OHC OSANG HEALTHCARE

OHC COVID-19/Flu Antigen Test Pro
Healthcare Provider Instructions for Use (IFU)

For *In vitro* Diagnostic Use
For use under an Emergency Use Authorization (EUA) Only
For Rx Use Only
For use with anterior nasal swabs specimens only

Table of Contents

1. INTENDED USE

The OHC COVID-19/Flu Antigen Test Pro is a lateral flow immunochromatographic assay intended for the 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.

Results are for the simultaneous in vitro detection and differentiation 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.

These viral antigens are generally detectable in anterior nasal swab samples 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.

All negative results are presumptive, and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out influenza or SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control measures 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 each respiratory infection.

The OHC COVID-19/Flu Antigen Test Pro is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

2. EXPLANATION OF THE TEST

The ongoing COVID-19 pandemic, along with other seasonally prevalent illnesses such as influenza (Flu), continue to be among the world's most pressing healthcare issues. While contagious respiratory illnesses such as COVID-19 and influenza share similar symptoms and means of transmission, they are caused by different viruses. The Centers for Disease Control and Prevention (CDC) has also raised concerns about the potential co-infection with two or more of the respiratory viruses.

The OHC COVID-19/Flu Antigen Test Pro is a lateral flow test. The OHC COVID-19/Flu Antigen Test Pro is designed to detect antigen from the SARS-CoV-2, Influenza A, and Influenza B in anterior nasal swab samples from those who are suspected of COVID-19, Influenza A, and Influenza B. The OHC COVID-19/Flu Antigen Test Pro is validated for testing direct samples without transport media.

The cassette contains membranes which are pre-coated with anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies and anti-influenza B nucleoprotein monoclonal antibodies on the test lines. Another anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies and anti-influenza B nucleoprotein monoclonal antibodies are each bound to the beads. When the sample is put into the sample well, the antibodies bound to the beads and the antigen in the sample bind to form complexes and migrate to the membrane. The complexes will be captured by coated antibodies on the membrane, and then the line will form a visible line. The presence of SARS-CoV-2, influenza A and influenza B antigens

are indicated by lines visible in the S-marked position, A-marked position, and B-marked position in the results window, respectively.

The results of the test are interpreted at 15 minutes. Refer to the Interpretation of Results section.

3. PRINCIPLE OF THE TEST

The OHC COVID-19/Flu Antigen Test Pro is a lateral flow test. The OHC COVID-19/Flu Antigen Test Pro is designed to detect antigens from the SARS-CoV-2, Influenza A, and Influenza B in anterior nares nasal swab samples from those with symptoms consistent with COVID-19, Influenza A, and Influenza B. The OHC COVID-19/Flu Antigen Test Pro is validated for testing direct samples without transport media.

The cassette contains membranes which are pre-coated with anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies and anti-influenza B nucleoprotein monoclonal antibodies on the test lines. Another anti-SARS-CoV-2 nucleocapsid protein monoclonal antibodies, anti-influenza A nucleoprotein monoclonal antibodies and anti-influenza B nucleoprotein monoclonal antibodies are each bound to the beads. When the sample is put into the sample well, the antibodies bound to the beads and the antigen in the sample bind to form complexes and migrate to the membrane. The complexes will be captured by coated antibodies on the membrane, and then the line will form a visible line. The presence of SARS-CoV-2, influenza A and influenza B antigens are indicated by lines visible in the S-marked position, A-marked position, and B-marked position in the results window, respectively.

The test does not use biotin-Streptavidin/avidin chemistry in any of the steps for coupling reagents. Refer to the Figure A below for an overview of the test principle.

4. MATERIALS AND REAGENTS PROVIDED

The OHC COVID-19/Flu Antigen Test Pro is offered in a 25 test/kit sizes. The kit configuration is provided below:

Component	Quantity/Kit
Test Cassette	25
Sterile Swab	25
Extraction Buffer Tube & Filter Cap	25
Quick Reference Instructions (QRI)	1

5. MATERIALS REQUIRED BUT NOT INCLUDED

- Materials required but not provided:
  - A clock or timer, and
  - OHC COVID-19/Flu Control Swab Kit (Ref no. RAQC110ENA1)
- Recommended materials: Disposable gloves and mask.

6. WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

General

- For *in vitro* diagnostic use.

- For prescription use only.
- For use under FDA Emergency Use Authorization only.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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 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.
- **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 (repeat) 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.**
- **The OHC COVID-19/Flu Antigen Test Pro is intended to be used with direct nasal swabs and is not validated for use with viral transport media.**
- Use appropriate precautions and personal protective equipment in the collection, handling, storage, and disposal of patient samples.
- Do not use if any of the test kit contents or packaging is damaged.
- Do not use kit past its expiration date. Use of expired tests can lead to incorrect results.
- Test components are single-use. Do not re-use.
- Use only components of this test kit. Do not mix kit content with reagents from other kit lots.
- Ensure all kit components are at room temperature before use.
- Do not touch the swab tip.
- Once opened, the test cassette should be used within 60 minutes.
- 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.
- 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 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 line position and in the correct line color should be read and interpreted.
- This product has been authorized only for the detection of SARS CoV-2 nucleocapsid antigen, Influenza A and B nucleoprotein not for any other viruses or pathogens.
- Make sure there is sufficient 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.
- To ensure accurate test results avoid contamination with hand soap liquid gel.
- Dispose of unused contents and containers in accordance with federal, state, and local regulations.
- For most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Nasal Sample Collection

- Use of personal protection materials such as gloves is recommended.
- Do not use any nasal sprays, gels, or creams at least 30 minutes before nasal sample collection.
- 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.

Warnings

- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- 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.

Agent/Component name	GHS Code for each ingredient	Concentration
Proclin 300 (55965-84-9)	H302+H332 Harmful if swallowed or inhaled. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H411 Toxic to aquatic life with long lasting effects.	0.05%
Triton X-100 (9036-19-5)	H302 Harmful if swallowed. H315 Causes skin irritation. H318 Causes serious eye damage. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.	1.0%

- 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

7. QUALITY CONTROL

Internal Quality Control

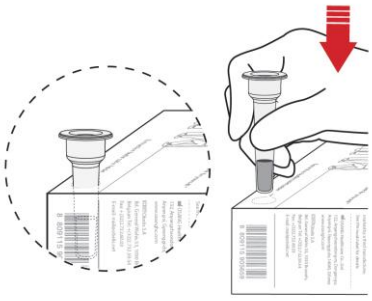
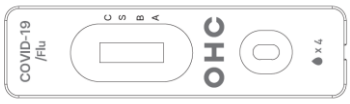
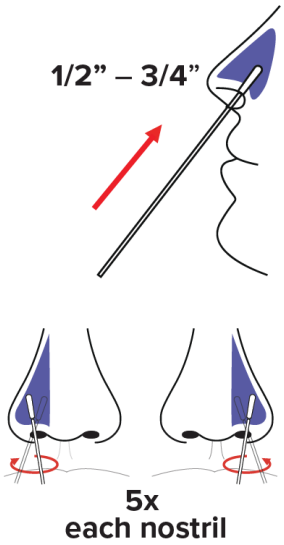
Each OHC COVID-19/Flu Antigen Test Pro has a built-in internal procedural control. The red line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test cassette has been maintained. A distinct red Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid, and a new test should be performed.

