Acu-MDx
LABORATORY AND RESEARCH CENTER

Molecular Diagnostic
Genetics

4679 310821

SRF ID : 2748301026842
ACUMAV : 4679
Sample Collection : 07/09/2021 11:10

Name : Ms. Kirti Sinha
Age : 26 Yrs. Sex : F
Sample Received : 07/09/2021 11:10

Ref. By : Self
Printed : 07/09/2021 18:26
Report Released : 07/09/2021 18:07

Sent By : CSMIA (Departure)

Aadhar : 476937661610

SARS-CoV2 (COVID-19) Real Time RT PCR Test

Type of Sample	:	Nasopharyngeal Swab in Viral Transport Medium
Method	:	RT PCR
E/N gene	:	Not Detected
ORF1a/ORF1b/N/N2 Gene	:	Not Detected
RdRP gene	:	Not Detected
SARS-CoV2 (COVID-19) RT PCR Test result	:	**NEGATIVE** .

Test Interpretation and Notes

Positive: Result indicated SARS-CoV-2 RNA is Detected from the patient's specimen by this assay.

Negative: Result indicated SARS-CoV-2 RNA is NOT Detected from the patient's specimen by this assay.

The results relate only to the specimens tested and should be correlated with clinical findings.

Methodology

- Reverse Transcriptase Polymerase Chain Reaction(RT PCR)
- Cumulative threshold (Ct Value) ranges from 15 - 40 cycle. According to many international guidelines, Ct cutoff of more than 35 is not considered as infective as it is extremely difficult to detect any live virus in a sample above the threshold of 35 Cycle. Test has been performed along with Internal Control (i.e. Rnase P). The Ct value of RnaseP should be below 38.
- Further, there are no reliable studies to definitively prove a direct correlation between disease severity / infectiousness and Ct values, therefore it is not recommended to rely on numerical Ct values for determining infectiousness of COVID-19 patients and deciding patient management protocols.

Clinical Significance:

1. Coronaviruses are a family of large RNA viruses with size ranging from 26 to 32 kb. These viruses are zoonotic and in human can cause respiratory infections.
2. As the coronavirus is an RNA virus it has a relatively high mutation rate resulting in rapid evolution.
3. In December 2019,a new deadly coronavirus known as 2019-nCoV, which has a high sequence similarity to SARS-CoV, was identified and has caused a pneumonia outbreak in Wuhan, China and spread globally

Limitation:

1. The results of this test are highly dependent on the sampling technique employed, sample type, cold-chain maintenance and clinical condition.
2. Presence of PCR inhibitors (cannot be traced by technologist), specimen collected very early/late in infection or viral load lesser than the assay lower limit of detection as well as presence of rare genotypes or mutations may result in false-negative report.
3. False-positive report may be obtained in cases where there is possibility of background RNA contamination from pre analytical or in lab environment.
4. There is poor standardization between commercially available PCR tests, and results from different institutions should not bedirectly compared. Results are best monitored using a single institution.

(The ICMR laboratory Registration no. of Acu-MDx Laboratory and Research Center Pvt. Ltd. is **AMLMMH**.)

---------- End Of Report ----------

Dr Sumedha Chaudhari
M.D. Microbiology

**Sample has been collected outside the laboratory. The results pertain to the sample received.

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