

PATIENT INFORMATION

Doe, Jane
DOB: Jan 01,1985
Sex: F
MR#:
Patient#: FT-PT000000

ACCESSION

FT-0000000
Test#: FT-TS000000
Order#: FT-OR0000000
Specimen Type:
Nasopharyngeal Swab
Collected: Apr 15, 2020

PHYSICIAN

Dr.
ATTN:
Fertility Clinic
101 W. Medical Dr., Suite 100
Dallas, TX 10101
Phone: 202-202-0000
Fax: 202-202-0001

LABORATORY

Fulgent Genetics
CAP#: 000000
CLIA#: 00D0000000
Laboratory Director: Dr.
Hanlin (Harry) Gao
Report Date: Apr 15,2020

RESULT

SARS-CoV-2/COVID-19



NEGATIVE

No evidence of the virus that causes COVID-19 was detected in the submitted specimen. This does not rule out that you may have the infection. Please refer to local, state, and federal authorities regarding restrictions that apply to healthy individuals.

METHODS & LIMITATIONS

Methods: RNA was extracted from the provided swab using standard protocols. 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.

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.

SIGNATURE



Dr. Harry Gao, DABMG, FACMG on Apr 15,2020

Electronically signed

DISCLAIMER

This test was developed and its performance characteristics determined by Fulgent Genetics. 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. FDA independent review of this validation is pending. 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.