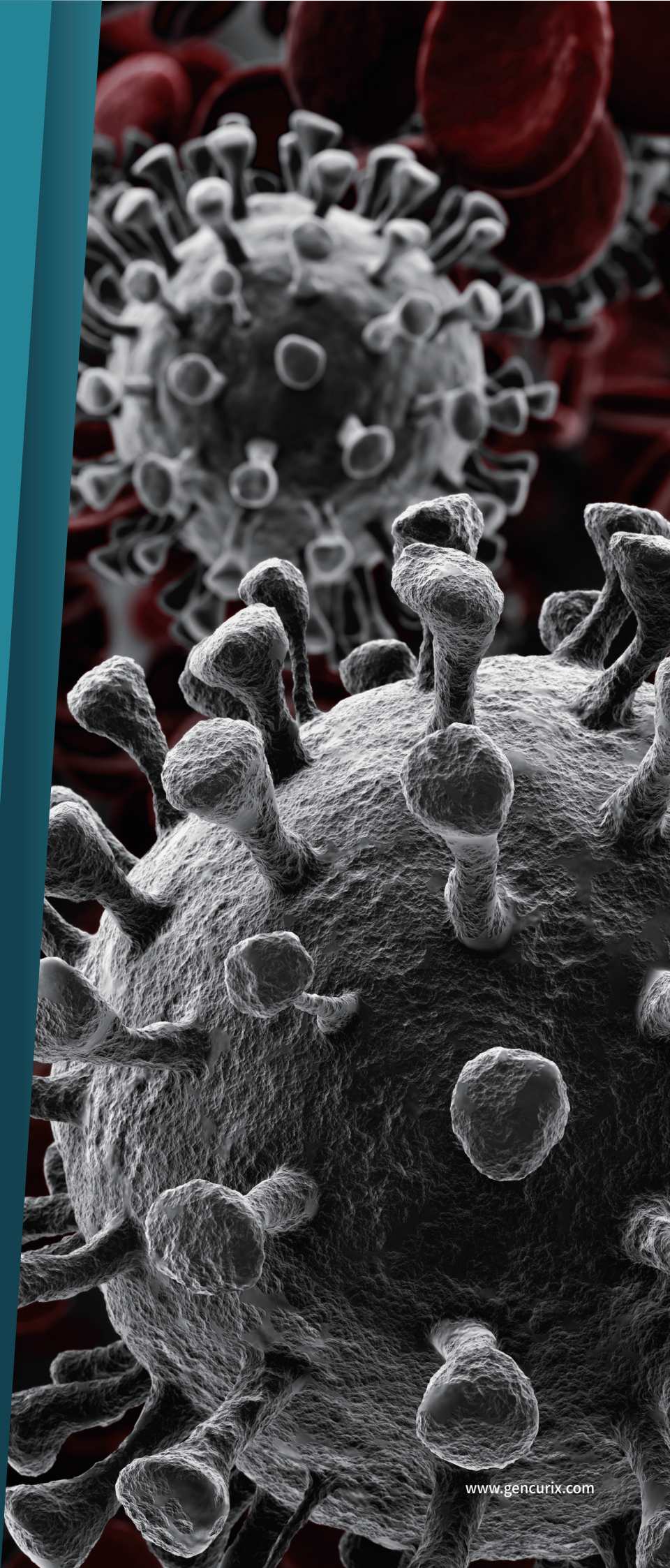

GenePro

COVID-19 Detection Test

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

GCH
GENCURIX

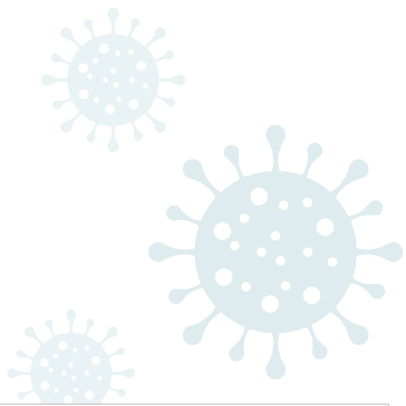
www.gencurix.com



GenePro COVID-19 Detection Test

GenePro COVID-19 Detection Test kit is developed based on “WHO interim guidance for laboratory testing for 2019 novel coronavirus (SARS-CoV-2) in humans” by WHO (World Health Organization), and qualitatively detects RdRP gene / E gene simultaneously. RdRP gene has specific sequence from SARS-CoV-2 and E gene is common sequence within coronaviruses. The validity of RT-PCR reaction is confirmed by using RNA template (SARS-CoV-2) as positive control.

- I Guidance** Developed in accordance to the WHO guideline for 2019 novel coronavirus (SARS-CoV-2) testing
- I Target gene** RdRP gene, E gene
- I Performance** Sensitivity : 1 copy / μ L
- I Running Time** < 1.5 hrs after RNA extraction
- I PCR Instruments** ABI7500 / CFX96
- I Reporting** Positive / Not detected / Inconclusive



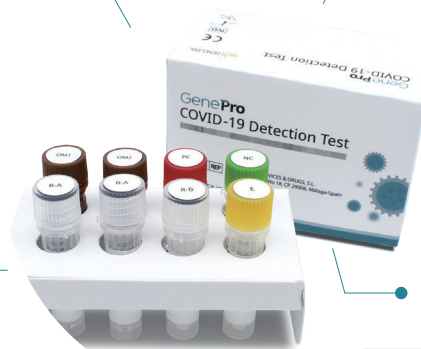
Target Genes(RdRp, E) Recommended by WHO

GenePro COVID-19 Detection Kit has been developed in accordance to the WHO guideline for 'Laboratory testing of 2019 novel coronavirus (SARS-CoV-2).'



Highest Performance Enzyme

The highest performance enzyme 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. Optimal primer and probe design facilitates minimal false positive and false negative results. RdRP and E gene have been designed to react in separate tubes, allowing the highest accuracy of the test results.

RNA Positive Control



The test monitors the whole real-time RT-PCR process including reverse-transcription and amplification. DNA as positive control can verify the amplification process of DNA, but cannot confirm the reverse-transcription process from RNA to DNA.

Specification

01 Genetic Assay

RT-PCR Reaction

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

Plate Design

	1	2	3	4
A	NC OM1	NC OM2	Sample OM1	Sample OM2
B	PC OM1	PC OM2	Sample OM1	Sample OM2
C	Sample 1 OM1	Sample 1 OM2	⋮	⋮
D	Sample 2 OM1	Sample 2 OM2		

02 Data Analysis and Interpretation

- Set the Baseline Threshold as 3,000 for CFX96.
- Set the Baseline Threshold as 100,000 for ABI7500.
- Interpretate the results according to Ct values (<40).

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

*Inconclusive : Recommend to re-test the specimen

03 Clinical Evaluation

Comparative Analysis

		Comparative test		Total
		Positive	Negative	
GenePro COVID-19	Positive	46	0	46
	Negative	1	53	54
Total		47	53	100

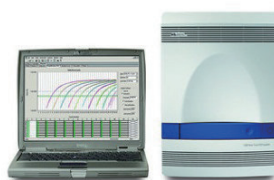
- OPA (Overall Percent Agreement) : 99.0%
- PPA (Positive Percent Agreement) : 97.9%
- NPA (Negative Percent Agreement) : 100.0%

04 Instrument System

CFX96 (Bio-Rad)



ABI 7500 (Applied Biosystems)



Ordering Information

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