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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.2.3.20
- BA.2.75
- BA.2.86 (BA.X) and BA.2.86.1
- BA.3
- BA.4
- BA.4.6
- BA.5 (including BQ.1 and BQ.1.1)
- BF.7
- BJ.1
- BN.1
- DV.7 and DV.7.1
- EG.1
- EG.5
- EG.10.1
- FL.1.5.1
- GS.4.1
- GW.5.1.1
- HK.3 and HK.6
- HV.1
- JD.1.1
- JF.1
- JG.3
- JN.1
- XBB recombinant, including XBB.1.5, XBB.1.16, XBB.1.9.1, XBB.1.9.2, XBB.1, XBB.2.3
- XE recombinant

Table 1

Kit name	Cat. No.	SARS-CoV-2 targets	Currently known impact*
TaqPath™ COVID-19 CE-IVD RT-PCR Kit	A48067	S, N, orf1ab (3 separate channels)	**No known impact to overall kit inclusivity** • 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 CE-IVD RT-PCR Kit	A51738		
TaqPath™ COVID-19 HT Kit for use with Amplitude Solution	A50883		
TaqPath™ COVID-19, Flu A, Flu B, RSV Combo Kit	A49867	S, N (single channel)	**No known impact to overall kit inclusivity** • 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.

* As of December 2023

[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	Yes
BA.2	No
BA.2.3.20	No
BA.2.75	No
BA.2.86 (BA.X)	Yes
BA.3	Yes
BA.4	Yes
BA.4.6	Yes
BA.5	Yes
BF.7	Yes
BJ.1	No
BN.1	No
DV.7 and DV.7.1	No
EG.1	No
EG.5	No
EG.10.1	No
FL.1.5.1	No

GS.4.1	No
GW.5.1.1	No
HK.3 and HK.6	No
HV.1	No
JD.1.1	No
JF.1	No
JG.3	No
JN.1	Yes
XBB	No
XE recombinant	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** to find the latest information and resources.

Best regards,

Rob Eardley

Rob Eardley
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