QuickFinder[™] COVID-19/Flu Antigen Self Test QUICK REFERENCE INSTRUCTIONS

For in vitro diagnostic use.

For use under Emergency Use Authorization (EUA) only. For use with anterior nasal swab specimens.

Carefully read the instructions below 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. Ensure all test components are at room temperature before use.

BEFORE GETTING STARTED

1. Check expiration date on the outside of the box. Do not use beyond the expiration date.

For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.

2. Wash hands thoroughly for at least 20seconds before and after handling nasal swab samples.

3. Before testing, read the Quick Reference Instructions carefully.

Bring the test kit to room temperature (59-86°F) when you are ready to begin the test.

PREPARE THE MATERIALS

MATERIALS PROVIDED:







Extraction buffer tube w/ solution

Materials required but not provided:

A clock or timer;

Recommended materials:

Disposable gloves and mask, if swabbing others

4. Arrange the materials on a clean, dry, flat surface. Your box may contain one or more test kits. Use only one of each individually packaged kit for each test.

DO NOT open the individual pouches until you are ready to begin the test.

5. Open the foil pouch that contains the extraction buffer tube and filter cap.



6. Pick up the extractionbuffer tube and remove the sealing foil of the tube without spilling the buffer solution inside the tube.

7. Push the extraction buffer tube into the perforated tube holder located at the front of the box, labeled "Insert Tube Here."

8. Removethe Test cassette from its foil pouch

DO NOT remove the test cassette until you are ready to begin the test.



PERFORMING THE TEST

false results.

9. Open swab package from the stick end, and remove the swab by the stick side.



DO NOT touch the swab head.

DO NOT contaminate the swab head
with any liquid gel soap as this can lead to

10. Gently insert the swab head 1/2 to 3/4 inch into a nostril. For young children, swab should not be inserted more than 1/2 inch.



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

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

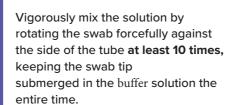


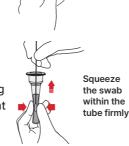
REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.

NOTE: If you are swabbing others, please wear a face mask. 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.

11. Place the swab into the extraction buffer tube and completely immerse the swab head in the solution.





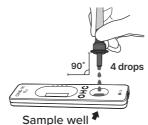
12. Remove the swab while squeezing the tube with your fingers to ensure that the sample on the swab is fully mixed into the buffer solution.



13. Attach the filter cap onto the test tube.

14. Squeeze only **4 DROPS** of the buffer solution into the sample well.

DO NOT squeeze more than 4 drops from the tube into the sample well.



15. Set a timer and read the test result after 15 minutes.

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

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



INTERPRETATION OF RESULTS

Test results are read and interpreted visually. Read result at 15-30 minutes with good lighting. Test results should not be read until after the sample has been added and the test has been allowed to run for 15 minutes, and only test lines that appear at the correct position and in the correct color should be read and interpreted.



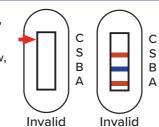
- **C** = Control (red line)
- **S** = COVID-19 (SARS-CoV-2) (red line)
- **B** = Influenza B (blue line)
- A = Influenza A (red line)

Look for lines next to 'C' (Control), 'A', 'B' and 'S'.

FOR EASE OF USE, HOLD TEST CASSETTE NEXT TO THE EXAMPLE RESULT IMAGES ON THIS SHEET

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 test kit and sample.

NOTE: The images displayed above are examples only; additional invalid outcomes are possible. For a complete set of invalid results, see http://www.osangllc.com/covid-19-flu-combo-self-testing

NEGATIVE RESULTS

If the control line at "C" is visible and you do not see a line at 'A', 'B' or 'S', the test is negative.

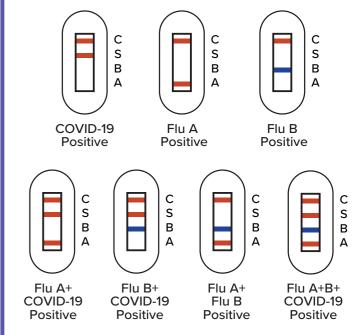
If you still have COVID-19, Flu A, or Flu B symptoms, you should seek follow up care with your healthcare provider.

To increase the chance that the negative result for COVID-19, Flu A and Flu B is accurate, you should test again in 48 hours if this is your first test and you have symptoms on the first day of testing.



POSITIVE RESULTS

If the control line at **C** is visible, and any other line or multiple lines on **S**, **B** and/or **A** appear, the test is **positive**.



Repeat testing does not need to be performed if you have a positive result at any time.

UNDERSTANDING YOUR RESULTS

INVALID RESULT:

This test did not work. The result should not be used. The test cannot determine if you have COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

NEGATIVE RESULT:

The virus from COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not mean that you do not have COVID-19, Flu A and/or Flu B infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If you tested negative and continue to experience COVID-19, Flu A and/or Flu B-like symptoms, you should seek follow-up care with your healthcare provider.

