



TEST REPORT		Report Type	: Final
Name	: JASBIR KAUR	Reg. No	: 201203205
Age/Sex	: Female / 57 Years	Reg. Date	: 24-Jan-2022 09:05 AM
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Test	Result	Unit	Biological Ref. Interval

Qualitative test of COVID - 19 RNA by Real Time PCR

SPECIMEN	Nasopharyngeal and Oropharyngeal swab in VTM
METHOD	Qualitative test of COVID - 19 RNA by Real Time PCR (RT PCR)
SAMPLE CONDITION	ACCEPTABLE
RdRp (CT VALUE)	DETECTED = 30
E Gene (CT VALUE)	DETECTED = 28
RESULT (COVID 19)	POSITIVE

ICMR REGISTRATION ID: 100944045

Principle: This Covid 19 Assay uses RNA extracted from clinical samples, such as Sputum, Bronchoalveolar lavage fluid and Oropharyngeal, Nasopharyngeal swab using the RNA extracted. The specific target of this assay are RdRp/ N gene and E gene.

Real Time Reverse Transcription Polymerase Chain Reaction (Real Time RT-PCR) is the gold standard test for detection of SARS-CoV-2

Result and Interpretation: Cutoff of Cycle threshold value or Ct value for RdRp/N gene and E gene is interpreted as per the manufacturers kit insert is interpreted as SARS-CoV-2 Positive.

Limitations:

- The results of this test are highly dependent on the sampling technique and maintenance of cold-chain during sample transport
 - False Negative result** can occur if there is any one of the following
 - Presence of PCR inhibitors in the sample
 - Specimen collected very early or late in infection
 - Viral load below the lower limit of detection of the PCR assay
 - Presence of rare genotypes or mutations
 - False-positive result** may occur if there is possibility of background RNA contamination from pre analytical or iatrogenic environmental causes.
 - RT-PCR kits used for this assay are approved by ICMR and are CE and IVD approved.
 - Reports will be provided to the treating physician, who is requested to communicate the same to the patient and follow MOHFW policy for isolation, quarantine and treatment of all positive cases along with contact tracing as recommended
 - The repeat specimens may be considered after a gap of 2-4 days after the collection of the first specimen for additional testing if required
- It is important to note that the presence of RNA does not always correlate with infectiousness, as the presence of nucleic acid does not always indicate live virus.

AS PER ICMR ADVISORY (05/08/2020)

There are no reliable studies to definitively prove a direct correlation between disease severity / infectiousness and Ct values. Viral load does not have much role in patient management. Ct values differ from one kit to the other. Comparability of Ct values among different kits is a challenge as different labs are using a mixed basket of kits now with different Ct cut-offs and different gene targets. Samples from asymptomatic/mild cases show Ct values similar to those who develop severe disease. Patients in early symptomatic stage may show a high Ct value which may subsequently change. eSeverity of COVID-19 disease largely depends on host factors besides the viral load.

Some patients with low viral load may land up in very severe disease due to triggering of the immunological responses.

RT-PCR test presently being conducted is qualitative in nature. Ct values may give a rough estimate of viral load. However, more specialized standards are required for quantitative assays which are currently unavailable for SARS-CoV-2.

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This is an Electronically Authenticated Report.

Page 1 of 1

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