GENESIS DIAGNOSTICS
CLIA # 39D1099562

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COVID-19 (SARS-CoV-2) Test Report

Patient		Analysis		Specimen	Nasal
First Name:	Una	**Indication For:**	Coronavirus Disease	**Collection Date:**	02/15/2021 12:00 AM
Last Name:	Morgan	**Analysis ID:**	1021700669	**Received Date:**	02/17/2021 09:08 AM
Patient ID:	328810114	**Specimen Type:**	Nasal	**Reported Date:**	02/17/2021 05:19 PM
DOB:	11/27/1953	**Ref. Physician:**	Rosenfeld, Fran		
Gender:	Female				

SUMMARY OF RESULTS — POSITIVE

Result: Positive

Methodology:
Genesis Diagnostics SARS-CoV-2 test is a laboratory developed test. It is a real time RT-PCR which specifically detects SARS-CoV-2 virus in patients' specimens. Patient's nasopharyngeal or oropharyngeal swab are treated to extract RNA and processed to detect the presence of SARS-CoV-2 virus using specific primers on a real time PCR machine. The results are compared to validated and established positive controls and Negative Extraction Controls (Quality Control Samples) run alongside the patient's samples for diagnosis of SARS-CoV-2 infection.

Limitations:
All molecular tests have limitations. If a patient is found 'NOT DETECTED or NEGATIVE' implies that he/she does not have the virus at the sample collection time. On the other hand, this doesn't discount the fact that he/she may be positive later if the patient becomes infected. Hence, we strongly recommend undergoing this test when the patient experiences symptoms consistent with SARS-CoV-2 etiology and to rule out any current symptoms that are not pertinent to SARS-CoV-2 infection with the clinician's advice and prescription.

Laboratory Statement:
This test was validated and performance characteristics have been determined by Genesis Diagnostics. This test is used for clinical purposes (see Eligibility for testing). Its use should not be regarded as investigational or for research. This laboratory is certified under Clinical Laboratory Improvements and Amendments of 1988 (CLIA 88) as qualified to perform high complexity clinical laboratory testing.

Eligibility for Testing:
This test is prescription use only and is limited to patients suspected of SARS-CoV-2 by their healthcare provider. Clinicians should evaluate eligibility for testing in light of criteria developed by the CDC, although the eligibility determination ultimately rests on the clinician's judgment.

Conduct of the Test:
This test is performed under strict compliance and guidelines of Genesis Diagnostics R&D team, including the instruments, reagents and other recommended procedures. This includes- the safety protocols where- all laboratory personnel are appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit/test and use this test in accordance with the authorized labeling.

Notifications and Reporting Results – Public Health Authorities:
The laboratory will notify the state public health department of the intent to begin testing prior to initiating testing. We have a process in place for reporting test results to "relevant public health authorities," as appropriate. Currently, all positive results are reported to the CDC and the state public health department. Note, however, that a requirement to report all results may be implemented soon.

Result Reports for Healthcare Providers and Patients:
We have a process for reporting test results to healthcare providers as appropriate. Result reports will be provided to healthcare providers and to patients.

Performance Data and Reporting:
We collect information on the performance of the test and report any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which we become aware to concerned authorities.

Recordkeeping:
As an authorized laboratory we ensure all records associated with this test are maintained until otherwise notified. Such records are available to regulatory bodies for inspection upon request at any time.

Advertisement:
No advertising or promotional descriptive printed matter relating to the use of the test may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

EMERGENCY USE AUTHORIZATION and FACT SHEET:
All patients and Healthcare providers whose specimens are tested with this assay will have to download, go through the Fact sheet and get acclimatized with this RT-PCR test and COVID-19. The link and QR code for the FACT SHEET are provided below.

FACT SHEET for HEALTHCARE PROVIDERS:
https://www.fda.gov/media/134920/download

FACT SHEET for PATIENTS:
https://www.fda.gov/media/134921/download