Bioline Laboratory

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ISO 9001:2015
Certified Laboratory

SID No : **96274403**

Branch : **Coimbatore**

Mr. VIVEKANANDAN S

Age / Sex : 25 Y / Male

Ref. By : **Dr. R.KARTHICK PRABHU M.B.B.S.,MD.,**

Patient ID : **9600276501**

Collected Date : 23/03/2022 / 14:02

Received Date : 23/03/2022 / 14:31

Reported Date : 23/03/2022 / 18:03

Final Test Report

MOLECULAR BIOLOGY

SARS-CoV- 2 (COVID-19) RT-PCR

Specimen	Combined swab (Nasal & Throat)
SARS - CoV-2	Negative

ICMR approved ID: BIOLCT for COVID-19 testing.

Method: Real-time *Reverse Transcription Polymerase Chain Reaction* (RT-PCR).

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a positive-sense, single-stranded RNA virus that causes Coronavirus disease 2019 (COVID-19). SARS-CoV-2 transmission occurs primarily via respiratory droplets. SARS-CoV-2 is likely to be at the highest concentrations in the nasopharynx during the first 3 to 5 days of symptomatic illness. As the disease progresses, the viral load tends to decrease in the upper respiratory tract, at which point lower respiratory tract specimens (eg, sputum, tracheal aspirate, bronchoalveolar fluid) would be more likely to have detectable SARS-CoV-2.

Interpretation Guidance:

- A "Negative" result indicates that SARS-CoV-2 is not present in the patient's specimen. However, this result may be influenced by the stage of the infection, quality, and type of the specimen collected for testing. Result should be correlated with patient's history and clinical presentation. A single negative test result, particularly if this is from an upper respiratory tract specimen, does not exclude infection. Importantly, combination of real-time RT-PCR and clinical features especially CT image could facilitate disease management.
- A "Positive" result indicates that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA is present and suggests the diagnosis of coronavirus disease 2019 (COVID-19). Test result should always be considered in the context of patient's clinical history, physical examination, and epidemiologic exposures when making the final diagnosis. A positive alternate pathogen does not necessarily rule out either, as little is yet known about the role of coinfections.
- The above qualitative result of COVID-19 using RT-PCR method is based on the threshold cycle (Ct) value on detection of highly specific and exclusive detection of the SARS-CoV-2 genes in respiratory samples along with simultaneous detection of a universally expressed human gene to exclude false negative results. The sensitivity of the assay is dependent on the timing of the specimen collection (in relation to symptom onset), quality, and type of the specimen submitted for testing.
- Real-Time RT-PCR Diagnostic kits have been designed to minimize the likelihood of false test results. Still, there is a very small chance that this test result can vary due to stray viral RNA , very low viral load, stage of infection, decreased viral shedding at the anatomic sampling site or improper sampling of the nasopharyngeal swab in some people with COVID-19.
- Results from two different lab are not comparable as the test depends on several factors including the viral load during sample collection procedure, timeline in the course/stage of disease, epidemiological prevalence of the disease, performance of the kit and type of target genes, etc.
- The above result should not be used for any thesis or presentations or for Publication in any Journal without the prior permission of the Director General, ICMR.
- As per ICMR advisory, numerical Ct values is useful for laboratory result interpretation only which may vary due to several factors and hence not recommended for determining infectiousness of COVID-19 patients (viral load) and deciding patient management protocols

The RT-PCR test presently being conducted is qualitative. So numerical cycle threshold (Ct)values for determining infectiousness of COVID-19 patients and deciding patient management protocols is not recommended (ICMR Dt 05/08/2020). Ct values shall be provided only to physicians verbally, on request

Verified By

Dr.T.Amalarajasundari

Dr.S.Santhosh Gandhi MD., (Micro)

Consultant Microbiologist