Ortho Clinical Diagnostics

Ortho Clinical Diagnostics Simultaneously Launches First Quantitative COVID-19 IgG Spike Antibody Test As Well As A Nucleocapsid Antibody Test to Help Differentiate Cause of Antibody Response

May 21, 2021

- Ortho is the only company that offers laboratories in the U.S. a quantitative test in combination with a nucleocapsid test

- Both new antibody tests help health care teams differentiate the cause of antibodies against SARS-CoV-2

- Ortho's new VITROS® Anti-SARS-CoV-2 IgG Quantitative Antibody 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

RARITAN, N.J., May 21, 2021 /PRNewswire/ -- Ortho Clinical Diagnostics (Nasdaq: OCDX), one of the world's largest pure-play in vitro diagnostics companies, today announced the launch of the first quantitative COVID-19 IgG antibody test in addition to a total COVID-19 nucleocapsid antibody test.

Ortho is the only company that offers laboratories in the U.S. a quantitative test in combination with a nucleocapsid test. Both tests help health care teams differentiate the cause of antibodies against SARS-CoV-2 and are processed on Ortho's trusted VITROS® Systems.

"In the United States, all vaccines administered are designed to create an antibody response against the spike protein of the SARS-CoV-2 virus," Ivan Salgo, M.D., head of medical, clinical and scientific affairs, Ortho Clinical Diagnostics. "Ortho's new quantitative IgG antibody test, together with its new nucleocapsid antibody test, can provide additional data to help determine whether an antibody response came from natural infection or a spike-protein targeting vaccine."[1]

Ortho's VITROS® Anti-SARS-CoV-2 IgG Quantitative Antibody test is the first antibody test available in the U.S. that provides numerical values calibrated to the World Health Organization (WHO) International Standard.[2] Standardized quantitative antibody tests help align SARS-CoV-2 serological methods and allow for unified data comparison across laboratories. This uniform data is a first step toward understanding the rise and fall of antibodies in individuals and long-term impacts of the COVID-19 pandemic on communities and the overall population.

Ortho's new IgG quantitative test is intended for the qualitative and quantitative measurement of IgG antibodies to SARS-CoV-2 in human serum and plasma with 100% specificity and excellent sensitivity.[3]

Ortho's new VITROS® Anti-SARS-CoV-2 Total Nucleocapsid Antibody Test is a highly accurate[4] test for the qualitative detection of SARS-CoV-2 nucleocapsid antibodies in patients who have been infected with the SARS-CoV-2 virus.

"We continue learn new things about the SARS-CoV-2 virus each day and Ortho is dedicated to equipping labs with highly accurate solutions that help them tackle both the present-day and future challenges of this ongoing pandemic," said Chockalingam Palaniappan, PhD, chief innovation officer, Ortho Clinical Diagnostics.

Ortho's COVID-19 quantitative antibody test completed the process for Emergency Use Notification (EUN) from the U.S. Food and Drug Administration (FDA) on May 19, 2021 and submitted an Emergency Use Authorization (EUA) for the test to the FDA. Its VITROS® Anti-SARS-CoV-2 Total Nucleocapsid Antibody Test completed the process for EUN on May 5, 2021 and an EUA was also submitted.

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 the same high-throughput system.

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, HIT levels, 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 and the VITROS Anti-SARS-CoV-2 IgG Quantitative Antibody test have not been cleared or approved by the U.S Food and Drug Administration (FDA).Ortho completed the FDA Section IV.D notification process. 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 VITROS antibody tests have been validated only for the detection of Total antibodies to the nucleocapsid protein of SARS-CoV-2, or for the measurement of IgG antibodies, not for any other viruses or pathogens, and results should not be used as the sole basis for diagnosis.

The VITROS-SARS-CoV-2 Antigen Assay, VITROS Anti-SARS-CoV-2 Total and VITROS Anti-SARS-CoV-2 IgG Antibody 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.

[1] Patients who received inactivated virus as vaccine will have anti-N and anti-S antibodies.

[2] https://www.who.int/publications/m/item/WHO-BS-2020.2403

[3] 100% Specificity, 92.4% Sensitivity greater than 15 days after symptom onset

[4] 99.2% specificity and 98.5% PPA ≥ 15 days post symptom onset

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