

REAL SARS-COV-2 & REAL SARS-COV-1/2 (COVID-19)

*Tests for the detection of coronavirus SARS-CoV-2
(COVID-19) by RT real time PCR*



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Targets: E gene + orf1ab gene + control gene

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Test for the detection of **E gene** and **orf1ab gene** from coronavirus SARS-CoV-2 by **RT-PCR real time (COVID-19)**

A new severe respiratory syndrome caused by a coronavirus was first observed in Wuhan (China) in December 2019. The infection has spread all over the world, and consequently, on March 2020, the disease was declared a pandemic by the WHO. The new virus was called SARS-CoV-2, causing COVID-19 disease.

Detection of the RNA of the virus by techniques as RT-PCR real time is important in early infections to isolate infected people and contain the outbreak. As a result, several testing protocols and target genes for molecular diagnosis of SARS-CoV-2 infection have been issued from Health Authorities, as China CDC, Charité – Germany, or US CDC¹.

According to the WHO, in an area with no COVID-19 virus circulation, a positive nucleic acid test result for at least two different targets on the COVID-19 virus genome is needed to confirm a positive result by RT-PCR real time, of which at least one target should be preferably specific for COVID-19. One positive result for the presence of betacoronavirus, and COVID-19 virus further identified by sequencing is also possible². In areas where COVID-19 virus is widely spread, a simpler algorithm might be adopted and screening by rRT-PCR of a single discriminatory target is considered sufficient².

The E gene detected by the Real SARS-CoV-1/2 test provides the higher sensitivity for the screening detection of SARS viruses using only one target, as needed in the current situation in most countries with high COVID-19 prevalence. As no other SARS-like coronaviruses are circulating now, the test is also very specific.

On the other hand, the Real SARS-CoV-2 detects both the E gene and the orf1ab gene, allowing for the possibility to detect and confirm the specific presence of the SARS-CoV-2 in just one test, in those situations where the detection of two targets is needed.

The Real SARS-CoV-2 and the Real SARS-CoV-1/2 tests are kits for the easy and sensitive detection of SARS-CoV-2 by RT-PCR real time using RNA extracted from human clinical samples.

¹ World Health Organization, <https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf>, last accessed January 17, 2020

² Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases. Interim guidance 2 March 2020; WHO

Procedure

RNA sample extraction










RT-PCR real time*

Data analysis

* The kit includes all the necessary reagents for reverse transcription and real time PCR amplification

TARGET	SIGNAL	DETECTION	
		Real SARS-CoV-1/2	Real SARS-CoV-2
SARS-CoV-2 (E gene)	TEXAS/ROX CHANNEL	✓	✓
SARS-CoV-2 orf1ab gene	FAM CHANNEL	-	✓
Internal control	HEX/JOE/VIC CHANNEL	✓	✓

Highlights

-  All the reagents are included, also positive and negative controls
-  Only 5 µl of extracted RNA required
-  Detection of E gene or E gene + orf1ab gene: versatility with high sensitivity and specificity
-  Internal control included for confirmation of RNA retrotranscription, extraction and amplification
-  Execution time of about 60 minutes
-  12 months shelf life
-  Many different types of validated samples: nasopharyngeal swab, lavage or aspirates and sputum, saliva and buccal smear.
-  CE IVD marked.
-  Compatible with several Real Time PCR instruments: CFX96 Real-Time PCR Detection System (BioRad); QuantStudio 5 Real-Time PCR System (Applied Biosystems); Gentier 96 Real-Time PCR (Tianlong) and Gentier 48 E Real-Time PCR (Tianlong).