STAGE ZERO LIFE SCIENCES

StageZero COVID-19 Antibody Testing
LABORATORY RESULTS

Patient

Name:	Phone #:	Patient ID #:
John Partick Doe		
Fasting Status:	Gender	Birthdate: / Age:
		11/06/1966
Height: / Weight:	BMI:	Prev. BMI:

Specimen

Collection Time:	Specimen ID:
09:15	A123456789
Collection Date:	Report Type:
2020-10-08	F
Received Date:	Report Date:

Provider

Requesting Provider
ZALZALA, SAJAD, MD
Root Cause Medical
835 Mason St, STE 250
Dearborn, MI 48124

Client ID:
02864

Test Results

Beckman Access SARS-CoV-2 IgM Test		Beckman Access SARS-CoV-2 IgG Test	
IgM	**Positive/Reactive for SARS-CoV-2 IgM antibodies**	**IgG**	**Negative/Non-Reactive for SARS-CoV-2 IgG antibodies**
Specimen Type	Serum		

Test Description

Beckman Access SARS-CoV-2 IgM Test
Developed by Beckman Coulter, the Access SARS-CoV-2 IgM assay is a paramagnetic particle, chemiluminescent immunoassay intended for the qualitative detection of IgM antibodies to SARS-CoV-2 in serum, serum separator tubes and plasma from individuals with current or prior COVID-19 infection.
The Access SARS-CoV-2 IgM assay is intended for use as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.
Results are for the detection of SARS CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Patients may have detectable virus present for several weeks following seroconversion. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Beckman Access SARS-CoV-2 IgG Test
Developed by Beckman Coulter, the Access SARS-CoV-2 IgG assay is a paramagnetic particle, chemiluminescent immunoassay intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in serum, serum separator tubes and plasma from individuals with current or prior COVID-19 infection.
The Access SARS-CoV-2 IgG assay is intended for use as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.
Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Patients may have detectable virus present for several weeks following seroconversion. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Clinical Recommendations

Please discuss these results with your physician.

Your patient tested positive for IgM antibodies and/or tested positive for IgG antibodies, which detects anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG antibodies. According to the FDA, the result of a single antibody test is not likely to be sufficiently accurate to make an informed decision regarding whether or not an individual has had a prior infection or truly has antibodies to the virus. A second test, typically one assessing for the presence of antibodies to a different viral protein, generally would be needed to increase the accuracy of the overall testing results.

Disclaimers

Beckman Access SARS-CoV-2 IgM Test
This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the presence of IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. Â§ 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Beckman Access SARS-CoV-2 IgG Test
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Specimen Type	Serum		

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Clinical Recommendations

Please discuss these results with your physician.

An antibody test may not be able to show if you have a current infection, because it can take 1-3 weeks after infection to make antibodies. Please discuss these results with your physician or other healthcare professional.

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FACT SHEET FOR RECIPIENTS

Beckman Coulter, Inc.
ACCESS SARS-CoV-2 IgM

October 8, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) is being tested or was tested for antibodies to the virus that causes Coronavirus Disease 2019 (COVID-19) using the **ACCESS SARS-CoV-2 IgM.**

You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.

This Fact Sheet contains information to help you understand the risks and benefits of using this test to evaluate your adaptive immune response to SARS-CoV-2, the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider. You have the option to refuse use of this test. However, your doctor may be recommending this test because they believe it could help with your care.

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 which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of.

symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

How are people tested for COVID-19?
Two kinds of tests are currently available for COVID-19: diagnostic tests and antibody tests.

- A diagnostic test tells you if you have a current infection.
- An antibody test tells you if you had a previous infection

What is the ACCESS SARS-CoV-2 IgM?.
This test is an antibody test. It will help assess if you have antibodies to the virus that causes COVID-19. An antibody test may not be able to show if you have a current infection, because it can take 1-3 weeks after infection to make antibodies.

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.

What does it mean if I have a positive test result?
If you have a positive test result, it is possible that you have or previously had COVID-19 and that you have developed an antibody response to the virus. Your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, your symptoms, possible exposures, and geographic location of places

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19
  In addition, please also contact your healthcare provider with any questions/concerns.

