

CareStart™

COVID-19 MDx RT-PCR Kit

Reliable, flexible, and sensitive portfolio of molecular tests to meet every need

The CareStart™ COVID-19 MDx RT-PCR molecular test provides a critical new resource in the fight against COVID-19 with a processing time of approximately 83 minutes.

The CareStart™ COVID-19 MDx RT-PCR test is an FDA EUA authorized molecular test for distribution and use by healthcare professionals and health systems conducting COVID-19 testing with 100% PPA/NPA results.

Analysis can be run on some of the most common PCR processing machines, such as Bio-Rad's CFX96 Dx system, Thermo Fisher Scientific's Applied Biosystems 7500, or 7500 Fast RT-PCR instrument.



Rx Only CE

Features

- Detect two gene regions and simultaneously detect N gene as well as RdRP gene of SARS-2 CoV.
- Preventing contamination using the UDG (Uracil-DNA Glycosylase System).
- Internal control included for sample extraction and amplification efficiency verification.
- Reaction time within 83 minutes improving laboratory efficiency.

The CareStart™ COVID-19 MDx RT-PCR has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Manufactured by Access Bio
In partnership with Intrivo™

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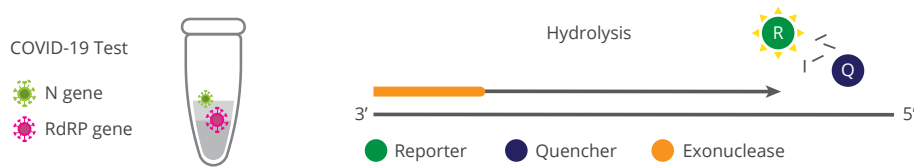
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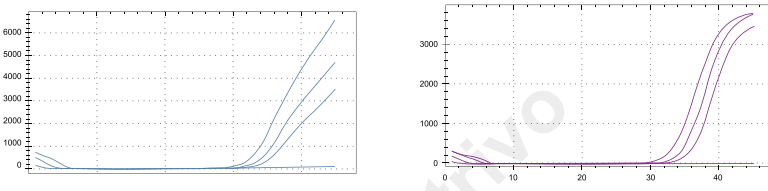
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Test Method: One Step Real-Time Reverse Transcription-PCR

The reverse transcription (RT) and qPCR step are both conducted in the same reaction well. As the specific sequence is amplified, the taqman probe hybridized to the target is dissociated to generate fluorescence.



Specification

Kit Composition	100 tests/kit
Technology	Real-time reverse transcriptional PCR, Reaction time: 83 minutes
Performance	Analytical sensitivity 
Analyte	2019-Novel CoV (COVID-19)
Specimen type	Nasopharyngeal swab, Oropharyngeal swab
Sample volume	10 µL RNA
Storage	Below -20°C
Shelf-life	6 months
Internal control	Endogenous internal control included
Quality control	Positive control, Negative control

* CFX96TM Dx system (Bio-Rad Laboratories, Inc.), Applied Biosystems 7500 Real-Time PCR system (Thermofisher Scientific)

Order Information

Cat No.	MCGM-10072
Package Unit	100 tests/kit
Kit Component	4 X 1 step RT-PCR Mix, 2019-nCoV primer/probe Mix, Nuclease Free Water, MS2 Phage Control, Positive control, Negative control, IFU

