Influenza A+B Ag Rapid Test Kit (Nasopharyngeal Swab)

The Influenza A/B Ag Rapid Test is a lateral flow immunoassay for the qualitative detection and differentiation of Influenza A virus (including H5N1 and H1N1), and Influenza B virus in nasopharyngeal swab or nasal aspirate specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PFLU 01
05 Tests	PFLU 05
10 Tests	PFLU 10
25 Tests	PFLU 25
50 Tests	PFLU 50

CLINICAL SIGNIFICANCE

Influenza is a highly contagious acute viral infection of the respiratory tract. It is a communicable disease easily transmitted from person to person through aerosol droplets excreted when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat and malaise. The type A influenza virus is more prevalent and is the primary pathogen associated with serious epidemics. The type B virus causes a disease that is generally not as severe as that caused by the type A virus. An accurate diagnosis of influenza based on clinical symptoms is difficult because the initial symptoms of influenza are similar to those of numerous other illnesses. Therefore, it can be confirmed only by laboratory diagnostic testing. Early differential diagnosis of influenza type A or type B can allow for proper treatment with appropriate antiviral therapy while reducing the incidence of inappropriate treatment with antibiotics. Early diagnosis and treatment are of particular value in a clinical setting where an accurate diagnosis can assist the healthcare professional with the management of influenza patients who are at risk for complications

PRINCIPLE

Influenza A+B Ag Rapid test is a lateral flow immuno-chromatographic assay which utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology. The test device is designed to detect antigens from influenza A, and /or influenza B in anterior nasal or nasopharyngeal swab specimens from individuals with signs and symptoms of respiratory infection, suspected of flu by their healthcare provider, within the first five days of onset of symptoms. It is intended to aid in the rapid differential diagnosis of influenza A, and /or influenza B viral infections.
In the test procedure, an anterior nasal or nasopharyngeal swab specimen is collected and placed into extraction reagent in the Extraction Well of the test device for one minute. During this time the antigen is extracted from disrupted virus particles. The test device is then raised, tapped and laid back down onto a level surface. Through this simple action, the solution of extracted specimen flows onto the test strip and migrates through the pads and membrane of the test strip. The pads contain detector antibodies conjugated to gold dye and the membrane contains immobilized capture antibodies. If influenza A, and/or influenza B antigens are present in the specimen, they will react with anti- influenza A+B antibody coupled to gold dye particles, migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized capture antibody line(s) on the membrane, and generate a colored line in the specific test line position. The rest of the sample and unbound/bound dye complexes continue to migrate to the Control line position (C), where immobilized antibodies to the anti-influenza antibodies capture the dye complexes and form the Control line.

Formation of the Control line serves as an internal control to demonstrate that test reagents are functional, antibody-dye conjugates in the dye pad have been hydrated and released and that sufficient sample has been applied to allow for migration through the Test and Control lines. If the Control line does not appear within the designated incubation time, the result is invalid and the test should be repeated using a new test device and specimen.

KIT COMPONENTS

• Test Cassettes • Extraction buffer vial • Droppers • Nasal Swab • Product insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Tube • Micropipette • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

- Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false negative test results. Training in specimen collection is highly recommended because of the importance of specimen quality
- Use fresh samples for best performance. Freshly collected specimens should be tested immediately. If necessary, swab samples can be stored for up to 4 hours at room temperature or up to 8 hours at 2-8°C.
- Use a flocked swab provided in the Influenza A+B Ag Rapid test kit only. Tilt patient's head back 70 degrees. Gently and slowly insert a mini tip swab with a flexible shaft through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.
- Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection. If a deviated septum or blockages create

difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

For swab samples:

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **Insert the nasal swab into the extraction buffer vial then rotate it inside and to mix the specimen-extraction buffer mix thoroughly (by shaking).**
4. **Add 2 drops (50 µL) of specimen-extraction buffer mix to the sample well of the device**

Wait for the colored line(s) to appear. Read results at 15 minutes.
Note: Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

1) **Influenza A POSITIVE:** Two distinct red lines appear. The control line (c) and influenza A (A) line are visible on the test cassette. This indicates the presence of influenza A in specimen. The result is positive

2) **Influenza B POSITIVE:** Two distinct red lines appear. The control line (c) and influenza B (B) line are visible on the test cassette. This indicates the presence of influenza B in specimen. The result is positive

3) **NEGATIVE:** One distinct red line appears. The control line (c) is the only line visible on the test cassette. No influenza A/B antigens were detected. The result does not exclude influenza infection.

4) **INVALID:** Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of line in the A/B region of the cassette. Repeat the test using a new cassette.

Quality Control
Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test
1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. Influenza A+B Ag rapid test is for in vitro diagnostic use only. This test should be used for detection of Influenza A/B infection. Neither the quantitative value nor the rate of increase in the concentration of Influenza A/B viral infection can be determined by this qualitative test.
3. A negative result can occur if the quantity of the Influenza A+B Ag present in the specimen is below the detection limits of the assay. Other clinically available tests are required. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Performance characteristics
A total of 71 specimens were collected (including 56 normal human swab samples and 15 Influenza control samples) tested by Influenza A+B Rapid Test and a commercial Influenza A+B Rapid Test as reference. Comparison for all subjects is showed in the following table.

Commercial rapid test	Influenza A+B Rapid test		
	Positive	Negative	Total
Positive	15	0	15
Negative	0	56	56
Total	15	56	71

Relative sensitivity: 100%, Relative specificity: 100%, Overall agreement: 100%

BIBLIOGRAPHY

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2. Lupulescu, E. et al. ELISA in the rapid diagnosis of Influenza using as the detecting antibodies polyclonal antinucleoprotein sera. Bacteriol. Virusol. Parazitol. Epidemiol., 41(1-2): 63-7 (1996).
3. Marinich, IG. et al. The immunoprophylaxis of Influenza among elderly persons. Zh. Mikrobiol. Epidemiol. Immunobiol. (1997/3): 60-4.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



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