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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 ***



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