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iHealth ICF-3000

iHealth COVID-19, Flu A&B 3-in-1 Antigen Rapid Test User Manual

Model: ICF-3000

1. Product Overview

The iHealth COVID-19, Flu A&B 3-in-1 Antigen Rapid Test is an FDA-authorized over-the-counter diagnostic test designed for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2, influenza A virus, and influenza B virus. This test is intended for home use and provides rapid results within 15 minutes, utilizing a non-invasive nasal swab sample.

Intended Use

This test is authorized for individuals aged 2 years and older. For individuals aged 2-13 years, sample collection must be performed by an adult. Individuals aged 14 years and older may self-collect their samples. The test aids in the rapid identification of COVID-19, Influenza A, and Influenza B infections, allowing for timely action to protect public health.

2. What's in the Box

Each iHealth COVID-19, Flu A&B 3-in-1 Antigen Rapid Test kit contains the following components:

- Nasal Swab
- Extraction Tube with Buffer Solution
- Test Card

Image: The iHealth COVID-19, Flu A&B 3-in-1 Antigen Rapid Test kit box, showing the product name and key features.

3. Setup and Preparation

Before performing the test, ensure you have read all instructions thoroughly. Gather all necessary materials and prepare your testing area.

- **Read Instructions:** Carefully read the entire instruction manual before starting the test.
- **Wash Hands:** Wash your hands thoroughly with soap and water for at least 20 seconds before handling the test components.

- **Check Expiry Date:** Verify the expiry date printed on the kit packaging. Do not use expired tests.
- **Room Temperature:** Ensure all test components are at room temperature (59-86°F / 15-30°C) before use.
- **Open Kit:** Open the foil pouch containing the test card just before use.

4. Operating Instructions: Performing the Test

Follow these four simple steps to perform the iHealth COVID-19, Flu A&B 3-in-1 Antigen Rapid Test:

Step 1: Swab Collection

Carefully insert the entire soft tip of the swab into one nostril about 1/2 to 3/4 inch (1 to 1.5 cm) until resistance is met. Rotate the swab 5 times against the inside of the nostril. Using the same swab, repeat the process in the other nostril. Ensure adequate sample collection from both nostrils.

Image: A diagram illustrating the correct depth and rotation for nasal swab collection.

Step 2: Sample Mixing

Immediately insert the swab into the extraction tube containing the buffer solution. Swirl the swab vigorously 10 times, pressing the swab head against the bottom and sides of the tube to ensure the sample is thoroughly mixed with the solution. Remove the swab while squeezing the sides of the tube to extract as much liquid as possible from the swab.

Image: A diagram demonstrating how to mix the nasal swab in the extraction tube.

Step 3: Applying Sample to Test Card

Place the dropper cap firmly onto the extraction tube. Hold the tube vertically above the sample well (marked 'S') on the test card. Gently squeeze the tube to dispense exactly 5 drops of the mixed solution into the sample well. Avoid touching the test card with the dropper tip.

Image: A diagram illustrating the process of dripping 5 drops of the sample onto the test card's sample well.

Step 4: Waiting for Results

Set a timer for 15 minutes. Read the results at exactly 15 minutes. Do not read the results before 15 minutes or after 30 minutes, as this may lead to inaccurate readings.

Image: A diagram depicting a timer indicating a 15-minute waiting period for test results.

5. Interpreting Results

The test card has three result lines: C (Control), A (Flu A), B (Flu B), and T (COVID-19 Test). The presence or absence of these lines determines the test result.

Image: Visual examples of test results, showing positive lines for Flu A, Flu B, and COVID-19.

Result Interpretation Guide

Result	Interpretation	Action
C line and A line present	Positive for Flu A	Consult a healthcare professional.
C line and B line present	Positive for Flu B	Consult a healthcare professional.

Result	Interpretation	Action
C line and T line present	Positive for COVID-19	Consult a healthcare professional and follow local guidelines.
C line, A line, and B line present	Positive for Flu A and Flu B	Consult a healthcare professional.
C line, A line, and T line present	Positive for Flu A and COVID-19	Consult a healthcare professional and follow local guidelines.
C line, B line, and T line present	Positive for Flu B and COVID-19	Consult a healthcare professional and follow local guidelines.
C line, A line, B line, and T line present	Positive for Flu A, Flu B, and COVID-19	Consult a healthcare professional and follow local guidelines.
Only C line present	Negative for Flu A, Flu B, and COVID-19	Continue to monitor symptoms. If symptoms persist, consider retesting or consulting a healthcare professional.
No C line, or C line and any other line(s) present	Invalid Result	The test is invalid. Repeat the test with a new kit.

6. Maintenance

Storage and Handling

Store the test kit at room temperature (59-86°F / 15-30°C) in its original sealed pouch until the expiry date. Do not freeze the kit. Keep away from direct sunlight and moisture. Ensure the kit is not damaged before use.

Disposal

After use, all test components, including the used swab, extraction tube, and test card, should be placed in a sealed plastic bag and disposed of according to local regulations for biohazardous waste. Do not dispose of used test components in regular household trash without proper containment.

