SIEMENS Healthineers

Press

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Siemens Healthineers IL-6 Test Receives Emergency Use Authorization to Help Assess Dysregulated Inflammation

- **FDA granted Emergency Use Authorization (EUA) for the ADVIA Centaur Interleukin-6 (IL-6) test in the U.S.**
- **IL-6 is a key biomarker to assess dysregulated inflammation due to severe immune responses in patients.**
- **IL-6 is an important predictive tool for hospitalized COVID-19 patients to aid in determining the risk of intubation with mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing.**

TARRYTOWN, N.Y., January 7, 2021 - The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for Siemens Healthineers' laboratory-based IL-6 assay[1] to measure the presence of Interleukin-6 (IL-6) in human serum or plasma. IL-6 is an indicator of potential severe inflammatory response in patients with confirmed SARS-CoV-2 infection. This simple blood test may be used to assist in identifying a severe inflammatory immune response in patients confirmed to have COVID-19, to aid in determining the risk of needing intubation with mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing. Emergency use of this test is limited to authorized laboratories. Approximately five percent of COVID-19 patients develop a systemic dysregulated cytokine response known as cytokine storm.[2]

IL-6 is a type of cytokine (intercellular messenger molecule) that plays a central role in the immune response to infection and can evoke many different actions when it is released. It is substantially elevated in patients presenting with cytokine storm. Cytokine release is a normal part of the body's immune response when fighting off a virus. However, a severe immune response can cause overproduction of cytokines leading to potential wide-scale cellular and organ damage, and ultimately death. IL-6 levels were found to be higher in COVID-19 patients with severe disease.[3-6]

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"The Siemens Healthineers' IL-6 assay is an important tool for the care of hospitalized COVID-19 patients. This assay expands Siemens Healthineers' already comprehensive portfolio of tests available to aid in fighting the COVID-19 pandemic," said Deepak Nath, PhD, President of Laboratory Diagnostics, Siemens Healthineers.

Siemens Healthineers' IL-6 assay is currently available across the U.S. on the ADVIA Centaur® Immunoassay Systems, the largest installed base of instruments in the U.S., with a time-to-result of 18 minutes. The IL-6 assay is also available outside the U.S.[7] with the CE mark on the ADVIA Centaur Systems, Atellica® IM Analyzer and IMMULITE Systems.

Siemens Healthineers has distinguished itself as a provider of quality assays to aid the COVID-19 pandemic. In addition to antibody, antigen, and molecular SARS-CoV-2 tests[1,7], Siemens Healthineers offers a broad diagnostics portfolio to aid in the prognosis, treatment and follow-up of COVID-19 patients. The company's broad and differentiated menu includes hematology, coagulation, cardiac, respiratory, inflammation and infectious disease panels. Blood gas and imaging solutions from Siemens Healthineers deliver actionable results that aid clinicians in caring for COVID-19 patients.

[1] These tests have not been FDA cleared or approved. They have been authorized by FDA under an EUA for use by authorized laboratories. The molecular ("PCR") test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The serology ("antibody") test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. The IL-6 test has been authorized only to assist in identifying severe inflammatory response, when used as an aid in determining the risk of intubation with mechanical ventilation in confirmed COVID-19 patients. These tests are 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. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Product availability may vary from country to country and is subject to varying regulatory requirements.

[2] Siddiqi HK, et al. J Heart Lung Transplant. 2020. https://doi.org/10.1016/j.healun.2020.03.012

[3] Zhou Y, et al. National Science Review 2020. DOI: 10.1093/nor/nwaa041

[4] Gao Y, et al. J Med Virol 2020. https://doi.org/10.1002/jmv.25770

[5] Gong J, et al. Lancet 2020. DOI: 10.1101/2020.02.25.20025643

[6] Del Valle, D.M., et al. Nat Med 2020. https://doi.org/10.1038/s41591-020-1051-9

[7] Assay availability varies by country and depends on local regulatory requirements.

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Siemens Healthineers AG (listed in Frankfurt, Germany: SHL) is shaping the future of Healthcare. As a leading medical technology company headquartered in Erlangen, Germany, Siemens Healthineers enables healthcare providers worldwide through its regional companies to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, improving the patient experience, and digitalizing healthcare. Siemens Healthineers is continuously developing its product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company's foundation in in-vitro diagnostics, image-guided therapy, and in-vivo diagnostics. Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers' ability to provide high-quality, efficient care to patients. In fiscal 2020, which ended on September 30, 2020, Siemens Healthineers, which has approximately 54,000 employees worldwide, generated revenue of €14.5 billion and adjusted EBIT of €2.2 billion. Further information is available at www.siemens-healthineers.com.