PRECISION GENETICS

Precision Genetics
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877.843.6544
Laboratory Director: Jeremy Stuart, Ph.D, MPH
CLIA#: 42D2115298 CAP#: 444456789
CLIA and CAP Number

COVID-19 Report

Patient Information

Name: Patient Name
DOB: Patient Date of Birth
Gender: Patient Gender
Ethnicity: Patient Ethnicity
Medical Record Number:
Clinical Notes from Ordering Physician:

Specimen Information

Accession Number:
Date Collected: Date And Time
Date Received: Date And Time
Report Date: Date And Time
Sample Type: Nasopharyngeal Swab

Facility Information

Facility Name: Umed Market
Provider Name: DAVID LAWRENCE GRISELL
Address:

COVID-19 Test Result Summary

Results (Positive or Negative)

SARS-CoV-2/2019-nCoV

Assay	Results
S Protein	Detected or Not Detected (Depending on Positive or Negative)
N Protein	
ORF1ab	

This test was developed and its performance characteristics determined by Precision Genetics. It has not been cleared or approved by the FDA. However, such approval/clearance is not required, as the laboratory is regulated and qualified under CLIA to perform high-complexity testing. 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" issued on February 29th, 2020. 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.

Test Type

Processing and Detection Methodology:
Test is performed by nucleic acid extraction from media containing nasopharyngeal swabs followed by reverse transcription and real-time PCR on a QuanStudio 12K Flex. Fluorescent probe sequences (TaqPath COVID-19 Combo Kit) are used to amplify three regions within the SARS-CoV-2 viral genome: ORF1ab, N-gene, and S-gene. MS2 Bacteriophage control is added to each extraction sample as a quality check for extraction and amplification. Cycle threshold analysis (Ct) of the targets is used to determine the presence or absence of SARS-CoV-2.

Disclaimer: The information contained in this report is intended to be interpreted by a licensed physician or other licensed healthcare professional. This report is not intended to take the place of professional medical advice. Decisions regarding course of medical treatment must be made only after consulting with a licensed physician or other licensed healthcare professional, and should consider each patient's medical history.

This test was performed by Precision Genetics, 1 Marcus Drive, Suite 104 Greenville, SC 29615 Phone: 877.843.6544 CLIA#: 42D2115298 CAP#: 444456789

Lab Name, Phone, Address, CLIA #, CAP #