

December 13th, 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 TaqMan COVID-19 portfolio of tests. Based on our *in silico* technical assessment, some of the TaqMan COVID-19 kits are impacted by the emerging Omicron variant (Table 1). However, since these tests are designed to detect multiple genetic targets, all TaqMan COVID-19 tests are expected to detect SARS-CoV-2 in samples containing the Omicron variant.

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

Kit name	Cat. No.	SARS-CoV-2 targets	S Gene Impact	N Gene Impact	Orf1ab Impact	Currently known impact*
TaqMan SARS-CoV-2 Pooling Assay Kit	A50790	S, N, orf1ab (3 separate channels)	S-Gene Dropout	No Impact	No Impact	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
TaqMan™ SARS-CoV-2, Flu A/B, RSV RT-PCR Assay Kit	A47702	S, N (single channel)	Loss of Signal <i>Not Observable</i>	No Impact	No Impact	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.
TaqCheck SARS-CoV-2 Fast PCR Assay	A47693					
TaqMan SARS-CoV-2 Fast PCR Combo Kit 2.0	A51607	N, orf1a, orf1b (3 separate channels)	N/A	No Impact	No Impact	Detection of SARS-CoV-2 in samples containing the Omicron variant is expected
TaqMan SARS-CoV-2 RNase P Assay 2.0	A51121					

TaqMan 2019nCoV Assay Kit v1	A47532	S, N, orf1ab (single channel)	No Impact	Loss of Signal	No Impact	Detection of SARS-CoV-2 in samples containing the Omicron variant is expected <ul style="list-style-type: none"> Loss of N Gene Signal is expected
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*As of 30 November 2021

For Research Use Only. Not for use in diagnostic procedures.

In summary, to date, the B.1.1.529 lineage variant has not been found to interfere with results from the products listed in Table 1. Furthermore, at this time, there are no documented mutations or variants that would require adaptations to the test or changes in use. However, we will continue to monitor emerging variants and their potential impact on our assays.

For additional information, please reference the following:

- For Product Information: [COVID Testing Kits](#)
- For TaqPath COVID-19 diagnostic tests: Visit [thermofisher.com/covid19mutations](https://www.thermofisher.com/covid19mutations) to find the latest information and resources

Best regards,

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