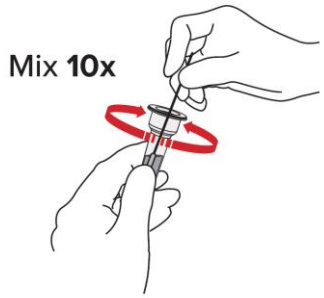
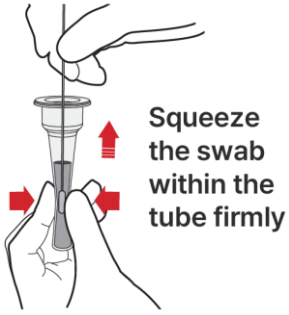
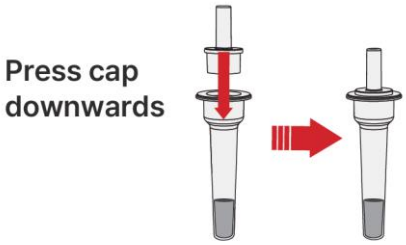
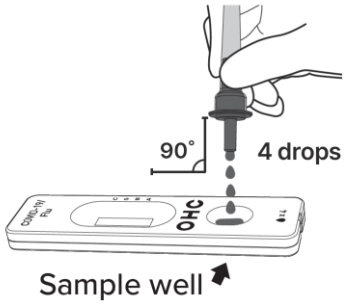
External Quality Control

COVID-19/Flu Control Swab Kit (OSANG Healthcare Co. Ltd., Ref no. RAQC110ENA1-Sold separately) is for use with the OHC COVID-19/Flu Antigen Test Pro. The COVID-19/Flu Control Swab Kit is specifically formulated and manufactured to ensure performance of the test and are used to verify an operator's ability to properly perform the test and interpret the results. The external controls should be processed and tested in accordance with the instructions for use below. The COVID-19/Flu Positive Control swab will produce a positive test result, with a red line appearing at the C, S, A, and a blue line at the B. The COVID-19/Flu Negative Control swab will produce a negative test result (Refer to 8. READ AND INTERPRET THE RESULTS section in these Instructions for Use).

Use of Kit Control reagents manufactured by any other source may not produce the expected results, and therefore, will not meet the requirements for an adequate quality assurance program for the OHC COVID-19/Flu Antigen Test Pro. If external controls do not perform as expected, testing of individuals should not be performed. Repeat the test or contact OSANG Healthcare's Technical Support. Please refer to 14. Customer support.

8. PREPARE TO PERFORM THE TEST

1. Open the foil pouch that contains the extraction buffer tube and filter cap.	
2. Pick up the extraction buffer tube and remove the sealing foil of the tube without spilling the buffer solution inside the tube.	
3. Push the extraction buffer tube into the perforated tube holder located at the front of the box, labeled "Insert Tube Here."	
4. Remove the test cassette from its foil pouch. NOTE: Use the test cassette within one hour of opening the foil pouch.	
5. 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 false results.	
6. Gently insert the swab head ½ to ¾ inch into the patient's 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 patient's nostril, making at least 5 circles. **REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.** **STOP: Did you swab BOTH nostrils? Inaccurate test results may occur if the nasal sample is not properly collected.** **NOTE:** When swabbing others, 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.	

7. Place the swab into the extraction buffer tube and completely immerse the swab head in the solution. 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 buffer solution the entire time.	
8. 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.	
9. Attach the filter cap onto the test tube.	
10. Squeeze only 4 DROPS of the buffer solution into the sample well. NOTE: DO NOT squeeze more than 4 drops from the tube into the sample well. Additional sample volume may yield inaccurate results.	
11. 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.	

9. READ AND INTERPRET THE 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.

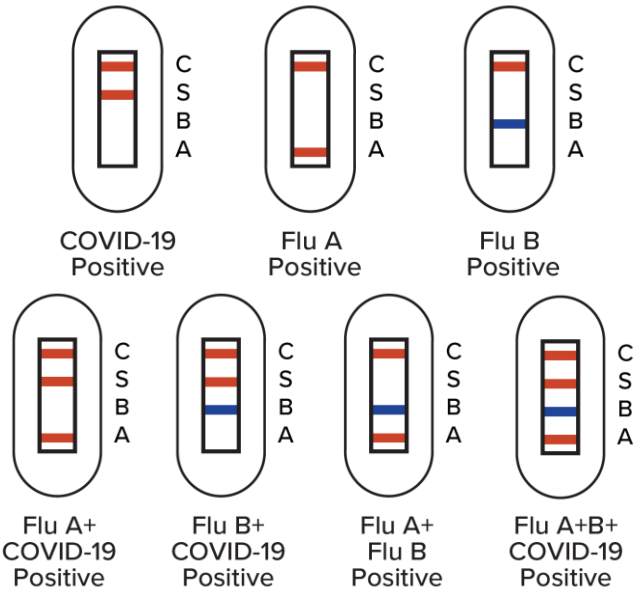
Look at the result window and locate the letters C and S, B, A on the side of the window.
A red line should always appear at the C position; this is a control line and signal that the test is working properly.
The information for each line is as follows:

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

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, Flu A and Flu B.

POSITIVE (+)

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.



Lines at the A and C positions indicate the presence of influenza type A viral antigen, lines at the B and C positions indicate the presence of influenza type B viral antigen and lines at the S and C positions indicate the presence of SARS-CoV-2 viral antigen in the specimen. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.
Repeat testing does not need to be performed if patients have a COVID-19 positive result at any time.
A positive S test result means that the virus that causes COVID-19 was detected in the sample, and it is very

likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the OHC COVID-19/Flu Antigen Test Pro should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Note: The Test line may vary in shade and intensity (light or dark, weak, or strong). The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result.

NEGATIVE (-)

If the control line at "C" is visible and you do not see a line at 'A', 'B' or 'S', it means the patient's sample may not have COVID-19, Flu A or Flu B virus. A negative result does not exclude influenza viral or SARS-CoV-2 viral infection. Determination of negative results should not be made before 15 minutes.

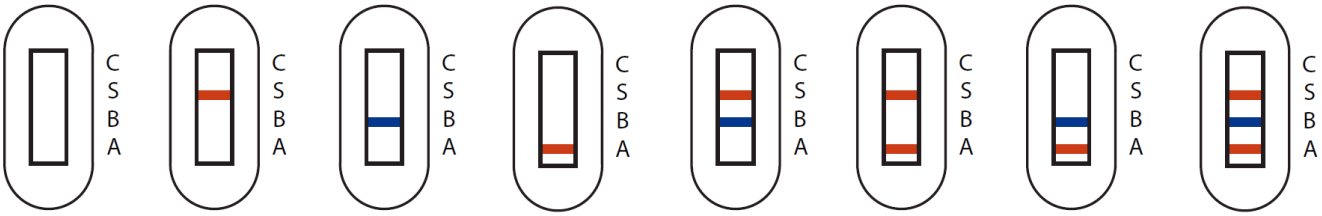
To increase the chance that the negative result for COVID-19 is accurate, the patient should test again in 48 hours if this is the first test, and the individual has symptoms on the first day of testing.

