LAB REPORT

Printed: 08/12/2020 10:33AM

Patient: Morales, Telma
Gender:F **DOB:**12/06/1962
Accession:ORM2022413216
Ordered Date: 08/11/2020 10:19PM

Facility:CDR Maguire - Miami Beach CC Mission 17388
Physician: Butler, Allison, MD
Collected:08/10/2020 12:00AM
Delivery Date: 08/11/2020 10:18PM

Reporting Group: Molecular

Coronavirus SARS-CoV-2 (COVID-19) (Swab)

RCA Laboratory Services LLC dba SID:202241379 GENETWORx[1] 3

Final - Approved 08/12/2020 10:26AM

Collected08/10/2020 12:00AM

The reference interval for this assay is Negative. A negative result does not rule out the presence of PCR inhibitors in the patient specimen, specimen collection errors or assay specific nucleic acid in concentrations below the limit of detection by the assay. This laboratory is regulated under the Clinical Laboratory Improvement Amendment (CLIA) of 1988 as qualified to perform high complexity clinical testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. Laboratory specimens were analyzed for COVID-19 using reverse-transcriptase-Real time PCR (rRT-PCR) using primer and probe sequences validated by the Centers for Disease Control (CDC) under the Emergency Use Authorization for Coronavirus Disease-2019 (EUA). This test has been validated as a laboratory developed test in accordance with the FDA's Guidance Document (Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency) issued on February 29th, 2020. Our test validation has undergone FDA review. FDA acknowledges that GENETWORx meets the conditions outlined in the Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff: Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency and the FDA FAQs on Diagnostic Testing for SARS-CoV-2 for the allowable modifications to the CDC EUA.

TEST	RESULT	REF RANGE	UNIT
COVID-19	Negative	Negative	

Reporting Laboratories:

(1) RCA Laboratory Services LLC dba GENETWORx (CLIA ID: 49D2060159), Lab Director: Jacobs-Helber, Sarah, PhD, HCLD (ABB), 4060 Innslake Dr, Glen Allen, VA 23060, 804-346-4363

Results sent to: PatientPortal (Host Interface)