

COVID-19 test

Sample Report

PATIENT Jane Doe

DOB: May 25, 1977

ID: 123456

Report date: March 25, 2020

Sex: Female

ORDERING PHYSICIAN

Dr. Jenny Jones Sample Medical Group 123 Main St. Sample, CA SPECIMEN

Type: Nasopharyngeal Barcode: 223 234234 2343 Collected: Mar 24, 2020 Received: Mar 24, 2020

INCONCLUSIVE RESULT for SARS-CoV-2.

This means that the test results were internally inconsistent and cannot be classified as either positive or negative.

If this patient is experiencing symptoms or is believed to have been exposed to COVID-19, consider collecting a new sample for COVID-19 testing or testing for other respiratory viruses.

DETAILS

TEST	RESULTS
SARS-CoV-2 amplification test	Inconclusive

To learn more about the technical details of this test, visit color.com/covid19-details.

HELPFUL INFORMATION FOR PATIENT

If you have symptoms of illness (such as fever, cough, and/or shortness of breath), you should discuss your symptoms and your test results with your doctor who can decide how to care for you.

The CDC has provided useful information on how to protect yourself and others. The CDC has also provided information on when to seek medical attention. Key points are outlined below for your reference, and you can find this information at https://www.cdc.gov/coronavirus/2019-ncov.

If you are a healthcare professional, first responder, or frontline worker who believes you have been directly exposed while at work, consider consulting your place of work for specific occupational health guidance about whether to stay home or continue working. Recommendations set forth by your employer or the Department of Health may differ from the CDC's guidelines.

CDC: FOR PEOPLE WHO ARE SICK

- The CDC recommends that if you are or might be sick with COVID-19 stay home except to get medical care, and avoid using public transportation if you must leave your home.
- Separate yourself from other people in your home as much as possible.



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CDC: FOR PEOPLE WHO ARE SICK (Continued)

- Wear a facemask if you are around other people. If a facemask is unavailable, you
 may use a bandana or scarf to cover your mouth and nose. If you feel too short of
 breath to wear a mask, alert those around you so that they may wear a mask.
- Cover your coughs & sneezes with a tissue, clean your hands often with soap and water for at least 20 seconds, and avoid sharing household items (for example, utensils, towels, glasses) as much as possible.
- Clean all 'high-touch' surfaces in your home frequently.
- Please work with your provider to determine appropriate next steps, including when to end self-isolation.
- Learn more at https://www.cdc.gov/coronavirus/2019-ncov.

This test is only for use under the Food and Drug Administration's Emergency Use Authorization, but is not FDA cleared or approved. This laboratory developed test has been validated in accordance with CLIA and the FDA's Guidance Document (Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff Document) issued on March 16, 2020. As per the EUA application process, validation data has been submitted to the FDA. FDA's independent review of this validation data is pending. This test is only authorized by FDA for the duration of time the declaration that circumstances exist justifying the authorization of the emergency use of laboratory developed 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.