# ICMR Registration number: COREG001

### SRF ID: 0605900060134

Hospital Location Bhiwani, Haryana, India

Hospital Name Krishna Medicare

Physician Name Dr SELF

Date & Time of Accessioning 06/10/2020 11:00 Hrs

Date & Time of Reporting 06/10/2020 11:30 Hrs

TEST NAME

SARS-COV-2 Qualitative Detection Test

SPECIMEN INFORMATION

Nasopharyngeal swab & Oropharyngeal swab Collected on 04/10/2020

CLINICAL HISTORY

Refer ICMR Form

METHODOLOGY

Real Time Polymerase Chain Reaction (RT PCR)

RESULTS

|  |  |
| --- | --- |
| Test Details | Result |
| N1 gene | Not-Detected |
| N2 gene | Not-Detected |
| RNAse P | Detected |
| SARS-CoV-2 Detection | Negative |

INTERPRETATION

|  |  |
| --- | --- |
| Result | Interpretation |
| Either N1 gene or N2 gene or both detected, but RNAse P can be detected/not detected | The Sample provided is positive for SARS-CoV-2. |
| N1 gene and N2 gene not detected, but RNAse P detected | The Sample provided is negative for SARS-CoV-2. |
| N1 gene and N2 gene not detected and RNAse P not detected (Non Diagnostic) | Inadequate sample due to poor collection/failure of RNA extraction procedure. Repeat sample is recommended |
| In-conclusive Result | In-conclusive Result and repeat sample is recommended. |

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COMMENT

1. SARS-CoV-2 is the causative agent of the coronavirus disease 2019 (COVID-19) and the virus belongs to Order: Nidovirales, Family: Coronaviridae, Genus: Betacoronavirus and structure of the virus is enveloped, positive sense, single stranded RNA virus.
2. The SARS-CoV-2 RT qPCR kit is an in vitro nucleic acid amplification test for the qualitative detection of severe acute respirato ry syndrome coronavirus 2 (SARS-CoV-2) specific RNA from respiratory specimens (including: nasopharyngeal or oropharyngeal aspirates or washes, nasopharyngeal or oropharyngeal swabs, bronchoalveolar lavage, tracheal aspirates & sputum) using Real time PCR.
3. The test is targeting two regions in the N gene (N1 and N2) of the SARS-CoV-2 genome.
4. Human RNaseP gene serves as an internal positive control. Detection of the Internal Control is not required for positive results. High viral load in the sample can lead to reduced or absent Internal Control.
5. The Limit of Detection (LOD) for the assay is 100 Genomic Copy Equivalents (GCE) per reaction.

## NOTE

### Negative results do not rule out the possibility of COVID-19 virus infection. A number of factors could lead to a negative result in an infected individual, including:

Poor quality of the specimen, containing little patient material (as a control, consider determining whether there is ade-quate human DNA in the sample by including a human target in the PCR testing) The specimen was collected late or very early in the infection

### The specimen was not handled and shipped appropriately

Technical reasons inherent in the test, e.g. virus mutation or PCR inhibition.

### Both External and Internal controls have been included in each and every run.

1. Test conducted as per guidelines recommended by WHO.

### The test result should be used in conjunction with clinical presentation.

1. Kindly consult referring Physician / Authorized Govt. hospital for appropriate follow-up.

If you have any questions about this report or would like to have a conversation about the genetic implications of these test results, please feel free to reach out to us at

1800 103 2673 (Toll Free) or [info@corediagnostics.in](mailto:info@corediagnostics.in)

1. The tests are carried out in the lab with the presumption that the specimen belongs to the patient named or identified in the bill/test request form.
2. The test results relate specifically to the sample received in the lab and are presumed to have been generated and transported per specific instructions given by the physicians/laboratory.
3. The reported results are for information and are subject to confirmation and interpretation by the referring doctor. 4.Some tests are referred to other laboratories to provide a wider test menu to the customer.

5.CORE Diagnostics Pvt. Ltd. shall in no event be liable for accidental damage, loss, or destruction of specimen,which is not attributable to any direct and mala fide act or omission of CORE Diagnostics Pvt. Ltd. or its employees. Liability of CORE Diagnostics Pvt. Ltd. for deficiency of services, or other errors and omissions shall be limited to fee paid by the patient for the relevant laboratory services.

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