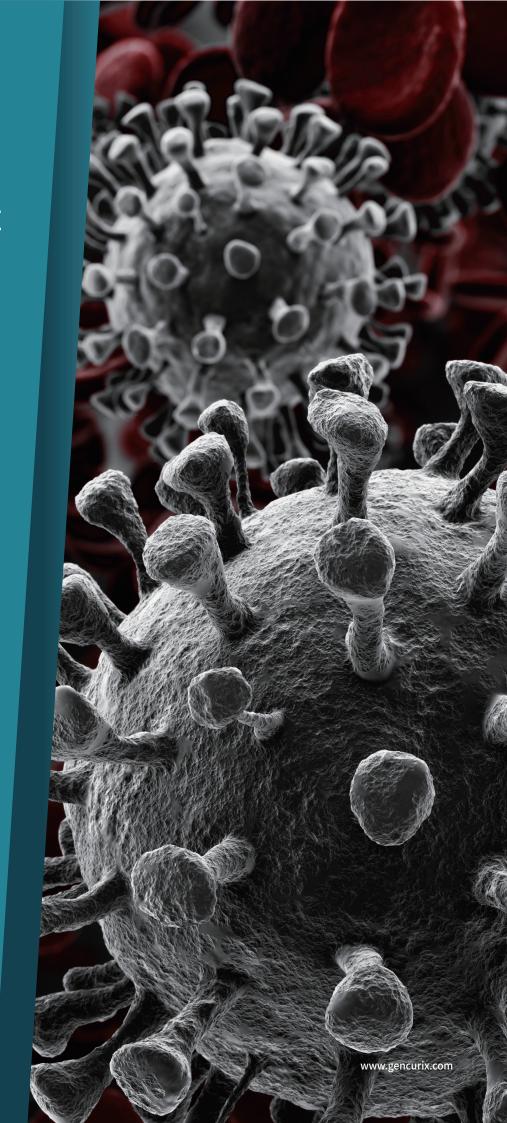
Gene**Pro**COVID-19 Detection Test

One-Step Real-time RT-PCR Test for COVID-19







Gene**Pro**COVID-19 Detection Test

GenePro COVID-19 Detection Test kit is developed based on "WHO interim guidance for laboratory testing for 2019 novel coronavirus (2019-nCoV) in humans" by WHO (World Health Organization), and qualitatively detects RdRP gene / E gene simultaneously. RdRP gene has specific sequence from COVID-19 and E gene is common sequence within corona viruses. The validity of RT-PCR reaction is confirmed by using RNA templet (2019-nCov) as positive control.

I Guidance Developed in accordance to the WHO guideline for 2019 novel coronavirus (2019-nCoV) testing

I Target gene RdRP gene, E gene

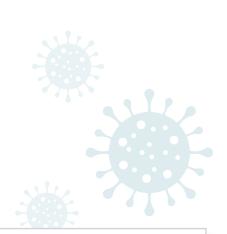
I Performance Sensitivity: 1 copy / μL

I Sample Type Nasopharyngeal swab / Oropharyngeal swab / Sputum

I RT-PCR Enzyme SuperScript III RT/Platinum Taq Mix

Running Time < 1.5 hrs after RNA extraction

Reporting Positive / Not detected / Inconclusive





Target Genes(RdRp, E) Recommended by WHO

GenePro COVID-19 Detection Kit has been developed in accordance to the WHO guideline for 'Laboratory testing of 2019 novel coronavirus (2019-nCoV).'



'SuperScript III RT/Platinum Taq DNA polymerase' provides highest detection sensitivity and specificity with minimum amount of sample avoiding false positive and false negative.



Highest Accuracy



High target specificity & low false negative rate. The kit minimizes false negative results with improved primer design, which allows accurate determination with amplification results.

RNA positive control



The test monitors the whole real-time RT-PCR process including reverse-transcription and amplification. DNA based positive controls cannot detect errors during reverse-transcription process.



How to Use

: Amplification and Detection (CFX96™, Bio-Rad)

01

Specimen Collection

- · Collect the nasopharyngeal or oropharyngeal swab into VTM.
- · Induce the cough and collect sputum while making sure that saliva is not deposited into the sterilization container.
- ·Transport specimens to the clinical laboratories at $4^{\circ}C \pm 3^{\circ}C$.

02

RNA Purification

- ·Total nucleic acids are isolated from the specimens using commercially available viral RNA isolation kits. We recommend Qiagen's or Roche's extraction kits.
- · Use the kits according to the user manual provided from manufacturers.

03

Genetic Assay

- · GenePro COVID-19 Detection Test is designed to use with CFX96™ Real Time PCR System.
- · Prepare the reaction mix (left) and set the plate* (right).

PCR Reaction

Component	Volume (μL)/test	
Oligo Mix (1 or 2)	4	
Reaction Mix A	12.5	
Reaction Mix B	2.5	
Enzyme	1	
Template RNA	5	
Total	25	

Plate Design

	1	2	3
Α	NC OM1	NC OM2	Sample OM1
В	PC OM1	PC OM2	Sample OM1
С	Sample 1 OM1	Sample 1 OM2	•
D	Sample 2	Sample 2	

04

Data Analysis and Interpretation

- ·Set the Baseline Threshold as 3000.
- · Interpretate the results according to Ct values.

Result Interpretation	RdRP Gene	E Gene
SARS-CoV-2 Positive	+	+
SARS-CoV-2 Not Detected	-	_
SARS-CoV-2 Not Detected	-	+
Inconclusive*	+	_

Inconclusive*: Recommend to re-test the specimen

Ordering Information

Cat no.	Product	Size
CV001	GenePro COVID-19 Detection Test	100 tests/kit





^{*}Hard-Shell® 96-Well PCR Plates white/white (Cat.No. HSP9655, Bio-Rad)