This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the COVID-Flu Multiplex Assay.

The COVID-Flu Multiplex Assay is authorized for use with anterior nasal swab specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

**All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Exact Sciences Laboratories - COVID-Flu Multiplex Assay.**

**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 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 COVID-Flu Multiplex Assay can be used to test anterior nasal swab specimens.
- The COVID-Flu Multiplex Assay should be ordered for the detection of SARS-CoV-2 in individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.
- The COVID-Flu Multiplex Assay is also for use with anterior nasal swab specimens that are collected at home by individuals 18 years and older using the Exact Sciences Nasal Swab Home Collection Kit or by individuals 18 years or older (self-collected), 16 years or older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) using the Everlywell COVID-19 & Flu Test Home Collection Kit when home collection is determined to be appropriate by a healthcare provider.
- The COVID-Flu Multiplex Assay is only authorized for use at Exact Sciences Laboratories, located at 650 Forward Drive, Madison, WI 53711, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform high complexity tests.

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 the virus that...
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.
the virus(es) and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines. Results (positive and negative) for influenza should be interpreted with caution. If a result is inconsistent with clinical presentation and/or other clinical and epidemiological information, FDA-cleared influenza NAATs are available for confirmation if clinically indicated.

The COVID-Flu Multiplex Assay has been designed to minimize the likelihood of false-positive test results. However, in the event of a false-positive result, risks to individuals 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 of friends, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of an antiviral medication or other therapy, or other unintended adverse effects.

**What does it mean if the specimen tests negative for influenza A and/or influenza B?**
A negative test result for influenza viruses means that influenza A and/or B RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out influenza A and/or influenza B infection and should not be used as the sole basis for treatment or patient management decisions.

When diagnostic testing results are 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 influenza. The possibility of a false-negative result should especially be considered if the patient’s recent exposures or clinical presentation indicate that influenza A and/or influenza B is likely, and diagnostic test results for other causes of illness (e.g., other respiratory illness) are negative. If influenza A and/or influenza B is still suspected based on exposure history and clinical findings, retesting should be considered by healthcare providers in consultation with public health authorities.

Laboratory test results should always be considered in the context of clinical findings and observations and/or epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines. Results (positive and negative) for influenza or RSV should be interpreted with caution. If an influenza result is inconsistent with clinical presentation and/or other clinical or epidemiological information, FDA-cleared influenza NAATs are available for confirmation if clinically indicated.

Risks to individuals from a false-negative COVID-Flu Multiplex Assay result for influenza A and/or influenza B include: delayed or lack of supportive treatment; lack of monitoring of infected patients and their household or other close contacts for symptoms, resulting in increased risk of spread of influenza A and/or influenza B within the community; or other unintended adverse events.

**What does it mean if the specimen tests positive for SARS-CoV-2, influenza A, and/or influenza B viruses? Is co-infection possible?**
Yes, it is possible for an individual to be infected with more than one virus simultaneously. A positive test result for the viruses that cause COVID-19, influenza A, and/or influenza B indicates that RNA from these viruses was detected, the patient may be co-infected, and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made with a healthcare provider and follow current CDC guidelines.

**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.

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**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](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)) or by calling 1-800-FDA-1088.
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 terminated or revoked (after which the test may no longer be used).

**What are the approved available alternatives?**

FDA has approved/cleared certain influenza tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: [https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases](https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases). A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: [https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization).

**Where can I go for updates and more information?**

**CDC webpages:**
- Isolation Precautions in Healthcare Settings: [https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html](https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html)

**FDA webpages:**
- General: [www.fda.gov/novelcoronavirus](https://www.fda.gov/novelcoronavirus)

**Exact Sciences Laboratories:**
- 650 Forward Drive
- Madison, WI 53711

**Customer Support:**
- Phone: 1-844-870-8870

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