



VIASURE SARS-CoV-2 Variant III 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, these specific genome modifications define the viral genepools currently circulating globally.

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 Concern (VOC) and Variants of Interest (VOI), in order to facilitate epidemiological control.

All these variants 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.

Due to genetic sequencing of the pathogen, genomic characterisation of the virus has been made possible and each of the mutations that determine the variants of concern can be identified. This information is of great use in implementing diagnostic tests to rapidly identify the spread of these variants, with molecular tests, which are capable of detecting RNA fragments, being of particular interest. For this reason, VIASURE SARS-CoV-2 Variant III Real Time PCR Detection Kit has been designed to allow the detection of the main mutations associated with one of the highest impact variants worldwide today; B.1.1.529 (Omicron).



"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 III Real Time PCR Detection Kit

VIASURE SARS-CoV-2 Variant III Real Time PCR Detection Kit is designed for the qualitative detection of RNA from genetic mutations in the S gene (Q954H) and in the ORF1a gene (A2710T) 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 (Q954H) and in the ORF1a gene (A2710T) 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 (Q954H) and in the ORF1a gene (A2710T).

Analytical sensitivity

VIASURE SARS-CoV-2 Variant III Real Time PCR Detection Kit has a detection limit of ≥ 100 genome copies per reaction for A2710T mutation (ORF1a gene) and ≥ 12.5 genome copies per reaction for Q954H mutation (S gene) with a positive rate of 95%.

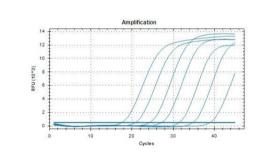


Figura 1.

Dilution series of A2710T mutation (ORF1a gene) (107-101 copies/rxn) template run on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (channel FAM).

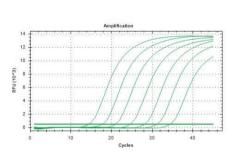


Figura 2.

Dilution series of Q954H mutation (S gene) (107-101 copies/rxn) template run on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (channel HEX).

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

| 1 x 8-well strips, low profile | VS-VAO101L |
|---------------------------------|-------------|
| 6 x 8-well strips, low profile | VS- VAO106L |
| 12 x 8-well strips, low profile | VS- VAO112L |
| 96-well plate, low profile | VS- VAO113L |

FORMATO TUBO: 4 tubes x 24 reactions

1 x 8-well strips, high profileVS- VAO101H6 x 8-well strips, high profileVS- VAO106H12 x 8-well strips, high profileVS- VAO112H96-well plate, high profileVS- VAO113H

| Ceri | Test |
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| - E | BIOTEC |

CerTest Biotec, S.L.

Pol. Industrial Río Gállego II · Calle J, N°1 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 For more information and use procedure, read the instructions for use included in this product.



VIASURE/VAO-0122EN