



GenePro SARS-CoV-2 Test

FDA

Emergency Use Authorization (EUA)

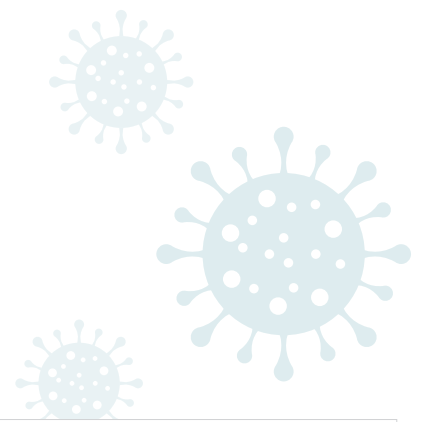
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www.gencurix.com

GenePro SARS-CoV-2 Test

GenePro SARS-CoV-2 Test kit is developed to enable high throughput analysis and flexibility in test numbers for a single run. It allows qualitative detection of Orf1-ab gene / E gene simultaneously. Orf1-ab 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.

- Target gene** · Orf1-ab gene : RNA-dependent RNA polymerase gene
· E gene : envelope protein gene
- Performance** Sensitivity : 77 genome copy equivalents / rxn
- Running Time** < 1.5 hrs after RNA extraction
- PCR Instruments** QuantStudio Dx (96 or 384 samples) / CFX96 (96 samples)
- Reporting** · SARS-CoV-2 Positive
· Presumptive SARS-CoV-2 Positive
· SARS-CoV-2 Not Detected
· Invalid



High Throughput



Cutting-edge multiplex technology allows to reduce time and sample loss, and also enables simultaneous monitoring of up to 384 samples.

* Max · **6,000** tests / day
- 2 × QS + 2 × KF + Lab automation, 16 hrs (2 shift)

Test Flexibility



The ideal product configuration for automatic and manual testing allows flexibility in test numbers for a single run.

Positive Control and Internal Control



Using RNA controls, it is possible to monitor the entire process of test from RNA extraction to interpretation of results.

Target Genes



Orf1-ab and E genes are the most well-conserved genes within coronaviruses allowing accurate test results for various types of SARS-CoV-2 mutations.



How to Use : Amplification and Detection (QuantStudio Dx, CFX96)

01

Specimen Collection

- Collect the nasopharyngeal swab into UTM.
- Collect specimen into the sterilization container.

02

Sample Preparation

- Nucleic acids are isolated and purified from specimens manually or automatically using following viral RNA isolation reagents and instruments, according to the manufacturer's instruction.

Protocol	Reagent	Instrument
Thermo Fisher	MagMAX Viral/Pathogen Nucleic Acid Isolation Kit	KingFisher Flex System (96 samples)
QIAGEN Auto	QIAamp Viral RNA Mini Kit	QIAcube Connect (12 samples)
	QIAamp DSP Viral RNA Mini Kit	
QIAGEN Manual	QIAamp Viral RNA Mini Kit	-
	QIAamp DSP Viral RNA Mini Kit	

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Genetic Assay

- GenePro SARS-CoV-2 Test is designed to use with QuantStudio Dx and CFX96 PCR Systems.

RT-PCR Reaction

Component	Volume per reaction
Oligo Mix	1 µL
Reaction Mix A	2.5 µL
Reaction Mix B	1 µL
Template RNA	5.5 µL
Total	10 µL

Plate Design (384-well Plate Map)

	1	2	3
A	NC OM	Sample 15 OM	Sample 31 OM
B	PC OM	Sample 16 OM	Sample 32 OM
C	Sample 1 OM	⋮	⋮
D	Sample 2 OM		

04

Data Analysis and Interpretation

- Interpretate the results according to Ct values (<31).

Orf-1ab	E	IC	Status	Result
Positive	Positive or Negative	Positive or Negative	valid	SARS-CoV-2 Positive
Negative	Positive	Positive or Negative	valid	Presumptive SARS-CoV-2 Positive ⁺
Negative	Negative	Positive	valid	SARS-CoV-2 Not Detected
Negative	Negative	Negative	Invalid	Invalid*

* Repeat test. If the repeat test also results invalid, collect a new specimen.

⁺ Repeat test. If same results are detected from the repeat test, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and human SARS virus or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management. Not detected result for the ORF-1ab gene target may be due to :

- 1) a sample at concentrations near or below the limit of detection of the test,
- 2) a mutation in the corresponding target region, or
- 3) other factors.

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Clinical Evaluation

Clinical Sensitivity and Specificity

Clinical Study (N=100)		COVID-19 patient		
		Positive	Negative	Total
GenePro SARS-CoV-2 Test	Positive	60	0	60
	Not Detected	0	40	40
Total		60	40	100
Sensitivity (95% CI)		100.0% (94.0% - 100.0%)		
Specificity (95% CI)		100.0% (91.2% - 100.0%)		

Ordering Information

Cat no.	Product	Size
CV002	GenePro SARS-CoV-2 Test	100 tests/kit

