

## DEPARTMENT OF LABORATORY SERVICES



Patient Name Mr. Divyansh Masiwal

Source OPD

538538 UHID

Age/Gender 21 years/Male

Bed No/Ward OPD

Referred By Dr. SELF

Bill No

OPCA321/159428

Sample Date

28/12/2021 5:17PM

Receiving Date 28/12/2021

Report Date

28/12/2021

6:21PM

Lab No

9:32PM

Report Status Final

392115399

ManualDept No. SRF

ID: 1970400404105

Investigation Name

Result

Units

Bio. Ref.Interval

MOLECULAR DIAGNOSTICS

\*SARS-CoV2 (COVID19) QUALITATIVE REAL TIME PCR (TRUNAT)

SPECIMEN

RESULT

NASOPHARYNGEAL & OROPHARYNGEAL SWABS

Negative

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SARS COVID-19 QUALITATIVE REAL TIME PCR is a chip-based Real Time duplex Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the detection of SARS CoV-2 RNA in human oropharyngeal and nasopharyngeal swab specimen in TRUNAT platform. The test detects the E and Orf1a genes of the virus. Optimal performance of this test requires appropriate specimen collection, handling, storage and transport to the test site. Though very rare, mutations within the highly conserved regions of the target genome where the assay primers and/or probe bind may result in the under-quantitation of or a failure to detect the presence of the concerned pathogen. A specimen for which the assay reports "Not Detected" cannot be concluded to be negative for the concerned pathogen. As with any diagnostic test, results from the assay should be interpreted in the context of other clinical and laboratory findings. Limit of detection of Orf1a and E gene was estimated to be 480 and 487 genome copies/ml respectively. Invalid samples have to be repeated with fresh specimen from the sample preparation stage.

## **ICMR Advisory on Interpretation of CT Values**

- -Ct values differ from one kit to the other. Comparability of Ct values among different kits is a challenge as labs are using a mixed basket of kits now with different Ct cut-offs and different gene targets.
- Ct values also depend on how the sample has been collected, type of specimen, transport temperature, technical competence of the person performing the test, calibration of equipment and pipettes and analytical skills of the interpreters amongst others.
- Severity 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. Hence, again high Ct value may give a false sense of security.
- Moreover, the 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.

In view of the above, it is not recommended to rely on numerical Ct values for determining infectiousness of COVID-19 patients and deciding patient management protocols.

*ICMR Regi	stration	number	for	Covid-	19	is	<b>TMHDMCWB</b>	١.
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