



Statement From Ortho Clinical Diagnostics Regarding the Omicron Variant

The logo for Ortho Clinical Diagnostics, featuring the word 'Ortho' in a large, white, sans-serif font above the words 'Clinical Diagnostics' in a smaller, white, sans-serif font, all set against a red square background.

Ortho
Clinical Diagnostics

Ortho Clinical Diagnostics has been actively monitoring all 26 SARS-CoV-2 variants, including Omicron, on the potential impact to the performance of the VITROS® COVID-19 Testing Solutions including:

- VITROS® Anti-SARS-CoV-2 Total Assay*
- VITROS® Anti-SARS-CoV-2 IgG Assay*
- VITROS® Anti-SARS-CoV-2 IgG Quantitative Antibody Test*
- VITROS® SARS-CoV-2 Antigen Test
- VITROS® Anti-SARS-CoV-2 Total N Antibody Test*

To date, based on our assessment, we are confident that the Omicron variant is unlikely to affect the ability of our tests to detect SARS-CoV-2 antigens or antibodies to the virus.

We closely monitor literature reports regarding emerging mutations, and as materials from the Omicron variant become available, we will test the performance of our assays against these variant proteins. Additional analyses include assessments and documentation done twice monthly to understand how the VITROS® Immunodiagnostic Systems perform over time regionally and globally, paying special attention to areas endemic with known variants.

Ortho Clinical Diagnostics has led the U.S. COVID-19 laboratory testing response, with the first emergency use authorization for mass-scale [antigen](#), [antibody](#), [quantitative antibody](#), and [nucleocapsid and spike antibody](#) tests to serve clinical laboratories' needs as variants have developed.

Now more than ever, COVID-19 testing solutions are vital to the fight against the pandemic and remain a priority, Because Every Test Is A Life™.

*The VITROS® Anti-SARS-CoV-2 Total, VITROS® Anti-SARS-CoV-2 IgG and VITROS® Anti-SARS-CoV-2 IgG Quantitative Antibody Tests use the S1 domain of SARS-CoV-2 in the assay architecture. The VITROS Anti-SARS-CoV-2 Total N Antibody Test (available only in the U.S.) uses the nucleocapsid protein of SARS-CoV-2 in the assay architecture.

Source : [Ortho Clinical Diagnostics](#)

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