STEADFAST HEALTHCARE PVT. LTD.
KC Theatre Complex,B C Road
Jammu & Kashmir
T: 01912740100
E: healthcare@atulaya.com
W: www.atulaya.com
Fb: www.fb.com/atulayahealthcare
CIN: U85195CH2008PTC031221

Visit ID: AJMU132535

Patient NAME	: Mrs.RENU BALA	Sample Collection Time	: 12/Mar/2022 12:21PM
Age/Gender	: 4 7 Y 0 M 0 D /F	Sample Received in Lab Time	: 13/Mar/2022 03:54AM
UAID/Oth.Lab Ref.	: AJMU.0000123861/	Reported Time	: 13/Mar/2022 10:56AM
SIN No.	: AAZ14315	Ref. Doctor	: Dr.SELF

DEPARTMENT OF MOLECULAR BIOLOGY **IN/OUT SAMPLE :Outhouse Sample**

COVID-19 (Real Time PCR)

ICMR Registration No.: ATHCC
Sample type: Nasopharyngeal & Oropharyngeal Swab
ICMR approved Kit : Meril COVID-19 One-step RT-PCR kit

COVID – 19 (Real Time PCR Qualitative)		
Test	**Results**	**Biological Reference Interval**
Result for SARS Coronavirus-2/COVID 19 (RT PCR)	**Positive**	Negative
CT value of N gene if positive	29.06	-
CT value of ORF 1ab gene if positive	30.67	-

Interpretation

Result	Remarks
Positive	RNA specific to SARS-CoV-2 Detected
Negative	RNA specific to SARS-CoV-2 Not Detected

Note:
1. The Ct value is inversely proportional to the amount of genetic material (RNA) in the starting sample and Lower Ct value generally correlate with high viral load.
2. Ct values differ from one kit to the other.
3. Ct values also depend on how the sample has been collected. A poorly collected sample may reflect inappropriate Ct values.
4. Ct values between nasal and oropharyngeal specimens collected from the same individual may differ.
5. Temperature of transportation as well as time taken from collection to receipt in the lab can also adversely impact Ct values.
6. According to ICMR guidelines CT values should not be used to monitor the severity of disease.

Methodology
Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the detection of RNA form SARS CoV2 in human nasopharyngeal and oropharyngeal swab specimens.

Clinical significance
SARS CoV 2 is the causative agent for corona virus disease 2019 or COVID-19 in Humans. SARS CoV 2 is a Beta Corona Virus, one of the four genera of Corona Viruses. Coronaviruses are enveloped non-segmented positive sense RNA viruses belonging to the family coronaviridae and the order Nidovirales and broadly distributed in humans and other mammals. The common signs of COVID-19 infection

Navreet Kaur

Dr.Navreet Kaur
MD Microbiology

Atulaya HEALTHCARE
Imaging & Laboratories

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include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death. Early and correct identification of infection with SARS CoV-2 is important for effective isolation, treatment and case management of COVID-19.

Principle

In the presence of the target, primers and probes will hybridize to the specific sequence and allow amplification by the polymerase. The level of fluorescence increases with the generation of amplicons and is proportional to the amount of pathogen nucleic acid contained in the sample. The increased fluorescence level is reported as a cycle threshold (Ct) value by the real-time thermocycler.

Target Selection

The target sequence is N and ORF 1ab gene of SARS CoV2.

Limitations

* Negative result does not rule out COVID-19 infection. It should be interpretated along with the history, clinical findings and other epidemiological factors.
* Positive results indicate infection but the possibility of infection with other similar viruses cannot be ruled out.
* This kit is a qualitative kit that does not provide a quantitative value for the detected pathogens in the specimen.
* This test shall not be the only element consulted for diagnosis or treatment decision. A specimen not detected cannot be presumed to be negative for this pathogen since results are dependent on several variables as explained above.
* Reliable results of this test require appropriate specimen collection as well as appropriate specimen and kit transport and storage and processing procedures. Failure to follow these procedures will produce incorrect results, leading to false positive and negative values or invalid results.
* Possibility of false negative results due to mutations and rapid evolution of the virus cannot be ruled out.
* Optimum timing for peak viral load during infections caused by novel Coronavirus have not yet been fully determined. So multiple samples might be needed from same patient at different times.
* False negative results may occur due to the presence of amplification inhibitors in the sample or insufficient organisms in the sample.
* Samples with low and very low viral load may give variable results on repeat testing.

Note: Test is performed using ICMR approved kit.

References:

* The Institut Pasteur website:
https://www.pasteur.fr/en/medical-center/disease-sheets/covid-19-disease-novel- coronavirus#symptoms. Accessed March 2020.
* Center for Disease Control (CDC) website: https://www.cdc.gov/urdo/downloads/SpecCollectionGuidelines.pdf. Accessed March 2020.
* CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus. https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html. Accessed May 2020.
* World Health Organization (WHO). Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases: Interim guidance, 2 March 2020.
*ICMR:https://www.icmr.gov.in/pdf/covid/techdoc/Advisory_on_correlation_of_COVID_severity_with_Ct_values.pdf

*** End Of Report ***

Dr.Navreet Kaur
MD Microbiology