

Ortho Clinical Diagnostics

Ortho's VITROS® SARS-CoV-2 Antigen Test for High-Volume COVID-19 Testing Receives CE Mark; Allows for More Convenient Sample Collection and Expanded Viral Transport Media

April 13, 2021

RARITAN, N.J., April 13, 2021 /PRNewswire/ -- [Ortho Clinical Diagnostics](#) (Nasdaq: OCDX), one of the world's largest pure-play in vitro diagnostics companies, today announced it received CE Marking for its VITROS® SARS-CoV-2 Antigen Test, initially launched in October 2020. The CE Mark allows for more convenient sample collection and expanded viral transport media.

"Regions across the world are in various stages of reopening and recovering, yet there remains a great need for reliable tests that can be performed quickly and in bulk to ensure the continued safety of these 'back-to-normal' measures," said Chockalingam Palaniappan, PhD, chief innovation officer, Ortho Clinical Diagnostics. "Ortho's customers continue to trust its COVID-19 testing solutions—including the updated antigen test—to efficiently meet the demand for accurate mass testing and fast, trusted results."

Updates to Ortho's COVID-19 antigen test include:

- **More Convenient Sample Collection**

When utilizing Ortho's antigen test, personnel at hospitals, reference labs, and other healthcare settings will now be able to use a nasal sample which is more convenient than the nasopharyngeal swab specimen collection method.

- **Additional Viral Transport Media (VTM)**

Laboratories will now be able to utilize three additional viral transport media (VTM) options. Designed to preserve the integrity of collected samples during transportation to laboratories, new VTM options authorized for use with the VITROS® SARS-CoV-2 Antigen Test include Saline, which is readily available and cost effective, or Phosphate Buffered Saline (PBS), Bartels FlexTrans™ transport media [Trinity Biotech], and the World Health Organization's formulation of VTM, in addition to the existing CDC's formulation of VTM, COPAN Universal Transport Media (UTM)®, and Hardy R99 VTM—expanding options and testing capacity for customers who use Ortho's antigen assay.

- **New Sensitivity Data**

The VITROS® SARS-CoV-2 Antigen Test now demonstrates 98 and 92.3 percent sensitivity (nasopharyngeal and nasal, respectively) for samples with a PCR cycle threshold (Ct— an assessment of viral load), of less than 30. Studies^{1,2} have shown that samples with PCR CT values at 30 - 33 or greater carry little to no live virus, suggesting these patients may no longer be infectious. This further solidifies the test's clinical utility in identifying individuals who are in the acute stage of COVID-19 infection when the risk for viral transmission is the highest.

About the VITROS® SARS-CoV-2 Antigen Test

Initially CE Marked in October 2020, Ortho's VITROS® SARS-CoV-2 Antigen Test offers reliable detection of SARS-CoV-2 in patients suspected of COVID-19 by their healthcare provider within seven days of the onset of symptoms 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.

About Ortho's VITROS® COVID-19 Testing Solutions

Ortho's SARS-CoV-2 Antigen Test is the latest addition to the company's [COVID-19 solutions, which include two COVID-19 antibody tests — Total and IgG](#) — both of which have U.S. Food and Drug Administration (FDA) Emergency Use Authorization and CE Mark.

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.

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/>.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics (Nasdaq: OCDX) is one of the world's largest pure-play in vitro diagnostics (IVD) companies.

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](#).

¹ Viral cultures for COVID-19 infectivity assessment. Systematic review. Tom Jefferson, Elizabeth Spencer, Jon Brassey, Carl Heneghan. medRxiv 2020.08.04.20167932; doi: <https://doi.org/10.1101/2020.08.04.20167932>.

² N Engl J Med 2020;382:2081-90. DOI: 10.1056/NEJMoa2008457

 View original content: <http://www.prnewswire.com/news-releases/orthos-vitros-sars-cov-2-antigen-test-for-high-volume-covid-19-testing-receives-ce-mark-allows-for-more-convenient-sample-collection-and-expanded-viral-transport-media-301267688.html>

SOURCE Ortho Clinical Diagnostics

Elaine Colón, Ortho Media Relations, M: +1 908 295 1579, media@orthoclinicaldiagnostics.com