Negative Results are presumptive and may need to be confirmed with a molecular assay.
A negative test result indicates that the viruses that cause COVID-19 and the influenza viruses were not detected in the sample. A negative result does not rule out COVID-19 and Influenza. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19 and flu-like symptoms, e.g., fever, cough, and/or shortness of breath, continue, follow up testing for SARS-CoV-2 or influenza with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider. All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

INVALID

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.

If the test cassette looks like the examples below then the test **result is invalid** and you must **repeat the test with a new swab sample, a new tube, and a new test cassette.**



Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on First Day of Testing	**Day 0 (Test 1)**	**Day 2 (Test 2)**
With Symptoms	COVID-19 (-) Serial testing recommended for COVID-19 Flu A or B (-) Flu A or B result is Negative	COVID-19 (-) COVID-19 result is Negative COVID-19 (+) COVID-19 result is Positive Flu A or B (-) Flu result is Negative Flu A or B (+) Flu result is Positive
	COVID-19 (-) Serial testing recommended for COVID-19 Flu (+) Flu A or B result is Positive	COVID-19 (-) COVID-19 result is Negative COVID-19 (+) COVID-19 result is Positive Flu A or B (-) **Maintain Flu Positive interpretation** Flu A or B (+) Flu A or B result is Positive
	COVID-19 (+) COVID-19 Positive Flu A or B (-) Flu A or B Negative	No serial testing recommended
	COVID-19 (+) COVID-19 Positive Flu A or B (+) Flu A or B Positive	No serial testing recommended

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Repeat testing does not need to be performed if patients have a positive SARS-CoV-2 test result at any time. To increase the chance that a negative result for COVID-19 is accurate, you should test again in 48 hours if the individual has symptoms on the first day of testing.

10. LIMITATIONS

- The performance of this kit was established based on the 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 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 COVID-19 and influenza and their prevalence, which change over time.
- 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.
- All antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. 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.
- The contents of this kit are to be used for the qualitative detection of influenza A, influenza B, and SARS-CoV-2 antigens directly from anterior nasal swabs only.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Positive test results do not identify specific influenza A virus subtypes.
- 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, Flu A and/or Flu B have been found in the patient's sample and the patient likely has COVID-19, Flu A and/or Flu B.
- This test is read visually and has not been validated for use by those with impaired vision or color- impaired vision. Because test lines can be very faint, users with conditions affecting their vision-such as far-sightedness, glaucoma, or color blindness-are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).

11. CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

The OHC COVID-19/Flu Antigen Test Pro Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

However, to assist in using the OHC COVID-19/Flu Antigen Test Pro ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

- Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined OHC COVID-19/Flu Antigen Test Pro Instructions for Use and Quick Reference Guide. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.

- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report any significant deviations from the established performance characteristics of your product of which they become aware to DMD/OHT7-OIR/OPEQ/CDRH [via email: CDRH-EUA-Reporting@fda.hhs.gov) and Osang, LLC by contacting Technical Services (via email at covidhometest@osangllc.com or via phone at (844) 760-0556).
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- OSANG LLC, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The Letter of Authorization refers to "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived 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" as "Authorized Laboratories".

12. PERFORMANCE CHARACTERISTICS

A. Analytical Performance

- **Limit of Detection (LoD) (Analytical Sensitivity)**

The Limit of Detection (LoD) of the OHC COVID-19/Flu Antigen Test Pro was determined using serial dilutions of one strain of UV inactivated SARS-CoV-2 (USA-WA1/202) and two live strains of Influenza A and Influenza B. Contrived samples were prepared by spiking the strain into pooled human negative swab matrix (PNSM) obtained from healthy volunteers confirmed negative by RT-PCR. The preliminary LoD initially determined by testing ten-fold serial dilution series of three (3) replicates was confirmed by testing twenty (20) replicates. The confirmed LoD for the OHC COVID-19/Flu Antigen Test Pro is shown in the table below.

Virus Strains	Stock Concentration ($TCID_{50}$/mL)	LoD Concentration ($TCID_{50}$/mL)	$TCID_{50}$/Swab	# Positive/ #Total Tested	Percent Detected (%)
SARS-CoV-2 (USA-WA1/2020)	3.16×10^6	1.58×10^3	7.90×10^1	20/20	100%
Influenza A H1N1pdm09: A/Victoria/4897/2022	2.02×10^5	2.02×10^2	1.01×10^1	20/20	100%
Influenza A H3N2: A/Darwin/6/2021	4.17×10^5	2.09×10^2	1.04×10^1	20/20	100%
Influenza B Victoria: B/Washington/02/2019	3.16×10^6	3.16×10^3	1.58×10^2	20/20	100%
Influenza B Yamagata: B/Florida/4/2006	1.17×10^5	2.93×10^1	1.46	20/20	100%

- **Analytical Reactivity**

The OHC COVID-19/Flu Antigen Test Pro had wet testing (analytical reactivity) performed by establishing the LoD for Influenza A strains, Influenza B strains and SARS-CoV-2 strains on the OHC COVID-19/Flu Antigen Test Pro to

determine if the device can detect target analytes across a variety of strains. A selection of temporal, geographic and genetically diverse Influenza strains were tested on the OHC COVID-19/Flu Antigen Test Pro for inclusivity. Individual virus strains were diluted in pooled negative swab matrix (PNSM) at 10-fold dilutions and tested in triplicate. PNSM, un-spiked, was tested in triplicate. After a 10-fold break point was established testing two-fold dilution points of the lowest positive ten-fold dilution was completed. The lowest 10-fold or 2-fold dilution that demonstrated three (3) positives replicates for each was identified.