7. Troubleshooting

If you encounter issues during testing or with your results, refer to the following common troubleshooting tips:

- **No Control Line (C line):** If the control line (C) does not appear, the test is invalid. This may be due to insufficient sample volume, incorrect procedure, or a defective test kit. Repeat the test with a new kit, ensuring all steps are followed precisely.
- **Faint Lines:** Faint test lines (A, B, or T) should still be considered positive. However, if the lines are extremely faint or unclear, it is recommended to retest with a new kit or consult a healthcare professional.
- **Reading Results Outside Window:** Reading results before 15 minutes or after 30 minutes can lead to inaccurate results. Always adhere strictly to the 15-minute reading window. If you missed the window, perform a new test.

- **Symptoms Persist After Negative Result:** A negative result does not rule out infection. If symptoms persist or worsen, consider retesting in 24-48 hours or consult a healthcare professional.

8. Specifications

Specification	Detail
Package Dimensions	6.38 x 3.66 x 1.46 inches; 2.82 ounces
Item Model Number	ICF-3000
Date First Available	May 10, 2024
Manufacturer	iHealth Labs, Inc.
ASIN	B0D3T1X1FS

9. Warranty and Support

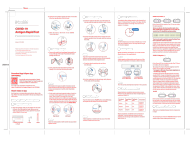
Warranty Information

The iHealth COVID-19, Flu A&B 3-in-1 Antigen Rapid Test comes with a 1-Year Limited Warranty from the date of purchase. Please retain your proof of purchase for warranty claims.

Customer Support

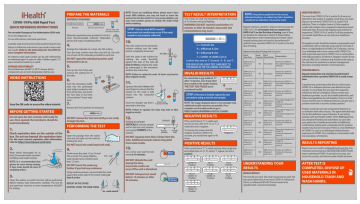
For technical assistance, questions about test results, or warranty inquiries, please contact iHealth's US-Based Customer Support. Visit the official iHealth website for contact details and additional resources.

Related Documents - ICF-3000

	iHealth COVID-19 Antigen Rapid Test: Self-Test At Home Results In 15 Mins Information about the iHealth COVID-19 Antigen Rapid Test for self-testing at home. Detects SARS-CoV-2 antigen in nasal swabs with results in 15 minutes. Includes product details, intended use, limitations, contents, manufacturer information, and handling precautions.
	iHealth COVID-19 Antigen Rapid Test Instructions for Use Comprehensive instructions for the iHealth COVID-19 Antigen Rapid Test (Model ICO-3000), detailing intended use, procedure, result interpretation, warnings, limitations, and clinical performance data for rapid SARS-CoV-2 detection.
	iHealth COVID-19 Antigen Rapid Test: Quick Reference Instruction Concise instructions for using the iHealth COVID-19 Antigen Rapid Test, including sample collection, processing, result interpretation, and disposal. Learn how to perform the test at home.

	[iHealth COVID-19/Flu A&B Rapid Test Pro: Quick Reference Instructions] This document provides quick reference instructions for the iHealth COVID-19/Flu A&B Rapid Test Pro, a diagnostic assay for the qualitative detection of influenza A, influenza B, and SARS-CoV-2 antigens from nasal swab specimens.
	[iHealth Track Blutdruckmessgerät Benutzerhandbuch] Umfassendes Benutzerhandbuch für das vollautomatische iHealth Track Arm-Blutdruckmessgerät (Modell KN-550BT). Erfahren Sie, wie Sie Messungen durchführen, Ihr Gerät mit der iHealth MyVitals App synchronisieren und Fehler beheben.
	[iHealth Wireless Scale Lina HS2 User Manual | Setup, Features, Troubleshooting] Comprehensive user manual for the iHealth Wireless Scale Lina (HS2). Learn how to set up, use, troubleshoot, and maintain your smart scale for accurate weight and BMI tracking.

Documents - iHealth – ICF-3000



[pdf] Quick Start Guide Instructions

iHealth COVID 19 Flu A B Rapid Test Instructions for Use Home Testing Carefully read all instructions before performing the test Failure to follow may result in inaccurate results 6 days ago — Before testing carefully The kit and specimen must be at room temperature 65 86°F 2 eua ihealth covid flu otc ifuht fda gov media 178554 |||

COVID-19/Flu A B Rapid Test QUICK REFERENCE INSTRUCTIONS For use under Emergency Use Authorization ... Maude Ave, Sunnyvale, CA 9408S USA Made in China 1-855-816-7705 www.ihealthlabs.com UDI Model: **ICF-3000** UPC iHealth COVID-19/Flu A B Rapid Test iHealth Rapid Self-Test I D Results In 15 M...

