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:02-Jul-2021 / 15:33 :02-Jul-2021 / 21:21

Authenticity Check

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Real time Qualitative RT-PCR detection of 2019-nCOV RNA / COVID-19 RNA RESULT PARAMETER

Result

SARS-CoV-2: Not Detected (Negative)

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

ICMR Registration No: Andheri-Mumbai- SUBUR001, Pune-SUDIIPLPMH Specimen: Nasopharyngeal & Oropharyngeal swab in VTM Method: Real time RT-PCR Note:

- * Ct Value indicates the infectivity and not severity of infection.
- * ICMR recommended kits are user for reporting. All the positive cases will be notified to ICMR for furher surveillance
- * Clinical correlation with patient history, radiology findings and co-infection with other virus infection is necessary to be deteremined especially in cases with Borderline positive Ct values.
- Borderline positive cases (Ct value>30) may give variable results on repeat testing. The possible reasons could be the variations in kits and nstruments used.

Limitations:

- * optimun specimen types and timing of peak viral levesls during infections cauused 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 a qualitative assay and does not quantify viral load. Various host factors, viral factors, variability in sample collection / site and techniques used by the laboratories can affect 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 genes 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 ***







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