This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the INDICAID™ COVID-19 Rapid Antigen Test.

The INDICAID™ COVID-19 Rapid Antigen Test is authorized for use using direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first five (5) days of symptom onset.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: PHASE Scientific International, Ltd. - INDICAID™ COVID-19 Rapid Antigen Test.

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). 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 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 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).

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).

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.

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
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
nucleocapsid antigens from SARS-CoV-2 were 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 (such as local prevalence rates and
current outbreak/epicenter locations) in making a final
diagnosis and patient management decisions. Patient
management should follow current CDC guidelines.

The INDICAID™ COVID-19 Rapid Antigen Test 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 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
nucleocapsid antigens from SARS-CoV-2 were 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, including infection
control decisions. Antigen tests are known to be less
sensitive than molecular tests that detect viral nucleic
acids.

The amount of antigen in a sample may decrease as the
duration of illness increases. Specimens collected after
day 5 of illness may be more likely to be negative
compared to a RT-PCR assay. Therefore, negative
results from patients with symptom onset beyond 5 days
should be treated as presumptive and confirmed with a
molecular assay, if necessary, for patient management.
It is possible to test a person too early or too late during
COVID-19 to make an accurate diagnosis via the
INDICAID™ COVID-19 Rapid Antigen Test.

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 or testing
with molecular methods 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 from a false negative result include:
delay 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.

A negative antigen test should not be the sole basis
used to determine if a patient can end isolation
precautions. For additional recommendations regarding
infection control, refer to CDC’s Discontinuation of
Isolation for Persons with COVID-19 Not in Healthcare
Settings (Interim Guidance) (see links provided in
“Where can I go for updates and more information?”
section).

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The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 2021 and March 2021. 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 SARS-CoV-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?
There are no approved available alternative antigen 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. 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:


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

FDA webpages:
General: www.fda.gov/novelcoronavirus

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