

To Whom It May Concern;

With the recent headlines related to the multiple variants of SARS-CoV-2, including Omicron variant, Delta variant, and others, 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 sensitivity should not be impacted (Table 1).

Overall sensitivity of our tests should not be impacted by the known variants below (WHO Label).

- B.1.617.2 and AY lineages (Delta)
- BA.1, BA.2, BA.3, BA.4, BA.5 and descendent lineages (Omicron)
- B.1.621, B.1.621.1 (Mu)
- C.37 (Lambda)
- P.1 and descendent lineages (Gamma)
- B.1.525 (Eta)
- B.1.351 (Beta)
- B.1.1.7 (Alpha)

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 CE-IVD RT-PCR Kit	A48067		No known impact to overall kit sensitivity <ul style="list-style-type: none"> • Decreased sensitivity 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 & potentially the Omicron variant
TaqPath™ COVID-19 CE-IVD RT-PCR Kit	A51738	S, N, orf1ab (3 separate channels)	
TaqPath™ COVID-19 HT Kit for use with Amplitude Solution	A50883		
TaqPath™ COVID-19 RNase P Combo Kit 2.0	A51334	N, orf1a, orf1b (3 separate channels)	No known impact to overall kit sensitivity
TaqPath™ COVID-19 Fast PCR Combo Kit 2.0	A51605		

TaqPath™ COVID-19, Flu A, Flu B, RSV Combo Kit	A49867	S, N (single channel)	No known impact to overall kit sensitivity <ul style="list-style-type: none"> Loss of S Gene Signal is expected for variants containing 69-70del mutation^[1] The targets for S & N Gene are in a single optical channel so they cannot be differentiated.
TaqPath™ COVID-19, Flu A, Flu/B, RSV HT Combo Kit	A52664		

* As of 12 April 2022

^[1]The Omicron and Alpha variants have 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.**

^[2] Presence of the S gene deletion in Omicron is summarized below:

BA.1	BA.2 (incl. BA.2.12.1)	BA.3	BA.4	BA.5
Yes	No	Yes	Yes	Yes

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 and when 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](#)
- [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](#)
- [eCDC: Threat Assessment Brief: Implications of the emergence and spread of the SARS-CoV-2 B.1.1.529 variant of concern \(Omicron\) for the EU/EEA](#)
- [Blog: 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 Early Identification of B.1.1.7](#)

Best regards,

Kindest Regards,

 Jody Schulz
 Director, Regulatory Affairs
 Thermo Fisher Scientific
 262-357-4605