Analyte	Strain	Lineage	Concentration
SARS-CoV-2	USA-WA1/2020	Wild-type	1.58×10^3 $TCID_{50}$/mL
	XBB.1.5	Omicron Variant	400 $TCID_{50}$/mL
Influenza A (H1N1)	A/California/04/2009	H1N1pdm09	2.8×10^3 $TCID_{50}$/mL
	A/Brisbane/02/2018	H1N1pdm09	1.9×10^2 $TCID_{50}$/mL
	A/Michigan/45/2015	H1N1pdm09	1.9×10^1 $TCID_{50}$/mL
	A/Guangdong-Maonan/SWL1536/2019	H1N1pdm09	1.0×10^3 $TCID_{50}$/mL
	A/NY/03/2009	H1N1pdm09	4.6×10^4 $TCID_{50}$/mL
	A/Indiana/02/2020	H1N1pdm09	9.7×10^6 $CEID_{50}$/mL
	A/Wisconsin/588/2019	H1N1pdm09	2.8×10^4 FFU/mL
	A/Sydney/5/2021	H1N1pdm09	6.0×10^3 $TCID_{50}$/mL
	A/Hawaii/66/2019	H1N1pdm09	7.4×10^7 $CEID_{50}$/mL
	A/Wisconsin/67/2022	H1N1pdm09	4.2×10^2 $TCID_{50}$/mL
	A/Ohio/09/2015	(H1N1)v	1.4×10^6 $CEID_{50}$/mL
Influenza A (H1N2)	A/Minnesota/19/2011	(H1N2)v	8.00×10^6 $CEID_{50}$/mL
Influenza A (H3N2)	A/Tasmania/503/2020	H3N2	1.3×10^5 FFU/mL
	A/New York/21/2020	H3N2	3.3×10^5 FFU/mL
	A/Alaska/01/2021	H3N2	3.8×10^4 FFU/mL
	A/Hong Kong/45/2019	H3N2	3.8×10^4 FFU/mL
	A/Hong Kong/2671/2019	H3N2	1.1×10^3 $TCID_{50}$/mL
	A/Indiana/08/2011	(H3N2)v	8.1×10^2 $TCID_{50}$/mL
Influenza A (H5N1)	A/mallard/Wisconsin/2576/2009	H5N1	4.00×10^6 $CEID_{50}$/mL
Influenza A (H7N3)	A/northern pintail/Illinois/10OS3959/2010	H7N3	2.80×10^6 $CEID_{50}$/mL
Influenza B non-Victoria, non-Yamagata	B/Maryland/1/1959	Non-Victoria, non-Yamagata	3.4×10^3 $CEID_{50}$/mL
Influenza B Victoria lineage	B/Brisbane/60/2008	Victoria	1.6×10^0 $TCID_{50}$/mL
	B/Colorado/06/2017	Victoria	2.9×10^1 $TCID_{50}$/mL
	B/Texas/02/2013	Victoria	2.5×10^1 $TCID_{50}$/mL
	B/Michigan/01/2021	Victoria	1.4×10^4 $TCID_{50}$/mL
Influenza B Yamagata lineage	B/Texas/06/2011	Yamagata	1.5×10^3 $TCID_{50}$/mL
	B/Utah/09/2014	Yamagata	1.26×10^3 $TCID_{50}$/mL
	B/Wisconsin/01/2010	Yamagata	1.78×10^2 $TCID_{50}$/mL

- **Competitive Interference**

Competitive interference testing (i.e., evaluation of potential for a high concentration of one targe virus to interfere with detection of a low concentration of another target virus) for the OHC COVID-19/Flu Antigen Test Pro was completed and no competitive interference across analytes was observed. The testing was performed with different combinations of low (3x LoD) and high concentrations (either

1000x LoD or the highest concentration achievable exceeding 10^5 PFU/mL, $CEID_{50}$/mL or $TCID_{50}$/mL) of live Influenza A, live Influenza B and UV inactivated SARS-CoV-2 on the OHC COVID-19/Flu Antigen Test Pro device to determine if the candidate device can detect target analytes across a variety of analyte concentrations.

Combination	**Viral Target in Sample**			
	Influenza A (H1N1pdm09/A/ Victoria/4897/2022)	**Influenza B (Yamagata/B/ Florida/4/2006)**	**SARS-CoV-2 (USA-WA1/2020)**	**Results**
1	High	3X LoD	Negative	Pass. No competitive interference.
2	High	Negative	3X LoD	Pass. No competitive interference.
3	High	3X LoD	3X LoD	Pass. No competitive interference.
4	3X LoD	High	Negative	Pass. No competitive interference.
5	Negative	High	3X LoD	Pass. No competitive interference.
6	3X LoD	High	3X LoD	Pass. No competitive interference.
7	3X LoD	Negative	High	Pass. No competitive interference.
8	Negative	3X LoD	High	Pass. No competitive interference.
9	3Xx LoD	3X LoD	High	Pass. No competitive interference.

- **<u>High-dose hook effect</u>**

No high dose hook effect was observed with the OHC COVID-19/Flu Antigen Test Pro when high concentrations of SARS-CoV-2, Influenza A and Influenza B were tested.

Viral Strain Tested	**Concentration ($TCID_{50}$/mL)**
SARS-CoV-2	3.16×10^6 $TCID_{50}$/mL
Influenza A (H1N1)	2.02×10^5 $TCID_{50}$/mL
Influenza A (H3N2)	4.17×10^5 $TCID_{50}$/mL
Influenza B (Victoria)	3.16×10^6 $TCID_{50}$/mL
Influenza B (Yamagata)	1.17×10^5 $TCID_{50}$/mL

- **<u>Cross-reactivity and microbial interference</u>**

Cross-reactivity and microbial interference studies were performed with related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimens of the nasal cavity. Each organism was tested with and without the presence of UV inactivated SARS-CoV-2, live Influenza A, and Influenza B viruses at 3X co-spike equivalency LoD.

For cross reactivity, each organism was tested in replicate of three (3) at the concentrations listed in the following table of results. All testing samples were prepared in the pooled nasal wash (PNW). No cross reactivity or interference was observed for any of the organisms tested.

IDI	Organism	Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
229E	Human coronavirus 229E	1.58E+05 $TCID_{50}$/mL	0/3	0/3	0/3
OC43	Human coronavirus OC43	7.00E+05 $TCID_{50}$/mL	0/3	0/3	0/3
NL63	Human coronavirus NL63	7.05E+04 $TCID_{50}$/mL	0/3	0/3	0/3
SARS	SARS-coronavirus	1.25E+05 PFU/mL	0/3	0/3	0/3
MERS	MERS-coronavirus	1.47E+05 $TCID_{50}$/mL	0/3	0/3	0/3
AV1	Adenovirus Type 1	2.23E+05 $TCID_{50}$/mL	0/3	0/3	0/3
AV7	Adenovirus Type 7	1.58E+05 $TCID_{50}$/mL	0/3	0/3	0/3
hMPV	Human metapneumovirus 4 Type B2	3.50E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P1	Parainfluenza virus 1	2.00E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P2	Parainfluenza virus 2	1.75E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P3	Parainfluenza virus 3	7.00E+05 $TCID_{50}$/mL	0/3	0/3	0/3
P4	Parainfluenza virus 4b	2.39E+05 $TCID_{50}$/mL	0/3	0/3	0/3
EV68	Enterovirus 68	2.23E+05 $TCID_{50}$/mL	0/3	0/3	0/3
RSVA	Respiratory syncytial virus A	3.50E+05 $TCID_{50}$/mL	0/3	0/3	0/3
RSVB	Respiratory syncytial virus B	2.29E+05 $TCID_{50}$/mL	0/3	0/3	0/3
RV	Rhinovirus	7.05E+04 $TCID_{50}$/mL	0/3	0/3	0/3
HI	*Haemophilus influenzae*	9.68E+06 CFU/mL	0/3	0/3	0/3
SPN	*Streptococcus pneumonia*	1.81E+07 CFU/mL	0/3	0/3	0/3
SPY	*Streptococcus pyogenes*	7.50E+07 CFU/mL	0/3	0/3	0/3
CA	*Candida albicans*	1.21E+07 CFU/mL	0/3	0/3	0/3
BP	*Bordetella pertussis*	2.90E+08 CFU/mL	0/3	0/3	0/3
MP	*Mycoplasma pneumonia*	2.50E+07 CFU/mL	0/3	0/3	0/3
CP	*Chlamydia pneumoniae*	4.33E+06 IFU/mL	0/3	0/3	0/3
LP	*Legionella pneumophila*	6.50E+06 CFU/mL	0/3	0/3	0/3
MT	*Mycobacterium tuberculosis*	3.03E+06 CFU/mL	0/3	0/3	0/3
PJ	*P. jiroveci-S. cerevisiae*	1.30E+07 CFU/mL	0/3	0/3	0/3
SA	*Staphylococcus aureus* subsp. *aureus*	2.60E+08 CFU/mL	0/3	0/3	0/3
SE	*Staphylococcus epidermidis*	9.00E+07 CFU/mL	0/3	0/3	0/3
CX	*Corynebacterium xerosis*	2.30E+07 CFU/mL	0/3	0/3	0/3
EC	*Escherichia coli*	1.79E+08 CFU/mL	0/3	0/3	0/3
LA	*Lactobacillus Acidophilus*	1.21E+07 CFU/mL	0/3	0/3	0/3
MC	*Moraxella catarrhalis*	2.50E+08 CFU/mL	0/3	0/3	0/3