POSITIVE RESULT:

The COVID-19, Flu A and/or Flu B virus(es) were detected in your sample. It is very likely that you have the respective infection(s) and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive). Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

AFTER TEST IS COMPLETED, DISPOSE OF USED MATERIALS IN HOUSEHOLD TRASH.



QuickFinder™ COVID-19/Flu Antigen Self Test

FOR EMERGENCY USE AUTHORIZATION (EUA) ONLY. FOR IN VITRO DIAGNOSTIC USE.



回报部回 Please refer to the Healthcare Provider (HCP) IFU online for specification in the kit: IFU online for specifics about materials

https://www.osangllc.com/covid-19-flu-combo-self-testing

INTENDED USE

The QuickFinder™ COVID-19/Flu Antigen Self 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, 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 QuickFinder™ COVID-19/Flu Antigen Self Test should self-isolate and seek followup 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 be used for the sole basis for treatment or patient manage-ment 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 consistent with SARS-CoV-2, influenza A and influenza B infection. Individuals who test negative and continue to experience SARS-CoV-2 and/or influenza like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 and/or influenza infection and should seek follow up care with their physician or healthcare

The QuickFinder™ COVID-19/Flu Antigen Self Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

HOW TO USE THIS TEST

Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and influenza, and initial negative results should be tested again after 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

If you test negative but continue to have symptoms of COVID-19 and influenza, and both your first and second tests are negative, you may not have COVID-19 or influenza,

however you should follow-up with your healthcare provider. If your test is positive, then proteins from the virus that causes COVID-19 and/or influenza have been found in your sample and you likely have COVID-19 and/or influenza.

WARNINGS, PRECAUTIONS AND SAFETY **INFORMATION**

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- · For in vitro diagnostic use.
- 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, influenza A and influenza 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 Section564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §.360bbb-3(b)(1), unless the declaration if terminated or authorization is revoked sooner.
- Serial testing should be performed in individuals with COVID-19 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 testing.
- · Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.
- · An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- · Do not use on anyone under 2 years of age.
- · Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- · Do not use if any of the test kit contents or packaging is damaged.
- · Do not use the test after the expiration date shown on the external packaging.
- · Use only components of this test kit.
- Ensure all kit components are at room temperature before use.
- Test components are single-use. Do not re-use.
- Do not touch the swab tip.
- Once opened, the test cassette should be used immediately.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- Faint lines may appear on the test strip prior to running the test when tests are stored at hot or humid conditions. Do not read or interpret test results until after the sample has been added to the test cassette and the test has been allowed to run for 15 minutes. • Faint blue lines can occur near the "A" position of the test strip with some Flu B samples at high viral loads. Only test lines that
- appear at both the correct position and in the correct color should be read and interpreted.
- Make sure there is sufficent light for testing. For best results, read test in a well-lit area.
- In the event of spillage, ensure that it is cleaned thoroughly using suitable disinfectant.
- Do not use any nasal sprays, gels or creams at least 30 minutes before you collect a nasal sample.
- The test sample must be collected from both nostrils with the same swab.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- · Remove any piercings from nose before starting the test.
- · To ensure accurate test results for Influenza B, avoid contamination with hand soap liquid gel.
- · Dispose of unused contents and containers after use.
- Keep testing kit and kit components away from children and pets before and after use.
- Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table in the next column). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice:

https://www.poison-help.org or 1-800- 222-1222.

Hazard Category (Mixture)	GHS Hazard Statement for Mixture	Labeling of Harm(s)	Hazardous Ingredients (%)
3	Mild skin irritation	Causes mild skin irritation (H316)	- Triton X-100 / 1% - Proclin 300 / 0.05%
2	Serious eye irritation	Causes serious eye irritation (H319)	- Triton X-100 / 1% - Proclin 300 / 0.05%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/ mcm-legal-regulatory-and-policy-framework/ emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

FREQUENTLY ASKED QUESTIONS

Q: WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

A: Potential risks include:

- · Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your
- The results of this test may help limit the potential spread of COVID-19 and influenza to your family and others in your community. For more information on EUAs go here: https://www.fda.gov/emergen-cypreparedness- and-response/ mcm-legal-regulatory-and-policy-framework/emergencyuseauthorization

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

A: There are different kinds of tests for the COVID-19 and influenza. Molecular tests detect genetic material from the virus. Antigen tests, such as the QuickFinder™ COVID-19/Flu Antigen Self Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 and influenza than a molecular test would.

Q: HOW ACCURATE IS THIS TEST?

A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that cause COVID-19 and influenza when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at https://www.osangllc.com/covid-19-flu-combo-self-testing

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?

