

CERTIFICATE OF ANALYSIS (COA)

Covibond 007TM - One Step RT- qPCR kit for SARS-COV2

Multiplex real-time RT-PCR test intended for the qualitative detection of nucleic acid from human SARS-CoV-2

Product Name: Covibond 007 TM	Catalog # PRX-CB007- 100T	Lot / Batch # PRX-CB-0921-001 PRX-CB-0921-002 PRX-CB-0921-003
Analysis Date: October 06 2021	Expiration Date: October 05	Storage conditions: -20° C

Product description

Covibond 007™, COVID-19 RT-PCR Kit (100 reactions) includes the following components:

- COVID-19 Assay Multiplex—Multiplexed assay that contains the following:
- a) Two primer/probe sets specific to different SARS-CoV-2 genomic regions (ORF1ab and N gene)
- b) One primer/probe set targeting the RNase P gene. The RNase P gene serves as an internal positive control to monitor the sample source.
 - > COVID-19 Control—RNA control that contains targets specific to the SARS-CoV-2 genomic regions and human RNase P gene targeted by the assay.
 - > One Step RT-PCR Master Mix contains RTase and Taq polymerase enzymes, dNTP Mixture, Mg2+ and RNase inhibitor

Shelf life: Up to 12 months from the date of manufacturing month.

Materials Provided

Color Code of the Vial	Components	For 100 rxn
GREEN	One Step Master mix	750 μL
RED	Primer / Probe Assay mix	450μL
BLUE	Nuclease free water (Supplied in excess)	1500μL
YELLOW	Positive RNA control	250μL

Component used per reaction	Volume [µl]
One Step Master Mix	7.5
Primer / Probe Assay mix	4.5
RNA Sample / RNA Controls	5
Nuclease free water	. 3
Total volume used in each reaction well	20

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Real-time PCR cycler programming

The following instrument settings and the temperature profile must be manually implemented in the real-time PCR cycler software:

Steps	Number cycles	Acquisition	Temperature[°C]	Time [min : sec]
Reverse transcription	1	None	52	05:00
Denaturation	1	None	95	00:10
Amplification	40	Data collection	95	00:05
			58	00:30

Tests Results: Meets Specification

PARTICULARS	Total Samples	Results	Test Results
Active COVID+ Patients deducted with SARS COV2 virus within 72 hours of Sampling. (5µl of Sample RNA)	25	Positive 100%	PASS / Meet specifications
Limit of Detection of COVID+ test sensitivity. (1/20 dilution of 5µl of Sample RNA)	10	Sensitivity 100%	PASS / Meet specifications
Limit of Detection of COVID+ test sensitivity. (1/50 dilution of 5µl of Sample RNA)	10	Sensitivity 100%	PASS / Meet specifications
Limit of Detection of COVID+ test sensitivity. (1/100 dilution of 5µl of Sample RNA)	10	Sensitivity 100%	PASS / Meet specifications
Confirmed COVID Negative samples	25	Negative 100%	PASS / Meet specifications
Total RTPCR tests	80		PASS / Meet specifications

Certificate can be used for Research or Validation purpose Only. Not for use in diagnostic procedures. If you have any further questions about this Certificate of Analysis, please contact Technical Services @ +91 4652 295352 or email us at prawnrx@gmail.com

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