

VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit (To be used with the BD MAX™ System)

Human-to-human transmission of the **SARS-CoV-2** has been confirmed, even in the incubation period without symptoms, and the virus causes severe respiratory illness like those SARS-CoV produced. Although the pneumonia is the principal illness associated, a few patients have developed severe pneumonia, pulmonary edema, acute respiratory distress syndrome, or multiple organ failure and death.

Centers of Disease Control and Prevention (CDC) believes that symptoms of **SARS-CoV-2** may appear in as few as 2 days or as long as 14 days after exposure, being the most common fever, cough, myalgia and dyspnea. Less common symptoms are sore throat, headache, diarrhea and vomiting. It seems that older males with comorbidities have been more affected.

In December 2019, some people that worked at or lived around the Huanan seafood market in Wuhan, Hubei Province, China, have presented pneumonia of unknown cause. Deep sequencing analysis of the respiratory samples indicated a novel coronavirus, which was named firstly 2019 novel coronavirus (2019-nCoV) and lately SARS-CoV-2.



VIASURE SARS-CoV-2 Real Time PCR Detection Kit

VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit is designed for the specific identification and differentiation of 2019 Novel Coronavirus (**SARS-CoV-2**) in respiratory samples from patients with signs and symptoms of COVID-19 infection.

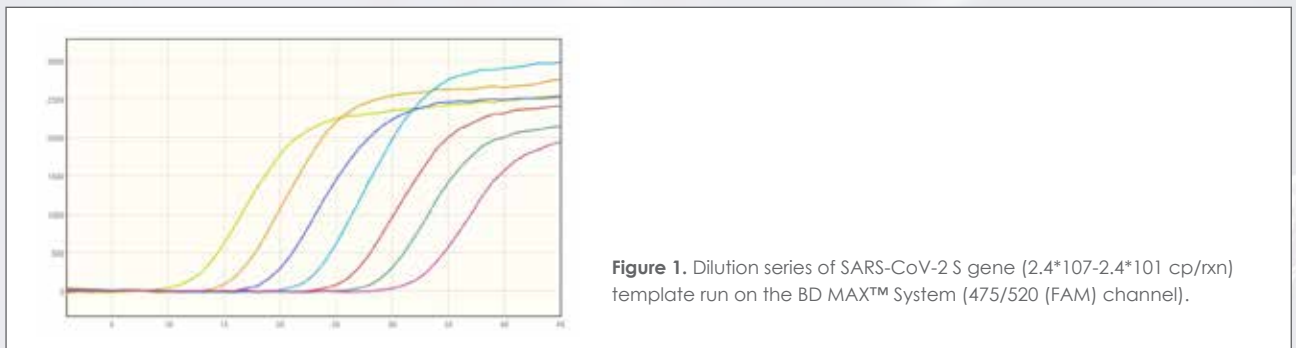
This test is intended to be used as an aid in the identification in the diagnosis of COVID-19 in combination with patient's clinical signs and symptoms and epidemiological risk factors.

The assay uses the BD MAX™ System for automated extraction of RNA and subsequent real-time PCR employing the reagents provided combined with universal reagents and disposables for the BD MAX™ System. RNA from respiratory specimens is detected using fluorescent reporter dye probes specific for SARS-CoV-2.

The detection is done in one step real time RT-PCR format where the reverse transcription and the subsequent amplification of specific target sequence occur in the same reaction well. The isolated RNA target is transcribed generating complementary DNA by reverse transcriptase which is followed by the **amplification of a conserved region of S gene** using specific primers and a fluorescent-labeled probe.

Analytical sensitivity:

VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit has a detection limit of ≥ 24 cDNA copies per reaction (cp/rxn) with a positive rate of $\geq 95\%$.



Reference:

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BD REF 444212

CerTest
BIOTEC

CerTest Biotec, S.L.

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



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