AG- INFLUENZA, COVID, RSV Ag RAPID TEST KIT

INSTRUCTION FOR USE

AstraGene – Influenza, COVID, RSV Ag Rapid Test kit is a rapid and convenient lateral flow immunochromatographic assay for the qualitative detection of SARS-CoV-2 nucleocapsid protein, influenza A, influenza B antigens and respiratory syncytial virus (RSV) antigen from nasal swab samples obtained from individuals suspected of COVID-19, influenza A/B, or RSV by their healthcare provider within five to seven days of symptom onset. The test can be performed twice within 2 to 3 days with at least 24 hours (and no more than 36 hours) between each test. Individuals without symptoms or other epidemiological reasons to suspect COVID-19, influenza A, influenza B infection, RSV or coinfection can also use the kit without adverse effects. The rapid test device is for professional use only and is intended to be used as an aid in the diagnosis of COVID-19, influenza A, or influenza B infection, RSV or co-infection.

This assay provides preliminary test results. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results from asymptomatic patients suspected of COVID-19, Influenza A/B or RSV exposure and patients with symptom onset beyond seven days should be treated as presumptive and confirmation with a molecular assay may be performed if necessary. Negative results do not rule out COVID-19, influenza A, influenza B, or RSV infection or co-infection and should not be used as the sole basis for treatment or patient management decisions including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, Influenza A/B or RSV infections.

AstraGene – Influenza, COVID, RSV Ag Rapid Test kit Antigen Test may be used in any laboratory environment that meets the requirements specified in the instructions for use and local regulation. This product is intended for use by healthcare professionals in clinical laboratories for research and diagnostical use. The result of this test should not be the sole basis for the diagnosis and the test results should be confirmed by local government approved Real-Time Reverse Transcriptase (RT)-PCR Diagnostic kit.

This assay provides only a preliminary result. The test is not intended to differentiate subtypes or variant strains. The test is intended for professionals and laboratories for research use.

PRINCIPLE

AstraGene – Influenza, COVID, RSV Ag Rapid Test kit is a rapid immunoassay to be used as an aid for the differential diagnosis of COVID-19, Influenza A/B and RSV within research and diagnostic settings. The test is an antigen-capture immunochromatographic assay, detecting presence of RSV nucleocapsid protein, influenza A/B antigens and SARS-CoV-2 nucleocapsid protein in nasal swab specimens. Pathogen specific antibody and a control antibody are immobilized onto a membrane support as four distinct lines: 3 Test lines (1, 2, 3) and a Control line (C) and combined with colloidal gold- monoclonal antibody against RSV or influenza A/B or SARS-CoV-2 antigens deposited on the conjugated pad to construct a test strip. When the specific pathogens migrate with the samples through the strip form the pink line, it indicates a positive result. If the specific pathogens are absent in the sample, no pink or purple line will appear in the test line, indicating a negative result.

To serve as an internal process control, a control band was designed to indicate that the test is performed properly. This control line should always be seen after the test is completed. Absence of a control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassettes with desiccant	10	1
Extraction tubes with caps	10	1
Extraction Buffer Bottle	1	1
Sterile Nasal Swab	10	1
IFU	1	1

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

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or Timer
- Personal protective equipment.
- Disposable Gloves

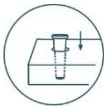
STORAGE &STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture, and heat.
- Shelf life:18 months.

SPECIMEN COLLECTION & PREPARATION

Note：Before proceeding with sample collection and testing, please read the instruction carefully, and operate strictly in accordance with the instructions.

- Freshly collected specimens should be processed immediately. Specimens in Artron sample extraction buffer are stable for up to 4 hours at 2-8ºC or room temperature.
- Tear off the aluminum foil seal from the extraction tube.



- Before collecting the sample, place the sample extraction tube into the tube rack
- Remove a swab from the pouch.

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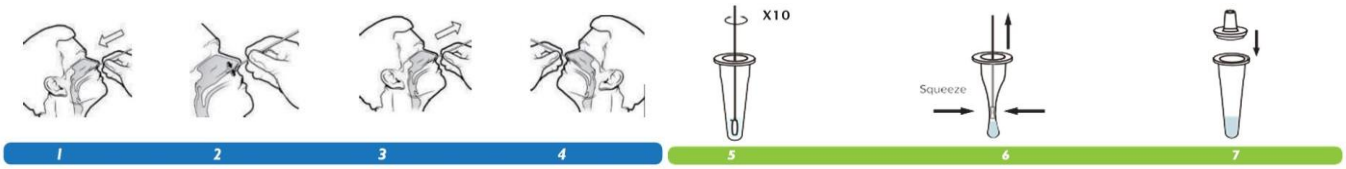
- Nasal swab Specimen collection.

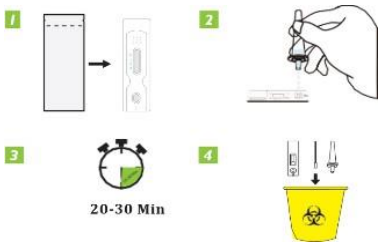
1 Insert the entire absorbent tip of the swab into your nostril, but do not insert the swab more than 3/4 of an inch (1.5 cm) into your nose.
2 Slowly rotate the swab in a circular path against the inside of your nostril at least 5 times for a total of 15 seconds.
3 Be sure to collect any nasal drainage that may be present on the swab.
4 Gently remove the swab. Using the same swab, repeat steps 1-3 in the other nostril.
5 Insert the swab in the extraction tube. Swirl the swab tip vigorously in the buffer fluid at least 10 times. Remove the swab by rotating against the extraction tube while squeezing the sides of the tube to release the solution from the swab. Properly discard the swab.



