iHealth®

COVID-19/Flu A&B Rapid Test Pro

QUICK REFERENCE INSTRUCTIONS

IVD Rx ONLY

For use under Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use.

For use with anterior nasal swab specimens.

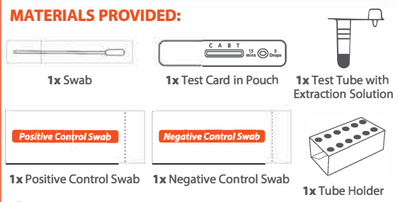
Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results. **Refer to the Instructions for Use (IFU) for more complete information.**

STORAGE AND STABILITY

Store kit between 36-86°F (2-30°C). Ensure all test components are at room temperature (65-86°F/18-30°C) before use.

PREPARE THE MATERIALS

MATERIALS PROVIDED:



1x Swab | **1x** Test Card in Pouch | **1x** Test Tube with Extraction Solution

1x Positive Control Swab | **1x** Negative Control Swab | **1x** Tube Holder

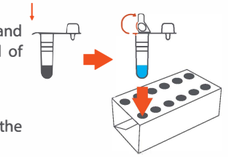
1.

Arrange the materials on a clean, dry, flat surface.

DO NOT open the individual pouches until instructed to do so.

2.

Pick up the Test Tube and remove the sealing foil of the tube.



3.

Place the Test Tube in the Tube Holder.

4.

Remove the Test Card from its foil pouch.

NOTE: Use the Test Card within one hour of opening the foil pouch.

PERFORMING THE TEST

5.

Open the package from the swab's stick end and take out the swab by holding the stick.

DO NOT touch the swab head (soft end).

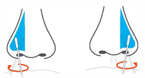
6.

Gently insert the swab 1/2 to 3/4 inch into a nostril.

DO NOT insert the swab any farther if you feel any resistance.

Using medium pressure, rub and rotate the swab against the inside walls of the nostril, making **at least 5 circles.**

REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.



5x , each nostril

NOTE: With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

STOP: Did you swab BOTH nostrils? Inaccurate test results may occur if the nasal sample is not properly collected.

7.

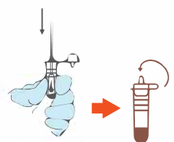
Place the swab into the extraction solution making sure the swab head is completely immersed.

Vigorously mix the solution by rotating the swab forcefully against the side of the tube **at least 10 times**, keeping the swab tip submerged in the extraction solution the entire time.

8.

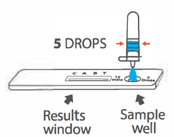
Squeeze the tube **5 times** with your fingers to ensure that the sample on the swab is fully mixed into the extraction solution.

Close the dropper cap that is attached to the tube.



9.

Holding the dropper **VERTICALLY** over the sample well on the test card, squeeze out exactly **5 DROPS** of the solution.



DO NOT squeeze more than 5 drops from the tube. Additional sample volume may yield inaccurate results.

10.

Set a timer and read the test result **at 15 minutes.**

DO NOT disturb the card during this time. Inaccurate results can occur if the card is disturbed.

DO NOT interpret test result before 15 minutes or after 30 minutes.

TEST RESULT INTERPRETATION

Test results are read and interpreted visually. Read result at 15 minutes with good lighting.

WARNING: DO NOT read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.

C = Control Line

A = Influenza A Line

B = Influenza B Line

T = COVID-19 (SARS-CoV-2)

Look for lines next to 'C' (Control), 'A', 'B', and 'T'.

FOR EASE OF USE, HOLD TEST CARD NEXT TO THE IMAGES IN THE FOLLOWING 3 SECTIONS.

INVALID RESULTS

If a control line is not visible at "C" after 15 minutes, even if any other line is visible in the results window, THE TEST HAS FAILED and is considered invalid.

STOP: If the test is invalid, repeat the test procedure using a new kit and sample.

NOTE: The image displayed above is one example only; additional invalid outcomes are possible. For a complete set of invalid results to go to https://support.ihealthlabs.com/3-in-1-results.

NEGATIVE RESULTS

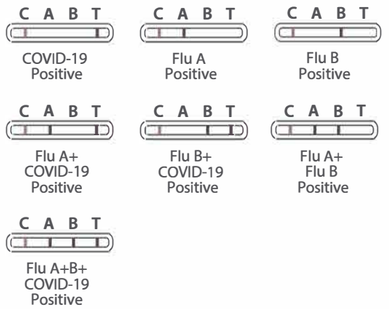
If the control line at "C" is visible and you do not see a line at 'A', 'B', or 'T', it means COVID-19, Flu A, or Flu B virus have not been detected.

Negative results should be reported as a presumptive negative for the presence of influenza and/or SARS-CoV-2 antigen.

Negative

POSITIVE RESULTS

If the control line at "C" is visible and any other line or multiple lines on 'A', 'B', and/or 'T' appear, the test is **positive.**



COVID-19 Positive | Flu A Positive | Flu B Positive

Flu A+ COVID-19 Positive | Flu B+ COVID-19 Positive | Flu A+ Flu B Positive

Flu A+B+ COVID-19 Positive

NOTE: Any pink or purple line, no matter how faint, should be considered an indication of a positive result.

It is possible to have more than one positive Test Line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2, the virus that causes COVID-19. If more than one positive Test Line is observed, retest with a new patient sample, Test Card and Test Tube. A differing result should be followed by confirmatory testing with another test method, such as PCR.

SERIAL TESTING

Repeat Testing is needed for **all samples that are negative for SARS-CoV-2 on the first day of testing**, even if they are positive for influenza A and/or B. Repeat testing is needed to improve test accuracy for SARS-CoV-2. Please follow the table below when interpreting test results. Serial (repeat) testing does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

Status on First Day of Testing: With Symptoms			
Day 0 (First Test)	**Serial Testing?**	**Day 2 (Second Test)**	**Interpretation**
SARS-CoV-2 (+) Influenza A and B (-)	NO	Not needed	Positive for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2 (+) Influenza A and/or B (+)	NO	Not needed	Positive for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/or B(-)	Positive for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/or B(+)	Positive for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/or B(+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/ or B (-)	Presumptive Negative for COVID-19 Presumptive Negative for Influenza
SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/or B (-)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 Positive for Influenza A and/or B

EXTERNAL QUALITY CONTROL PROCEDURE

To perform a positive or negative control test, complete the steps in the Test Procedure section, treating the control swab in the same manner as a patient swab. Minimally, iHealth recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.

WARNINGS AND PRECAUTIONS

- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- This test may only be used in symptomatic individuals.

EUA - WARNINGS AND PRECAUTIONS

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, and influenza A and B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

INTENDED USE

Please see the Instructions for Use for the full intended use.

The iHealth COVID-19/Flu A&B Rapid Test Pro is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 by their healthcare provider 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests.

This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

SUPPORT

If you have questions regarding the use of this product, or if you want to report a problem with

iHealth

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