AG-INFLUENZA A+B Ag RAPID TEST KIT

INSTRUCTIONS FOR USE

AstraGene Influenza A+B Ag rapid test kit is an *in vitro* diagnostic test for the qualitative detection of influenza A and B antigens in human nasopharyngeal swabs.

PRINCIPLE

This product uses immunochromatography technology to detect influenza A and B virus antigens by double antibody sandwich immunoassay. During detection, add the processed sample to the test trip sample well. When the sample contains influenza A and (or) B virus antigen and the concentration is higher than the limit of detection, influenza A and (or) B virus antigen first forms a reaction complex with the labeled antibody, and the reaction complex moves forward along the nitrocellulose membrane through chromatography. It is captured by the monoclonal antibody of influenza A virus nucleoprotein and/or influenza B virus nucleoprotein precoated in the detection area (1) and (or) (2) on the nitrocellulose membrane, and finally forms a red band on the detection area (1) and (or) (2). And the result is positive. On the contrary, when the sample does not contain influenza A and B virus antigens or the concentration is lower than the limit of detection, there is no band in the detection area, and the result is negative.

Whether or not the sample contains influenza A or B antigens, a red band will be formed in the quality control zone (C), and the red band displayed in the quality control zone (C) is the standard for judging whether the chromatography process is normal or not, and it also serves as the internal control standard of the reagent.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassette and Desiccant	10	1
Buffer	1	1
Sterilized Nasal Swab	10	1
Instruction for Use	1	1

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/FLUAg/22/01	AG/RTK/FLUAg/22/02

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

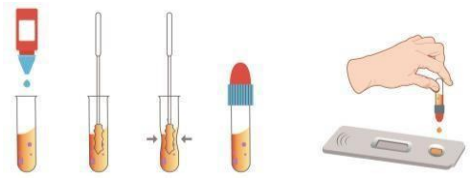
- Fresh human nasopharyngeal swab samples.
- Sample collection procedure:
- Insert the swab provided in the kit into either nostril, passing it into the posterior nasopharynx.
- Rotate swab by firmly brushing against the nasopharynx 2-3 times.
- Remove and place the swab into the sample treatment buffer tube.
- The sample should be processed immediately with the sample treatment buffer provided in this kit after collection. If it cannot be processed immediately, the sample should be stored in a dry, sterilized and strictly sealed plastic tube. It can be stored for 8 hours at 2-8°C and for no more than 6 months at -70°C.

PROCEDURE

Refer to manual for the test. Return the reagents and the sample treatment buffer to room temperature before the test, and the test should be carried out at room temperature.

1. Extraction of specimens

1) Add 450μL of buffer (13 drops) to the empty buffer container.
2) Insert the sampled swab into the sample treatment buffer and rotate it close to the tube inner wall about 10 times so that the sample can be dissolved in the buffer as much as possible.
3) Squeeze the swab head along the tube inner wall to keep the liquid in the tube as much as possible, remove and discard the swab.
4) Cap the dropper.



2. Detection procedure:

1) Open the aluminum foil bag and take out the test strip.
2) Add 80 µL (3 drops) of the processed sample to the test strip sample well.
3) Read result is within 15-20 mins and the result is invalid after 20 mins.

RESULT INTERPRETATIONS

Flu A Positive: Two red bands appear, one in zone 1 and one in zone C (quality control zone).

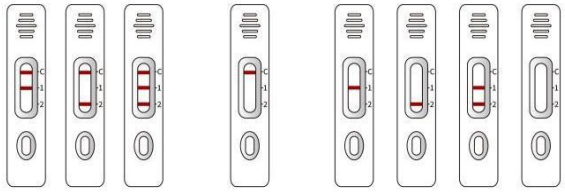
Flu B Positive: Two red bands appear, one in zone 2 and one in zone C (quality control zone).

Flu A/B Positive: Three red bands appear, one in zone 1, one in zone 2, and one in zone C (quality control zone).

Negative: only one red band appears in zone C (quality control zone), and no visible red band appears in zone 1 and zone 2.

Invalid: there is no red band in the zone C (quality control zone), regardless of whether there is a red band in the detection zone, it is determined that the detection is invalid, and it is recommended to use a new test strip to test again.

Note: The color depth of the test line is related to the content of the analyte contained in the sample. Regardless of the color intensity, the result should be judged according to whether the color of the test line is developed.



Flu A + Flu B + FluA/B + Flu A/B - Invalid

Good Laboratory Practice (GLP) Laboratories recommend quality control should be carried out in accordance with laboratory-proposed procedures, guided by national or local regulations.

SENSITIVITY AND SPECIFICITY

- The correlation between influenza A virus antigen accuracy and RT-PCR is as follows:
  Sensitivity: 91.35% ; Specificity: 98.47%; Overall consistency: 95.32%
- The correlation between influenza B virus antigen accuracy and RT-PCR is as follows:
  Sensitivity: 88.64%; Specificity: 97.38%; Overall consistency = (225/235) × 100% = 95.74%

LIMITATION OF THE PROCEDURE

- This reagent is a qualitative test and cannot be used for quantitative determination of antigen content.
- This reagent is used for the detection of human nasopharyngeal swab samples and cannot be used for the detection of blood, saliva, urine or other body fluids.
- The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, stale samples, or repeated freezing and thawing of samples can affect the test results.
- The test results of this kit are for reference only by clinicians and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered in combination with their symptoms, signs, medical history, other laboratory tests and treatment response.
- Restricted by the methodology of antigen-based detection reagents, the limit of detection (analytical sensitivity) is generally lower than that of nucleic acid-based reagents. Therefore, laboratory personnel should pay more attention to negative results and make comprehensive judgments based on other test results. Negative results were verified by nucleic acid detection or virus isolation and culture identification methods.
- If the test result is positive for influenza A virus, further experiments are recommended to confirm the subtype of influenza A virus, and consultation with the local public health prevention agency is required.
  For the possibility of false negative results:
- Improper sample collection, transportation and processing, and low virus titers in the sample may lead to false negative results.
- Variation of viral genes may lead to changes in antigenic determinants, resulting in false negative results, which are more likely to occur with reagents using monoclonal antibodies.
- For a sudden new type of influenza A virus, the optimal sample type for detection and the optimal sampling time (peak virus titer) after infection may not be confirmed. Therefore, samples should be collected from the same patient at different times and at multiple sites, which will reduce the possibility of false negative results.
- Other unverified interference factors, etc. may lead to false negative results.

WARNING AND PRECAUTION

- For This product is for *in vitro* diagnostic use only.
- Operation steps should not be omitted or simplified.
- The positive samples detected by this kit need to be further confirmed by other methods.
- Disinfect or dispose of all potential sources of contamination of samples and reagents in accordance with relevant local regulations.
- Compared with adults, children are more likely to spread the virus over a larger area and for a longer period, so detection of children may be

more sensitive than adults.

- For influenza A virus or subtype detection reagents, when the antibodies used are monoclonal in nature, small changes in epitopes due to small mutations in the nucleotide sequence may result in false negative results or the analytical sensitivity of the reagents reduce.

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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