FACT SHEET FOR HEALTHCARE PROVIDERS

Mayo Clinic SARS-CoV-2 Molecular Detection Assay

PROVIDERS

COVID-19 (Coronavirus)

This fact sheet provides information on the significant and known potential risks and benefits of the emergency use of the Mayo Clinic SARS-CoV-2 Molecular Detection Assay.

The Mayo Clinic SARS-CoV-2 Molecular Detection Assay is authorized for use on respiratory specimens from individuals meeting the CDC SARS-CoV-2 clinical and epidemiological criteria.

All patients tested using this assay will have access to the FACT SHEET FOR PATIENTS for the Mayo Clinic SARS-CoV-2 Molecular Detection Assay via mayocliniclabs.com.

Symptoms of COVID-19:
The majority of patients with confirmed COVID-19 infection have fever and/or symptoms of acute respiratory illness such as coughing and difficulty breathing. Due to the limited information available at this time, characterization of the full spectrum of clinical illness associated with COVID-19 is difficult. Based on what is known, signs and symptoms of the virus may appear anytime from 2 to 14 days following exposure, with a median incubation period of approximately 4 days.

COVID-19 infections have been identified in all 50 states within the United States, which poses a significant national public health risk. Internationally, 115 locations have confirmed cases of COVID-19. Globally, there have been reports of human-to-human transmission through close contact with individuals known to be infected with the SARS-CoV-2 virus. The CDC website has the most current information available.

COVID-19 Testing Indications:
COVID-19 case definitions and infection control information for healthcare providers are available on the CDC website titled “Information for Healthcare Professionals.”

This test should only be performed on specimens collected from individuals meeting the clinical or epidemiological criteria for COVID-19 testing.

Mayo Clinic SARS-Cov-2 Molecular Detection Assay:

- Can be used to test nasopharyngeal, nares/nasal, and oropharyngeal swabs, as well as bronchial lavage, tracheal aspirate/secretion, and sputum specimens.
- Should be ordered to detect COVID-19 in individuals meeting the CDC SARS-CoV-2 clinical and epidemiological criteria.
- Authorized for use at Mayo Clinic laboratories with CLIA certification for high-complexity testing.

Collect specimens using appropriate infection control precautions following CDC Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings.

Use appropriate personal protective equipment when collecting and handling patient specimens that are suspected of having COVID-19 as defined in CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19. An added resource is available for reference in the CDC Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from Persons Under Investigation (PUIs) for COVID-19.

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SARS-CoV-2 Positive for Virus That Causes COVID-19

A positive result indicates that the SARS-Cov-2 virus was detected, and the patient tested is presumptively infected and contagious for COVID-19. All laboratory results should be correlated and reviewed with the patient's clinical findings and epidemiologic data to make a diagnosis and manage patient treatment. There are current CDC guidelines available for patient management.

The Mayo Clinic SARS-Cov-2 Molecular Detection Assay was developed to minimize false-positive results. Risks to patients for false-positive results could include unnecessary patient isolation, additional symptom monitoring of patient household and close contacts, isolation from family friends and exposure to potential COVID-19 patients, limited ability to work, delay in diagnosis for real infection-causing symptoms, inappropriate treatment (e.g., prescription, therapy), or other adverse events.

Mayo Clinic will follow the requirements for confirmatory tests and reporting to appropriate public health authorities.

SARS-CoV-2 Negative for Virus That Causes COVID-19

A negative result indicates that SARS-Cov-2 virus was not detected in the specimen above the lower limit of detection. It is important to remember that negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

When SARS-Cov-2 test results are negative, the possibility for a false-negative should be considered along with the patient's recent exposures and clinical signs and symptoms consistent with COVID-19.

This possibility should be strongly considered when the patient's recent exposures and clinical presentation are indicative that COVID-19 is likely and other diagnostic tests for other respiratory illness are negative.

When providers still suspect COVID-19 based on patient's exposure history and clinical picture, retesting should be considered in consultation with public health experts/ authorities.

Risks to patients for false-negative results could include delay in or lack of supportive treatment, missed symptom monitoring of infected patient and household and close contacts resulting in increased risk of COVID-19 spreading within the community, or other adverse events.

Definition of EUA

The United States FDA is making this test available to the public under an emergency access mechanism defined as an Emergency Use Authorization (EUA). The Secretary of Health and Human Services (HHS) supports the EUA process and has declared that circumstances exist to justify emergency use of lab developed tests (LDTs) for detection of the virus that causes COVID-19.

An LDT made available under an EUA has not undergone the same type of review as an FDA approved or cleared test. The FDA may issue an EUA when certain criteria exist, including circumstances when there are no appropriate, approved alternatives, and based on scientific evidence available it is reasonable to assume that this LDT will be effective in detecting the SARS-CoV-2 virus that causes COVID-19.

The EUA is in effect for the duration of the FDA COVID-19 declaration which justifies emergency use LDTs unless terminated or revoked by the FDA. Should it be terminated or revoked, this test would no longer be used to detect SARS-CoV-2 virus.

Report adverse events to Mayo Laboratory Inquiry at 800-533-1710 or visit http://www.mayocliniclabs.com.

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