

January 9th, 2023

The TaqMan 2019-nCoV Assay Kit v1 contains a set of TaqMan® RT-PCR assays for use in research for the qualitative detection and characterization of SARS-CoV-2 RNA. The kit includes three assays that target SARS-CoV-2 genes and one positive control assay that targets the human RNase P RPPH1 gene.

SKU	SKU Name	Unit	Product Description	Unit Size	
	TaqMan 2019nCoVAssay Kit v1	1 wet tube	2019nCoV Assay (Gene Orf-1ab) –FAM, 20X	50 reactions (75 ul)	
A47522		1 wet tube	1 wet tube 2019nCoV Assay (Gene S protein) –FAM, 20X		
A47332		1 wet tube	2019nCoV Assay (Gene N protein) –FAM, 20X	50 reactions (75 ul)	
		1 wet tube	RNase P – VIC, 20X	150 reactions (225 ul)	

Based on in-silico mutation analysis performed on November 18<sup>th</sup> 2022, the TaqMan 2019nCoV Assay Kit v1 is expected to detect SARS-CoV-2 in samples containing the following (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

The Omicron variant has a specific mutation in the N gene which is expected to result in a loss of N Gene assay signal. However, since this kit is designed to detect multiple genetic targets, the TaqMan 2019nCoV Assay Kit v1 is expected to detect SARS-CoV-2 in samples containing the Omicron variant. Presence of the N gene mutation 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	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes

We will continue to 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,

Schulz

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