

QuantiVirus™ SARS-CoV-2 Variants Detection Test

Screens for the SARS-CoV-2 virus and simultaneously identifies and differentiates all the new mutating COVID-19 variants

Key Highlights

- CE Marked
- Screen for infection of SARS-CoV-2 viruses in general
- Identifies and differentiate all the new mutating COVID-19 variants, especially variants of concern, including:
 - ☞ Alpha (UK)
 - ☞ Beta (S. Africa)
 - ☞ Gamma (Brazil)
 - ☞ Delta (India)
 - ☞ Delta Plus (India)
 - ☞ Omicron
 - ☞ Epsilon (California)
 - ☞ Kappa (India) variants
- Enhanced sensitivity (100 copies/mL) and specificity powered by DiaCarta's proprietary XNA Technology
- Sample type: Sputum, saliva, nasopharyngeal, and oropharyngeal



Variants of Concern (VoC) and Significance of Detection

Since the first outbreak of COVID-19 in 2019, SARS-CoV-2, the virus that causes COVID-19, has mutated aggressively at different parts of the world and now, some dangerous variants that either increase transmission speed or hospitalization have been characterized and named variants of concern (VoC). These variants include Alpha, Beta, Gamma, Delta, Delta plus, Omicron, and a few others.

Accurately detecting different variants helps understand the infection transmission and severity of the health threat, and provides useful information for the variants spread in different regions and implementation of public health guidelines.

Methods for Variants Detection

Different molecular diagnostic methods have been successfully used for variants detection. These methods are complementary to each other and have their own value in detection of VoC.

Whole Genome Sequencing and Sanger Sequencing

The sequencing methods have great advantages as it can detect different variants as well as discover new variants. But these methods are generally more costly and time-consuming.

qPCR Genotyping

qPCR methods can selectively identify the limited and known variants with high specificity and fast speed.

QuantiVirus™ SARS-CoV-2 Variants Detection Test Kit

We successfully developed and launched the QuantiVirus™ SARS-CoV-2 Test and QuantiVirus™ SARS-CoV-2 Multiplex Test, both are FDA EUA authorized. The tests are widely used by global healthcare services for generic SARS-CoV-2 testing.

Now, we have developed **QuantiVirus™ SARS-CoV-2 Variants Detection Test**, using the RT-qPCR detection method to detect infection of SARS-CoV-2 in general and specifically mutant for the important VoCs based on our proprietary XNA technology.

The use of the **XNA technology** not only identifies the variants in individual samples, but also variants in sample population, which is valuable for determination of variants prevalence in certain regions by local public health agencies.

The QuantiVirus™ SARS-CoV-2 Variants Detection Test identifies seven important variants of SARS-CoV-2, including Alpha, Beta, Gamma, Delta, Delta Plus, Omicron, Epsilon and Kappa. Using samples from sputum, saliva, and upper respiratory specimens, the test goes through RNA extraction and RT-qPCR steps to identify different variants on commonly used qPCR instruments. The test can also be adapted to high-throughput platforms if necessary. With Limit of Detection of 100 copies/mL, the QuantiVirus™ SARS-CoV-2 Variants Detection Test has been validated using hundreds of clinical samples we have collected since January 2021.



List of Mutations Detected by QuantiVirus™ SARS-CoV-2 Variants Detection Kit

S Gene Mutation	Alpha (B.1.1.7)	Beta (B.1.351)	Gamma (P.1)	Delta (B.1.617.2)	Delta Plus	Omicron (B.1.1.529)	Epsilon (B.1.427/B.1.429)	Kappa (B.1.617.1)
D614G	✓	✓	✓	✓	✓	✓	✓	✓
N501Y	✓	✓	✓			✓		
T478K				✓	✓	✓		
L452R				✓	✓		✓	✓
K417T			✓					
K417N		✓			✓	✓		

Test Performance

Using serial dilutions of the virus reference materials, the Limit of Detection (LoD), the lowest concentration of template that could be reliably detected with 95% detection rate, is determined to be 100 copies/mL of sample.

The tested organisms all show negative for the targeted genes of SARS-CoV-2, suggesting no cross-reactivity between SARS-CoV-2 and the organisms tested. The cross-reactivity with SARS-coronavirus (MK062184.1) was tested and did not show any cross reactivity at 10⁵ PFU/mL.

Test Validation Using Clinical Samples

Data show that there is 100% agreement with the spiked sample at 1xLoD (1x100 copies/mL), and 100% agreement at all other concentrations including 200 copies/mL, 300 copies/mL, and 500 copies/mL. For negative control, all the 30 samples were tested negative.

