

## SARS-CoV-2 & UK Variant

(S UK, ORF1ab and N genes)

- ▶▶ The appearance of mutations is a natural and expected phenomenon within the evolution process of the virus. In fact, some specific mutations define the viral genetic groups that are currently circulating worldwide.

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

- ▶▶ On December 14<sup>th</sup>, 2020, the United Kingdom declared an increase in the incidence of SARS-CoV-2 in some regions associated with a new virus variant with a supposed greater transmission capacity. This variant, called VOC202012 / 01 (B.1.1.7), presented 23 different mutations: 13 non-synonymous, including a series of mutations in the Spike (S) protein, 4 deletions, and 6 silent or synonymous mutations. By the end of December, this variant had been detected in 31 countries and in five of the six World Health Organization regions.

One of these mutations is the deletion of nucleotides at positions 69-70 of protein S. Detection of the HV 69/70 deletion is of vital importance since it has been associated with the loss of immunity in immunosuppressed patients and with increased viral infectivity. Another concern related to the HV 69/70 deletion is that it affects the sensitivity of virus detection using molecular techniques (RT-PCR) that detect the S gene.

- ▶▶ The presence of the HV 69/70 deletion is associated with the Alpha variant, lineage B.1.1.7, however, other variants such as B.1.1.298 (Danish lineage) or B.1.258 also have this deletion.



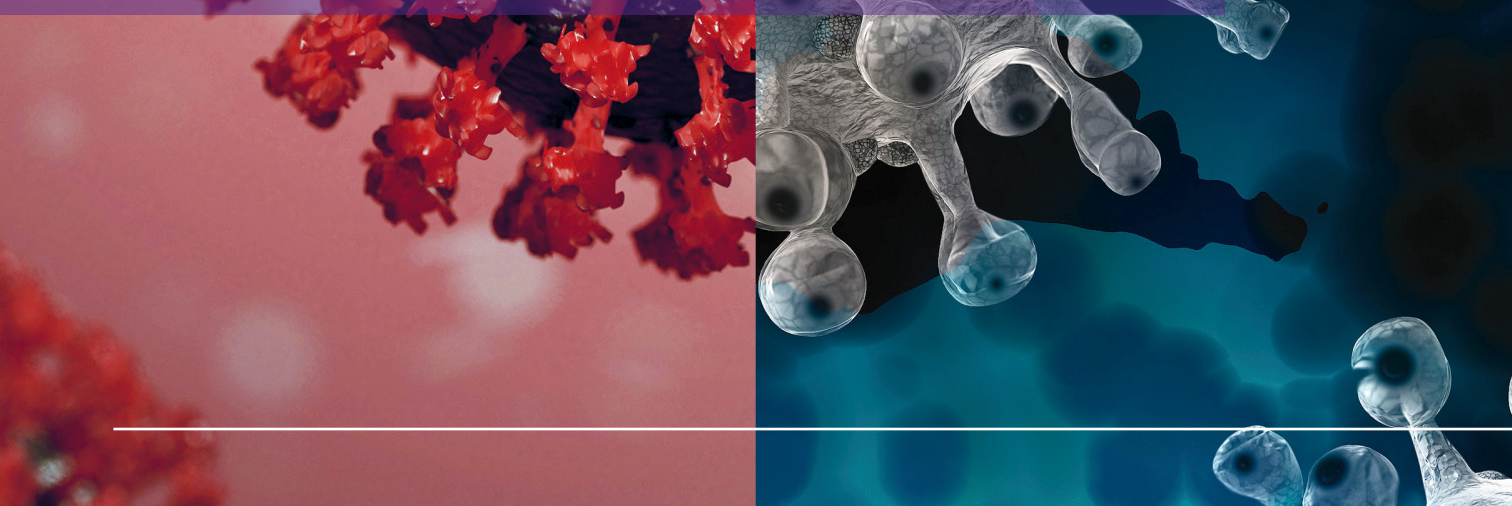
"Ready & Easy-to-use" kits.  
**Lyophilised product**