IDI	Organism	Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
NM	*Neisseria meningitidis*	3.43E+06 CFU/mL	0/3	0/3	0/3
NE	*Neisseria Elongata*	2.68E+08 CFU/mL	0/3	0/3	0/3
PA	*Pseudomonas aeruginosa*	3.45E+08 CFU/mL	0/3	0/3	0/3
SS	*Streptococcus salivarius*	1.01E+06 CFU/mL	0/3	0/3	0/3
ME	Measles	8.48E+05 $TCID_{50}$/mL	0/3	0/3	0/3
MU	Mumps	8.48E+05 $TCID_{50}$/mL	0/3	0/3	0/3
EBV	Epstein Barr Virus	1.83E+06 CP/mL	0/3	0/3	0/3
CMV	Cytomegalovirus	7.05E+04 $TCID_{50}$/mL	0/3	0/3	0/3

Microbial interference:
For evaluating microbial interference against the SARS-CoV-2, Influenza A (H1N1pdm09), Influenza B (Yamagata) test lines, the organisms were tested with SARS-CoV-2 UV-inactivated SARS-CoV-2: USA-WA1/2020 (ZeptoMetrix # 0810587UV), Live Flu A: H1N1pdm09/A/Victoria/4897/2022 (ZeptoMetrix # 0810684CF), Live Flu B: Yamagata/B/Florida/4/2006 (ZeptoMetrix # 0810255CF) diluted to 3x LoD concentration in negative pooled nasal wash (PNW). No microbial interference was seen with the organisms tested at the concentrations shown below.

IDI	Organism	Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
229E	Human coronavirus 229E	1.58E+05 $TCID_{50}$/mL	3/3	3/3	3/3
OC43	Human coronavirus OC43	7.00E+05 $TCID_{50}$/mL	3/3	3/3	3/3
NL63	Human coronavirus NL63	7.05E+04 $TCID_{50}$/mL	3/3	3/3	3/3
SARS	SARS-coronavirus	1.25E+05 PFU/mL	3/3	3/3	3/3
MERS	MERS-coronavirus	1.47E+05 $TCID_{50}$/mL	3/3	3/3	3/3
AV1	Adenovirus Type 1	2.23E+05 $TCID_{50}$/mL	3/3	3/3	3/3
AV7	Adenovirus Type 7	1.58E+05 $TCID_{50}$/mL	3/3	3/3	3/3
hMPV	Human metapneumovirus 4 Type B2	3.50E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P1	Parainfluenza virus 1	2.00E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P2	Parainfluenza virus 2	1.75E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P3	Parainfluenza virus 3	7.00E+05 $TCID_{50}$/mL	3/3	3/3	3/3
P4	Parainfluenza virus 4b	2.39E+05 $TCID_{50}$/mL	3/3	3/3	3/3
EV68	Enterovirus 68	2.23E+05 $TCID_{50}$/mL	3/3	3/3	3/3

IDI	Organism	Concentration	Influenza A Test Results (positive/total)	Influenza B Test Results (positive/total)	SARS-CoV-2 Test Results (positive/total)
RSVA	Respiratory syncytial virus A	3.50E+05 $TCID_{50}$/mL	3/3	3/3	3/3
RSVB	Respiratory syncytial virus B	2.29E+05 $TCID_{50}$/mL	3/3	3/3	3/3
RV	Rhinovirus 1A	7.05E+04 $TCID_{50}$/mL	3/3	3/3	3/3
HI	*Haemophilus influenzae*	9.68E+06 CFU/mL	3/3	3/3	3/3
SPN	*Streptococcus pneumonia*	1.81E+07 CFU/mL	3/3	3/3	3/3
SPY	*Streptococcus pyogenes*	7.50E+07 CFU/mL	3/3	3/3	3/3
CA	*Candida albicans*	1.21E+07 CFU/mL	3/3	3/3	3/3
BP	*Bordetella pertussis*	2.90E+08 CFU/mL	3/3	3/3	3/3
MP	*Mycoplasma pneumonia*	2.50E+07 CFU/mL	3/3	3/3	3/3
CP	*Chlamydia pneumoniae*	4.33E+06 IFU/mL	3/3	3/3	3/3
LP	*Legionella pneumophila*	6.50E+06 CFU/mL	3/3	3/3	3/3
MT	*Mycobacterium tuberculosis*	3.03E+06 CFU/mL	3/3	3/3	3/3
PJ	*P. jiroveci-S. cerevisiae*	1.30E+07 CFU/mL	3/3	3/3	3/3
SA	*Staphylococcus aureus* subsp. *aureus*	2.60E+08 CFU/mL	3/3	3/3	3/3
SE	*Staphylococcus epidermidis*	9.00E+07 CFU/mL	3/3	3/3	3/3
CX	*Corynebacterium xerosis*	2.30E+07 CFU/mL	3/3	3/3	3/3
EC	*Escherichia coli*	1.79E+08 CFU/mL	3/3	3/3	3/3
LA	*Lactobacillus acidophilus*	1.21E+07 CFU/mL	3/3	3/3	3/3
MC	*Moraxella catarrhalis*	2.50E+08 CFU/mL	3/3	3/3	3/3
NM	*Neisseria meningitidis*	3.43E+06 CFU/mL	3/3	3/3	3/3
NE	*Neisseria elongata*	2.68E+08 CFU/mL	3/3	3/3	3/3
PA	*Pseudomonas aeruginosa*	3.45E+08 CFU/mL	3/3	3/3	3/3
SS	*Streptococcus salivarius*	1.01E+06 CFU/mL	3/3	3/3	3/3
ME	Measles	8.48E+05 $TCID_{50}$/mL	3/3	3/3	3/3
MU	Mumps	8.48E+05 $TCID_{50}$/mL	3/3	3/3	3/3
EBV	Epstein Barr Virus	1.83E+06 CP/mL	3/3	3/3	3/3
CMV	Cytomegalovirus	7.05E+04 $TCID_{50}$/mL	3/3	3/3	3/3
PNW	Pooled Negative Nasal Wash	N/A	3/3	3/3	3/3

- **Endogenous/Exogenous Interfering Substances**

The OHC COVID-19/Flu Antigen Test Pro was evaluated for performance in the presence of potentially interfering substances that might be present in a respiratory specimen. The positive (3x LoD co-spike PNW with UV inactivated SARS-CoV-2, and live Influenza A and B) and negative specimens were tested with the addition of the potentially interfering substances. Each substance was tested in replicates of three (3). The performance of the OHC COVID-19/Flu Antigen Test Pro was not affected by any of the potentially interfering substances listed in the table below at the concentrations noted.

