

December 6, 2021

To whom it may concern,

With the recent classification of Omicron (B.1.1.529) as a SARS-CoV-2 Variant of Concern, I want to provide you with an update on the TaqPath™ COVID-19 portfolio of tests. Based on our in-silico technical assessment, all TaqPath COVID-19 tests are expected to detect SARS-CoV-2 in samples containing the Omicron variant (Table 1).

Impact of 69-70del in S Gene on TaqPath COVID-19 Kits

- **TaqPath COVID-19 CE-IVD RT-PCR Kit and TaqPath COVID-19 HT Kit**

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 (also known as S gene target failure (SGTF)) in results from the TaqPath COVID-19 CE-IVD RT-PCR Kit and TaqPath COVID-19 HT Kit. This does not mean a result is negative, only that the S gene was not detected. **The WHO, CDC & ECDC have noted that this pattern of detection (i.e. S-gene dropout) can be used as marker for this variant, pending sequencing confirmation.**

- **TaqPath COVID-19, Flu A/B, RSV Combo Kit**

The TaqPath COVID-19, Flu A/B, RSV Combo Kit does not exhibit an observable S-gene dropout for the 69-70del mutation because the S & N Gene are in a single optical channel so they cannot be differentiated. None of the other mutations in B.1.1.529 sequences are expected to impact the N gene target so loss of S Gene Signal is not expected to impact detection of SARS-CoV-2 in samples containing the Omicron variant.

- **TaqPath COVID-19 2.0 Assays**

The S gene is not included in the assay design for the following TaqPath COVID-19 detection kits

- TaqPath COVID-19 RNase P Combo Kit 2.0
- TaqPath COVID-19 Fast PCR Combo Kit 2.0

For all TaqPath COVID-19 Kits, the orf1ab and N gene targets are not impacted by any of the mutations in the Omicron variant, based on assessment of B.1.1.529 sequences in the GISAID public database.

Table 1: TaqPath COVID-19 Tests are expected to detect SARS-CoV-2 in samples containing the Omicron Variant

| Kit name | Cat. No. | SARS-CoV-2 targets | Observable S Gene Dropout? | Currently known impact* |
|---|------------------------|---------------------------------------|----------------------------|---|
| TaqPath COVID-19 CE-IVD RT-PCR Kit | A48067 OR A51738 | S, N, orf1ab (3 separate channels) | Yes | Detection of SARS-CoV-2 in samples containing the Omicron variant is expected <ul style="list-style-type: none"> Decreased sensitivity of only S gene (S gene dropout) S gene advantage: S gene dropout may signal presence of 69-70del & potentially the Omicron variant |
| TaqPath COVID-19 HT Kit for use w/ Amplitude Platform | A50883 | | | |
| TaqPath COVID-19, Flu A/B, RSV Combo Kit | A49867 | S, N (single channel) | No | Detection of SARS-CoV-2 in samples containing the Omicron variant is expected <ul style="list-style-type: none"> Loss of S Gene Signal is expected The targets for S & N Gene are in a single optical channel so they cannot be differentiated. |
| TaqPath COVID-19 RNase P Combo Kit 2.0 | A51334 | N, orf1a, orf1b (3 separate channels) | No | Detection of SARS-CoV-2 in samples containing the Omicron variant is expected |
| TaqPath COVID-19 Fast PCR Combo Kit 2.0 | A51605 | | | |

*As of 30 November 2021

As part of our post-market surveillance efforts, we routinely collect, review, and analyze data on the performance of our tests, including assessing whether any emerging mutations overlap with our assay design. Based on such analyses and communication with appropriate health authorities, we will communicate if and when any impact on test results is expected.

Visit thermofisher.com/covid19mutations to find the latest information and resources.

For additional information, please reference the following:

- WHO: [Classification of Omicron \(B.1.1.529\): SARS-CoV-2 Variant of Concern](#)
- CDC: [New SARS-CoV-2 Variant of Concern Identified: Omicron \(B.1.1.529\) Variant](#)
- ECDC: [Implications of the emergence and spread of the SARS-CoV-2 B.1.1. 529 variant of concern \(Omicron\) for the EU/EEA](#)
- African CDC: [Africa Centres for Disease Control and Prevention's Statement regarding the new SARS-CoV-2 virus variant B.1.1.529](#)

- Press Release: [Thermo Fisher Scientific Confirms Detection of SARS-CoV-2 in Samples Containing the Omicron Variant with its TaqPath COVID-19 Tests](#)
- Blog Post: [TaqPath COVID-19 Tests Support Detection of SARS-CoV-2 in Samples Containing the Omicron Variant](#)
- Blog Post: [The S Gene Advantage: TaqPath COVID-19 Tests May Help with Early Identification of Omicron Variant](#)

Best regards,

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