This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the ID NOW COVID-19.

The ID NOW COVID-19 is authorized for use on respiratory specimens collected from individuals who are suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: ID NOW COVID-19.

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 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. 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 ID NOW COVID-19 can be used to test direct nasal, nasopharyngeal or throat swabs.
- The ID NOW COVID-19 should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider.
- The ID NOW COVID-19 is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high and moderate complexity tests.
- The ID NOW COVID-19 Test is authorized to be distributed and used in patient care settings using the ID NOW Instrument outside of the clinical laboratory environment.

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

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).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 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 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 in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The ID NOW COVID-19 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 and healthcare providers in patient care settings using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

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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FACT SHEET FOR HEALTHCARE PROVIDERS

ID NOW COVID-19 – Abbott Diagnostics Scarborough, Inc. Updated: June 1, 2020

Coronavirus Disease 2019 (COVID-19)

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. Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of the 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, 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 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 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

FDA webpages:
- General: www.fda.gov/novelcoronavirus
- EUAs:(includes links to patient fact sheet and manufacturer’s instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Abbott Diagnostics Scarborough, Inc.
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME, USA, 04074

Customer Support:
+1 855 731-2226
ts.scc@abbott.com

Technical Support:
+1 855 731-2226
ts.scc@abbott.com

Website:

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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) or by calling 1-800-FDA-1088
You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the ID NOW COVID-19 test. This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:
  - [https://www.cdc.gov/COVID19](https://www.cdc.gov/COVID19)

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat or new loss of taste or smell.

What is the ID NOW COVID-19 test?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?
Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make
FACT SHEET FOR PATIENTS

ID NOW COVID-19 –
Abbott Diagnostics Scarborough, Inc.
June 1, 2020

Coronavirus
Disease 2019
(COVID-19)

informed recommendations
about your care.

The results of this test may help
limit the spread of COVID-19 to
your family and others in your
community.

What does it mean if I have a
positive test result?
If you have a positive test result, it is
very likely that you have COVID-19.
Therefore, it is also likely that you
may be placed in isolation to avoid
spreading the virus to others. There
is a very small chance that this test
can give a positive result that is
wrong (a false positive result). Your
healthcare provider will work with you
to determine how best to care for you
based on the test results along with
medical history, and your symptoms.

What does it mean if I have a
negative test result?
A negative test result means that the
virus that causes COVID-19 was not
found in your sample. For COVID-19,
a negative test result for a sample
collected while a person has
symptoms usually means that
COVID-19 did not cause your recent
illness.

However, it is possible for this test to
give a negative result that is incorrect
(false negative) in some people with
COVID-19. This means that you
could possibly still have COVID-19
even though the test is negative. If
this is the case, your healthcare
provider will consider the test result
together with all other aspects of your
medical history (such as symptoms,
possible exposures, and
geographical location of places you
have recently traveled) in deciding
how to care for you.

It is important that you work with your
healthcare provider to help you
understand the next steps you should
take.

Is this test FDA-approved or
cleared?
No. This test is not yet approved or
cleared by the United States FDA.
When there are no FDA-approved or
cleared tests available, and other
criteria are met, FDA can make tests
available under an emergency
access mechanism called an
Emergency Use Authorization (EUA).
The EUA for this test 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
for the detection and/or diagnosis of
the virus that causes COVID-19. This
EUA will remain in effect (meaning
this test can be used) for the duration
of the COVID-19 declarations
justifying emergency of IVDs, unless
it is terminated or revoked by FDA
(after which the test may no longer
be used).

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- Where can I go for updates and more information? The most up-to-date
information on COVID-19 is available at the CDC General webpage:
https://www.cdc.gov/COVID19. In addition, please also contact your
healthcare provider with any questions/concerns.