Substance	**Concentration**	**Interference** (Yes/No)
Human Whole Blood (EDTA tube)	4% v/v	No
Mucin (porcine stomach, type II)	0.5%	No
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	No
Naso GEL (NeilMed)	5% v/v	No
Nasal Drops (Phenylephrine)	15% v/v	No
Nasal Spray (Oxymetazoline)	15% v/v	No
Nasal Spray (Cromolyn)	15% v/v	No
Zicam	5% v/v	No
Homeopathic (Alkalol)	10% v/v	No
Sore Throat Phenol Spray	15% v/v	No
Tobramycin	4 µg/mL	No
Mupirocin	10 mg/mL	No
Fluticasone Propionate	5% v/v	No
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No
FluMist/FluMist Quadrivalent Live intranasal influenza virus vaccine	15% v/v	No
Zanamivir	282 ng/mL	No
Biotin	3,500 ng/mL	No
Body and Hand Lotion	0.5% w/v	No
Body Lotion with 1.2% dimethicone	0.5% w/v	No
Hand Lotion	5% w/v	No
Hand Sanitizer with Aloe, 62% ethyl alcohol	5% v/v	No
Hand Sanitizer with cream lotion	15% v/v	No
Hand Sanitizer, 80% ethanol, fast drying	15% v/v	No
Hand soap liquid gel*	0.05% w/v	No

*** Interference was observed with ≥ 0.1% (w/v) for hand soap liquid gel and influenza B results.**

13. CLINICAL EVALUATION

A prospective clinical study was completed at six (6) sites in the United States for clinical validation of the OHC COVID-19/Flu Antigen Test Pro for the detection of SARS-CoV-2, Influenza A and/or Influenza B in subject-collected anterior nasal swab (ANS) samples. The study evaluated the OHC COVID-19/Flu Antigen Test Pro performance in symptomatic individuals (those suspected of COVID-19, Influenza A and/or Influenza B). A total of 608 symptomatic subjects were enrolled who were currently experiencing symptoms associated with COVID-19, Influenza A and/or Influenza B. Each enrolled subject either self-collected one sample from their anterior nasal passages (from both nostrils), or had one sample collected from him/her by another individual. Each of the subjects also had an ANS sample (from both nostrils) collected from him/her by one of the study personnel. Test results from the OHC COVID-19/Flu Antigen Test Pro were compared to highly sensitive molecular FDA cleared SARS-CoV-2, Influenza A, and Influenza B RT-PCR assays. Out of 608 enrolled subjects, there were 577 evaluable subjects. Of the 577 evaluable subjects for SARS-CoV-2, the analysis resulted in a positive percent agreement (PPA) of 88.7% (95% CI: 81.2%-93.4%) and negative percent agreement (NPA) of 99.6% (95% CI: 98.5%-99.9%). There were 577 evaluable subjects for Influenza A, the analysis resulted in a PPA of 88.5% (95% CI: 77.0% – 94.6%) and a NPA of 98.9% (95% CI: 97.5% - 99.5%). There were 577 evaluable subjects for Influenza B, the analysis resulted in a PPA of 85.4% (95% CI: 71.6% –

93.1%) and a NPA of 99.6% (95% CI: 98.6% to 99.9%).

SARS-CoV-2 Primary Analysis

SARS-CoV-2	Comparator Positives	Comparator Negatives	Total
OHC COVID-19/Flu Antigen Test Pro Positives	94	2	96
OHC COVID-19/Flu Antigen Test Pro Negatives	12	469	481
Total	**106**	**471**	**577**
Positive Percent Agreement (94/106) = 88.7% (95% CI: 81.2%-93.4%) Negative Percent Agreement (469/471) = 99.6% (95% CI: 98.5% - 99.9%)			

Positive Results Broken Down by Days Since Symptom Onset for SARS-CoV-2

Days post COVID-19 Symptoms Onset	Number of Subject samples tested	OHC COVID-19/Flu Antigen Test Pro Positives	Comparator Positives	% Positive Rate (by Comparator)	PPA
0	11	0	0	0.0%	NA
1	137	23	27	19.7%	85.2%
2	224	35	41	18.3%	85.4%
3	126	26	27	21.4%	96.3%
4	79	10	11	13.9%	90.9%
Total	**577**	**94***	**106**	**18.4%**	**88.7% (95% CI: 81.2% -93.4%)**

*NOTE: Two false positive subjects were excluded from the OHC COVID-19/Flu Antigen Test Pro Positives count for the purposes of this table.

Influenza A Primary Analysis

Influenza A	Comparator Positives	Comparator Negatives	Total
OHC COVID-19/Flu Antigen Test Pro Positives	46	6	52
OHC COVID-19/Flu Antigen Test Pro Negatives	6	519	525
Total	**52**	**525**	**577**
Positive Percent Agreement (46/52) = 88.5% (95% CI: 77.0%-94.6%) Negative Percent Agreement (519/525) = 98.9% (95% CI: 97.5% - 99.5%)			

Influenza B Primary Analysis

Influenza B	Comparator Positives	Comparator Negatives	Total
OHC COVID-19/Flu Antigen Test Pro	35	2	37

Positives			
OHC COVID-19/Flu Antigen Test Pro Negatives	6	534	540
Total	**41**	**536**	**577**
Positive Percent Agreement (35/41) = 85.4% (95% CI: 71.6%-93.1%) Negative Percent Agreement (534/536) = 99.6% (95% CI: 98.6% - 99.9%)			

