This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Abbott RealTime SARS-CoV-2 assay.

The Abbott RealTime SARS-CoV-2 assay is authorized for use with 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: Abbott RealTime SARS-CoV-2 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, and the median incubation period 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 at the end of this document.

Public health officials have identified cases of COVID-19 infection 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) 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 respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

- The Abbott RealTime SARS-CoV-2 assay can be used to test nasal swabs, self-collected at a healthcare location or collected by a healthcare worker and nasopharyngeal (NP) and oropharyngeal (OP) swabs, and bronchoalveolar lavage fluid (BAL) collected by a healthcare worker.
- The Abbott RealTime SARS-CoV-2 assay should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The Abbott RealTime SARS-CoV-2 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 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
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Abbott RealTime SARS-CoV-2 Assay

epidemiological data in making a final diagnosis and
patient management decisions. Patient management
should be made by a healthcare provider and follow
current CDC guidelines.

The Abbott RealTime SARS-CoV-2 assay has been
designed to minimize the likelihood of false positive test
results. However, in the event of a false positive result,
risk 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 individuals
with COVID-19, 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.

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 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.

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?
There are no approved available alternative tests. 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

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
Where can I go for updates and more information?

**CDC webpages:**
- **General:** [https://www.cdc.gov/COVID19](https://www.cdc.gov/COVID19)

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

**ABBOTT MOLECULAR INC.:**
For technical assistance, call Abbott Molecular Technical Services at 1-800-553-7042 (within the US) or +49-6122-580 (outside the US), or visit the Abbott Molecular website at www.molecular.abbott/portal.

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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**