Contrived clinical sample evaluation with viral particles (QuantStudio 5)

Specimen Type	Viral RNA Spiked	SARS-CoV-2			Performance Agreement	95% CI
		Positive	Negative	Total		
viral RNA +sputum	100 copies /mL (1x LoD)	20	0	20	100%	69.9-97.2%
	200 copies/mL (2x LoD)	20	0	20	100%	76.4-99.1%
	300 copies/mL (3x LoD)	10	0	10	100%	72.3-100%
	500 copies/mL (5x LoD)	10	0	10	100%	72.3-100%
H ₂ O + sputum	0 copy/mL	0	30	30	100%	90.6-100%

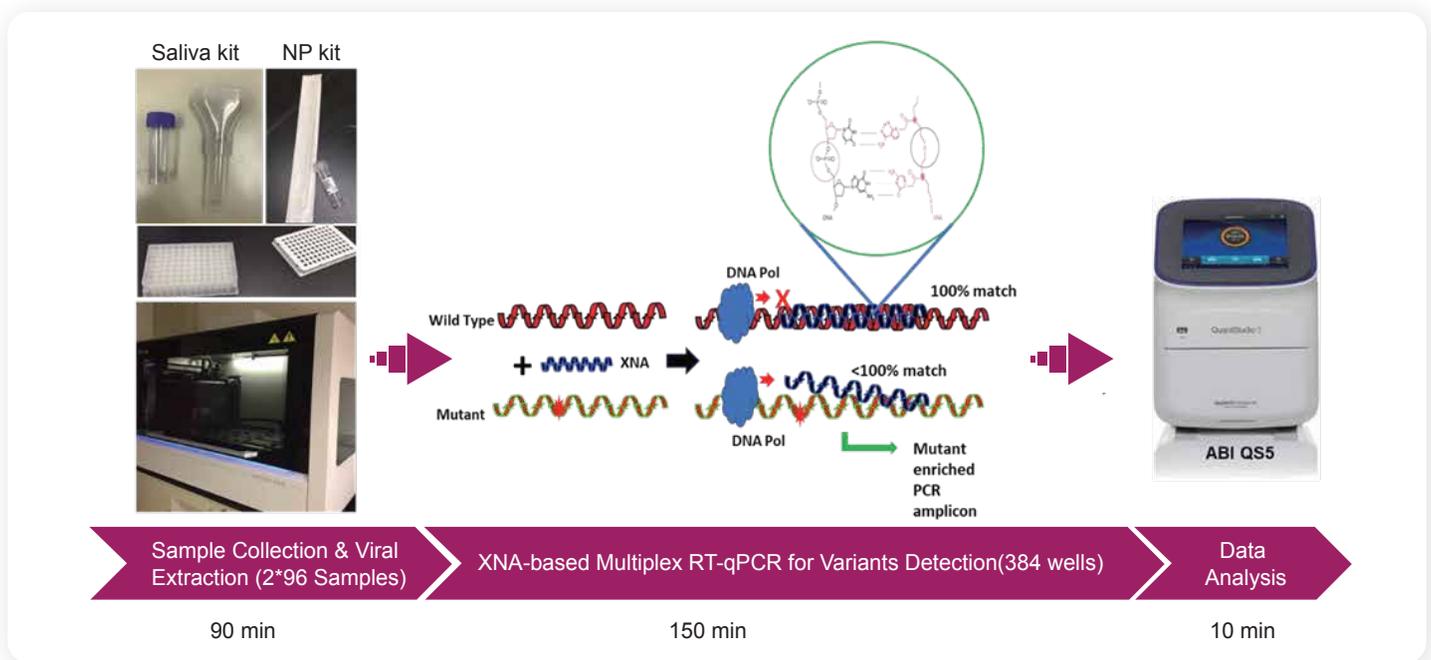


Workflow of QuantiVirus™ SARS-CoV-2 Variants Detection Kit

Sampling methods: sputum, saliva, and upper respiratory specimens taken using nasal or oropharyngeal swabs.

Viral RNA extraction: Isolation of viral RNA with sample lysis or extraction to obtain qPCR templates. Can be adapted to high-throughput platform.

RT-qPCR: Kit performance is validated on three most popular qPCR instruments: ABI QuantStudio 5 (Thermo), CFX384 (Bio-Rad), and ABI 7500 Fast Dx (Thermo).



Ordering Information

Product Name	Pack Size	Intended Use	Catalog Number
QuantiVirus™ SARS-CoV-2 Variants Detection Kit	48 Reactions	CE Marked	DC-11-0057
	480 Reactions	CE Marked	DC-10-0058

