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Collected : 02-Jan-2022 / 08:27  
Reported : 02-Jan-2022 / 22:05

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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 description-E gene as screening and ORF1ab/RdRp or N gene as target gene,Cutoff:<35	

### 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, CPL, Andheri West

\*\*\* End Of Report \*\*\*



MC-2111



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