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Patient Information

FINAL REPORT SARS RT-PCR FLY

Genentox Labs/Nova Diagnostics 2001 E 1st St Ste 109, Santa Ana, CA 92705 Ph # 833-668-2522 CLIA# 05D0871568 Lab Director Rosaura Williams MD

Sample Information Clinic Information

 Name:
 Yu, Hang
 Client:
 Chinese Consulate

 DOB:
 02/12/1998
 Collected:
 05/21/2021 09:34
 Site:
 LAX Walk In

 Gender:
 Male
 Received:
 05/21/2021
 Reported:
 05/21/2021
 Physician:
 Rosaura Williams

Address: 236 Livingston Street, Apt.15F

Brooklyn, NY 11201

MRN: E52126529
Comments: VAX

Detailed Results Summary

Test CoV-2 (Covid-19) by RT-PCR (NAAT)	Specimen Type Nasopharyngeal Swab	Results Not Detected (negative)	Not Detected
CoV-2 (Covid-19) by RT-PCR (NAAT)	Nasopharyngeal Swab	Not Detected (negative)	Not Detected
OVID-19 IgM (Chemiluminescence)	Venous Blood Draw	Detected (2.00 s/co)	<1
N-Protein	Blood Drop	Not Detected	N/A

Resulted By: Sangjun Lee Date: 05/21/2021

Final Result for SARS CoV-2 (COVID-19): NOT DETECTED (negative)

Not Detected (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. Collection of multiple specimens or types of specimens may be necessary to detect virus. Improper specimen collection and handling, sequence variability under primers/probes or viruses present below the limit of detection may lead to false negative results. Positive and negative predictive values of testing are highly dependent on prevalence. False negative test results are more likely when prevalence is high.

This test has been authorized by the FDA under an Emergency Use Authorization (EUA). The test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of SARS-CoV-2 under Section 564(b)(1) of the Act, 21 U.S.C. section 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. FDA review of the validation is pending.

The SARS-CoV-2 test is intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasal, nasopharyngeal and oropharyngeal swab samples from patients who meet COVID-19 clinical and/or epidemiological criteria. Testing methodology is (Real Time) RT-PCR. The assay targets the S, N and ORF1ab genes. Test results must be correlated with clinical presentation and evaluated in the context of another laboratory and epidemiologic data. Test performance can be affected because the epidemiology and clinical spectrum of infection caused by SARS-CoV-2 is not fully understood.

Genentox Laboratories, LLC. DBA Nova Diagnostics Labs CLIA Certification Number: 05D0871568 is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. section 263a, to perform high complexity tests.

CLS Signature:

Ce Soft



Doctor Signature:

Dr. Rosaura Williams