



# VIASURE SARS-CoV-2 Variant II Real Time PCR Detection Kit

The appearance of genetic mutations is a **natural and expected event within the evolution process of a virus**. In fact, some specific mutations define the viral genetic groups currently circulating globally. Besides, thanks to the genetic sequencing of the pathogen worldwide, it has been possible to establish patterns of dispersal and evolution of the virus.

All viruses, including SARS-CoV-2, mutates over time. Some changes may affect the virus's properties, such as how easily it spreads, the associated disease severity, or the performance of vaccines, therapeutic medicines, diagnostic tools, or other public health and social measures.

At the end of 2020, the appearance of variants with a higher risk prompted the characterization of **Variants of Interest** (VOI) and Variants of Concern (VOC), in order to facilitate epidemiological control.

All these variates described above show potential reduction in neutralization by some immunotherapies and reduction of expected effects of vaccines or has been identified to cause community transmission.

That is why, their appearance constitute a first-order public health problem that can have an important impact on control of the pandemic.

A concern regarding the new variants is that their detection by molecular techniques (RT-PCR) could be affected. For this reason, VIASURE SARS-CoV-2 Variant II Real Time PCR Detection Kit has been designed to allow the detection of the main mutation associated with the variant under surveillance.



"Ready & Easy-to-use" kits.

Lyophilised product



Transport and storage at room temperature. Shelf-life: 24 months



Validated according to ISO 13485 and CE marked



### VIASURE SARS-CoV-2 Variant II Real Time PCR Detection Kit

VIASURE SARS-CoV-2 Variant II 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 (P681R, L452R and E484Q) and the housekeeping gene Rnase P from positive SARS-CoV-2 nasopharyngeal samples.

This test is intended for use as an aid to monitor the prevalence of genetic mutations in the S gene (P681R, L452R and E484Q) and to assist in control measures.

RNA is extracted from respiratory specimens, complementary DNA (cDNA) is synthetised and amplified using RTqPCR and detected using fluorescent reporter dye probes specific for genetic mutations in the S gene (P681R, L452R and E484Q).

## **Analytical sensitivity**

- VIASURE SARS-CoV-2 Variant II Real Time PCR Detection Kit has a detection limit (LoD) of 320 genome copies/ rxn for P618R mutaton and 160 genome copies/rxn for L452R and E484Q mutations.
- The limit of detection has been measured using the SARS-CoV-2 B.1.617.1 lineage.

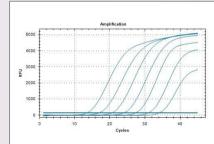


Figure 1. Dilution series of mutation P618R (107-101 copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (FAM channel).

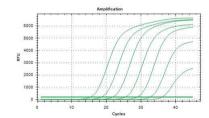


Figure 2. Dilution series of mutation L452R (107-101 copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (HEX channel).

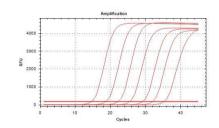


Figure 3. Dilution series of mutation E484Q (107-101 copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (ROX channel).

#### References - VIASURE SARS-CoV-2 Variant II Real Time PCR Detection Kit -

VS-VAI106L 6 x 8-well strips, low profile\_ 12 x 8-well strips, low profile\_\_\_ VS-VAI112L 96-well plate, low profile\_ VS-VAI113L 1 x 8-well strips, low profile\_\_\_ VS-VAI101L

TUBE FORMAT: 4 tubes x 24 reactions\_\_\_\_

VS-VAI106H 6 x 8-well strips, high profile\_ 12 x 8-well strips, high profile\_\_ \_VS-VAI112H 96-well plate, high profile\_\_\_ VS-VAI113H 1 x 8-well strips, high profile\_ VS-VAI101H

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

#### CerTest Biotec, S.L.

Pol. Industrial Río Gállego II · Calle J, Nº1 50840, San Mateo de Gállego, Zaragoza (Spain) Tel. (+34) 976 520 354 · Fax (+34) 976 106 268 certest@certest.es | viasure@certest.es

www.certest.es







VIASURE/VAI-0621EN