A: A positive result means that it is very likely you have COVID-19 or influenza because proteins from the virus that causes COVID-19 or influenza were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?

A: A negative test result indicates that antigens from the virus that cause COVID-19 and influenza were not detected in your sample. However, if you have symptoms of COVID-19 or influenza, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out COVID-19 and influenza; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?

A: An invalid result means the test was not able to tell if you have COVID-19 and influenza or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

LIMITATIONS

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the 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 and influenza as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on he evaluation of a limited number of clinical specimens collected between October 2023 to January 2024, when omicron was the predominant SARS-CoV-2 strain. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the p revalent 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 COVID-19 and influenza and their prevalence, which change over time.
- All COVID-19 and influenza antigen test negative results are presumptive and confirmation with a molecular assay may be
- If you continue to have symptoms consistent with COVID-19 and influenza, and both your first and second tests are negative, you may not have COVID-19 or influenza; however, you should follow-up with a healthcare provider.
- · Based on sequence analysis, a potential for cross-reactivity between the SARSCoV-2 test and HKU1 exists. Wet testing for HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.
- Liquid gel hand soap may cause false negative results with this test. Please ensure that hands are dry after washing prior to performing the test
- If the test is positive, then proteins from the virus that causes COVID-19 and Flu A and/or Flu B have been found in the sample and you likely have COVID-19 and/or influenza.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- · Incorrect test results may occur if a specimen is incorrectly collected or handled.

INDEX OF SYMBOLS

***	Manufacturer	W	Date of manufacture
\sum_{n}	Contains sufficient for <n> tests</n>	REF	Catalogue number
	Temperature limit	Ω	Use-by date
2	Do not reuse	LOT	Batch code
®	Do not use if seal or packaging is broken or damaged	[]i	Consult instructions for use
<u> </u>	Caution	[IVD]	<i>In vitro</i> diagnostic

If you have any questions about using the test or reading the results, please call our customer care hotline.

Telephone: 844-760-0556

Email: covidhometest@osangllc.com

Manufactured for OSANG LLC.

215 N Marengo Ave. 3rd Fl. Pasadena, CA 91101

Manufacturing Site:

OSANG Healthcare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Korea (14040) www.osanghc.com

NEXUS DX, INC.

6759 Mesa Ridge Road San Diego, CA 92121

ISC03150 Rev. 2024-04 (00)











READ





QuickFinder™ COVID-19/Flu Antigen Self Test



Scan this QR Code or more information



LOT













QuickFinder™



4 Test Cassettes

4 Sterile Swabs 4 Extraction Buffer Tubes & Filter caps 1 QRI (Quick Reference Instructions) Needed but not provided: Timer

The Box Contains

Manufacturing Site: OSANG Healthcare Co., Ltd. 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, S.Korea

NEXUS DX, INC. 6759 Mesa Ridge Road San Diego, CA 92121

Manufactured for OSANG LLC 215 N Marengo Ave. 3rd Floor. Pasadena, CA 91101 Tel: 1-844-760-0556 Technical Support: hometest@osangllc.com

OHC







QuickFinder[™] COVID-19 / Flu Antigen Self Test

This test can be used at home on people aged 2 years and older.

This test is more likely to give you a false negative result when you

Do not use if you've had symptoms longer than 4 days or no symptoms at all.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use

This test is authorized for non-prescription home use with selfcollected anterior nares nasal swab samples from individuals with symptoms of SARS-CoV-2, influenza A and influenza B within the first 4 days of symptom onset.

The emergency use of this product is only authorized for the duration 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

This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other

viruses or pathogens.

This test does NOT determine if you had COVID-19 in the past or if

Determining a negative result requires multiple tests.



Antigen Self Test REF MODEL

ISC03196 Rev. 2024-03 (03)

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QuickFinder™ COVID-19/Flu

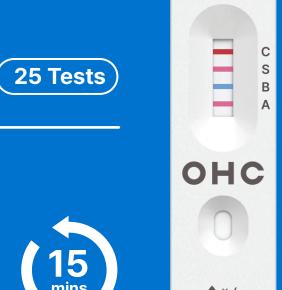
QuickFinder™ COVID-19/Flu **Antigen Self Test**

The Same Test with 3 Results For Emergency Use Authorization (EUA) only. For in vitro diagnostic use. For Ages 2 and Up.

OHC OSANG HEALTHCARE







OHC

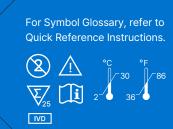
The Kit Contains

25 Test Cassettes 25 Sterile Swabs 25 Extraction Buffer Tubes & Filter caps 1 QRI (Quick Reference Instructions) Needed but not provided: Timer

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Manufacturing Site: OSANG Healthcare Co., Ltd. 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, S.Korea NEXUS DX, INC. 6759 Mesa Ridge Road San Diego, CA 92121

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COVID-19



