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Rapid-VIDITEST

Influenza A+B

One step Influenza A+B Card Test for qualitative detection of Influenza type A and type B antigens from human nasopharyngeal specimens

Instruction manual

INTENDED USE:

The Rapid-VIDITEST Influenza A+B is a rapid chromatographic immunoassay for the qualitative detection of *Influenza* type A (including subtypes A/H1N1, A/H3N2, A/H5N1) and type B antigens in human nasopharyngeal specimens to aid in the diagnosis of *Influenza* infection. Only for laboratory use.

INTRODUCTION:

Although a wide variety of viral agents are capable of causing lower respiratory tract infections in children and adults, influenza A & B; respiratory syncytial virus (RSV); parainfluenza viruses 1, 2, and 3; and adenovirus are the most common. Of these, influenza A & B and RSV are the most important causes of medically attended acute respiratory illness. In addition to sharing a similar seasonal prevalence, it is important to remain cognizant that influenza A & B and RSV share overlapping clinical features and infection potential for certain high-risk patient groups (e.g., extremes of age, underlying cardiopulmonary disease and immunosuppression).

PRINCIPLE OF THE TEST:

The Rapid-VIDITEST Influenza A+B is a qualitative lateral flow immunoassay for the detection of Influenza type A and type B antigens in human nasopharyngeal samples. The membrane is pre-coated with monoclonal antibodies against Influenza type A and type B antigens on the test line region. During testing, the sample reacts with the particle coated with anti-Influenza antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate one or two coloured lines. A green coloured line always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

MATERIALS PROVIDED:

- Rapid-VIDITEST Influenza A+B Card tests (Plastic pipettes included)
- Instructions for use
- Diluent (Sample diluent)
- Swabs

- Testing tubes or vials
- Influenza A+B Control swabs

MATERIALS REQUIRED BUT NO PROVIDED:

- Specimen collection container
- Disposable gloves
- Shaker or vortex
- Timer

SPECIMEN COLLECTION AND PREPARATION:

Nasopharyngeal swab method:

- Bend shaft to follow curve of nasopharynx.
- Insert swab through nostril to posterior nasopharynx.
- Rotate swab a few times to obtain infected cells.
- For an optimal sample, repeat procedure using other nostril.

Nasopharyngeal aspirate method (suction apparatus, sterile suction catheter):

- Instill several drops of solution saline into each nostril.
- Place catheter through nostril to posterior nasopharynx.
- Apply gentle suction. Using rotating motion, slowly withdraw catheter.
- For an optimal sample, repeat procedure using other nostril.

Send specimen to lab immediately (testing sensitivity decrease over time)

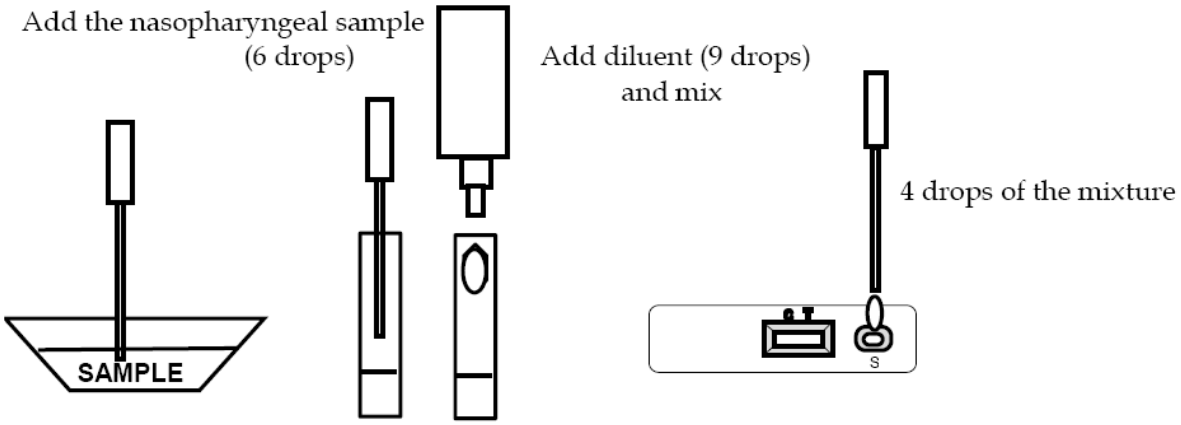
Cool specimen to 2º-8ºC during storage and transport for 8 hours prior to testing.

