ICU MANAGEMENT & PRACTICE

Ortho's VITROS® SARS-CoV-2 Antigen Test for High Volume COVID-19 Testing Receives CE Mark

Ortho Clinical Diagnostics

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.

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. Studies1,2 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.

Source: Ortho Clinical Diagnostics

Published on : Tue, 13 Apr 2021