PROCEDURE

Follow the procedures described below:

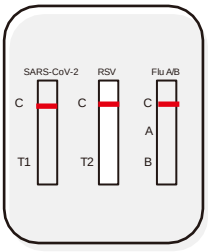
- Get the test cassette from the sealed pouch by tearing at the notch and place the cassette on a flat, dry surface.
- Hold the extraction tube vertically above the sample well, slowly add 5 drops of the specimen without air bubbles into the sample well. DO NOT touch the card with the dropper tip while dispensing.
- Read and interpret the test result within 20-30 minutes. The test result should not be read and interpreted after 30 minutes. If a test shows a negative result at the 20 minutes, do not discard the device immediately as some positive results may develop later in the 20-30 min interval.
- All used test components should be disposed of in the Biohazard Container.
- Read results at 20 minutes. Do not interpret the result after 20 minutes.



RESULT INTERPRETATIONS

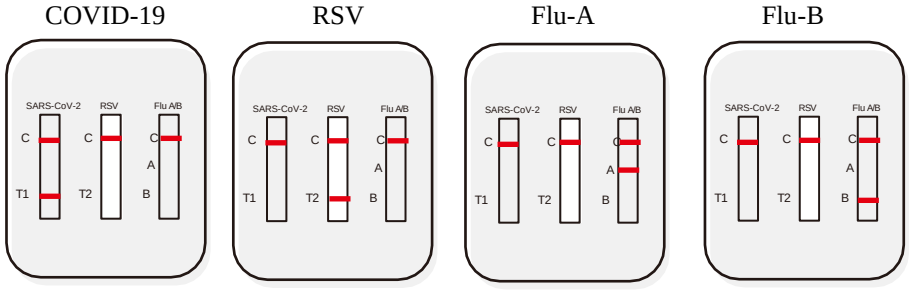
Negative

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



Positive:

A clear pink control band (C) and one or more detectable test band appears, indicating a positive result



Invalid

No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with a lot number.

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QUALITY CONTROL

Although the testing device contains an internal quality control (colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

PERFORMANCE

Target	Sensitivity	Specificity	Accuracy
2019-nCoV	96.44%	100%	96.62%
Influenza A	91.35%	98.47%	95.32%
Influenza B	88.64%	97.38%	95.74%
RSV	93.98%	98.13%	96.23%

LIMITATION OF THE PROCEDURE

- The test is only intended for nasal swab specimens that are collected and tested directly, not for swab specimens stored in virus transport media.
- Failure to follow the Test procedures may adversely affect test performance and/or invalidate the test result.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- False results may occur if specimens are tested past 4 hours of collection. Specimens should be tested as quickly as possible after specimen collection.
- The freshly collected specimens can be stably stored in the sample extraction buffer at room temperature up to 4 hours of collection.
- False negative results may occur if inadequate extraction buffer is used (e.g., <300µl) or inadequate specimen is added in the sample well (e.g., <4 drops).
- False negative results may occur if specimen swabs are not twirled sufficiently in the sample extract buffer.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results do not rule out possible other respiratory tract viral infections.
- Negative results, from asymptomatic patients suspected of SARS-CoV-2 and FLU A/B and RSV exposure and patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay or approved viral culture, if necessary, for patient management, may be performed.
- Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 or FLU A/B or RSV infection or to determine infection status.
- Results from the test should be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
- This test only provides qualitative test results and cannot provide information about the virus concentration in the sample.
- The performance of the device has not been assessed on specimens from individuals who have been infected with emerging variants of SARS-CoV-2 of public health concern and the subtype of influenza A/B or RSV.
- For mutant virus strains or virus strains from different regions, the detection ability of the device may be different, which may lead to false negative.
- If the differentiation of specific SARS viruses and subtype of influenza A/B strains are needed, additional testing, in consultation with state or local public health departments, is required.
- The performance of this device has not been assessed in a population vaccinated against COVID-19 and Influenza. Individuals who received a vaccine may have a positive test.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low virus activity when prevalence is moderate to low.
- Clinical studies in asymptomatic patients using serial testing are ongoing to establish clinical performance.
- The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications. Note that performance may differ in these populations.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect test performance and/or invalidate the Test Result.
- 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 influenza A test results do not identify specific influenza A virus subtypes.

WARNING AND PRECAUTION

- For in vitro diagnostic use only. The test is designed only for the detection of nasal swab specimens.
- This test is only for the detection of proteins from SARS-CoV-2, Influenza A/B and RSV, not for any other viruses or pathogens.
- Do not reuse. Do not use if the pouch seal or its packaging is compromised.
- Do not use it after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- The swabs in the kits are specifically for use with SARS-CoV-2 & Influenza A/B & RSV Test. Do not use other swabs.

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- If the test is stored refrigerated, ensure that the test units are brought to room temperature (15-30˚C) at least 30 mins before performing testing.
- Use immediately after opening the test device in the pouch.
- Complete the test within 1 hour after the reagent is opened.
- To obtain accurate results, the test must follow this package insert.
- Wear personal protective equipment such as laboratory coats, disposable gloves and eye protection when running each test and handling patient specimens. Wash your 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 biohazard container. The handling and disposal of hazardous materials should follow local, national, or regional regulations.
- Keep out of children's reach. If the extraction buffer contacts the skin or eye, flush with copious amounts of water.

SYMBOLS

 Do not use if package is damaged  Manufacturer  Batch Code

 CE mark of Conformity  Refer to the instructions  ISO  GMP

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