Ortho Clinical Diagnostics

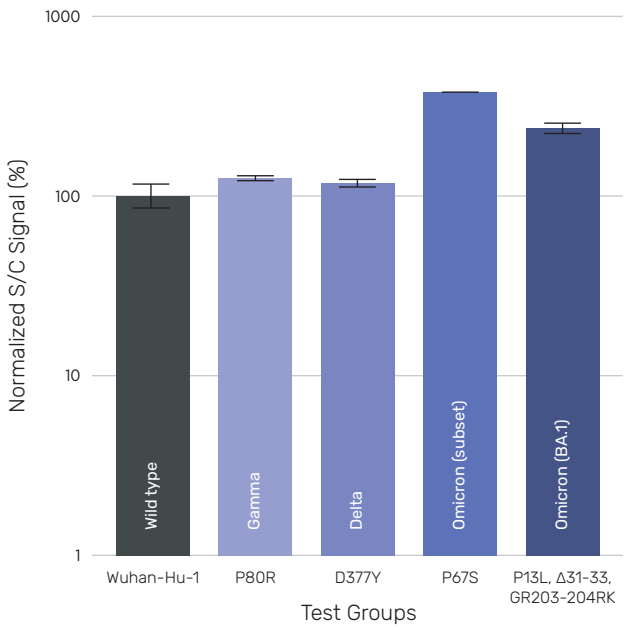
Because Every Test Is A Life™

Analytical Testing of Ortho's VITROS® SARS-CoV-2 Antigen Assay With SARS-CoV-2 Recombinant Nucleocapsid Antigens Containing Current and Past Variant Mutations

Ortho Clinical Diagnostics continually monitors emerging mutations and variants of SARS-CoV-2 with formal assessments and documentation done twice monthly. These efforts include in silico analyses of reported variants and mutations, scientific literature and database searches, lab testing of variants and specific mutations when possible, and post-market surveillance. These are conducted to assess the real-world performance of the VITROS SARS-CoV-2 Antigen assay over time regionally and globally,[1] with special attention paid to areas endemic with known variants.

- All SARS-CoV-2 variants have been assessed for their potential impact to all Ortho Clinical Diagnostics' VITROS SARS-CoV-2 assays
- None of the SARS-CoV-2 variant proteins evaluated are expected to have a significant impact on the performance of the VITROS SARS-CoV-2 antibody or antigen assays
- None of the mutations in variant nucleocapsid proteins that have been evaluated in wet lab testing negatively affected the VITROS SARS-CoV-2 Antigen assay (Figure 1)[2]

Figure 1: Recombinant Nucleocapsid Testing Data



Mutations in recombinant nucleocapsid proteins tested are shown below the colored bars. Residues were chosen based on proximity to epitopes of monoclonal antibodies used in the assay architecture. Most variants do not have mutations that could interfere with assay performance. Variants represented here are P80R; Gamma, D377Y; Delta, P67S; a fraction of Omicron lineages in the U.S. Midwest; and in dark blue, all mutations carried by Omicron BA.1. In four separate experiments, 2-8 replicates of WT and 3-4 replicates of mutant protein were tested and presented together with the normalized control values for each experiment (black bars).

1. Assessments are done by countries across the world and by states within the United States.

2. Information up to date as of March 1, 2022

The VITROS SARS-CoV-2 Antigen assay has not been cleared or approved by the U.S. Food and Drug Administration (FDA). These tests have been authorized by the FDA under an Emergency Use Authorization (EUA) and are limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate- or high-complexity tests.

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics dedicated to improving and saving lives through innovative laboratory testing and blood-typing solutions. We never stop innovating to offer streamlined, sustainable laboratory solutions that deliver fast, accurate, reliable test results to support exceptional patient care. **OrthoClinicalDiagnostics.com**