Subjects Demographics

	Subjects (by lay-user collection and testing (N=86)	Self-collecting and testing (N=491)	Overall (N=577)
Mean (SD)	12.0 (13.5)	36.7 (15.8)	33 (17.8)
Median [Min, Max]	10 [2, 74]	33 [14, 80]	29 [2, 80]
Age Group			
≥2-<14 years of age	79 (91.9%)	0 (0.0%)	79 (13.7%)
14-24 years of age	2 (2.3%)	145 (29.5%)	147 (25.5%)
>24-64 years of age	1 (1.2%)	313 (63.7%)	314 (54.4%)
≥65 years of age	4 (4.7%)	33 (6.7%)	37 (6.4%)
Sex at Birth			
Female	34 (39.5%)	300 (61.1%)	334 (57.9%)
Male	52 (60.5%)	191 (38.9%)	243 (42.1%)
Ethnicity			
Hispanic/Latino	4 (4.7%)	87 (17.7%)	91 (15.8%)
Not Hispanic/Latino	82 (95.3%)	404 (82.3%)	486 (84.2%)
Race			
American Indian or Alaskan Native	0 (0.0%)	0 (0.0%)	0 (0.0%)
Asian	0 (0.0%)	11 (2.2%)	11 (1.9%)
Black or African American	4 (4.7%)	38 (7.7%)	42 (7.3%)
Native Hawaiian/Pacific Islander	0 (0.0%)	5 (1.0%)	5 (0.9%)
White	77 (89.5%)	428 (87.2%)	505 (87.5%)
Unknown/Prefer not to answer	0 (0.0%)	2 (0.4%)	2 (0.3%)
Other (Mixed race/biracial)	5 (5.8%)	7 (1.4%)	12 (2.1%)

**Total up to 99.9 or 100.1 due to rounding*

14. SERIAL TESTING

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical - 13 - representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS CoV- 2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection.

Performance of the antigen test with serial testing in symptomatic individuals is described in the table below. Data establishing PPA of COVID-19 antigen serial testing compared to molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in the study combined.

Data establishing PPA of COVID-19 antigen serial testing compared to molecular comparator single day testing throughout the course of infection with serial testing. Data is for all antigen tests in study combined.

Days After First PCF Positive Test Result	**Symptomatic on First Day of Testing**		
	Antigen Positive/PCR Positive (Antigen Test Performance % PPA)		
	1 Test	**2 Test**	**3 Test**
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.1%)	43/43 (100.0%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	N/A

1 Test = one (1) test performance on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performance an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours apart.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated date, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

15. CUSTOMER SUPPORT

For questions, or to report a problem, please call Technical Support at 844-760-0556 (Available Hours: Mon. to Fri.: 9 a.m. – 5 p.m. PST) or covidhometest@osangllc.com .

Test system problems may also be reported to the FDA using the MedWatch reporting system (phone: 1-800 FDA-1088; fax: 1-800 FDA-1078: or http://www.fda.gov/medwatch).

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,
14040, South Korea

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

16. SYMBOLS USED ON THE PRODUCT LABELS

The table below describes the symbols on the OHC COVID-19/Flu Antigen Test Pro package.

SYMBOL	DESCRIPTION
	Use by Date
	Reference number
	Contains sufficient for <n> test
	Caution
	Batch Code
	Consult instructions for use
	Storage temperature range
	Do not use if seal or packaging is broken or damaged
	*In vitro* diagnostic
	Manufacturer
	Do not reuse
	Date of manufacture

ISC03248 Rev. 2024-03(00)

Distributed by OSANG LLC

OHC COVID-19/Flu Antigen Test Pro
QUICK REFERENCE INSTRUCTIONS

Study the Healthcare Provider Instructions for Use thoroughly before using Quick Reference Instructions.
This is not a complete instructions for use.

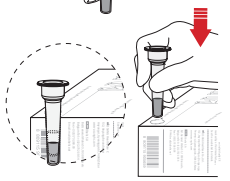
FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY
FOR IN VITRO DIAGNOSTIC USE
FOR RX USE ONLY

PREPARE THE MATERIALS

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

2. Pick up the extraction buffer tube and remove the sealing foil of the tube without spilling the buffer solution inside the tube.

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



4. Remove the Test cassette from its foil pouch.

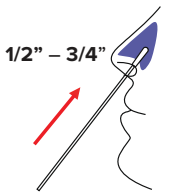
NOTE: Use the Test cassette within one hour of opening the foil pouch.

PERFORMING THE TEST

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

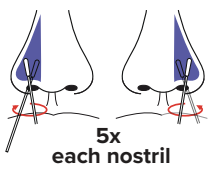
DO NOT touch the swab head.

6. Gently insert the swab head 1/2 to 3/4 inch into the patient's 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 patient's nostril, making at least 5 circles.



REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.

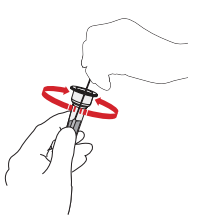
STOP: Did you swab BOTH nostrils?
Inaccurate test results may occur if the nasal sample is not properly collected.



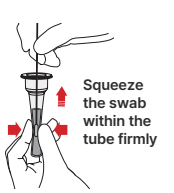
NOTE: When swabbing others, wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

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

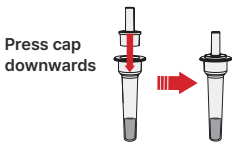
Vigorously mix the solution by rotating the swab forcefully against the side of the tube **at least 10 times,** keeping the swab tip submerged in the buffer solution the entire time.



8. 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.

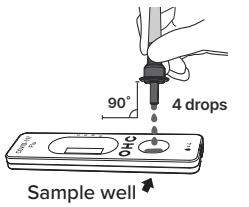


9. Attach the filter cap onto the test tube.



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

NOTE: DO NOT squeeze more than 4 drops from the tube into the sample well. Additional sample volume may yield inaccurate results.



11. 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.

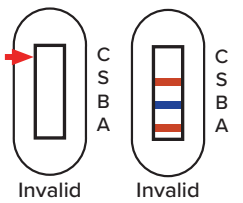
DO NOT interpret test result before 15 minutes or after 30 minutes.

TEST RESULT INTERPRETATION

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.

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.**
Repeat with new sample and test kit.



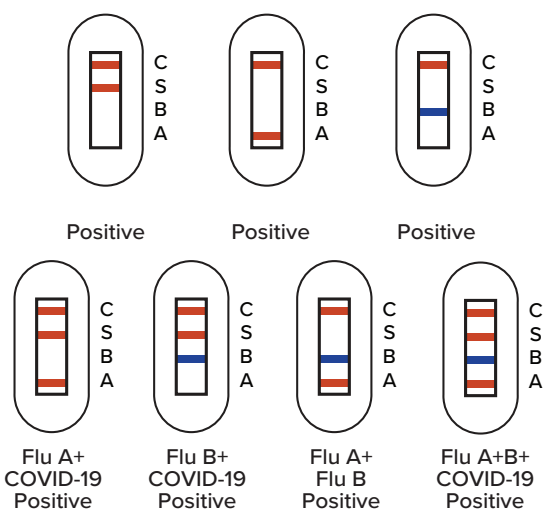
NOTE: The image displayed above are examples only; additional invalid outcomes are possible. For a complete set of invalid results, refer to the OHC COVID-19/Flu Antigen Self Test Pro Healthcare Provider Instructions for Use.

NEGATIVE RESULTS

If the control line at "C" is visible and you do not see a line at 'A', 'B' or 'S', it means the test is negative. Negative results are presumptive and may need to be confirmed with a molecular assay.

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.**



To increase the chance that the negative result for COVID-19 is accurate, you should,
• Test again in 48 hours if this is the first test, and the individual has symptoms on the first day of testing.

