

To Whom It May Concern;

With the recent headlines related to the multiple variants of SARS-CoV-2, including Omicron variant we wanted to provide you with an update on our TaqPath™ COVID-19 portfolio of tests. Based on our technical assessment, because the TaqPath COVID-19 tests are designed to detect multiple genetic targets, all tests are expected to detect SARS-CoV-2 and overall test inclusivity should not be impacted (Table 1).

Overall inclusivity of our tests should not be impacted by the Omicron variant, its sublineages, and the recombinant lineages below (WHO Label).

- BA.1
- BA.2
- BA.3
- BA.4
- BA.5 (including BQ.1 and BQ.1.1)
- BA.2.75
- BJ.1
- BA.4.6
- BA.2.3.20
- XE recombinant
- XBB recombinant, including XBB.1.5

Please visit [our blog “A Reference Guide to Notable SARS-CoV-2 Variants”](#) for additional information.

Table 1

Kit name	Cat. No.	SARS-CoV-2 targets	Currently known impact*
TaqPath COVID-19 Combo Kit	A47814		No known impact to overall kit inclusivity
TaqPath COVID-19 High-Throughput Combo Kit	A49869	S, N, orf1ab (3 separate channels)	<ul style="list-style-type: none"> • Decreased detection of only S gene (S gene dropout) for variants containing 69-70del mutation^[1] • S gene advantage: S gene dropout may signal presence of 69-70del
TaqPath COVID-19 Pooling Kit	A49918		
TaqPath COVID-19, Flu A, Flu B Combo Kit	A49868	S, N (single channel)	<ul style="list-style-type: none"> • No known impact to overall kit inclusivity • Loss of S Gene Signal is expected for variants containing 69-70del mutation • 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	A51333	N, orf1a, orf1b (3 separate channels)	No known impact to overall kit inclusivity
TaqPath COVID-19 Fast PCR Combo Kit 2.0	A51606		

* As of 18 November 2022

^[1]The Omicron variant has a specific mutation in the S gene which results in a deletion of two amino acids at sites 69 (histidine) and 70 (valine), commonly referred to as 69-70del. In this case, the S gene is not detected when this mutation is present (called S gene dropout). This does **not** mean a result is negative, only that the S gene was not detected. In late 2021, **the WHO, CDC & ECDC have noted that this pattern of detection (i.e. S-gene dropout) can be used as marker for the Omicron variant, pending sequencing or genotyping confirmation.**

Presence of the S gene deletion in Omicron is summarized below:

BA.1	BA.2	BA.3	BA.4	BA.5	BA.2.75	BJ.1	BA.4.6	BA.2.3.20
Yes	No	Yes	Yes	Yes	No	No	Yes	No

As part of our post-market surveillance efforts, we 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, we will communicate if any impact on test results is expected. Visit [thermofisher.com/covid19mutations](https://www.thermofisher.com/covid19mutations) to find the latest information and resources.

For additional information, please reference the following:

- [European CDC Threat Assessment Brief](#)
- [US FDA Letter to Clinical Laboratory Staff and Health Care Providers](#)
- [Blog post: A reference guide to notable SARS-CoV-2 variants](#)
- [Blog post: Thermo Fisher's COVID-19 tests: designed with virus mutations in mind](#)
- [World Health Organization: Classification of Omicron \(B.1.1.529\): SARS-CoV-2 Variant of Concern](#)
- [African CDC: Prevention's Statement regarding the new SARS-COV-2 virus variant B.1.1.529](#)

Best regards,

kindest regards,

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