Mokan Labs, LLC
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Laboratory Director: Ning Liu, PhD
CLIA#: 17D2273601
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Patient Information

Name: Test Patient

DOB: 02.28.1996

Gender: M

Clinical Notes from Ordering Physician:

Specimen Information

Accession Number: 000413

Date Collected: 03.13.2023 10:00

Date Received: 03.14.2023 09:48

Report Date: 03.14.2023 10:10

Sample Type: Anterior or Mid-Turbinate Nasal Swab

Facility Information

Facility Name: House Account

Provider Name: Test Provider

Address:

COVID-19 Test Result Summary

POSITIVE

In addition to functional testing, an in silico study was performed to assess cross-reactivity between the TaqPath™ COVID 19 RNase P Combo Kit 2.0 primer/probe sequences and the organisms in Table 15, using BLAST analysis. With the exception of SARS-CoV, no bacterial, viral, or fungal microbe sequence aligned with ≥80% identity to more than one TaqPath™ COVID-19 RNase P Combo Kit 2.0 assay component. The majority of the 285 SARS coronavirus isolates tested in this study shared ≥80% identity with more than one assay component for N gene and ORF1b assays.

The Mokan SARS-CoV-2 test has not been FDA cleared or approved. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. 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. 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.

Processing and Detection Methodology:
The Applied Biosystems™ TaqPath™ COVID-19 RNase P Combo Kit 2.0 contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swabs and anterior or mid-turbinate nasal swabs from any individual, including individuals without symptoms or other epidemiological reasons to suspect COVID-19. Results are for the identifcation of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the defnite cause of disease. Laboratories within the United States and its territories are required to report all test results to the appropriate public health authorities. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Disclaimer: This test was developed and its performance characteristics determined by Mokan Labs. It has not been cleared or approved by the US Food and Drug Administration (FDA). The FDA has determined that such clearance or approvals is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) as qualified to perform high complexity clinical testing.

This test was performed by Mokan Labs, LLC, 14215 MetcalfAvenue, Overland Park, KS 66223 Phone:(913) 624-9005 Fax:(913) 261-9117 CLIA#: 17D2273601

This report, associated with order #000413, has been approved by the following reviewers:

Comment: Test samples, Reports are for fake patient

Report Reviewer:

Electronically signed and dated on 03.14.2023 10:11
Domenick Palmieri