody tests or up to 130 antigen tests can be processed each hour on Ortho's VITROS Systems, already installed in more than 1,000 labs across all 50 states in the U.S and in over 5,400 labs across the world.

The VITROS® SARS-CoV-2 Antigen Test is a high-throughput, highly accurate test that detects acute infection of SARS-CoV-2. The VITROS® COVID-19 antibody tests include IgG and Total tests that target the S1 spike protein.

The VITROS® COVID-19 Performance Dashboard allows labs to easily view COVID-19 antibody testing data and enables more informed decisions. The web-based system provides productivity information regarding Ortho analyzers, test volumes, workload balance, sample quality metrics, and reagent efficiency.

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 N Antibody test, the VITROS Anti-SARS CoV-2 IgG Quantitative test, the VITROS-SARS CoV-2 Antigen test, the VITROS Anti-SARS-CoV-2 Total and VITROS Anti-SARS-CoV-2 IgG tests 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 antigen test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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. 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 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® Service and Support, an award-winning, holistic 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] 97.8% PPA for K-2 EDTA samples and 90.0% serum samples collected greater than 15 days after symptom onset

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