

CE IVD

KFDA



WizDx™ COVID-19 Real-time PCR Kit

One-step Real-time RT-PCR test for COVID-19

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WizDx™ COVID-19 Real-time PCR Kit

WizDx™ COVID-19 Real-time PCR Kits provide components for one-step Real-time RT-PCR in a convenient format that is compatible with both rapid and standard qPCR cycling conditions. Both cDNA synthesis and PCR are performed in a single tube using gene-specific primers and probes. These one-step Real-time RT-PCR kits have been formulated for use with fluorogenic probe-based 5' nuclease technology probes. The 2X qRT-PCR Mix includes Reverse Transcriptase, Ribonuclease Inhibitor and Hot-start Taq DNA Polymerase in an optimized formulation.

Also, the COVID-19 Detection Mix contains one set of primers and fluorescent probes to differentiate between COVID-19 and beta coronavirus. The probes are readout in different channels. COVID-19 RNA targets are amplified and detected in the FAM channel, Beta coronavirus RNA targets are amplified and detected in the HEX, and Internal control is amplified and detected in the Cy5 channel.



WizDx™ COVID-19 CrystalMix PCR Kit received an export license from MFDS
MFDS license No. : 20-330

Product Name	WizDx™ COVID-19 Real-time PCR Kit
Packaging Unit	100 tests/kit, box
Target	RdRP gene (COVID-19), E gene (Beta coronavirus)
Running Time	1.5 hour, after RNA extraction
Storage	-20°C or below
Shelf-life	1 year from manufacturing date
Limit of Detection	RdRP gene : 15.3 copy/rxn, E gene : 14.4 copy/rxn
Manufacturing	ISO 13485:2016
PCR Machine	Bio-Rad CFX96 / Thermo Fisher Scientific ABI7500
Guidance	Developed in accordance to the WHO guideline for 2019 novel coronavirus (SARS-CoV-2) testing

Specifications

Target gene



Amplicon Target on COVID-19 genome. ORF: open reading frame; E: envelope protein gene; M: membrane protein gene; N: nucleocapsid protein gene; RdRp: RNA-dependent RNA polymerase gene; S: spike protein gene.

RT-PCR Reaction Set-up

Component	Sample	PTC	NTC
2X qRT-PCR Mix	10 ul	10 ul	10 ul
COVID-19 Detection Mix	5 ul	5 ul	5 ul
Sample (RNA)	5 ul		
COVID-19 Positive Control		5 ul	
RNase-Free Water			5 ul
Total	20 ul	20 ul	20 ul

PTC : Positive Template Control; NTC : Negative Template Control

Fluorescence Probe Setting

Target	Fluorescence	Detection
RdRP gene	FAM	COVID-19
E gene	HEX	Beta coronavirus
Internal Control	Cy5	

Data Analysis & Interpretation

FAM (RdRP)	HEX (E)	Cy5 (IC)	Results
+	+	+	COVID-19 detected
+	-	+	Re-test; If E gene is still (-), COVID-19 detected
-	+	+	Beta coronavirus positive, COVID-19 not detected
-	-	+	COVID-19 not detected

Diagnostic Accuracy

Parameter	RdRP gene	E gene
Limit of detection	15.3 copy/rxn	14.4 copy/rxn
Specificity	100%	100%
Detection	COVID-19 specific	Beta coronavirus (SARS-related coronavirus)

Ordering Information

Product	Cat No.	Package
WizDx™ COVID-19 Real-time PCR Kit	DX1200	100 tests
WizPrep™ Viral DNA/RNA Mini Kit (V2)	W73052-100	100 prep