IHEALTH COVID-19/FLU A&B RAPID TEST

iHealth Labs, Inc.

May 7, 2024

All individuals who use this assay are required to receive and should carefully review the iHealth COVID-19/Flu A&B Rapid Test Quick Reference Instructions before they use the test.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the iHealth COVID-19/Flu A&B Rapid Test.

WHERE CAN I GO FOR GENERAL INFORMATION ON COVID-19 AND INFLUENZA?

For general information on COVID-19 and influenza, including the symptoms of COVID-19 and influenza, infection control precautions, and other information please check the CDC COVID-19 and influenza webpages (see links provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdiction's website for the most up to date information.

WHAT DO I NEED TO KNOW ABOUT COVID-19 AND INFLUENZA TESTING WITH THIS PRODUCT?

- The iHealth COVID-19/Flu A&B Rapid Test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older.
- The iHealth COVID-19/Flu A&B Rapid Test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first four (4) days of symptom onset when tested at least twice over three days with at least 48 hours between tests.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the lower sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR SARS-COV-2, INFLUENZA A, OR INFLUENZA B VIRUSES?

A positive test result for COVID-19 or influenza indicates that antigens from either SARS-CoV-2, influenza A or influenza B were detected, and therefore the individual being tested is infected with the virus and presumed to be contagious. 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 determining individual diagnosis and patient management decisions and should follow current CDC guidelines.

The iHealth COVID-19/Flu A&B Rapid Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks could include the following: a needless recommendation for the patient to isolate that might limit contact with family or friends and the ability to work, delayed diagnosis and treatment for the true infection causing the patient's symptoms, potentially increased likelihood that the patient could contract COVID-19 or influenza from other potentially COVID-19 or influenza positive patients isolated in the same areas, unnecessary prescription of a treatment or therapy, needless monitoring of close contacts

for symptoms, or other unintended adverse effects. False positive results for any virus are more likely when prevalence of that virus in the community are low.

WHAT DOES IT MEAN IF THE SPECIMEN TESTS NEGATIVE FOR THE SARS-COV-2, INFLUENZA A, AND INFLUENZA B VIRUSES?

COVID-19 negative samples should be repeated as per the FDA Serial Testing Guidance (see link provided in "*Where can I go for updates and more information?*" section at the end of this document). A negative serial test result for this test means that SARS-CoV-2, influenza A and influenza B antigens were not present in the specimen above the limit of detection. All SARS-CoV-2 negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. All negative influenza A and B test results are presumptive. It is recommended these results be confirmed by an FDA-cleared influenza A and B molecular assay. However, a negative result does not rule out COVID-19 or influenza and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions (such as discontinuation of isolation precautions). 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. For COVID-19 testing, specimens collected after day four (4) of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative SARS-CoV-2 results from patients with symptom onset beyond four (4) days should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19 or influenza. The possibility of a false negative result should especially be considered if the individual's recent exposures or clinical presentation indicate that COVID-19 or influenza is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 or influenza 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 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 COVID-19 or influenza spread within the community, or other unintended adverse events. For additional recommendations regarding infection control, refer to CDC's *Ending Isolation and Precautions for People with COVID-19: Interim Guidance* and CDC's general isolations precautions webpage (see links provided in "*Where can I go for updates and more information*?" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October 2023 and February 2024. 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 or influenza and their prevalence, which change over time.

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR SARS-COV-2 AND ONE OR BOTH INFLUENZA (A AND/OR B) VIRUSES? IS CO-INFECTION POSSIBLE?

Yes, it is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 simultaneously. A positive test result for the viruses that cause COVID-19 and influenza A and/or B indicates that antigens from these viruses were detected, the patient may be co-infected, and is presumed to be contagious. 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 DO I NEED TO KNOW ABOUT SERIAL TESTING?

Serial testing of individuals whose initial COVID-19 test result is negative assists in identifying infected individuals earlier and facilitate timely infection control practices. A negative test result for COVID-19 does not rule out infection in symptomatic individuals; repeating testing twice over three days with at least 48 hours between tests may decrease the risks of false negative results. If COVID-19 infection is still suspected based on symptoms, exposures, or other factors, additional testing with a laboratory-based molecular test should be considered.

For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's *Guidance for Antigen Testing for SARS-CoV-2 for Healthcare Providers Testing Individuals in the Community* (see links provided in "*Where can I go for updates and more information*" section).

WHAT IS AN EUA?

The U.S. 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 the declaration is terminated or authorization is revoked sooner.

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. 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.

WHERE DO I REPORT ADVERSE EVENTS?

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 COVID-19 WEBPAGES:

General: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html

Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html

Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html

Discontinuation of Isolation: https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html

Antigen Testing: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

CDC WEBPAGES

Flu General: https://www.cdc.gov/flu/index.htm

Infection Control – Isolation Precautions: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

FDA WEBPAGES:

General: www.fda.gov/novelcoronavirus

EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

Serial Testing: https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-results-fda-safety

IHEALTH LABS, INC.:

880 W Maude Ave

Sunnyvale, CA 94085

Customer and Technical Support:

Phone: (855) 816-7705

Email: support@ihealthlabs.com

Website: http://www.ihealthlabs.com