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

results@novadxlabs.com

FINAL REPORT

Covid-19 by RT-PCR SDAY

Patient Information	Sample Information	Clinic Information
Name: Doe CR, John		**Client:** TEST
DOB: 10/10/2010	**Collected:** 05/26/2021 12:48	**Site:** TEST SITE
Gender: Male	**Received:** 05/26/2021 **Reported:** 05/26/2021	**Physician:** Test Doctor
Address: 123 Main Street Miami, FL 33134		

MRN: MRN-221126
Comments:

Detailed Results Summary

Specimen ID	Test	Specimen Type	Results	Expected Value
106531	SARS CoV-2 (Covid-19) by RT-PCR (NAAT)	Nasopharyngeal Swab	Not Detected (negative)	Not Detected
106532	COVID-19 IgG (Chemiluminescence)	Venous Blood Draw	Detected (15 s/co)	<1
106532	COVID-19 IgM (Chemiluminescence)	Venous Blood Draw	Not Detected (negative) (0.2 s/co)	<1

Resulted By: Amer Khan Date: 05/26/2021

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:

Doctor Signature:

Sample Report