TEST PROCEDURE

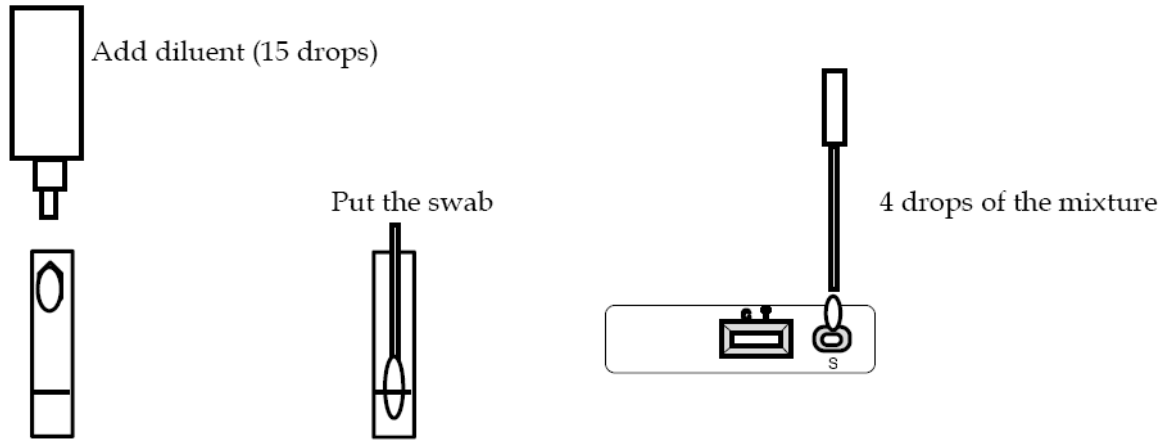
Allow the tests, samples and buffer to reach room temperature (15-30ºC) prior to testing. Do not open pouches until ready to perform the assay.

To process the collected nasopharyngeal wash or aspirate samples:

Use a separate pipette and testing tube for each sample. Add the nasopharyngeal wash or aspirate sample (6 drops) in a testing tube or vial. Add the diluent (9 drops) and mix with a shaker (1 minute). Remove the Rapid-VIDITEST Influenza A+B Card test from its sealed pouch and use it as soon as possible. Use a separate device for each sample. Dispense 4 drops into the specimen well (S). Start the timer. Read the result at 10 minutes after dispensing the sample.



To process the collected nasopharyngeal swab:
Use a separate testing tube or vial for each sample (swab). Add the diluent (15 drops) into the testing tube or vial, put the nasopharyngeal swab, mix and extract as much liquid possible from the swab. Remove the - Rapid-VIDITEST Influenza A+B Card test from its sealed pouch and use it as soon as possible. Use a separate device for each sample. Dispense 4 drops into the specimen well (S). Start the timer. Read the result at 10 minutes after dispensing the sample.



INTERPRETATION OF RESULTS (please refer to the illustration below):

Influenza A | Influenza B | Influenza A+B | Negative | Invalid

POSITIVE:

Influenza A positive: Two lines appear across the central window, a **red** test line marked with the letter T1 and a **green** control line marked with the letter C**.**

Influenza B positive: Two lines appear across the central window, a **red** test line marked with the letter T2 and a **green** control line marked with the letter C.

Influenza A+B positive: Three lines appear across the central window, two **red** test lines marked with the letter (T1 and T2) and a **green** control line marked with the letter C.

NEGATIVE: Only one **green** line appears across the control line region marked with the letter C (control line).

INVALID: Total absence of the green control coloured line regardless the appearance or not of the red test lines. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPRETATION OF RESULTS:

The intensity of the red coloured test lines in the result line region (T1 and T2) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL:

Internal procedural controls are included in the test. A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS:

1. The Rapid-VIDITEST Influenza A+B Card will only indicate the presence of Influenza in the specimen (qualitative detection) and should be used for the detection of Influenza type A and type B antigens in nasopharyngeal specimens only (from swab, aspirate or wash). Neither the quantitative value nor the rate of increase in Influenza antigens concentration can be determined by this test.
2. 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 Influenza infection
3. This test provides a presumptive diagnosis of Influenza infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

Influenza types A or B viruses cause epidemics of disease almost every winter. In the United States, these winter influenza epidemics can cause illness in 10% to 20% of people and are associated with an average of 36,000 deaths and more than 200,000 hospitalizations per year.

PERFORMANCE:

Sensitivity and specificity:

Different virus extract dilutions were tested directly in the sample diluent or spiked in a negative nasal specimen in accordance with the kit instructions.

The detection of *Influenza* type A and/or type B with Rapid-VIDITEST Influenza A+B Card showed >99% of sensitivity compared with another commercial rapid test (BINAXNow® Influenza A&B) and showed >99% of specificity compared with the commercial rapid test.

Cross-Reactivity:
It was performed an evaluation to determine the cross reactivity of Rapid-VIDITEST *Influenza A+B* Card. There is not cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples: *Respiratory syncytial virus*, *Adenovirus*.

STORAGE AND STABILITY:

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC). The test is stable through the expiration date printed on the sealed pouch. Do not freeze

PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

REFERENCES:

- BARENFANGER et al., “Clinical and Financial Benefits of Rapid Detection of Respiratory Viruses: an Outcomes Study”. Journal of Clinical Microbiology. August 2000, Vol 38 No 8, p. 2824-2828.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer
Σ	Number of tests		

Last Revision: 01/2015/A