DIACARTA

DIACARTA INC

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LABORATORY REPORT

PATIENT	SPECIMEN	PHYSICIAN
Name: [redacted]	Specimen Type: **SALIVA**	Name: [redacted]
[redacted] Address (2 lines) [redacted]	Collection Date: **09/02/20**	Address: [redacted]
Date of Birth: [redacted] Gender: [redacted]	Received Date: **09/03/20 11:48**	[redacted]
Accession #: [redacted]	Reported Date: **09/03/20 18:04**	Phone: ( ) -

SARS-CoV-2 (COVID-19) RT-PCR Test (Nucleic Acid Test)

Test Name	Within Range	Outside Range	Prev. Result
SARS-CoV-2 (COVID-19) RT-PCR Test	NOT DETECTED		NOT DETE

RESULT INTERPRETATION

DETECTED (Positive) results do not rule out co-infection with other respiratory viruses. A positive test result indicates that RNA of the SARS-CoV-2 virus (cause of COVID-19) was detected in the patient sample. Patient actively infected with this virus is presumed to be contagious even if asymptomatic.

NOT DETECTED (Negative) results do not always preclude SARS-CoV-2 virus infection and should not be used as the sole basis for diagnostic decisions. A negative test result means that the virus that causes COVID-19 was not detected in patient sample at the time the sample was taken. A negative test result for a sample collected while a person has symptoms usually means that SARS CoV-2 did not cause the illness, but does not definitively rule out COVID-19 because the virus level could be below the test detection limit (e.g., late-stage of COVID-19).

The QuantiVirusTM SARS-CoV-2 Test is a real-time reverse transcription-polymerase chain reaction (rRT-PCR) test for the qualitative detection of RNA from SARS-CoV-2 in nasopharyngeal swab, oropharyngeal swab, saliva, and sputum specimens from patients who are suspected of COVID-19. This test has been approved by the US FDA under an Emergency Use Authorization (EUA) and was validated in accordance with the FDA Guidance Document Policy. Extracted RNA is reverse-transcribed and amplified in a single reaction. The unique gene sequences of the SARS-CoV-2 are targeted in the rRT-PCR assay. Primers and TaqMan probes designed for conserved regions of the SARS-CoV-2 virus genes allow specific amplification and detection of viral RNA from respiratory specimens. The Human RNAse P gene is used as Internal Control to demonstrate the testing process has proceeded correctly for each patient sample.

The DiaCarta Clinical Laboratory is Clinical Laboratory Improvement Amendments (CLIA) certified and qualified for performing high complexity testing.