This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Advanta Dx COVID-19 EASE Assay.

The Advanta Dx COVID-19 EASE Assay is authorized for use with certain respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Fluidigm Corporation - Advanta Dx COVID-19 EASE 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).

This test is to be performed only using certain respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

- The Advanta Dx COVID-19 EASE Assay can be used to test nasopharyngeal swab, oropharyngeal swab, mid-turbinate nasal swab, and anterior nasal swab specimens.
- The Advanta Dx COVID-19 EASE Assay should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The Advanta Dx COVID-19 EASE Assay is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet 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 causes 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).

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 therefore 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 (such as local prevalence rates and

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
current outbreak/epicenter locations) in making a final 
diagnosis and patient management decisions. Patient 
management should be made by a healthcare provider 
and follow current CDC guidelines.

The Advanta Dx COVID-19 EASE Assay has been 
designed to minimize the likelihood of false positive test 
results. However, it is still possible that this test can give 
a false positive result, even when used in locations 
where the prevalence is below 5%. 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, 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. It 
is possible to test a person too early or too late during 
SARS-CoV-2 infection to make an accurate diagnosis 
via Advanta Dx COVID-19 EASE Assay.

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. 
Additional testing may be helpful to ensure testing was 
not conducted too early.

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.

The performance of this test was established based on 
the evaluation of a limited number of clinical specimens. 
The clinical performance has not been established in all 
circulating variants but is anticipated to be reflective of 
the prevalent variants in circulation at the time and 
location of the clinical evaluation. Performance at the 
time of testing may vary depending on the variants 
circulating, including newly emerging strains of 
SARSCoV-2 and their prevalence, which change over 
time.

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 terminated or revoked (after which the test may no longer be used).

**What are the approved available alternatives?**

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](http://www.fda.gov/novelcoronavirus)

**Fluidigm Corporation:**
- 2 Tower Place, Suite 2000
  South San Francisco, CA 94080
- Customer Support:
  +1 866 358 4354
  techsupport@fluidigm.com
- Technical Support:
  +1 866 358 4354
  techsupport@fluidigm.com

**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**.