FACT SHEET FOR HEALTHCARE PROVIDERS

Alimetrix® SARS-CoV-2 RT-PCR Assay

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of a Molecular Laboratory Developed Test (LDT) for the detection and identification of SARS-CoV-2 RNA usually present in upper respiratory tract specimens of infected patients during the acute phase of infection. The **Alimetrix® SARS-CoV-2 RT-PCR Assay** has been issued an Emergency Use Authorization (EUA) by the FDA. The Alimetrix test is authorized for use on on upper respiratory tract and BAL specimens specimens collected from individuals suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this authorized assay will receive the Fact Sheet for Patients

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, difficulty breathing). The broad, diverse, clinical presentation of CoVID-19 includes respiratory symptoms, hypercoagulability disorders such as stroke, coronary thrombosis, deep vein and pulmonary thrombosis, extreme inflammation attacking multiple organ systems, and neurological complications ranging from headache, dizziness, loss of taste and/or smell, seizures, confusion, and lapses in memory. In addition gastrointestinal complaints of nausea and diarrhea may be present. Multisystem inflammatory syndrome in children has also been associated with COVID-19. Limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. 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 Alimetrix® SARS-CoV-2 Assay

- Is to be performed on upper respiratory tract specimens (nasopharyngeal (NP) swab, oropharyngeal (OP) swab, nasal swab, mid turbinate nasal swab, nasopharyngeal washes/aspirates or nasal aspirates) and BAL specimens from individuals who meet clinical and/or epidemiological criteria for COVID-19 testing.
- Should be ordered for the detection of nucleic acid from SARS-CoV-2 in individuals suspected of COVID-19 by their healthcare provider.
- Testing is limited to Alimetrix Laboratories, which is a CAP accredited, Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, certified high-complexity laboratory.
- 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).

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for COVID-19

- Is indicative of the presence of SARS-CoV-2 RNA.
- Positivity is a result of detecting viral RNA, which may or may not be present in the context of live virus.
- Clinical correlation with patient history is required to determine whether there is active infection.
- Positive results do not exclude bacterial infection or co-infection with other viruses.
- Positive results may be related to CoVID in the setting of comorbid conditions.
- Laboratories within the United States and its territories are required to report all positive results to public health authorities in compliance with local laws.

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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The **Alimetrix® SARS-CoV-2 RT-PCR Assay** has been designed to minimize the likelihood of false positive test results. However, 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, 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 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 (U.S.) 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 the detection of 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).

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: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

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