Ortho Clinical Diagnostics

Ortho's VITROS® SARS-CoV-2 Antigen Test helps meet the needs of the pandemic with fast, high-volume infection testing with trusted results.

Because Every Test is a Life™

VITROS® SARS-CoV-2 Antigen **is a random-access, high-throughput test for the accurate detection of SARS-CoV-2 infection.**

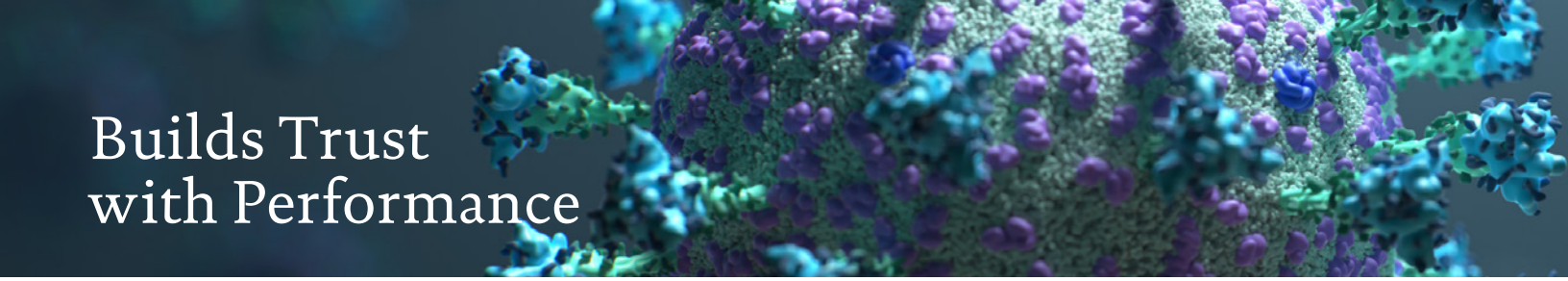
High sensitivity provides trust in results.

Available on the **high-throughput, fully automated** VITROS® XT 7600 and 5600 Integrated Systems, and the VITROS® 3600 Immunodiagnostic System.

100% sensitivity (95% CI: 92.0-100%) concordance to <34 CT (PCR Cycle Count) - **making it a viable alternative to RT-PCR tests.**

For the qualitative detection of SARS-CoV-2 **nucleocapsid antigen** to identify infection.

- Designed for performance, the **VITROS® SARS-CoV-2 Antigen test** targets the Nucleocapsid Protein, the most **abundant** protein of the SARS-CoV-2 virus, optimizing test sensitivity.
- **95.7% sensitivity** (95% CI: 85.5–99.5%) *tested on 47 RT-PCR confirmed positive samples collected from 1-6 days of symptom onset.
- **100% sensitivity** (95% CI: 92.0-100%) concordance to <34 CT (PCR Cycle Count)
- **99.2% specificity** (95% CI: 95.4%-100%) tested on 120 RT-PCR confirmed negative samples.
- **98.2% (95% CI: 94.8%-99.6%) overall agreement** with 167 RT-PCR positive and negative samples.
- Instrument throughput targeted for **up to 130 tests per hour** on-board instrument.
- **Maximum flexibility** in workflow due to **waterless** and **fully automated** VITROS® Systems with **random-access** testing and **continuous sample loading** and **STAT sample** option.
- **Simple specimen preparation**
- **Easy results interpretation** with reactive and non-reactive results – no gray zone or repeat testing to significantly impact workflow advantages.



Builds Trust with Performance

The performance of the VITROS® SARS-CoV-2 Antigen test is enhanced by the proprietary technologies and benefits only available on VITROS Systems:

INTELLICHECK® Technology monitors, verifies and documents diagnostic checks throughout sample and assay processing for accurate and efficient reporting.

MicroSensor technology helps in managing poor quality samples and reports results faster with confidence by only flagging impacted tests

MicroWell technology combined with our Enhanced Chemiluminescence Detection Technology improves signal detection. Contributes to excellent specificity while using small volumes (80 µL).

Disposable Tips for Samples and Reagents avoids risk of false positive results caused by cross contamination.

VITROS® Systems deliver consistently fast, accurate, reliable results and operational simplicity with the ability to load while running and excellent reagent/calibration stability.

Available on the same instruments are the **VITROS® Anti-SARS-CoV2 Total and IgG** tests including other routine immunoassays for COVID-19 patient management.

Ortho Care™ is Ortho's global award-winning service and support program that allows you to focus on patient care, not analyzer care.

Gain access to unlimited Virtual Key Operator, General Operator and Continuing Education Training – enabling you to leverage Ortho's solutions **wherever you are.**

Ranked #1 for overall service by IMV Service Trak™ 5 years in a row. (2016-2020)

Other Characteristics

Time to first result	48 minutes on Instrument
Sample Volume Pre-Extracted	400 µL
Sample Volume Post-Extraction	80 µL not including dead volume
Calibration Interval	Lot change or every 28 days
Reagent on-board stability	Up to 4 weeks
Reagent Type	Liquid Ready to Use
Specimens Recommended	Nasopharyngeal (NP)*
Quality Controls	Positive and Negative

PRE-ANALYTICAL STEPS

1. Prepare Sample for Extraction
2. Add Extraction Buffer to Sample
3. Load to Instrument

*Ortho continues to validate other specimen types. See Instructions for Use for transport media validated by Ortho.

VITROS® SARS-CoV-2 Antigen Ordering Information	
VITROS® Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack	619 9949
VITROS® Immunodiagnostic Products SARS-CoV-2 Antigen Calibrator	619 9950
VITROS® Immunodiagnostics Products SARS-CoV-2 Antigen Controls	619 9943
VITROS® Immunodiagnostics Products SARS-CoV-2 Antigen Extraction Buffer	619 9944

A combination you can count on for your patients and your lab.

The VITROS® SARS-CoV-2 Antigen test has met the requirements for a diagnostic test cited in Section IV, Policy C in the following FDA Guidance: Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff -- Document issued on the web on May 11, 2020. The VITROS SARS-CoV-2 Antigen has been validated but FDA's independent review of the labeling and validation is pending. 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.

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