

COVID-19 RT-PCR Kit

1-step Real-Time RT-PCR assay



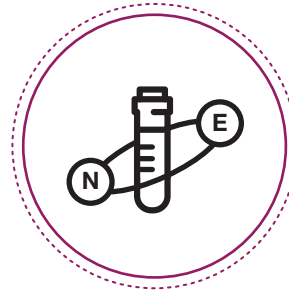
Test time

90 mins



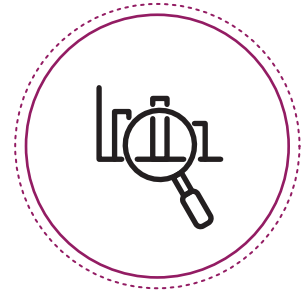
Detection

E gene, N gene (target)
RNase P (IPC)



Easy to use

1 tube reaction



Accurate

High Sensitivity
& Specificity

The En-swer™ COVID-19 RT-PCR Kit, an *in-vitro* diagnostic medical device using 1-step RT-qPCR, is a test method that detects genes (the N gene, and the E gene) of the 2019 novel coronavirus (SARS-CoV-2) through qualitative analysis from nasopharyngeal swab or sputum specimen of patients suspected of being infected with the virus.

This kit has a function of detecting multiple targets, such as N gene, E gene, and IPC (Internal Positive Control, RNase P) which is derived from human cells, simultaneously in one tube to detect SARS-CoV-2. It can be used for rapid detection and outbreak control of COVID-19.



Clinical Performance Evaluation

The PPA* and NPA* were evaluated by comparing the results of the En-swer™ COVID-19 RT-PCR Kit with that of Allplex™ 2019-nCoV Assay from Seegene Inc (FDA Emergency Use Authorization approved). A total of 143 clinical samples were compared.

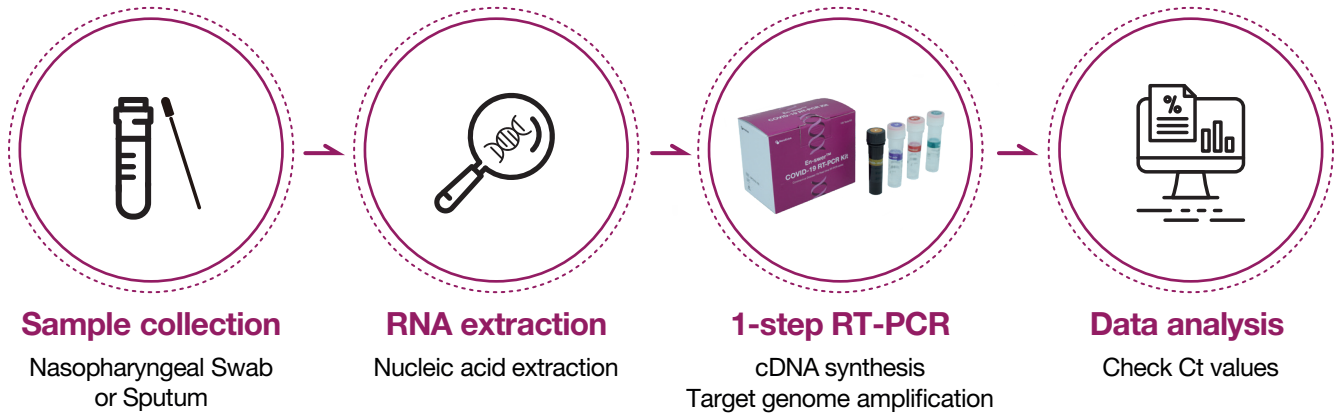
CFX96™ Dx		By comparator method confirmed		Total
		Positive	Negative	
En-swer COVID-19 RT-PCR Kit	Positive	72	0	72
	Negative	0	71	71
Total		72	71	143



*Positive Percent Agreement (PPA), Negative Percent Agreement (NPA)

Procedure

The following workflow is the instructions of using En-swer™ COVID-19 RT-PCR Kit.



Compatible instruments (CE-IVD Marked)

The En-swer™ COVID-19 RT-PCR Kit is compatible with instruments which can detect at least 3 different fluorescence such as FAM, HEX, and Cy5.



CFX96™ Dx System
(Bio-Rad)



Rotor-Gene Q
(Qiagen)

Components

Components	Quantity
COVID-19 primer/probe mix	265 µL X 2 Tubes
1-step RT-qPCR master mix	265 µL X 2 Tubes
COVID-19 positive control	65 µL X 2 Tubes
PCR grade water	500 µL X 2 Tubes

Specification

Item	Specification
Reaction	100 reaction/kit
Specimen	Nasopharyngeal swab, Sputum
Test time	90 minutes
Target gene	N gene, E gene
Storage	-20 °C
Shelf-life	12 months

Ordering information

Product	Cat. No.
En-swer™ COVID-19 RT-PCR Kit	EPCO19 100



Scan for more information.



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