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you have recently traveled. There is also a chance that this test can give a positive result that is wrong (a false positive result). Even a high-performing antibody test when used in a population without many cases of COVID-19 infection may produce as many or more false results as true results because the likelihood of finding someone who has been infected is very small.

Your healthcare provider will work with you to determine the likelihood of false result.

It is not known how long antibodies to SARS-CoV-2 will remain present in the body after infection. It is not known whether having antibodies to SARS-CoV-2 will protect you from getting infected again or help reduce the severity or duration of a future COVID-19 infection. Regardless of your test result, you should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.

What does it mean if I have a negative test result?
A negative test result means that the antibodies to the virus that causes COVID-19 were not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. Additionally, a negative result may occur if you are tested early in your illness and your body hasn't had time to produce antibodies to infection. 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 all other aspects of your medical history (such as 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 the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?
There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19
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FACT SHEET FOR RECIPIENTS

Beckman Coulter, Inc.
Access SARS-CoV-2 IgG **June 26, 2020**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) is being tested or was tested for antibodies to the virus that causes Coronavirus Disease 2019 (COVID-19) using Access SARS-CoV-2 IgG.

This Fact Sheet contains information to help you understand the risks and benefits of using this test to evaluate your adaptive immune response to SARS-CoV-2, the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on COVID19 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. The virus, which can cause mild to severe respiratory illness, has spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

How are people tested for COVID-19?
Two kinds of tests are currently available for COVID-19: diagnostic tests and antibody tests.

- A diagnostic test tells you if you have a current infection.
- An antibody test tells you if you had a previous infection.

What is this test?
This test is an antibody test. It will help assess if you have antibodies to the virus that causes COVID-19. An antibody test may not be able to show if you have a current infection, because it can take 1-3 weeks after infection to make antibodies.

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

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

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.

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If you have a positive test result, it is possible that you have or previously had COVID-19 and that you have developed an antibody response to the virus. Your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, your symptoms, possible exposures, and geographic location of places you have recently traveled. There is also a chance that this test can give a positive result that is wrong (a false positive result).

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UNDERSTANDING YOUR RESULTS

COVID-19 PCR Test (Nasal Swab & Saliva)

PCR tests can detect COVID-19 nucleic acid from your nasal swab or sliva specimen to help diagnose an active COVID-19 infection.

COVID-19 Antibody Test (Blood Test)

Antibodies, are proteins that are produced by the immune system to attack viruses. This test looks for two types of antibodies from your blood sample.

IgM antibodies indicates recent infection
IgG antibodies gradually appear and increase in the later stage of infection

Interpreting Your Results

SARS-CoV-2 is the virus that causes COVID-19

Test	Positive Result	Negative Result
PCR Test	**Indicates Active Infection** If the PCR test is positive, self quarantine & consult your physician. 	**SARS-CoV-2 RNA not Detected** If the PCR test is negative, you most likely did not have the virus at the time you were tested. Consider testing for antibodies to see if you had a past infection that has cleared.
IgM Antibodies (blood test)	**IgM Antibodies to SARS-CoV-2 Were Detected** Consider a PCR test to ensure you are not infectious.	**SARS-CoV-2 IgM Antibodies not Detected** No further testing is required.
IgG Antibodies (blood test)	**IgG Antibodies to SARS-CoV-2 Were Detected** You're potentially been exposed to the virus and produced antibodies, no need for further testing.	**SARS-CoV-2 IgG Antibodies not Detected** No further testing is required.

Fequently Asked Questions

What does Positive MS2 means on my PCR test Report?

- MS2 is used by the lab to confirm that your test was done properly. A positive MS2 result and a negative SARS-CoV-2 test result supports that your SARS-CoV-2 test is negative.

How do I read My Antibody Test Report?

- If your IgG and IgM were negative, antibodies to COVID-19 SARS-CoV-2 are not present.
- If your IgM antibody test is positive, you have had a recent infection. Consider getting a PCR test as you still may be infectious.
- If your IgG antibody test is positive, you have had a past infection.

Test Results			
Beckman Access SARS-CoV-2 IgM Test		**Beckman Access SARS-CoV-2 IgG Test**	
IgM	**Negative/Non-Reactive for SARS-CoV-2 IgM antibodies**	**IgG**	**Negative/Non-Reactive for SARS-CoV-2 IgG antibodies**
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