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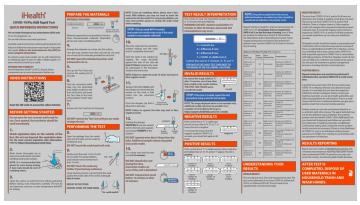

[pdf] Quick Start Guide Instructions

iHealth COVID 19 Flu A B Rapid Test Instructions for Use Home Testing Quick Reference InstructionsiHealth with Fast Results Unite Medical Medical®iHealth QuickReferenceInstructionscdn shopify s files 1 0265 2009 2731 QuickReferenceInstructions v 1722347798 |||

COVID-19/Flu A B Rapid Test QUICK REFERENCE INSTRUCTIONS For use under Emergency Use Authorization ... Maude Ave, Sunnyvale, CA 9408S USA Made in China 1-855-816-7705 www.ihealthlabs.com UDI Model: **ICF-3000** UPC iHealth COVID-19/Flu A B Rapid Test iHealth Rapid Self-Test I D Results In 15 M...

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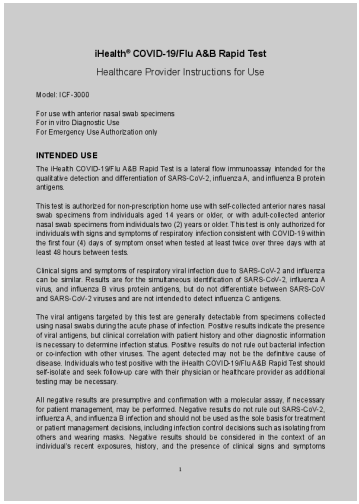

iHealth® COVID-19/Flu A&B Rapid Test

Healthcare Provider Instructions for Use

Model: ICF-3000

For use with anterior nasal swab specimens
For in vitro Diagnostic Use
For Emergency Use Authorization only

INTENDED USE

The iHealth COVID-19/Flu A&B Rapid Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens.

This test is authorized for non-prescription home use with self-collected anterior nares nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals two (2) years or older. This 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.

Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Results are for the simultaneous identification of SARS-CoV-2, influenza A virus, and influenza B virus protein antigens, but do not differentiate between SARS-CoV and SARS-CoV-2 viruses and are not intended to detect influenza C antigens.

The viral antigens targeted by this test are generally detectable from specimens collected using nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with the iHealth COVID-19/Flu A&B Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2, influenza A, and influenza B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms

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[pdf] Instructions

iHealth®COVID 19 FluA BRapidTest Instruction for use Health Care Provider Instructions UseiHealth Rapid COVID Flu Test with Fast Results Unite Medical Medical®iHealth For Usecdn shopify s files 1 0265 2009 2731 iHealth Use v 1722347797 |||

iHealth COVID-19/Flu A B Rapid Test Healthcare Provider Instructions for Use Model: **ICF-3000** For use with anterior nasal swab specimens For in vitro Diagnostic Use For Emergency Use Authorization only INTENDED USE The iHealth COVID-19/Flu A B Rapid Test is a lateral flow immunoassay intended for the...

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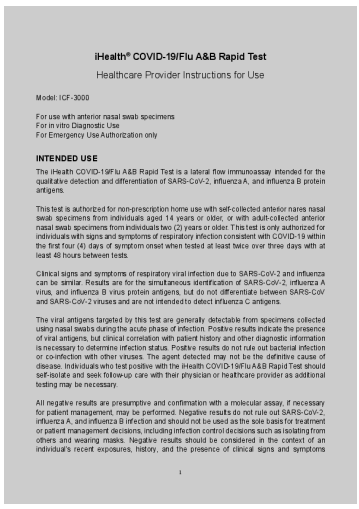

iHealth® COVID-19/Flu A&B Rapid Test

Healthcare Provider Instructions for Use

Model: ICF-3000

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[pdf] Instructions

iHealth®COVID 19 FluA BRapidTest Instruction for use Health Care Provider iHealth® COVID Flu A B Rapid Test Healthcare Read all instructions carefully before performing the test Failure to follow may result in inaccurate results 3 Page 4 For in 6 days ago — Before testing read The kit and specimen must be at room temperature 65 86°F Prepare Materials eua ihealth covid flu otc ifu fda gov media 178553 attachment |||

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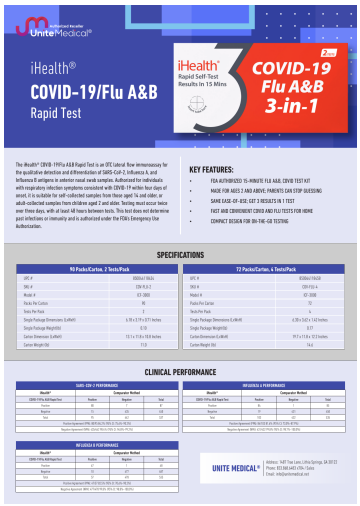

[pdf] Specifications Dimension Guide

iHealth Covid 19 Flu A B Rapid Test Key Features SpecificationsiHealth COVID with Fast Results Unite Medical Medical®iHealth UniteMedicalcdn shopify s files 1 0265 2009 2731 UniteMedical v 1721930141 |||

Authorized Reseller iHealth COVID-19/Flu A B Rapid Test The iHealth COVID-19/Flu A B Rapid Test is ... ING SPECIFICATIONS 90 Packs/Carton, 2 Tests/Pack UPC # 850044118434 SKU # COV-FLU-2 Model # **ICF-3000** Packs Per Carton 90 Tests Per Pack 2 Single Package Dimensions LxWxH 6.18 x 3.19 x ...

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