

COVID-19 RT-qPCR Plus (TFDA) Detection Kit | TFDA detection kit

COVID-19 RT-qPCR Detection Kit Plus (TFDA)

CATALOG #
AAA13626

PRODUCT SYNONYMS

COVID-19 RT-qPCR Plus (TFDA); COVID-19 RT-qPCR Detection Kit Plus (TFDA); COVID-19 RT-qPCR Detection Kit Plus; TFDA detection kit

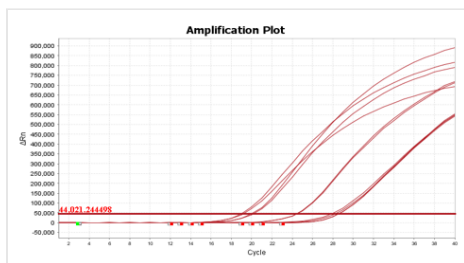
PRODUCT SPECIFICATIONS

Procedure	Gene Expression (mRNA) Analysis Copy Number Analysis SNP Genotype Analysis
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IMAGES

Part No.	Component	Description	Amount Supplied (per 100 rxns)
QP019T-1	2X RT-qPCR MasterMix	Multiplex assay primers/probes for N1 and RP (human) genes with HotStart DNA polymerase, dNTPs, and buffer	1000µL x 1
QP019T-2	RScript Enzyme Mix	RScript reverse transcriptase with RIBOAssure RNase inhibitor	20µL x 1
QP019T-3	Positive Control	Pseudo-virus DNA containing N1 gene	50µL x 1
QP019T-4	Negative Extraction Control	Cancer cell line with RP gene	1mL x 1
QP019T-5	Nuclease-Free Water	DEPC-treated water	1mL x 1

Application Data



Application Data

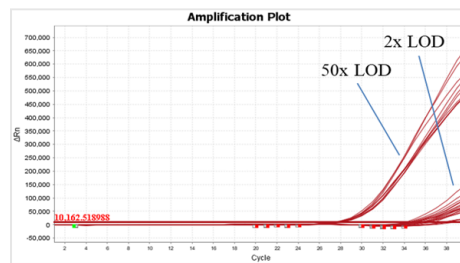
Figure 2. The result of clinical SARS-CoV-2 positive specimens.

RNA Concentration	Replicants	N1 gene		RP gene	
		Detection Rate	Mean Ct	Detection Rate	Mean Ct
Unspiked	30/30	0%	ND	100%	28.103
2X LoD (100 copies)	20/20	100%	35.935	100%	28.278
50X LoD (2500 copies)	10/10	100%	27.936	100%	27.851
Clinical Positive Sample	5/5	100%	23.929	100%	27.851
Clinical Negative Sample	5/5	0%	ND	100%	27.851

ND = Not Detected

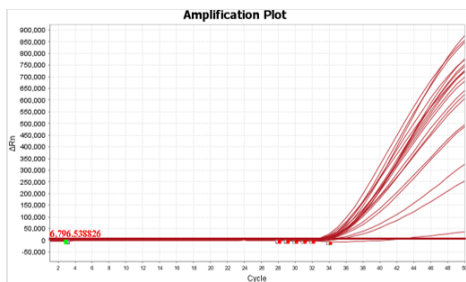
Application Data

A study was performed to assess the clinical performance of COVID-19 RT-qPCR Detection Kit Plus. A testing of 20 replicates at low positive with 100 copies/reaction, 10 replicates at high positive with 2500 copies/reaction and 30 replicates were unspiked. Samples were spiked SARS-CoV-2 RNA in pooled negative clinical nasopharyngeal swab matrix, then extracted with QIAamp Viral RNA Mini Kit and tested on QuantStudio™ 5 Real-Time PCR System. The synthetic SARS-CoV-2 RNA was obtained from Twist Biosciences (Assay Ready Control 14,EPI_ISL_710528). The clinical samples were provide by Shuang Ho Hospital, Ministry of Health and Welfare, Republic of China (Taiwan).



Application Data

Figure 1. The result of specimens spiked with synthetic SARS-CoV-2 RNA.



SARS-CoV-2		Interpretation	Action
N1	RP		
+	+/-	Positive	Report results to health authority.
-	+	Negative	SARS-CoV-2 not detected. Report results to health authority
-	-	Invalid Result *	Repeat from extraction step. If the repeated result remains invalid, recommend collection of a new specimen(s) from the patient.

Application Data

Application Data

A study was performed to assess the performance of COVID-19 RT-qPCR Detection Kit Plus. A testing of 20 replicates at the tentative Limit of Detection (LoD) concentration was carried out with 50 copies/reaction at 95% detection rate. Samples were spiked SARS-CoV-2 RNA in pooled negative clinical nasopharyngeal swab matrix, then extracted with QIAamp Viral RNA Mini Kit and tested on QuantStudio™ 5 Real-Time PCR System. The synthetic SARS-CoV-2 RNA was obtained from Twist Biosciences (Assay Ready Control 14, EPI_ISL_710528).

ADDITIONAL INFORMATION

Related Product Information for TFDA detection kit

In view of the joint global efforts of advancing collaborative research in tests, therapeutics, and vaccination in the fight against the COVID-19 (SARS-CoV-2) pandemic, has specifically developed the LifeDireX COVID-19 RT-qPCR Detection Kit Plus for human respiratory tract specimens. The kit is characterized by:

- (1) High specificity for the N target markers as recommended by WHO and US CDC;
- (2) Data obtained in less than 2 hours; and
- (3) Compatible with standard RT-qPCR machines (ABI 7500, Bio-Rad CFX96, QuantStudio's 7 Flex).

Product Categories/Family for TFDA detection kit

LifeDireX; IVD; IVD Products; COVID-19; SARS-CoV-2; RT-qPCR; N1 Gene; TFDA

For Research Use Only. Not for use in diagnostic or therapeutic procedures. Small volumes of product may become entrapped in the seal of the vial during shipment and storage; if necessary, briefly centrifuge the vial on a tabletop centrifuge to dislodge any liquid in the cap.

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Online datasheet: <https://stage.aaabiotech.com/detection-kits/covid-19-rt-qpcr-plus-tfda/13626>