FACT SHEET FOR HEALTHCARE PROFESSIONALS

Cue Health Inc.

Cue COVID-19 Test for Home and Over The Counter (OTC) Use

March 5, 2021

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Cue COVID-19 Test for Home and Over The Counter (OTC) Use.

The Cue COVID-19 Test for Home and Over The Counter (OTC) Use is a molecular diagnostic test for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal (nasal) swab specimens collected with the Cue Sample Wand. The Cue COVID-19 Test for Home and Over The Counter (OTC) Use is intended for use in adults (self-swabbing) or children ≥2 years of age (swabbed by an adult) with or without symptoms or other epidemiological reasons to suspect COVID-19. It is authorized for non-prescription home use.

All individuals whose specimens are tested with this test will have access to the Fact Sheet for Individuals: Cue Health Inc.- Cue COVID-19 Test for Home and Over The Counter (OTC) Use.

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 infection 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 Cue COVID-19 Test for Home and Over The Counter (OTC) Use can be used to test anterior nasal (nasal) swab samples collected with the Cue Sample Wand either by adults (self-swabbing) or children ≥2 years of age (swabbed by an adult).
- The Cue COVID-19 Test for Home and Over The Counter (OTC) Use can be used for the detection of COVID-19 in individuals with or without symptoms or other epidemiological reasons to suspect COVID-19.
- The Cue COVID-19 Test for Home and Over The Counter (OTC) Use is authorized for non-prescription home use.

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 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.

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What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and therefore the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The Cue COVID-19 Test for Home and Over The Counter (OTC) Use has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result, even when used in locations where the prevalence is below 5%. In the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via

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