SARS-CoV-2 PCR

Order RD000-063-944

Patient:	Jane Doe
DOB:	01/01/1902
Gender:	Female

Provider:	Albert C Domm
Practice:	Lifetime Sciences Test Account 4037 Rural Plains Circle, Suite 150 Franklin, TN, 37064

Specimen:	Swab - Nasopharyngeal
Identifier:	SP000-063-923
Collected:	06/02/2022 02:18pm
Received:	06/02/2022 02:28pm
Reported:	06/03/2022 10:39am

Result

NEGATIVE

Interpretation

SARS-CoV-2 Not Detected (Negative) test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection.

Comments

SARS-CoV-2 Not Detected (Negative) test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. A negative result does not rule out the possibility of COVID-19 and clinical presentation of the patient should be considered in patient treatment or management decisions.

Clinical presentation and findings should be considered in consultation with the Public Health Department when diagnostic testing is negative. Laboratory test orders and results should always be considered in conjunction with clinical observations and epidemiological data in making patient management decisions and diagnosis. Please review the "Fact Sheet for Healthcare Providers" and FDA authorized labeling available for health care providers and patients using the following websites:

Healthcare Provider PCR Fact Sheet
https://www.fda.gov/media/136111/download

Patient Fact Sheet PCR
https://www.fda.gov/media/136114/download

Specimens collected from individuals who meet clinical and/or epidemiological criteria and are submitted from the appropriate clinical sources, nasopharyngeal swab or a nasal swab from the anterior nares, are acceptable for testing. Test results derived from specimens received in non-FDA approved collection devices or transport media should be evaluated with caution and patients may require extra clinical monitoring, including repeat testing. The test kit used has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories. A Bridging Study was performed to validate the test at Lifetime Sciences. Lifetime Sciences is regulated under the Clinical Laboratory Improvement Act (CLIA) and is accredited by CAP to perform high complexity testing.

Methodology: Realtime Reverse transcription polymerase chain reaction (RT-PCR)

SARS-CoV-2 is performed by Real Time RT-PCR. It is for use under a FDA Emergency Use Authorization. The SARS-CoV-2 test was developed and it's performance characteristics determined by MyGenetx Laboratory, LLC DBA Lifetime Sciences. The laboratory is regulated under CLIA and is accredited to perform high-complexity testing.