

Ortho Clinical Diagnostics

Ortho's New COVID-19 Total and IgG Antibody Tests Receive CE Mark for Semi-Quantitative Results

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- Ortho's new VITROS® Anti-SARS-CoV-2 Total 2 Antibody assay and VITROS® Anti-SARS-CoV-2 IgG 2 Antibody assay receive CE Mark
- Both tests can aid in identifying individuals with an adaptive immune response (acquired naturally or through vaccination) to SARS-CoV-2
- These new anti-SARS-CoV-2 antibody assays are the latest addition to Ortho's COVID-19 solutions, which include COVID-19 antibody tests and an antigen test.

RARITAN, N.J., March 8, 2021 /PRNewswire/ -- Ortho Clinical Diagnostics (Nasdaq: OCDX), one of the world's largest pure-play IVD companies dedicated to transforming patient care, today announced that its new VITROS® Anti-SARS-CoV-2 Total 2 Antibody assay and VITROS® Anti-SARS-CoV-2 IgG 2 Antibody assay received CE Mark for the qualitative and semi-quantitative detection of COVID-19 antibodies.

In addition to generating a positive (reactive) or negative (non-reactive) result, Ortho's Total 2 and IgG 2 antibody assays offer a measurement value of SARS-CoV-2 antibodies with easy-to-read results that eliminate the need for repeat testing and improve lab workflow.

With both assays showing 100% specificityⁱ and excellent sensitivity,ⁱⁱ Ortho's new COVID-19 Total 2 and IgG 2 antibody assays help clinicians understand each patient's adaptive immune response (acquired naturally post-infection or through vaccination) to SARS-CoV-2. The tests can also be used to assess titers of neutralizing antibodies—which are responsible for protective immune response—and can be used to identify plasma suitable for convalescent plasma therapy.

"Across the world, there continues to be a great need for COVID-19 testing—to understand if a person is infected, how they are responding to treatment or a vaccine, or to help assess the spread of the disease," said Chockalingam Palaniappan, PhD, chief innovation officer, Ortho Clinical Diagnostics. "As a trusted partner to our customers from the beginning of this pandemic, Ortho will continue to bring to market solutions that help them quickly provide critical results to clinicians while keeping their lab running as efficiently as possible."

The assays run on Ortho's high-throughput, fully automated analyzers including its flagship VITROS® XT 7600 Integrated System, the VITROS® 3600 Immunodiagnostic System, the VITROS® 5600 Integrated System and VITROS® ECi/ECiQ Immunodiagnostic Systems.

Ortho's high-volume VITROS® Systems are installed in over 5,600 laboratories around the world. These analyzers normally run a broad menu of over 150 different tests from blood and body fluid samples. Additional analyzers are available for shipment and can be installed rapidly to further increase capacity since they don't require an external water source to operate.

These new anti-SARS-CoV-2 antibody assays are the latest addition to Ortho's [COVID-19 solutions, which include COVID-19 antibody tests and an antigen test](#).

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.

Ortho plans to manufacture several million COVID-19 antibody tests each month in Pencoed, Wales.

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](#).

ⁱ 95% CI: 99.1-100%

ⁱⁱ 90% sensitivity and positive agreement on samples from 40 discrete individuals confirmed positive to COVID-19 by PCR tested greater than 15 days after symptom onset. Data on file.

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