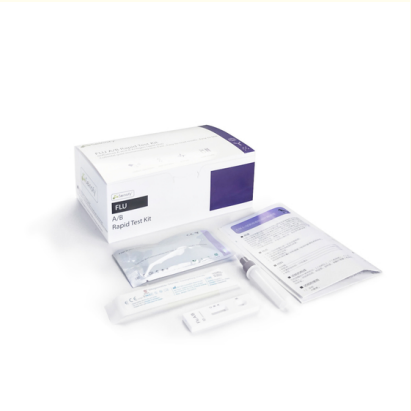
BfArM PEI Medical Diagnostic Test Kits Rapid Detection For Disposable Influenza A And B

Our Product Introduction

Basic Information

- Place of Origin: China
- Brand Name: DVOT
- Certification: CE/BfArM/ PEI
- Model Number: Influenza A+B
- Minimum Order Quantity: 1250Test
- Price: 0.32USD per Test
- Packaging Details: Each boxes 25tests
- Delivery Time: 5-8 Working days
- Payment Terms: T/T, Western Union
- Supply Ability: 1000000pcs



Product Specification

- Product Name: Influenza A+B Antigen Rapid Tes
- Formats: Cassette
- Reaction Time: 10-15 Minutes
- Shelf Life: 24 Months At Room Temperature 4- 30 Degrees
- Others: The Kits Can Be Made According To The Customers' Artwork Or Design
- Time Of Use: Disposable
- Highlight: **PEI Medical Diagnostic Test Kits**, **BfArM Medical Diagnostic Test Kits**, **Disposable Influenza A And B Antigen Test**

Product Description

Rapid Detection Of Influenza A And B Antigens Easy To Use Efficient And Fast

The Influenza A+B Antigen Rapid Test Device is a rapid visual immunoassay for the qualitative, presumptive detection of influenza A and B viral antigens form throat 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 infection

Detection Principle

The Influenza A+B Rapid Test Device detects influenza A and B viral antigens through visual interpretation of color development on the strip. Anti-influenza A and B antibodies are immobilized on the test region A and B of the membrane respectively. During testing, the extracted specimen reacts with anti- influenza A and B 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. If there is sufficient influenza A and B viral antigens in the specimen, colored band(s) will form at the according test region of the membrane. The presence of a colored band in the A and/or B region indicates a positive result for the particular viral antigens, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

SPECIMEN COLLECTION AND STORAGE

Specimen Collection Nasal swab sample: For proper test performance, 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 nasal wail. 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 secretion 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.
Specimen Transport and Storage: Specimens should be tested as soon as possible after collection. If transport of the samples is required, the following transport media are recommended and have been tested and shown not to interfere with the performance of the test: Hank' s BalanceMKd salt solution, M5 Media, or saline. Alternatively, samples may be stored refrigerated (2-8), or at room temperature(15-30), in a clean, dry, closed container for up to eight hours prior to testing. Nasal wash/aspirate specimens may also be stored frozen(-70 or colder) for up to one month

ROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.
Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
Gently mix Extraction reagent solution. Add 6 drops of the Extraction Solution into the Extraction tube.
Place the patient swab specimen into the Extraction Tube. Roll the swab at least 10 times while pressing the swab against the bottom and side of the Extraction Tube. Roll the swab head against the inside of the Extraction Tube as you remove it. Try to release as much liquid as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
Put on the tube tip, then add 3 drops of extracted sample into the sample well. Do not handle or move the Test Device until the test is complete and ready for reading.
As the test begins to work, color will migrate across the membrane. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes

INTERPRETATION OF RESULTS

POSITIVE RESULT:

Flu A Positive:* A colored band appears in the control band region (C) and another colored band appears in the A region.

Flu B Positive:* A colored band appears in the control band region (C) and another colored band appears in the B region.

Flu A+B Positive:* A colored band appears in the control band region (C) and two other colored bands appear in the A region and B regions, respectively.

NEGATIVE RESULT:

Only one colored band appears, in the control band region (C). No band appears in either test band region (A/B).

INVALID RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

The intensity of color in the test region (A/B) may vary depending on the concentration of analyses present in the specimen. Therefore, any shade of color in the test region (A/B) should be considered positive. Please note that this is a qualitative test

only, and cannot determine the concentration of analytes in the specimen.
Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure

PRECAUTIONS

For professional in vitro diagnostic use only.
Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
The extraction reagent solution contains a salt solution if the solution contacts the skin or eye, flush with copious amounts of water.
Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
Read the entire procedure carefully prior to testing.
Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ is available to receive and culture specimens.
Do not interchange or mix reagents from different lots.
Humidity and temperature can adversely affect results.
Used testing materials should be discarded in accordance with local regulations.

Preservation and stability of products

The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
The test must remain in the sealed pouch until use.
Do not freeze.
Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

Individually packed Test Devices	Each test contains colored conjugates and reactive reagents precoated at the corresponding regions
Extraction solution	For specimens extraction.
Extraction tubes	For specimen preparation
Sterile nasal swabs	For specimen collection
Package insert	For operating instructions

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