Ortho Clinical Diagnostics

Ortho Clinical Diagnostics' Quantitative COVID-19 IgG Antibody Test First to Receive FDA Emergency Use Authorization

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- Ortho's new VITROS® Anti-SARS-CoV-2 IgG Quantitative Test targets the S1 spike protein and is calibrated to the WHO International Standard for anti-SARS-CoV-2 IgG antibodies, which gives clinicians and public health leaders a standard tool to measure antibody response to SARS-CoV-2

- Ortho is the only company that offers laboratories in the U.S. a quantitative IgG test to the spike protein in addition to a total antibody test to the nucleocapsid protein

RARITAN, N.J., July 9, 2021 /PRNewswire/ -- Ortho Clinical Diagnostics (Nasdaq: OCDX), one of the world's largest pure-play in vitro diagnostics companies, today announced its VITROS® Anti-SARS-CoV-2 IgG Quantitative Test is the first quantitative COVID-19 IgG antibody test to receive U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA).

Ortho's new quantitative COVID-19 IgG antibody test targets the S1 spike protein and is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2. The test offers 100% specificity and excellent sensitivity.[1]

The new test is calibrated to the World Health Organization (WHO) International Standard[2] for anti-SARS-CoV-2 IgG antibodies, which gives clinicians and public health leaders a standard tool to measure antibody response to SARS-CoV-2. This uniform data is a first step toward understanding the rise and fall of antibodies in individuals and the long-term impacts of the COVID-19 pandemic on communities and the overall population.

"The development of the VITROS Anti-SARS-CoV-2 IgG Quantitative Test shows Ortho's leadership in response to the need for standardization of SARS-CoV-2 serological methods currently used," said Ivan Salgo, MD, head of medical, clinical, and scientific affairs, Ortho Clinical Diagnostics. "Ortho's quantitative COVID-19 IgG antibody test, which targets the spike protein, is an important tool to help health care and policy teams to understand long-term antibody responses to SARS-CoV-2."

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, and a Total test that targets the nucleocapsid 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, HIT levels and reagent efficiency.

Questions from laboratories, health care providers or government officials regarding Ortho's VITROS COVID-19 Testing 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 Antibody test, the VITROS SARS-CoV-2 Antigen Assay and the VITROS Anti-SARS-CoV-2 Total Antibody Tests have not been cleared or approved by the U.S Food and Drug Administration (FDA). The VITROS Anti-SARS-CoV-2 Total N Antibody Test is being commercialized under FDA Policy D and testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high-complexity tests. The other tests listed 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 are intended 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 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 among the first 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.

[1] 100% Specificity, 91.9% Sensitivity greater than 15 days after symptom onset

[2] World Health Organization. Accessed July 9, 2021. https://www.who.int/publications/m/item/WHO-BS-2020.2403

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