Paradigm Laboratories
8222 S 48th St., Suite 195, Phoenix, AZ 85044; 6115 E Grant Rd., Tucson, AZ 85712
520-901-2969
Laboratory Director: Dr. Wenli Zhou
CLIA#: 03D2164595; 03D2089365 COLA#: 29577; 26094

COVID-19 Report

Patient Information

Name: Robert Schartz

DOB: 03/30/1944

Gender: M

Ethnicity: Non-Hispanic

Medical Record Number:

Clinical Notes from Ordering Physician:

Specimen Information

Accession Number: UC0138357

Date Collected: 11/17/2020

Date Received: 11/18/2020

Report Date: 11/18/2020

Sample Type: Nasopharyngeal Swab

Facility Information

Facility Name: PCHD Udall Event Center

Provider Name: THERESA CULLEN

Address:

COVID-19 Test Result Summary

NEGATIVE

Results Comment: A negative test result means that the virus that causes COVID-19 was not detected in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. You and your healthcare provider should consider this test result together with all other aspects of your medical condition (such as symptoms, possible exposures, recent travel history, etc.) in deciding whether further testing is needed.

If Sample Type displays “Saliva”: When saliva screening is performed,positive results are indicative of the presence of SARS-CoV-2 RNA, whereas the negative results means that the virus was not detected in your saliva but does not rule out the possibility of COVID-19 infection with certainty. Saliva screening is not intended for the individuals with the onset of symptoms or the SARS-CoV-2 virus positivity longer than 14 days. If you have any COVID-19 symptoms, yourhealthcare provider may want you to take nasopharyngeal swab test.

Processing and Detection Methodology:
Paradigm Laboratories uses magnetic-bead technology to recover SARS-CoV-2 viral RNA from various upper respiratory tract specimens including anterior nasal swabs, mid-turbinate nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, and saliva. The assay uses real-time RT-PCR technology to qualitatively detect nucleic acids from SARS-CoV-2. The analytical specificity of this assay is high as determined by BLAST analysis for the assay’s primers and probes against public domain nucleotide sequences, and the analytical sensitivity is greater than 95% at the Limit of Detection (LoD) of 500 copies/mL as determined by the serial dilution method.

Disclaimer: This test is used for clinical purposes and should not be regarded as investigational or for research. This test has been validated 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 (Revised)”. FDA independent review of this validation is pending. This test is only authorized for the duration of time the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of SARS-CoV-2 virus and/ or diagnosis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

This test was performed by Paradigm Laboratories, 8222 S 48th St., Suite 195, Phoenix, AZ 85044; 6115 E Grant Rd., Tucson, AZ 85712 Phone: 520-901-2969 CLIA#: 03D2164595; 03D2089365 COLA#: 29577; 26094

This report, associated with order #UC0138357, has been approved by the following reviewers:

Report Reviewer:

Electronically signed and dated on 11/18/2020 16:29
Matthew Murphy