CerTest BIOTEC

VIASURE
Real Time PCR Detection Kits

VIASURE *SARS-CoV-2 TRIPLEX*
Real Time PCR Detection Kit

- The current coronavirus 2019 (COVID-19) pandemic, caused by the SARS-COV-2 virus, is a substantial challenge for healthcare systems and their infrastructure. Diagnostic confirmation based on RT-PCR of infected individuals is crucial to contain the spread of the virus, since the infection can be asymptomatic despite a high viral load.

  The presence of COVID-19 is manifested by several symptoms, ranging from asymptomatic to severe illness and death. Common symptoms include cough, fever, tiredness, and loss of taste and/or smell. Other reported symptoms are sore throat, headache ,weakness, muscle pain or rash on skin.

- Clinical diagnosis of COVID-19 is based on clinical manifestations and molecular diagnostics methods like **real-time RT-PCR** of samples from the upper and/or lower respiratory tract specimens.

- Currently, several RT PCR assays are available based on different protocols recommended by international institutions such as CDC China (target genes ORF1ab and N), Charité Germany CDC (target genes RdRP and E) or CDC United States (target genes N1 and N2). However, due to the evolution of the virus and the need to update and improve diagnostic tools, Certest Biotec has developed a new assay that includes the detection of 3 specific targets that allow a more accurate detection of the SARS-CoV-2 virus.

"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**

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VIASURE *SARS-CoV-2 TRIPLEX* Real Time PCR Detection Kit

VIASURE *SARS-CoV-2 Triplex (ORF1ab, E & N* genes) Real Time PCR Detection Kit is designed for diagnosis of *SARS-CoV-2* in respiratory clinical samples. Detection is carried out by real-time polymerase chain reaction where reverse transcription and subsequent amplification of the specific target: a conserved region of the *SARS-CoV-2* genes *ORF1ab, E* and *N* occurs using specific oligonucleotides and a fluorescently labeled probe.

VIASURE *SARS-CoV-2 Triplex (ORF1ab, E & N* genes) Real Time PCR Detection Kit contains in each well all the necessary components to carry out real-time PCR (specific primers / probes, dNTPS, buffer, polymerase and reverse transcriptase) in stabilized format, as well as an **Endogenous Internal Control**, the human *housekeeping RNase P* gene, present in human DNA. Human housekeeping genes are involved in basic cellular maintenance and are therefore expected to be present in all nucleated human cells and to maintain relatively constant levels of expression.

Target	Channel	Gene
SARS-CoV-2	FAM	ORF1ab
SARS-CoV-2	HEX	E
SARS-CoV-2	Cy5	N
Endogenous Internal Control (EIC)	ROX	Human RNase P

Analytical sensitivity

VIASURE SARS-CoV-2 *Triplex (ORF1ab, E & N genes)* Real Time PCR Detection Kit has a detection limit ≥ 0.625 genomic copies per reaction for the ORF1ab gene, ≥ 1.25 genomic copies per reaction for the E gene and ≥ 1.25 genomic copies for the N gene with a positivity rate of 95%.

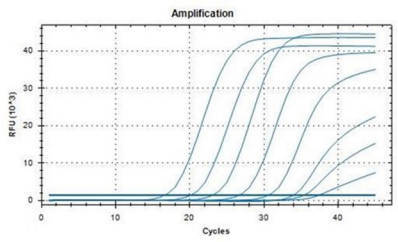

Figure 1.
Serial dilutions of a SARS-CoV-2 standard (ORF1ab gene) (10^7-10^1 copies/reaction). Experiment performed on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (FAM channel).

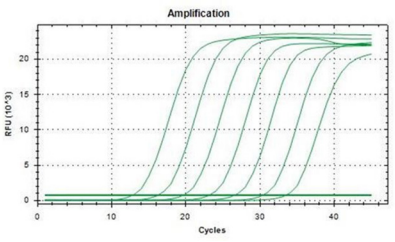

Figure 2.
Serial dilutions of a SARS-CoV-2 standard (E gene) (10^7-10^1 copies/reaction). Experiment performed on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (HEX channel).

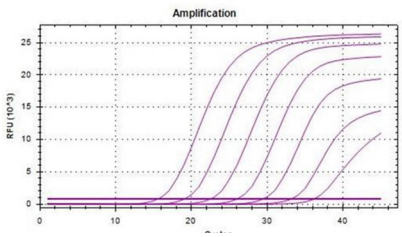

Figure 3.
Serial dilutions of a SARS-CoV-2 standard (N gene) (10^7-10^1 copies/reaction). Experiment performed on the CFX96TM Real-Time PCR Detection System (Bio-Rad) (Cy5 channel).

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

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