CerTest BIOTEC

VIASURE
Real Time PCR Detection Kits

SARS-CoV-2 Variant I

The SARS-CoV-2 virus was detected for the first time in Wuhan (China) on 31 December 2019. During 2020, the virus spread progressively throughout the world and on March 11, the WHO decreed the status of pandemic. The appearance of mutations is a natural and expected event within the evolutionary process of the virus. Some specific mutations define the lineages that are currently circulating globally.

Since the initial genomic characterization of SARS-CoV-2, the virus has divided into different lineages. Thanks to the genetic sequencing of the pathogen, it has been possible to establish patterns of dispersal and evolution of the virus.

On 14 December 2020, the United Kingdom declared an increase in the incidence of SARS-CoV-2 in some regions of its country associated with a new variant of the virus with a greater transmission capacity. By the end of December, this variant was detected in 31 countries and in five territories of the six World Health Organization regions. This variant is called VOC 202012/01 (B.1.1.7) and is characterized by presenting the N501Y mutation as well as the 69/70 deletion, among others.

Variant B.1.351 was first identified at Nelson Mandela Bay, South Africa, in samples dating from early October 2020. The variant was also identified in Zambia in late December 2020. It appeared to be the predominant variant in the country. This variant has multiple mutations in the Spike protein, including K417N, E484K, and N501Y. There is evidence showing that it has a potential reduction in neutralization by some EUA monoclonal antibody treatments.

The SARS-CoV-2 epidemic in Brazil was dominated by two lineages designated as P1 and P2 which harbor mutations in the receptor-binding domain of the Spike (S) protein. The P.1 lineage (previously referred to as the B.1.1.28 lineage) is considered a *variant of concern* (VOC) due to the presence of multiple mutations in protein S (including K417T, E484K, N501Y). Its appearance was associated with a second epidemic peak of COVID-19 in the state of Amazonas, while the P.2 lineage (previously named B.1.1.33) only harbors the E484K mutation and is considered a *Variant Under Investigation* (VUI) . The P.2 lineage has been detected as the most prevalent variant in several states of the country in late 2020 and early 2021.

Summary of mutations associated with known Variants of Concern (VOC) and Variants Under Investigation (VUI):

	Originally identified at:	Mutations in the *S* gene			
		E484K	K417T	K417N	N501Y
P.1 (B.1.1.28 lineage)	Brazil	●	●		●
P.2 (B.1.1.33 lineage)	Brazil	●			
B.1.351 lineage	South Africa	●		●	●
B.1.1.7 lineage	UK				●

Other variants not reflected in the interpretive table may be positive for the selected mutations, as they are not unique to them.

Lyophilised product

Shelf-life: 24 months

ISO 13485 and **CE marked**

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VIASURE *SARS-CoV-2 Variant I* Real Time PCR Detection Kit is a real-time RT-PCR test designed for the qualitative detection of RNA from genetic mutations in the *S* gene (E484K, K417N, K417T and N501Y) from positive SARS-CoV-2 nasopharyngeal samples.

RNA is extracted from respiratory specimens. Complementary DNA (cDNA) is synthetised and amplified using RT-PCR and detected using fluorescent reporter dye probes specific for genetic mutations in the *S* gene (E484K, K417N, K417T and N501Y).

Analytical sensitivity

VIASURE *SARS-CoV-2 Variant I* Real Time PCR Detection Kit has a detection limit (LoD) results are as follows:

1. Detection limit (LoD) of 40 genome copies/rxn for N501Y measured using the SARS-CoV-2 B.1.1.7 lineage and 80 genome copies/rxn measured with RNA from SARS-CoV-2 B.1.351 lineage.
2. Detection limit (LoD) of 40 genome copies/rxn for E484K measured using RNA from SARS-CoV-2 B.1.351 lineage and SARS-CoV-2 P.1 lineage.
3. Detection limit (LoD) of 40 genome copies/rxn for K417N measured using RNA from SARS-CoV-2 B.1.351 lineage.
4. Detection limit (LoD) of 80 genome copies/rxn for K417T measured using RNA from SARS-CoV-2 P.1 lineage.

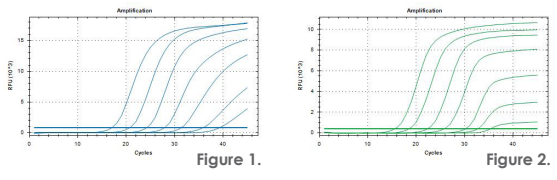

Figure 1.

Figure 2.

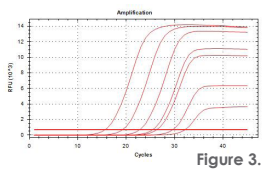

Figure 3.

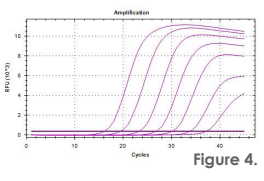

Figure 4.

Figura 1. Dilution series of mutation E484K (10^7-10^1 copies/rxn) template run on the Bio Rad CFX96™ Real Time PCR Detection System (FAM channel).

Figura 2. Dilution series of mutation K417N (10^7-10^1 copies/rxn) template run on the Bio Rad CFX96™ Real Time PCR Detection System (HEX channel).

Figura 3. Dilution series of mutation K417T (10^7-10^1 copies/rxn) template run on the Bio Rad CFX96™ Real Time PCR Detection System (ROX channel).

Figura 4. Dilution series of mutation N501Y (10^7-10^1 copies/rxn) template run on the Bio Rad CFX96™ Real Time PCR Detection System (Cy5 channel).

Referencias -VIASURE *SARS-CoV-2 Variant I* Real Time PCR Detection Kit-

6 x 8-well strips, low profile_____VS-VAR106L
12 x 8-well strips, low profile_____VS-VAR112L
96-well plate, low profile_____VS-VAR113L

6 x 8-well strips, high profile_____VS-VAR106H
12 x 8-well strips, high profile_____VS-VAR112H
96-well plate, high profile_____VS-VAR113H

TUBE FORMAT: 4 tubes x 24 reactions_VS-VAR196T

CerTest BIOTEC

For more information and use procedure,
read the instructions for use included in this product.

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