Fulgent Genetics
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PATIENT INFORMATION	ACCESSION	PHYSICIAN	LABORATORY
[redacted] **DOB:** Nov 27,1973 **Sex:** M **MR#:** XCKKT **Patient#:** FT-PT1696225 **Address:** 3751 Motor Ave ste 173 Los Angeles, CA 90034 **Phone:** [redacted]	**NF127037821** **Test#:** FT-TS2457273 **Order#:** FT-OR2450316 **Specimen Type:** Nasal Swab **Collected:** Nov 21,2020 **Ethnicity:** African/African American	[redacted] ATTN: US Health Clinics 3751 Motor Ave Suite 1392 Los Angeles, CA 90034 **Phone:** 805-625-9245 **Fax:**	**Fulgent Genetics** **CAP#:** 8042697 **CLIA#:** 05D2043189 **Laboratory Director:** Dr. Hanlin (Harry) Gao **Report Date:** Nov 23,2020

RESULT

SARS-CoV-2/COVID-19

NEGATIVE

A negative result means that the virus was not detected in the sample you provided. The results suggest you were negative at the time of testing.

METHODS & LIMITATIONS

Methods: RNA was extracted from the provided specimen using standard protocols. This test is a nucleic acid amplification test (NAAT). The RT-PCR test was performed using the primer pairs unique to SARS-CoV-2 virus (also called 2019-nCoV or "novel coronavirus 2019") designed by US CDC. According to CDC guideline, the result is positive when both Ct values of N1, N2 targets are less than 40; the result is inconclusive when either one of N1, N2 target is less than 40; the result is negative when Ct value of Human RP is less than 40, Ct values of N1 and N2 are greater than 40.

Limitations: All laboratory tests have limitations. Test results and interpretation are based on the proper identification of the submitted specimen. In very rare instances, errors may result due to mix-up or co-mingling of specimens. Positive results do not imply that there are no other contributions, genetic or otherwise, to the patient's current health state, and negative results do not rule out infection entirely. This test is only valid for the detection of the SARS-CoV-2 virus. Efforts have been made in the design of this test to minimize the chances of a false positive result due to the presence of other infectious agents, but this cannot be ruled out. False negative results may occur if the virus is not present in the tested specimen or is present at a very low level. The limit of detection for the test is 3.6 copies/µl. Samples with viral load less than 3.6 copies/µl may not be detected.

SIGNATURE

Hi Gao

Dr. Harry Gao, DABMG, FACMG on **11/23/2020 5:32 AM PST**

Electronically signed

DISCLAIMER

This test was developed and its performance characteristics determined by Fulgent Genetics CAP #8042697 CLIA #05D2043189; 4978 Santa Anita Ave., Temple City, CA 91780.This test has not been FDA cleared or approved. 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 has been authorized by the FDA under an EUA for use on May 15, 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.