Promis Diagnostics
1 Post, Suite 100, Irvine, CA 92618
Laboratory Director: Safedin Sajo Beqaj, PhD, HCLD, CC (ABB)
Clinical Molecular Pathology Supervisor: Dr. Bo Ram Bang, PhD.
CLIA#: 05D2185450 CAP#: 879466501

PDX COVID+Flu Combo Test Report

Patient Information

Name: firstName15 lastName15
DOB: 2000.12.03
Gender: M
Ethnicity: undisclosed
Email: test@email.com

Specimen Information

Accession Number: C19-00216
Date Collected: 2022.11.30
Date Received: 2022.11.30
Report Date: 2023.02.07
Sample Type: Nasopharyngeal Swab

Physician Information

Facility Name: Promis Dx
Provider Name: MARIA DEL CARMEN FRIAS KLETECKA
Address: 1 Post, Suite 100 - Suite 100 - Irvine - California

Tested Organisms and Results

Panel: PDX COVID+Flu Combo Test

Organism	Results
Influenza virus A (RT-PCR)	Positive
Influenza virus B (RT-PCR)	Negative
SARS-CoV-2 (RT-PCR)	Negative

Reference normal range: Influenza virus A - Negative, Influenza virus B - Negative, SARS-CoV-2 - Negative

Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.
Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

Testing was performed at a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meets the requirements to perform high-complexity tests.

This test employs the kit authorized by FDA under an Emergency Use Authorization (EUA) and it 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.

This test was performed by Promis Diagnostics, 1 Post, Suite 100, Irvine, CA92618 CLIA#: 05D2185450 CAP#: 879466501

This report, associated with order #C19-00216, has been approved by the following reviewers:

Comment: Test files

Admin:

Electronically signed and dated on 2023.02.17 10:57
Dr. Bo Ram Bang