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



Validated according to **ISO 13485**  
and **CE marked**





## SARS-CoV-2 & UK Variant (S UK, ORF1ab and N genes)

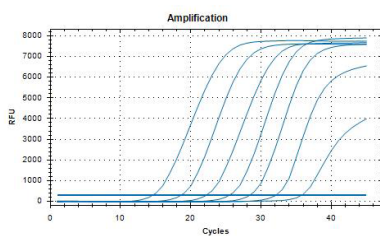
**VIASURE SARS-CoV-2 & UK Variant (S UK, ORF1ab and N genes) Real Time PCR Detection Kit** is designed for the qualitative detection of RNA from the SARS-CoV-2 and the HV 69/70 deletion of the S gene for SARS-CoV-2 associated to the SARS-CoV-2 Alpha variant (lineage B.1.1.7) and other variants in nasopharyngeal swabs from individuals suspected of COVID-19 infection by their healthcare professional (HCP).

**This test is intended for use as an aid in the diagnosis of SARS-CoV-2 as well as variants that carry the HV 69/70 deletion in combination with clinical and epidemiological risk factors.**

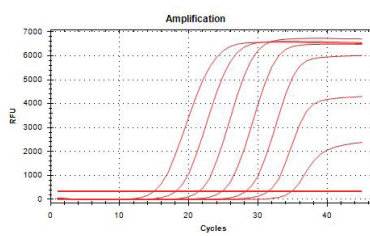
RNA is extracted from respiratory specimens, amplified using RT-PCR and detected using fluorescent reporter dye probes specific for SARS-CoV-2 and HV 69/70 deletion.

### Analytical sensitivity

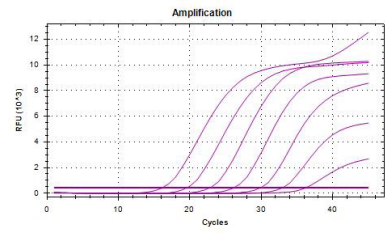
**VIASURE SARS-CoV-2 & UK Variant (S UK, ORF1ab and N genes) Real Time PCR Detection Kit** has a detection limit (LoD) of 40 genome copies/rxn for S gene (HV 69/70 deletion), 40 genome copies/rxn for ORF1ab gene and 80 genome copies/rxn for N gene. (Figures 1, 2 and 3).



**Figure 1.**  
Dilution series of S gene (HV 69/70 deletion) ( $10^7$ - $10^1$  copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (FAM channel).



**Figure 2.**  
Dilution series of ORF1ab gene ( $10^7$ - $10^1$  copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (ROX channel).



**Figure 3.**  
Dilution series of N gene ( $10^7$ - $10^1$  copies/rxn) template run on the Bio-Rad CFX96™ Real-Time PCR Detection System (Cy5 channel).

### References - VIASURE SARS-CoV-2 & UK Variant (S UK, ORF1ab and N genes) Real Time PCR Detection Kit -

6 x 8-well strips, low profile \_\_\_\_\_ VS-SUK206L  
12 x 8-well strips, low profile \_\_\_\_\_ VS-SUK212L  
96-well plate, low profile \_\_\_\_\_ VS-SUK213L  
1 x 8-well strips, low profile \_\_\_\_\_ VS-SUK201L

6 x 8-well strips, high profile \_\_\_\_\_ VS-SUK206L  
12 x 8-well strips, high profile \_\_\_\_\_ VS-SUK212H  
96-well plate, high profile \_\_\_\_\_ VS-SUK213L  
1 x 8-well strips, high profile \_\_\_\_\_ VS-SUK201H

TUBE FORMAT WITH INTERNAL CONTROL: 4 tubes x 24 reactions \_\_\_\_\_ VS-SUK296T

**CerTest**  
BIOTEC

**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](http://www.certest.es)

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



VIASURE/SUK2-0821EN