

# 3DMed SARS-CoV-2 Mutations Assay

## Background

The emergence of a heavily mutated SARS-CoV-2 variant (B.1.1.529, Omicron) and its spread to 6 continents within a week of initial discovery has set off a global public health alarm. Characterizing the mutational profile of Omicron is necessary to interpret its shared or distinctive clinical phenotypes with other SARS-CoV-2 variants.

As of Dec 14<sup>th</sup>, 2021, WHO has designated 5 variants of concerns (VOC) and 2 variants of interest (VOI). 3DMed offers two versions of SARS-CoV-2 Mutations Assays which can identify the N501Y, E484K, T547K and P681R mutations that can help to differentiate all 5 VOCs and 1 VOI, and at the same time, re-confirm the SARS-CoV-2 positive cases (intended use).

## Features



### Screening for COVID-19 variants

Product 1 covering N gene can be used for initial screening for COVID-19 positive cases, and the LoD is 1000 copies/mL



### Reliable result

Endogenous internal control can monitor the entire process including sampling and nucleic acid extraction, minimize false-negative results and enable the application of self-collected samples



### Accurate detection

Accurate multiplex test for notable S gene mutations, providing individual Ct value for each target, the LoD of target is 1000 copies/mL



### Automated solution

Compatible to 3DMed automated platform offering short turnaround time and high-throughput testing capacity



### Variant surveillance

Three product package options offer surveillance solution of SARS-CoV-2 variants for efficient pandemic control and patient care

## Specifications

Product 1 targets	N501Y in S gene, E484K in S gene, N gene	Specimens	Nasopharyngeal or oropharyngeal swabs
Product 2 targets	T547K in S gene P681R in S gene	RT-qPCR run time	~75 mins
Internal control	RNase P (endogenous)	Reaction Volume	25µL (12.5µL sample + 12.5 µL enzyme and master mix)
Detection method	RT-qPCR	Limited of detection	1000 copies/µL
Package	50 tests/kit	Compatible qPCR machines	ABI 7500, QuantStudio 5, Bio-Rad CFX96 Touch Deep Well

## Three product package options

### 3DMed SARS-CoV-2 Mutations Assay Product 1 (CE-IVD)

Target 1 (FAM)	Target 2 (VIC)	Target 3 (ROX)	Endogenous IC (CY5)	Indication for Variants
N501Y in S gene	E484K in S gene	N gene	RNase P	
+	-	+	+	Omicron/Alpha
+	+	+	+	Beta/Gamma/Mu
-	+	+	+	Eta

Note: “+” means “Detected”, and “-” means “Not Detected”.

### 3DMed SARS-CoV-2 Mutations Assay Product 2 (CE-IVD in progress) (especially for Omicron identification)

Target 1 (FAM)	Target 2 (ROX)	Endogenous IC (CY5)	Indication for Variants
T547K in S gene	P681R in S gene	RNase P	
+	-	+	Omicron
-	+	+	Kappa/Delta
+	-	-	SARS-CoV-2 (Wild Type) or other Variants

Note: “+” means “Detected”, and “-” means “Not Detected”.

### 3DMed SARS-CoV-2 Mutations Assay Product 1+ Product 2 for differentiation of all 5 VOCs and 1 VOI

Tube 1 for Product 1				Tube 2 for Product 2			Indication for Variants
Target 1 (FAM)	Target 2 (VIC)	Target 3 (ROX)	Endogenous IC (CY5)	Target 1 (FAM)	Target 2 (ROX)	Endogenous IC (CY5)	
N501Y in S gene	E484K in S gene	N gene	RNase P	T547K in S gene	P681R in S gene	RNase P	
+	-	+	+	+	-	+	Omicron
+	+	+	+	-	-	+	Beta/Gamma/Mu
-	+	+	+	-	-	+	Alpha
-	-	+	+	-	+	+	Kappa/Delta
-	-	+	+	-	-	+	SARS-CoV-2 (Wild Type) or other Variants

Note: “+” means “Detected”, and “-” means “Not Detected”.

The kits only assist to investigate the prevalence and frequency of virus variants.  
The specific type should be determined according to the sequencing results.



Website



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