AG-FLU A/FLU B/COVID-19 Ag RAPID TEST KIT

INSTRUCTIONS FOR USE

AstraGene Flu A/Flu B/ COVID-19 Ag rapid test kit is a rapid visual immunoassay for the qualitative, presumptive detection of influenza A and B viral antigens and COVID-19 Antigen form Nasal swabs and nasopharyngeal swab specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B virus and COVID-19 infection.

PRINCIPLE

AstraGene Flu A/Flu B/ COVID-19 Ag rapid test kit detects influenza A and B viral antigens and COVID-19 Antigen through visual interpretation of color development on the strip. Anti-influenza A and B antibodies, Anti- COVID-19 antibodies and Goat anti-Rabbit IgG Antibodies are immobilized on the test region A, B, N and C of the membrane respectively. During testing, the extracted specimen reacts with anti-influenza A, B, COVID-19 antibodies and rabbit IgG Antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane.

PACKAGE CONTENTS

Description	**10 tests**	1 test
Test Cassette and Desiccant	10 Cassette's	1 Cassette
Reagent Solution Bottle	1 No	1 No
Reagent Tube with Filter Tip	10 No's	1 No.
Sterilized Nasal Swab	10 No's	1 No.
Control set	1 No.	1 No.

Catalogue Number	**10 tests**	**1 test**
Cassette Model	AG/RTK/FCAg/24/01	AG/RTK/FCAg/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or timer.
- Pipette
- Latex gloves

STORAGE &STABILITY

- Store as packaged in the sealed pouch at 2-30ºC. The test is stable until the expiration date marked on its sealed pouch.
- The test must remain in the sealed pouch until use. Do not freeze

SPECIMEN COLLECTION & PREPARATION

- Nasal Swab Sample (for optimal test performance with a Nasal Swab specimen, use the Swabs supplied in the kit)
- It is important to obtain as much secretion as possible. Therefore, to collect a Nasal Swab sample, insert the sterile Swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the Swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the Swab a few times against the nasal wall
- Nasopharyngeal Swab Sample:
- It is important to obtain as much secretion as possible. Therefore, to collect a nasopharyngeal Swab sample, carefully insert the sterile Swab into the nostril that presents the most secretions under visual inspection. Keep the Swab near the septum floor of the nose while gently pushing the Swab into the posterior nasopharynx. Rotate the Swab several times.
- Note: Specimens should be tested as soon as possible after collection. However, if transport of Swab samples is required, minimal dilution of the sample is recommended, as this may result in decreased test sensitivity. Nasal wash/aspirate specimens may be stored frozen (-70°C or lower) for up to 1 month. All clinical specimens must be at room temperature before beginning the assay.

PROCEDURE FOR POSITIVE OR NEGATIVE SAMPLE

- Add 300ul reagent solution (approximately 9 drops) into the reagent tube.
- Add positive control swab or negative control swab to the tube with reagent solution.
- Vigorously rotate and twist the swab against the side of the tube at least 10 times.
- Squeeze the sides of the tube to obtain as much liquid as possible. Dispose of swab properly.
- Hold the sample dropper vertically. Add 5 drops (about 120 µl) of the specimen without air bubbles into the sample well.
- Please follow the results interpretation procedure to verify the validity of the device.

PROCEDURE

A) Add 300ul reagent solution (approximately 9 drops) into the reagent tube.	

