

FACT SHEET FOR HEALTHCARE PROVIDERS

Access IL-6 – Beckman Coulter, Inc.

October 1, 2020

Coronavirus
Disease
2019

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Access IL-6.

The Access IL-6 is authorized for use in human serum and plasma specimens collected from patients with confirmed Coronavirus Disease-2019 (COVID-19) to assist in identifying severe inflammatory response to aid in determining the risk of intubation with mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Access IL-6 – Beckman Coulter, Inc.

What are the severe clinical manifestations of COVID-19 associated with IL-6?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of severe inflammatory response, sometimes referred to as “cytokine release syndrome” (CRS) or “cytokine storm”. Severe symptoms may occur in <20% of COVID-19 patients. Symptoms of severe inflammatory response in COVID-19 may include, but are not limited to: fever, hypotension, dyspnea, organ dysfunction, and organ failure. Among the different cytokines that may contribute to systemic inflammation, measurement of IL-6 can be indicative of the severity of such inflammation because IL-6 is known to have a central role in inflammation.

What do I need to know about IL-6 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 Access IL-6 can be used to test serum or plasma.
- The Access IL-6 can be ordered by a healthcare provider to assist in identifying severe inflammatory response in patients with confirmed COVID-19 illness to aid in determining the risk of intubation with

This test is to be performed only using serum or plasma specimens collected from individuals confirmed positive for SARS-CoV-2.

mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing.

- The Access IL-6 is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or 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 having 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 Access IL-6 measures elevated IL-6 levels?

Measurement of IL-6 in COVID-19 confirmed patients is used to identify patients with severe inflammatory response who may be at risk of intubation with mechanical ventilation. Healthcare professionals may use the IL-6 measurement together with other laboratory and clinical findings. Elevated IL-6 levels may be an important indicator of severe inflammatory response.

In an external study using Access IL-6 on samples from 151 apparently healthy individuals, the upper limit of the reference range for IL-6 was 6.4 pg/mL (95th percentile).

Individual IL-6 levels need to be considered in combination with other clinical findings to mitigate the

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possible risks of false positive or false negative IL-6 results.

However, in the event of a false positive result, risks to patients could include additional, unnecessary intensive care admission, intubation with mechanical ventilation, and other unnecessary supportive therapy.

What does it mean if the Access IL-6 measures low IL-6 levels?

Low IL-6 levels indicate that it is less likely that the patient suffers from a cytokine release syndrome and the risk for respiratory support is reduced. However, low levels of IL-6 do not preclude disease progression and future development of severe inflammatory response.

A false negative result may occur if the test reports lower values than actual levels of IL-6 that are in the sample. When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's clinical presentation and the presence of clinical signs and symptoms consistent with severe inflammatory response.

Risks to a patient of a false negative result include: delayed or lack of supportive respiratory treatment, or other unintended adverse events.

Is the Access IL-6 FDA-approved or cleared?

No. The Access IL-6 is not FDA-approved or cleared. The FDA has authorized this use of the Access IL-6 as an emergency access mechanism called an Emergency Use Authorization (EUA).

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#2019-ncov>.

What is an EUA?

The United States (U.S.) 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 Services' (HHS's) declaration that circumstances exist to

justify the emergency use of in vitro diagnostics (IVDs) for the COVID-19 public health emergency.

An IVD made available under an EUA has not undergone the same level 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 the benefits outweigh the potential risks of this IVD in the setting of 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).

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Where can I go for updates and more information?

CDC webpages:

General: <https://www.cdc.gov/COVID19>

Symptoms:

<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

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 Information

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