

FACT SHEET FOR PATIENTS

Access IL-6 – Beckman Coulter, Inc.

October 1, 2020

Coronavirus
Disease
2019

You are being given this Fact Sheet because you tested positive for SARS-CoV-2 and your healthcare provider is checking the inflammatory response caused by the infection. Therefore, your sample was tested for elevated levels of interleukin-6 (IL-6) using the Access IL-6 test. This assay measures the IL-6 level in your blood.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for identifying a severe inflammatory response in COVID-19, which may increase your risk for possible complications. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

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- **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>
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What is a “severe inflammatory response”?

Coronavirus Disease 2019 (COVID-19) is caused by infection with the SARS-CoV-2 virus. Some patients develop a severe inflammatory response, which is a sign of an immune reaction that may cause damage to a number of organs including your lungs. Such immune damage to the body may sometimes be called “cytokine release syndrome” (CRS) or “cytokine storm”. Inflammation is caused by different cytokines, and interleukin-6 (IL-6) is one of those cytokines.

What is interleukin-6, commonly known as IL-6?

IL-6 is a type of protein known as a cytokine, produced by cells of the immune system in response to an infection. IL-6 acts like a messenger which tells other immune cells to fight the infection. Some amount of IL-6 will be made to help prepare your body to fight an infection. When your body makes too much IL-6, it can cause a severe inflammatory response.

What does an IL-6 test result mean?

IL-6 test results measure the amount of IL-6 circulating in the blood, and are used as one sign of systemic inflammation. A normal level of IL-6 may represent people who do not have an infection or inflammation. A low level of IL-6 may be expected for most patients with a less severe inflammatory response. A high level of IL-6 may be one sign that the inflammation is severe and could lead to complications.

Why was my sample tested?

You were tested for IL-6 because you have already confirmed positive for SARS-CoV-2 and your healthcare provider would like to check your inflammatory response to the infection by the virus, based on your signs and symptoms (for example: fever, cough, difficulty breathing, low blood pressure). With this test, your healthcare provider is evaluating if you may need additional supportive measures (such as oxygen, intensive care therapy, mechanical ventilation).

What are the known and potential risks and benefits of the test?

Potential risks may include:

- Possible discomfort or other complications that can happen during a routine blood draw.
- The IL-6 assay is run in a hospital laboratory on automatic analyzers. As with any other test, there could be potential incorrect test results (see below for more information); that is why the test result is always considered in the context of the clinical evaluation done by your healthcare provider.
 - If you receive false positive results (the test reports your IL-6 levels being higher than they actually are), you may be evaluated for additional, unnecessary supportive respiratory therapy or treatment.
 - If you receive false negative results (the test reports your IL-6 levels being lower than they actually are), you may be evaluated for additional therapy, or your supportive treatment may be delayed.

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- **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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Potential benefits may 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 to quickly identify if you need additional supportive respiratory measures while you are in the hospital.

What does it mean if I have elevated IL-6 levels?

Depending on the result of the test, it may be more likely that you have a severe inflammatory response and that you may need supportive respiratory therapy and/or other supportive care to fight COVID-19. As for any test, there is also the small chance that this test can give a falsely high result (false positive), which is why the assay is used with other clinical findings. Your healthcare provider will work with you to determine how to best care for you, based on all test results along with other evaluation and factors of your medical history.

What does it mean if I have a low IL-6 level?

Low IL-6 levels indicate that it is less likely you might develop a severe inflammatory response. As is the case with any other test, it is possible for this test to give a falsely low result (false negative), which is why the assay is used with other clinical findings. Your healthcare provider will work with you to determine how to best care for you based on all test results along with other evaluation and factors of your medical history.

You should discuss any questions or concerns with 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.

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the 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 Services' (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the COVID-19 public health emergency. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying the emergency of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?

There are no approved available alternative tests. Any EUAs FDA issues for such tests can be found at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

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