FACT SHEET FOR HEALTHCARE PROVIDERS

SARS-CoV-2 CoviLamp Fluorometric Diagnostic Assay - CardiAI, Inc.

November 23, 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 CardiAI SARS-CoV-2 CoviLamp Fluorometric Diagnostic Assay.

The CardiAI SARS-CoV-2 CoviLamp Fluorometric Diagnostic Assay is validated for use with nasal swab specimens collected from individuals suspected of COVID-19 by their health care provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: CardiAI SARS-CoV-2 CoviLamp Fluorometric Diagnostic Assay.

What are the symptoms of COVID-19?
Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage 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 CardiAI SARS-CoV-2 CoviLamp Fluorometric Diagnostic Assay can be used to test nasal swab specimens.

This test is to be performed only using specimens collected from individuals suspected of COVID-19.

- The CardiAI SARS-CoV-2 CoviLamp Fluorometric Diagnostic Assay should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19.
- The CardiAI SARS-CoV-2 CoviLamp Fluorometric Diagnostic Assay is only validated for use at a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform 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 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 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 in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines. The CardiAI SARS-CoV-2 CoviLamp Fluorometric Diagnostic Assay has been designed to minimize the likelihood of false positive test results. However, in the event of a false

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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, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their 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 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. A negative result does not exclude the possibility of COVID-19.

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 with an alternative method should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative 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.

What is an EUA?
The United States FDA has made COVID-19 tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). Per the U.S. President's direction in Executive Orders 13771 (Executive Order on Reducing Regulation and Controlling Regulatory Costs) and 13924 (Executive Order on Regulatory Relief to Support Economic Recovery), the Health and Human Service (HHS) Department has determined that the Food and Drug Administration ("FDA") will not require premarket review of laboratory developed tests ("LDT") absent notice-and-comment rulemaking. LDTs in their laboratories without FDA premarket review or authorization may offer testing with the understanding that the test will not be eligible for PREP Act coverage absent approval, clearance or authorization and would remain subject to regulation by the Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, and its implementing regulations at 42 C.F.R. pt. 493. The CardiAI SARS-CoV-2 CoviLamp Fluorometric Diagnostic Assay is a LDT offered by CardiAI, Inc. and performed only at a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests.

Where can I go for updates and more information?
CDC webpages:
General: https://www.cdc.gov/COVID19
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

CardiAI, Inc.:

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/medw atch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

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