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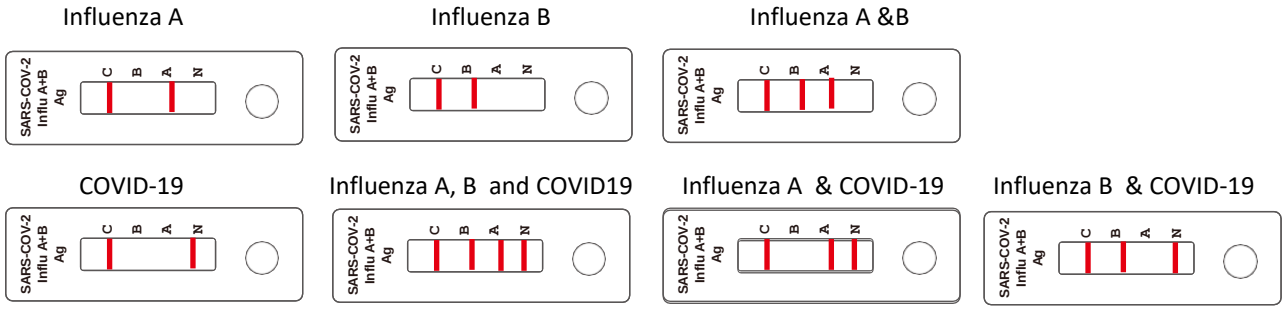
B) Add Nasal/Nasopharyngeal swab to the tubewith reagent solution.	
C) Vigorously rotate and twist the swab againstthe side of the tube at least 10 times.	
D) Squeeze the sides of the tube to obtain as much liquid as possible. Dispose of swab properly. Then place the filter tip onto reagent tube tightly.	
E} Hold the reagent tube vertically with the filtertip pointing downward. Add 5drops (about 120 µl) of the specimen without air bubbles into thesample well. *Note: Read results at 20 minutes.	**Note:** 1. For condensed samples, if the sample does not migrate to the membrane within 20 seconds, to apply one to two more drops of reagent solution to help the sample migrate on the membrane. 2. Do not interpret results after 30 minutes

RESULT INTERPRETATIONS

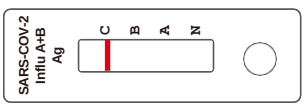
Positive

A clear pink control band (C) and a detectable test band (T1) or (T2) or (T3) appears, indicating a positive result.
Band T1 (B): Positive for Influenza A
Band T2 (A): Positive for Influenza B
Band T3 (N): Positive for COVID-19



Negative:

A pink colored band appears only at the control region (C), indicating a negative result



Invalid

No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number

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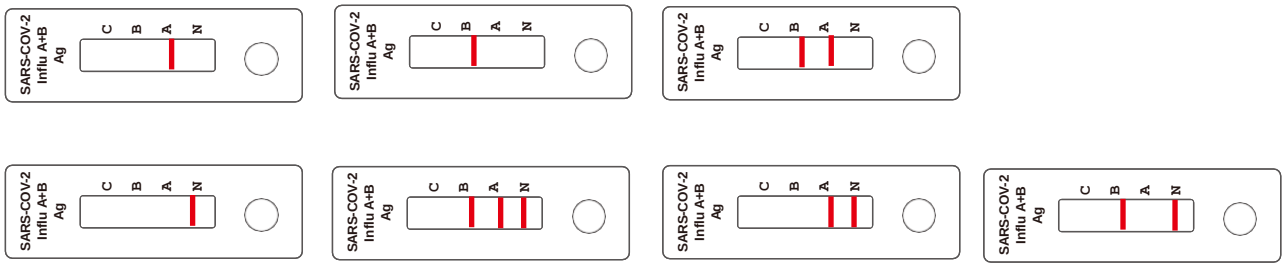

SENSITIVITY AND SPECIFICITY

- The overall Specificity of AstraGene Influenza A+B Ag rapid test kit was observed to be 99% and sensitivity is 98% in comparison with PCR test.

LIMITATION OF THE PROCEDURE

- AstraGene Flu A/Flu B/ COVID-19 Ag rapid test kit is for In-Vitro Diagnostic use only. This test should be used for the detection of SARS-CoV-2 antigens and Influenza A+B antigens in human Nasal swab specimens.
- The AstraGene Flu A/Flu B/ COVID-19 Ag rapid test kit will only indicate the presence to SARS-CoV-2/Influenza A+B in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 and Influenza A+B infections.
- If the symptom persists, while the result from AstraGene Flu A/Flu B/ COVID-19 Ag rapid test kit is negative or non-reactive result, it is recommended to re-sample the patient few hours later.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of SARS-CoV-2 and Influenza A+B infection.
- The potential impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated in the test.
- Due to inherent differences between methodologies, it is highly recommended that, prior to switching from one technology to the next, method correlation studies are undertaken to qualify technology differences. One hundred percent agreement between the results should not be expected due to differences between technologies.
- Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

WARNING AND PRECAUTION

- For in vitro diagnostic use only. Do not reuse. Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch. Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay. Wash hands thoroughly after finishing the tests.
- Do not eat, drink, or smoke in the area where the specimens or kits are being handled. Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national, or regional regulations. Keep out of children's reach.

SYMBOLS

Do not use if package is damaged Manufacturer LOT Batch Code

CE mark of Conformity Refer to the instructions ISO 13485:2016 GMP

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