



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

Stealth Omicron detection

On 26 November 2021, WHO designated the variant B.1.1.529 a variant of concern (VOC), it was given the name Omicron. This is a highly divergent variant with a high number of mutations, including 26-32 mutations some of which are associated with humoral immune escape potential and higher transmissibility.

Omicron has a significant growth advantage over Delta VOC, leading to **rapid spread** in the community with higher levels of incidence than previously seen in this pandemic. Despite a lower risk of severe disease and death following infection than previous SARS-CoV-2 variants, the very high levels of transmission have resulted in significant increases in hospitalization, continue to pose overwhelming demands on health care systems in most countries, and may lead to significant morbidity, particularly in vulnerable populations.

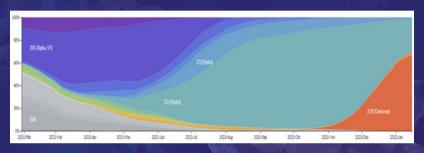


Figure I: Evolution of the main SARS-CoV-2 variants during the COVID-19 pandemic.

Therefore, an effective diagnosis is crucial to track the spread of emergent variants, monitor their prevalence or detect changes in the genome. Different approaches have been used for this purpose, such as whole genome sequencing or PCR mutations testing. Other algorithms have been used to identify Omicron variant, such as \$ gene amplification failure. However, the emergence of other Omicron sub-lineages that do not contain the spike deletion, increases the importance of specific and sensitive diagnostic tools.

The Omicron variant comprises four lineages including B.1.1.529, BA.1, BA.2 and BA.3. BA.2 Omicron lineage, also called "Stealth Omicron" because it lacks the deletion, is replacing BA.1 lineage in some countries. BA.2 has overtaken BA.1 in Denmark, India, Nepal or Philippines. In Europe the number of cases of BA.2 is increasing, it has been sequenced in the UK, Germany, Belgium, Italy and France.

On the other hand, the prevalence of BA.3 Omicron lineage is low, only some cases have been reported worldwide.

VIASURE SARS-CoV-2 Variant III Real Time PCR Detection Kit has been designed for the detection of two specific mutations of Omicron variant: Q954H located in S gene and A2710T located in ORF1a gene. In addition, amplification of these mutations allows differentiation of the most prevalent lineages of Omicron variant:

Omicron	VIASURE VAO	
lineage	A2710T G	Q954H
B.1.1.529	*	*
BA.1	*	*
BA.2		*



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 RT-qPCR 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%.

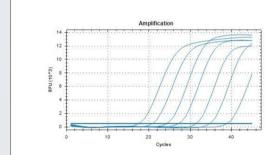


Figura 1.

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).

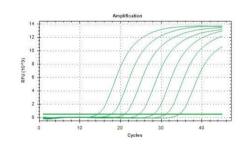


Figura 2.

Dilution series of Q954H mutation (\$ 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	1 x 8-well strips, high profile	VS- VAO101H
6 x 8-well strips, low profile	VS- VAO106L	6 x 8-well strips, high profile	VS- VAO106H
12 x 8-well strips, low profile	VS- VAO112L	12 x 8-well strips, high profile	VS- VAO112H
96-well plate, low profile	VS- VAO113L	96-well plate, high profile	VS- VAO113H
TUBE FORMAT: 4 tubes x 24 reaction	S VS-VAO196T		

CerTest

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

CerTest Biotec, S.L.

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