

Ortho Clinical Diagnostics

Ortho Clinical Diagnostics Launches Quantitative COVID-19 IgG Antibody Test with CE Mark

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- Ortho's VITROS® Anti-SARS-CoV-2 IgG Quantitative Antibody test is traceable to the WHO International Standard for anti-SARS-CoV-2 IgG antibodies, which is developed to facilitate the standardization of SARS-CoV-2 serological methods

- The test gives clinicians and public health leaders a standard tool to evaluate immune response after infection or vaccination

RARITAN, N.J., May 5, 2021 /PRNewswire/ -- [Ortho Clinical Diagnostics](#) (Nasdaq: OCDX), one of the world's largest pure-play in vitro diagnostics companies, today announced its quantitative COVID-19 IgG antibody test achieved CE Mark.

Ortho's new VITROS® Anti-SARS-CoV-2 IgG Quantitative (QN) Antibody assay provides numerical values traceable to the [World Health Organization \(WHO\) International Standard](#),ⁱ which helps standardize SARS-CoV-2 serological methods and allows for unified data comparison across laboratories. This key advantage will help clinicians determine the level of an individual's immune response to SARS-CoV-2 after infection or vaccination and provide public health leaders with a standardized tool to measure changes in patients' antibody levels to better track the spread of the virus.

"Ortho's new quantitative IgG antibody test provides healthcare teams and researchers with a standardized data 'ruler,' to assess immune response, acquired through infection or from vaccines, over time, offering additional data to help manage and understand this devastating virus," said Chockalingam Palaniappan, PhD, chief innovation officer, Ortho Clinical Diagnostics.

With 100% specificity and excellent sensitivity,ⁱⁱ the VITROS® Anti-SARS-CoV-2 IgG QN Antibody assay is intended for the qualitative detection and quantitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma and is processed on Ortho's trusted VITROS® system. Up to 6.8 million of Ortho's COVID-19 tests can be processed daily on Ortho's globally installed base of over 5,600 analyzers.

Ortho plans to manufacture up to eight million quantitative IgG antibody tests each month.

Ortho's quantitative IgG test is the latest addition to [Ortho's COVID-19 solutions](#), which help clinicians diagnose and treat SARS CoV-2 infections and follow the patient's immune response.

About Ortho's VITROS® COVID-19 Testing Solutions

Ortho's VITROS® COVID-19 testing solutions help labs meet demands of the pandemic and take control of the spread of the coronavirus in their communities.

Ortho's COVID-19 Total Antibody Test, designed to indicate recent or prior SARS-CoV-2 infection, detects all COVID-19 related antibodies (IgA, IgM and IgG). The company's COVID-19 IgG antibody test detects the IgG antibody, which appears in a patient's blood in the later phase of infection and remains elevated even after recovery. Offering high sensitivity and specificity, both the Total and IgG tests – which have FDA EUA and CE Mark – provide public health leaders with an exceptional tool in tracking viral community spread, bolstering serological surveillance efforts, and managing patient treatment pathways.

Ortho's VITROS® SARS-CoV-2 Antigen Test, which achieved CE Mark in November 2020 and was authorized for use in the U.S. in January 2021, offers reliable detection of acute COVID-19 infection 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.

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/>.

ⁱ <https://www.who.int/publications/m/item/WHO-BS-2020.2403>

ⁱⁱ 100% Specificity, 94% Sensitivity greater than 15 days after symptom onset

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