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Patient: Race Bannon
DOB: 02-05-1960
Gender: Male
Accession: 500001

PCR - Coronavirus Panel

Referring Physician: Doe, John
Client: Demo Account
Collection Date: 03-03-2020 08:22 AM
Report Date: 03-11-2020 05:22 PM

Organism(s) Tested	Result	Flag
SARS-CoV2 coronavirus (COVID-19)	**POSITIVE**	**CRITICAL**

SARS-CoV2 (COVID19) Legend

POSITIVE	Viral RNA detected for the COVID-19 causative agent	CRITICAL	Seek medical attention immediately
NEGATIVE	Viral RNA NOT detected for the COVID-19 causative agent	NORMAL	Consider testing for other respiratory viruses if clinically indicated
INCONCLUSIVE	Viral RNA UNABLE to reliably be determine due to inconsistent amplification	ABNORMAL	Recollect sample if clinically indicated
INVALID	Internal control failure for repeat runs with the given sample	RUN FAILURE	Recollect sample if clinically indicated

Organism(s) Tested	Result	Flag
Human coronavirus (229E)	NEGATIVE	NORMAL
Human coronavirus (HKUI)	NEGATIVE	NORMAL
Human coronavirus (NL63)	NEGATIVE	NORMAL
Human coronavirus (OC43)	NEGATIVE	NORMAL
SARS coronavirus (SARS)	NEGATIVE	NORMAL

Laboratory Notice

Methodology: This test was developed, and its performance characteristics determined by Advanta Analytical Laboratories for analysis of respiratory samples by real-time PCR, utilizing lab developed and validated TaqMan based qPCR assays on the Roche Lightcycler II instrument.

Limitations: These tests have not been cleared or approved by the Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Rare false positive or false negative results may occur. These tests are used for clinical purposes and should not be considered as investigational

Disclaimer: The Coronavirus Diagnostic Panel includes the COVID19 test, a modification of the CDCâ€™s Emergency Use Authorization (EUA) approved assays. The COVID19 (N1,N2 and RP genes) 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 EUA for Coronavirus Disease-2019 during the Public Health Emergency) issued on February 29th, 2020 (updated March 31,2020). The COVID19 test in the panel 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.

FACT SHEET FOR HEALTHCARE PROVIDERS

CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Updated: March 15, 2020

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Centers for Disease Control and Prevention (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Testing is to be conducted on specimens from people who meet Coronavirus Disease 2019 (COVID-19) clinical and/or epidemiological criteria for testing.

What are the symptoms of COVID-19?
Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days but may range 2-14 days.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Public health officials have identified cases of COVID-19 throughout the world, including in the United States. Please check the CDC webpage for the most up to date information.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel can be used to test upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, bronchoalveolar lavage, sputum, lower respiratory tract aspirate, nasopharyngeal wash/aspirate or nasal aspirate).

This test is to be performed only using respiratory specimens collected from individuals who meet COVID-19 clinical and/or epidemiological criteria for testing.

- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered for the detection of the virus that causes COVID-19 in individuals who meet the COVID-19 clinical and/or epidemiological criteria for testing.
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized for use in laboratories in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with COVID-19 as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (*see links provided in "Where can I go for updates and more information" section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and the patient is presumptively infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management

decisions should be made with a healthcare provider and follow current CDC guidelines.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

What is an EUA?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Manufacturer: CDC

CDC Emergency Operations Center (EOC)
1600 Clifton Road
Atlanta, Georgia, USA, 30329
Phone: **CDC EOC (770-488-7100)**

FACT SHEET FOR PATIENTS

CDC - 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Updated: March 15, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the virus that causes Coronavirus Disease 2019 (COVID-19) using the Centers for Disease Control and Prevention's (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. If you have questions or would like to discuss the information provided after you read this Fact Sheet, please talk to your healthcare provider.

- **For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:**
- **https://www.cdc.gov/COVID19**

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. COVID-19 can cause mild to severe respiratory illness, was first idenitifed in Wuhan, China, and has now spread globally, including the United States. There is limited information available about the spectrum of illness associated with COVID-19 but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What is the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Your samples will help find out if you have COVID-19.

What are the known and potential risks and benefits of the test?
Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

Where can I go for updates and more information? The most up-to-date information on 2019-nCoV is available at the CDC General webpage: **https://www.cdc.gov/COVID19**. In addition, please also contact your healthcare provider with any questions/concerns.

What does it mean if I have a negative test result?
A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with your symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

Where can I go for updates and more information? The most up-to-date information on 2019-nCoV is available at the CDC General webpage: **https://www.cdc.gov/COVID19**. In addition, please also contact your healthcare provider with any questions/concerns.