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Lab No.: SL2/26-08-2021/SR4997094Lab Add.: Newtown, Kolkata-700156Patient Name: ANIRUDHA CHATTERJEERef Dr.: Dr.SIDDHARTHA CHATTERJEE

**Age** : 35 Y 0 M 0 D

**Gender** : M **Report Date** : 27/Aug/2021 12:09AM



# COVID-19 QUALITATIVE REAL TIME PCR SARS-COV-2 VIRUS DETECTION BY REAL TIME PCR

Primary Sample: Nasopharyngeal and Oropharyngeal swab in Viral Transport Media.

Methodology: This is a qualitative amplification assay for the detection of the RNA of SARS-COV2 in respiratory samples. The lab is using FDA/ CE- IVD/ ICMR approved Real Time PCR assay.

#### Result:

TEST NAME	RESULTS
SARS-COV2 (COVID-19 Virus) QUALITATIVE, REAL TIME PCR	NEGATIVE

\* Condition of specimen received/quality on arrival: Good quality specimen/ in cold chain.

## Interpretation:

- \* Positive (according to the CT cut off criteria of the reaction) amplification of target genes shall be considered as positive of SARS nCOV-2.
- \* No amplification of both the target genes but positive amplification in internal control shall be considered as negative for nCOV-2019.
- \* Amplification of confirmatory gene in absence of screening gene shall be interpreted as INCONCLUSIVE. It is not possible to say for certain that SARS nCOV-2 was present in the sample when tested. A repeat, fresh sample is suggested ideally after 3-4 days for all INCONCLUSIVE test results to achieve adequate viral load. However considering patient's deteriorating clinical status in certain cases, repeat sample may be collected earlier as per treating physician's discretion.
- \* No amplification of both the target gene as well as internal control shall be interpreted as invalid result.

### Note:

- 1. ICMR Registration number for Covid-19 is SUDPLO01
- 2. Negative result does not rule out the possibility of covid-19 infection. Presence of inhibitors, mutations and insufficient RNA specific to SARS-COV-2 can influence the test result. Kindly correlate the results with clinical findings.
- 3. Covid-19 Test conducted as per kits approved by ICMR/CE-IVD/USFDA.
- 4. Kindly consult referring Physician / Authorized Govt. hospital for appropriate follow-up.
- 5.The result relates only to the specimen tested and should be correlated with clinical findings.
- 6. Not in NABL Scope.

# Interpretation guidance:

- 1. Please ensure and maintain the confidentiality of the test report.
- 2. A single negative test result, particularly if this is from an upper respiratory tract specimen, doesn't exclude infection.
- 3. Repeat sampling and testing of lower respiratory specimen is strongly recommended for severe or progressive disease. The repeat specimens can be considered after a gap of 2 to 4 days after the collection of first specimen for additional testing if required.
- 4. A positive alternate pathogen doesn't necessarily rule out either, as little is yet known about the role of coinfections. Testing of non-viral agent has not been undertaken.
- 5. Please note that these results are not to be used for any thesis or presentations or for Publications in any Journal without prior permission of Director General, ICMR.

Background: Several coronaviruses can infect humans, the globally endemic human coronaviruses HCOV-229E, HCOV-NL63, HCOV-HKU1 and HCOV-OC43 that tend to cause mild respiratory disease, and the zoonotic Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome coronavirus (SARS-COV) that have a higher case fatality rate. In December 2019, a cluster of patients with a novel coronavirus was identified in Wuhan, China. Initially tentatively named 2019 novel coronavirus (2019-nCOV), the virus has now been named SARS-COV-2 by the International Committee of Taxonomy of Viruses (ICTV). This virus can cause the disease named coronavirus disease 2019 (COVID-19). WHO refers to the virus as COVID-19 virus in its current documentation.

References: 1. Laboratory testing for corona virus disease 2019 (COVID-19) in suspected human cases. WHO interim guidance 2<sup>rd</sup> March, 2020.

In case of COVID 19 POSITIVE report Please contact for any information : Call Centre : 1800414444222, 033-23312701

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( Source: Department of Health & Family Welfare, Government of West Bengal )

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