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PATHOLOGY LABORATORIES
A Sonic Healthcare Clinical Laboratory

SARS-CoV-2 Omicron Variant of Concern

On November 30, 2021, the U.S. SARS-CoV-2 Interagency Group (SIG), which includes the Centers for Disease Control and Prevention (CDC), the National Institutes of Health, the Food and Drug Administration (FDA), and Health and Human Services (HHS), classified the Omicron variant as a Variant of Concern. The current understanding of the Omicron VOC at this time is as follows:

- Preliminary data from South Africa suggest that the mutations to the receptor-binding protein of the variant virus will confer increased infectivity.
- Preliminary studies indicate that there are no unusual symptoms associated with Omicron variant infection, and as with other variants, some patients are asymptomatic. Symptoms may be milder in persons who have been vaccinated or previously infected with SARS CoV-2.
- The presence of mutations in the SARS-CoV-2 virus in a patient sample has the potential to impact test performance. The impact of mutations on a test's performance is influenced by several factors, including the sequence of the variant, prevalence of the variant in the population, and the design of the test including the analytic target. Indeed, tests which interrogate for a single target are particularly vulnerable.

Laboratory evaluation of SARS-CoV-2, including the Omicron Variant of Concern, at Pathology Laboratories:

- All high-throughput SARS-CoV-2 molecular assays performed at Pathology Laboratories are designed to interrogate for multiple targets of the viral genome and have received emergency-use authorization by the FDA.
- Based on *in silico* analysis, all molecular assays are expected to detect the Omicron variant of concern.
- For some assays, including the Thermo Fisher Taq Path PCR assay, a specific deletion in the spike (S) gene (Δ69-70) in the Omicron variant results in an S-gene dropout, also referred to as an S-gene target failure (SGTF).
    - The S-gene target failure pattern may be identified in the Omicron variant (BA.1 sub-lineage), but this pattern is also seen in previously identified variants (e.g., Alpha).
    - Since these tests are designed to detect multiple genetic targets, the overall test sensitivity is not significantly impacted.
    - The S-gene target failure pattern provides a signal that the Omicron variant (BA.1) may be present and that the isolate may be suitable for sequencing and/ or other public health considerations.
    - The S-gene target failure pattern does not necessarily mean that an individual with SARS-CoV-2 has the Omicron variant.
- For clients who have concerns about antigen or other point of care assays that they provide, the assay manufacturer can be contacted for information about expected analytical performance impact.

References:

- New SARS-CoV-2 Variant of Concern Identified: Omicron (B.1.1.529) Variant. Health Alert Network 00459. December 1, 2021.
- SARS-CoV-2 Viral Mutations: Impact on COVID-19 Tests. U.S. Food and Drug Administration. December 6, 2021.
- Technical Brief: Predicted Impact of Variants on Abbott SARS-CoV-2/COVID-19 Diagnostic Tests. Abbott. November 26, 2021
- Impact of SARS-CoV-2 mutations (including Omicron) on the cobas® SARS-CoV-2 and cobas® SARS-CoV-2 & Influenza A/B Tests for use on the cobas® 6800/8800 Systems and the cobas® SARS-CoV-2 and cobas® SARS-CoV-2 & Influenza A/B Tests for use on the cobas® Liat® System. Roche Client Bulletin. November 30, 2021.
- Thermo Fisher Scientific Confirms Detection of SARS-CoV-2 in Samples Containing the Omicron Variant with its TaqPath COVID-19 Tests. Thermo Fisher Client Bulletin. November 29, 2021.