



Patient Information

Name: Marie A Dahdah
DOB: 10-03-1991 **Gender:** Female
Phone: 9173465901
Address: 68 SE 6th St Apt 3803
Florida, 33160
Passport #: 158795894

Specimen Information

Accession No: 22013168146
Date Collected: 04-09-2022 07:17 AM
Date Received: 04-09-2022 10:47 PM
Date Reported: 04-09-2022 11:20 PM
Performed By: Pinnacle Genetics Labs Inc
Collection Instrument: Nasopharyngeal Swab

Provider Information

Facility Name: FL - Wynwood
Submitted By: GoMeyra Admin
Address: 586 NW 27th St
Miami FL 33127

SARS Coronavirus 2 N gene

NEGATIVE

The Pinnacle SARS CoV 2 Molecular Assay is a NAAT Real-time PCR based test for detection of COVID 19 disease which is also referred as severe acute respiratory syndrome Coronavirus 2. This test has not been FDA cleared or approved. This test has been authorized by the FDA under an Emergency Use Authorization and it has been validated in accordance with the FDA's Guidance Document Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CUA. This test is performed on a real-time RT PCR instrument and results indicate presumptive detection of nucleic acid of SARS CoV 2 from upper respiratory specimens, such as nasopharyngeal and oropharyngeal swabs or sputum, collected from individuals for testing. Testing using this assay is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. 263A, to perform high complexity tests. Pinnacle Laboratory is licensed under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. 263A, to perform high complexity tests. This test is only authorized for the duration of time the declaration that circumstances exist justifying the authorization of the emergency use of invitro 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. 360B8B 3 B 1 unless the authorization is terminated or revoked sooner.

Positive results: If RNA from SARS CoV 2 is detected it is interpreted as a positive test result for COVID 19. In this case, the patient is infected with SARS CoV 2 and is presumed to be contagious. This test does not rule out co infection involving viral and bacterial infections. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Not Detected: Not detected, negative result indicates the absence of SARS CoV 2 RNA in the patient sample. Negative results do not disqualify SARS CoV 2 infection and should not be used as an only basis of patient treatment decision. Factors like clinical symptoms and patient history should be considered. There is a possibility of a false negative result in some patients. Therefore, a patient can be infected with SARS CoV 2 even after negative result. For SARS CoV 2, a negative test result for a sample collected while a person has symptoms usually means that SARS CoV 2 did not cause the recent illness. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with SARS CoV 2. This test performance characteristics determined by Pinnacle Laboratory.

Inconclusive: An invalid sample result is deemed inconclusive. Inconclusive results indicate the specimen could not accurately be defined as positive or not detected for SARS CoV2 RNA. The specimen should be recollected and resubmitted.