FACT SHEET FOR HEALTHCARE PROFESSIONALS

Ellume Limited

Ellume COVID-19 Home Test

December 15, 2020

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Ellume COVID-19 Home Test.

The Ellume COVID-19 Home Test is a rapid, lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from mid-turbinate nasal swabs that are self-collected by an individual aged 16 years or older, or are collected by an adult from an individual 2 years of age and older. This test is intended for use in individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection. The Ellume COVID-19 Home Test is authorized for non-prescription home use.

All individuals whose specimens are tested with this assay will have received the Ellume COVID-19 Home Test Product Information Leaflet.

What are the symptoms of COVID-19?

Many patients with COVID-19 develop 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) or your local jurisdiction's website for the most up to date information.

This test is to be performed only using mid-turbinate nasal swab specimens self-collected by an individual aged 16 years or older, or collected by an adult from any individual (≥2 years old). This test is authorized for use in these individuals regardless of whether they have symptoms or other epidemiological reasons to suspect a COVID-19 infection.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare professionals 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 Ellume COVID-19 Home Test can be used to test directly collected mid-turbinate Nasal Swab specimens (using the Nasal Swabs provided with the Ellume COVID-19 Home Test) using a dual nares collection (Swab inserted in both nares).
- The Ellume COVID-19 Home Test can be used for the detection of COVID-19 in individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19 infection.
- The Ellume COVID-19 Home Test is authorized for non-prescription home use.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions 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 links provided in "Where can I go for updates and more information?" section).

FACT SHEET FOR HEALTHCARE PROFESSIONALS

Ellume Limited

Ellume COVID-19 Home Test

December 15, 2020

Coronavirus Disease 2019 (COVID-19)

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 antigens from SARS-CoV-2 were detected, and therefore the patient is very likely infected with the virus and presumed to be contagious. 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 professional and follow current CDC guidelines.

The positive predictive value of diagnostic tests (PPV), including antigen assays, varies with the prevalence of disease. PPV is the percent of positive test results that are true positives (i.e., test results are positive when the infection is present). As disease prevalence decreases, the percent of test results that are false positives (i.e., test results are positive in the absence of infection) increases. When prevalence is very low, false positive results are more likely than true positive results. For example, the Ellume COVID-19 Home test would have a PPV of 63% when disease prevalence is relatively high at 5%. This means that 37 out of 100 positive results would be false positives. The Ellume COVID-19 Home test would have a PPV of 25% when disease prevalence is very low at 1%. This means that 75 out of 100 positive results would be false positives. It is difficult to determine disease prevalence in asymptomatic individuals and false positive results may be more likely in these patients.

In asymptomatic individuals, positive results from the Ellume COVID-19 Home Test should be considered presumptive and may need to be confirmed with a molecular SARS-CoV-2 assay, particularly in individuals without a known SARS-CoV-2 exposure or who are in areas known to have low prevalence of SARS-CoV-2 infections. For low-risk individuals, the CDC recommends that persons who receive a positive antigen test should isolate until they can be confirmed by an RT-PCR test. For further recommendations regarding antigen tests, please see the link provided in "Where can I go for updates and more information?" section.

The Ellume COVID-19 Home Test has been designed to minimize the likelihood of false positive test results. 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 COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true cause of the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

The Ellume COVID-19 Home Test Application automatically reports test results according to the reporting guidelines of appropriate public health authorities.

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 antigens were 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, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. As days post-symptom onset increase, antigen test results may be more likely to be negative compared to a molecular SARS-CoV-2 assay. Therefore, negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. It is possible for a person to test too early or too late during COVID-19 infection to make an accurate diagnosis using the Ellume COVID-19 Home Test.

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

FACT SHEET FOR HEALTHCARE PROFESSIONALS

Ellume Limited
Ellume COVID-19 Home Test

December 15, 2020

Coronavirus Disease 2019 (COVID-19)

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 professionals in consultation with public health authorities.

The Ellume COVID-19 Home test is more likely to return a false negative result for asymptomatic individuals than symptomatic patients. Negative results, particularly in asymptomatic individuals, should be considered to be presumptive and additional testing with a highly sensitive molecular SARS-CoV-2 test may be necessary to help rule out infection.

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).

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 COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless it is terminated or revoked sooner (after which the test may no longer be used).

What are the approved available alternatives?

There are no approved, available, alternative tests. The FDA has issued EUAs for other antigen tests that can be found at:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov

FACT SHEET FOR HEALTHCARE PROFESSIONALS
Ellume Limited
Ellume COVID-19 Home Test

December 15, 2020

Coronavirus Disease 2019 (COVID-19)

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

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

Discontinuation of Isolation:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/

Influenza: https://www.cdc.gov/flu/index.htm

Antigen Tests: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs: (includes links to patient fact sheet and manufacturer's instructions)
https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov

Ellume Limited

57 Didsbury St, East Brisbane, QLD 4169, Australia

Customer Support phone number: 1-888-885-6121
www.ellumehealth.com