This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) assay.

The ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) assay is authorized for use using anterior nasal swab specimens in Siemens Healthineers Sample Inactivation Media (SIM) collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Siemens Healthcare Diagnostics Inc. – ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag).

What are the symptoms of COVID-19?
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in “Where can I go for updates and more information?” section.

Public health officials have identified cases of COVID-19 throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in “Where can I go for updates and more information?” section at the end of this document) or your local jurisdictions website 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 ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) assay can be used to test anterior nasal swab specimens collected in Siemens Healthineers Sample Inactivation Media.
• The ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) assay should be ordered for the detection of COVID-19 antigen in individuals who are suspected of COVID-19 by their healthcare provider and who are within the first seven days of onset of symptoms.
• The ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) assay test is 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 high or moderate complexity tests.
• Please refer to the ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) assay instructions for use for additional information.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC’s website (see links provided in “Where can I go for updates and more information?” section).

When collecting and handling specimens from individuals suspected of being infected with the virus that causes COVID-19, appropriate personal protective equipment should be used 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

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088
Therefore, negative results are presumptive and likely to be negative compared to a RT-PCR assay. The amount of antigen in a sample known to be less sensitive than molecular tests that detect viral nucleic acids. The limit of detection. However, a negative result does not rule out COVID-19 infection to make an accurate diagnosis via the ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) assay.

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 or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative test result 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.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC’s Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings (Interim Guidance) (see links provided in “Where can I go for updates and more information?” section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January 2022 and February 2022. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

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FACT SHEET FOR HEALTHCARE PROVIDERS
Siemens Healthcare Diagnostics Inc.
ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag)

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 the virus that causes 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 diagnosing recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to 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).

What are the approved available alternatives?
There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. 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?

CDC webpages:
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

FDA webpages:
General: www.fda.gov/novelcoronavirus

Siemens Healthineers Diagnostics Inc.:
511 Benedict Avenue
Tarrytown NY 10591

Website: http://www.siemens-healthineers.com/en-us/