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Collected : 09-Sep-2021 / 19:30  
Reported : 10-Sep-2021 / 12:40

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**Real time Qualitative RT-PCR detection of 2019-nCoV RNA / COVID-19 RNA**

PARAMETER	RESULT
SARS-CoV-2	SARS-CoV-2 : Not Detected (Negative)
Kit: Geneset SARS-CoV-2, Target gene (N1 & N2), Cutoff <37	

**Clinical Significance:**

ICMR Registration No: Andheri-Mumbai-SUBUR001, Pune-SUDIPLPMH

Specimen : Nasopharyngeal & Oropharyngeal swab in VTM Method: Real time RT-PCR

**Note:**

- \* Ct Value indicates the infectivity and not the severity of infection.
- \* ICMR Recommended kits are used for reporting. All the positive cases will be notified to ICMR for further surveillance.
- \* Clinical correlation with patient history, radiology findings and co-infection with other virus infections is necessary to be determined especially in cases with Border line positive Ct Values. Borderline Positive cases (Ct value >30) may give variable results on repeat testing. The possible reasons could be the variations in kit and instruments used.

**Limitations:**

- \* Optimum Specimen types and timing of peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens (Types & Time Points) may be necessary in view of suspected clinical history. The repeat specimen may be considered after a gap of 2-4 days after the collection of first specimen for additional testing if required (other respiratory pathogens).
- \* Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
- \* This test is qualitative assay and does not qualify viral load. Various host factors, Viral factors, Variability in the sample collection /site and techniques used by laboratory can effect the ct values. Therefore, Ct values are not an absolute indication of viral load and should be interpreted with caution.

**Factors leading to false negative RT-PCR report:**

- \* Inadequate specimen collection, poor quality of sample and non-representative sample.
- \* Technical reasons- PCR inhibitor, analytical sensitivity of kit used.
- \* Active recombination & mutations in target gene used for detection of SARS-CoV-2 virus

**References:**

1. Diagnostic detection of 2019-nCoV by real-time RT-PCR, Berlin Jan 17th, 2020.
2. Labcorp COVID-19 RT-PCR test EUA Summary/ COVID 19 RT-PCR test (Laboratory corporation of America)

\* Sample processed at Molecular Diagnostics Laboratory, Pune Lab, Pune Swargate  
\*\*\* End Of Report \*\*\*



MC-2463

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Page 1 of 1