



To: Shield T3 Clients and Staff

Re: Newly identified COVID Omicron variant

The World Health Organization (WHO) has recently identified a new mutation or variant strain of the SARS-CoV-2 virus. The variant was identified in South Africa and has since been found in many other countries. Undoubtedly, it will be found in the U.S. population.

As the WHO and CDC collect data on this new strain, we will stay updated on any concerning trends. Currently, little is known about ease of spread, disease severity of those infected, or vaccine breakthrough infections compared to other strains. This data will take weeks to compile and lead to any updates regarding the prevention of transmission.

We do know that the **PCR testing methods (single individuals or pooled samples) utilized by ShieldT3 are effective in detecting infection by all known COVID variants, including Omicron.** This was vetted by our test component vendor, ThermoFisher. Please see the references and FAQs below for more detailed information.

We will remain vigilant and update you all with any pertinent information. As always, we are committed to keeping you and your staff safe and able to continue to operate.

Sincerely,

Christopher Lemelle, MD, MBA
Chief Medical Officer
Shield T3 Health

References:

1. [https://www.who.int/news/item/26-11-2021-classification-of-omicron-\(b.1.1.529\)-sars-cov-2-variant-of-concern](https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern)
2. <https://thermofisher.mediaroom.com/2021-11-29-Thermo-Fisher-Scientific-Confirms-Detection-of-SARS-CoV-2-in-Samples-Containing-the-Omicron-Variant-with-its-TaqPath-COVID-19-Tests>

Frequently Asked Questions

1. What is the Omicron variant (B.1.1.529) of SARS-CoV-2?
 - The Omicron variant, which was designated a "variant of concern" by the World Health Organization (WHO), has more than 30 mutations in the spike protein alone.
 - The WHO has reported that preliminary evidence suggests an increased risk of transmission compared to other variants of concern. This designation and information are leading to renewed travel restrictions and research to examine the variant's impact on the efficacy of existing vaccines and tests.
 - Cases of the variant were first identified in South Africa and have now been reported in at least a dozen countries around the world.

[https://www.who.int/news/item/26-11-2021-classification-of-omicron-\(b.1.1.529\)-sars-cov-2-variant-of-concern](https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern)

2. Does covidSHIELD assay detect the presence of COVID-19 infection when the Omicron variant is present?
 - Yes. covidSHIELD assay, our saliva-based RT-qPCR detection of SARS-CoV-2 uses the TaqPath COVID-19 assay reagents manufactured by ThermoFisher Scientific.
 - Our molecular assay can detect SARS-CoV-2 infections by identifying the presence of three gene targets from the orf1a/b, S, and N regions of the virus.
 - By surveying across multiple genes, the test can report accurate results even in the case where one of the targets is impacted by a mutation.
 - While the S gene target in the test is impacted in the presence of Omicron variant mutations, the orf1a/b and N gene targets in the TaqPath COVID-19 tests have been determined to not be impacted by any of the mutations in the Omicron variant, based on the assessment of sequences in the GISAID public database. As a result, the overall accuracy of the TaqPath COVID-19 assays is not impacted.
3. Does covidSHIELD assay detect the Omicron variant?
 - No. A positive test does not identify the specific variant; it can only indicate the possibility of an Omicron variant infection.
 - The Omicron variant has been found to include the 69-70del mutation of the S gene, first identified as a mutation in the Alpha variant. This mutation causes a dropout of the S-gene target in results from the TaqPath test, which could indicate to clinicians and researchers a possible Omicron variant infection.
 - Confirmation must then be performed by sequencing the sample.

4. Does the presence of the Omicron variant (B.1.1.529) of the SARS-CoV-2 variant impact the accuracy of our pooled test?
- No. Our pooled test performance is not affected by this variant, as our pooled test chemistry is based on our covidSHIELD assay, which can detect SARS-CoV-2 infections by identifying the presence of three gene targets from the orf1a/b, S, and N regions of the virus.
 - While the S gene target in the test is impacted in the presence of Omicron variant mutations, the orf1a/b and N gene targets in the TaqPath COVID-19 tests have been determined to not be impacted by any of the mutations in the Omicron variant, based on the assessment of sequences in the GISAID public database. As a result, the overall accuracy of the TaqPath COVID-19 assays is not impacted.