Invalid:
A red line should always appear at the Control line position (C position). If a line does not form at the Control line position in 15

Positive:
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. The influenza A, B and/or SARS-CoV-2 antigen(s) were detected in patient's sample. Lines at the A and C positions indicate the presence of influenza type A viral antigen, lines at the B and C positions indicate the presence of influenza type B viral antigen and lines at the S and C positions indicate the presence of SARS-CoV-2 viral antigen in the specimen. A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype. **Repeat testing does not need to be performed if patients have a positive result at any time.**

Note: The Test line may vary in shade and intensity (light or dark, weak or strong). The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result.

Negative:
A Control line (C position) only, with no Test line at the A, B, and S positions, indicates that influenza A, B antigen or SARS-CoV-2 antigen has not been detected. A negative result does not exclude influenza viral or SARS-CoV-2 viral infection. Determination of negative results should not be made before 15 minutes.

Serial Testing:
Repeat testing is needed to improve test accuracy.
Please follow the table below when interpreting test results.
Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on First Day of Testing	Day 0 (Test 1)	Day 2 (Test 2)
With Symptoms	COVID-19 (-) Serial testing recommended for COVID-19 Flu A or B (-) Flu A or B result is Negative	COVID-19 (-) COVID-19 result is Negative COVID-19 (+) COVID-19 result is Positive Flu A or B (-) Flu result is Negative Flu A or B (+) Flu result is Positive
	COVID-19 (-) Serial testing recommended for COVID-19 Flu (+) Flu A or B result is Positive	COVID-19 (-) COVID-19 result is Negative COVID-19 (+) COVID-19 result is Positive Flu A or B (-) **Maintain Flu Positive interpretation** Flu A or B (+) Flu A or B result is Positive
	COVID-19 (+) COVID-19 Positive Flu A or B (-)	No serial testing recommended
	COVID-19 (+) COVID-19 Positive Flu A or B (+) Flu A or B Positive	No serial testing recommended

Repeat testing does not need to be performed if patients have a positive SARS-CoV-2 test result at any time.
To increase the chance that a negative result for COVID-19 is accurate, you should:
• Test again in 48 hours if the individual has symptoms on the first day of testing.

OHC COVID-19/Flu Antigen Test Pro

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

INTENDED USE

The OHC COVID-19/Flu Antigen Test Pro is a lateral flow immuno chromatographic assay intended for the in vitro rapid, simultane ous qualitative detection and dierentiation 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.

Results are for the simultaneous in vitro detection and dierentia tion of SARS-CoV-2, influenza A virus, and influenza B virus protein antigens, but does not dierentiate, between SARS-CoV and SARS-CoV-2 viruses and is not intended to detect influenza C antigens.

These viral antigens are generally detectable in anterior nasal swab samples 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.

All negative results are presumptive, and should be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out influenza or SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection control measures 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 symp toms consistent with each respiratory infection. foh

The OHC COVID-19/Flu Antigen Test Pro is only for in vitro diagnostic use under the Food and Drug Administration's Emer gency Use Authorization. This product has not been FDA cleared or approved.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- This test may only be used in symptomatic individuals.
- 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/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.
- 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.
- 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, and only test lines that appear at the correct position and in the correct color should be read and interpreted.
- 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 line position and in the correct line color should be read and interpreted.
- Dispose of unused contents and containers in accordance with federal, state, and local regulations.

INDEX OF SYMBOLS

	Manufacturer		Date of manufacture
	Contains sufficient for <n> tests	REF	Catalogue number
	Temperature limit		Use-by date
	Do not reuse	LOT	Batch code
	Do not use if seal or packaging is broken or damaged		Consult instructions for use
	Caution	IVD	*In vitro* 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

ISC03241 Rev. 2024-03 (00)

OHC COVID-19/Flu Control Swab Kit

For *in vitro* diagnostic use.
For professional use only.
For use under Emergency Use Authorization only.
For prescription use.

Please follow the instructions carefully when performing the test.

INTENDED USE

The OHC COVID-19/Flu Control Swab Kit is an external qualitative quality control intended for ensuring that reagents and materials are working and that the test procedure is correctly performed.

Components	Qty	Description
COVID-19/Flu Positive Control Swab	10 ea	The COVID-19/Flu Positive Control Swab consists of non-infectious recombinant SARS-CoV-2 nucleocapsid antigen and inactivated Influenza A&B virus culture fluid spiked onto a sterile swab.
COVID-19/Flu Negative Control Swab	10 ea	The COVID-19/Flu Negative Control Swab consists of a sterile swab with *Streptococcus* group A or B antigens.
Instructions for use	1 ea	User manual

Materials required but not provided

1. Test kit (OHC COVID-19/Flu Antigen Test Pro, etc.)
2. Disposable glove
3. Timer

STORAGE

1. Store at 2-30 °C (35.6 - 86 °F).
2. Do not freeze the product or store it above 30 °C (86 °F).

TEST PROCEDURE

For full instructions for use on how to use these controls, please refer to OHC COVID-19/Flu Antigen Test Pro Healthcare Provider Instructions for Use (IFU).

We recommend controls be run once for:

- Each new kit lot,
- Each new operator,
- Each new shipment,
- As required by site quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

If either or both external control results are unexpected or invalid, repeat the external controls with a new swab, extraction buffer tube and test cassette and if results continue to be unexpected or invalid, contact customer service (ohc_cs@osanghc.com).

WARNING 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/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.

1. For in vitro diagnostic use.
2. For professional use only.
3. Do not use control swabs for patient specimen collection; use only as a test quality control.
4. Do not re-use any contents in the product.
5. Do not use if any content package is damaged.
6. Use of Nitrile or Latex gloves is recommended when working with these controls.
7. Follow the instructions for use carefully. If they are not followed, the reliability of the test results cannot be guaranteed.
8. Do not use the product beyond the labeled expiry date.
9. Incompatibilities between this product and other manufacturers test kits may occur.
10. If stored at 2-8°C, keep it at 18-30°C for 30 minutes before opening the product before use.
11. The swab should remain in the sealed pouch until use.
12. After the inspection, clean your hands and disinfect them with disinfectant.
13. Controls contain inactivated materials but no test result guarantees products non-infectious. All the products should be handled as potentially hazardous and infectious.
14. Do not arbitrarily disassemble or alter the product.
15. Use such as disassembling or taking the product may cause serious harm, so never use it for anything other than its intended purpose.

SYMBOL

IVD	*In vitro* Diagnostic medical device	CONTROL	Control
REF	Catalogue number	CONTROL -	Negative Control
LOT	Batch code	CONTROL +	Positive Control
	Use-by date		Caution
	Manufacturer		Temperature limit
	Consult Instruction For Use		Do not re-use

OHC OSANG HEALTHCARE

OSANG Healthcare Co., Ltd.
132, Anyangcheondong-ro,Dongan-gu, Anyang-si, Gyeonggi-do, Korea (14040)
www.osanghc.com Tel : +(82)31.460.0300 E-Mail : ohc_cs@osanghc.com

REF RAQC110ENA1
ISC03198 Rev. 2024-03 (00)