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Rapid-VIDITEST

Influenza A+B

(One step Influenza A+B blister Test for the detection of Influenza type A and type B from nasal swabs, nasal wash or nasal aspirate specimens).

Instruction manual

INTENDED USE:

The Rapid-VIDITEST Influenza A+B test 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 test 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 regions. 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:

- Strips (blister test)
- Instructions for use
- Diluent (Sample diluent)
- Swabs
- Plastic pipettes
- 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.

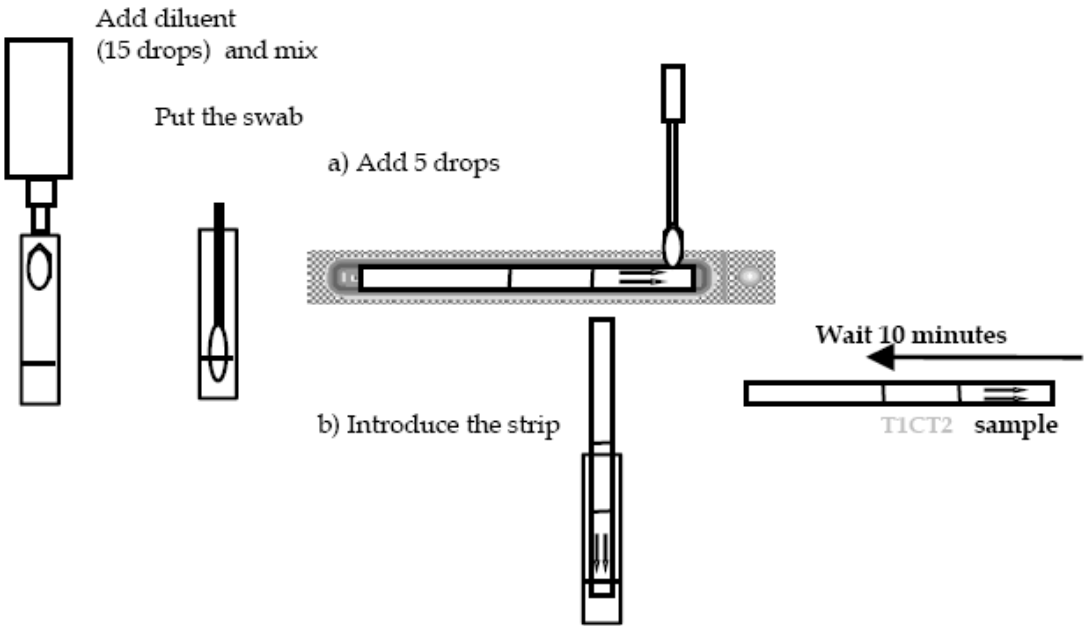
Send specimen to lab immediately (testing sensitivity decrease over time).
Cool specimen to 2º-8ºC (36º-46.4ºF) during storage and transport for 8 hours prior to testing.

TEST PROCEDURE:

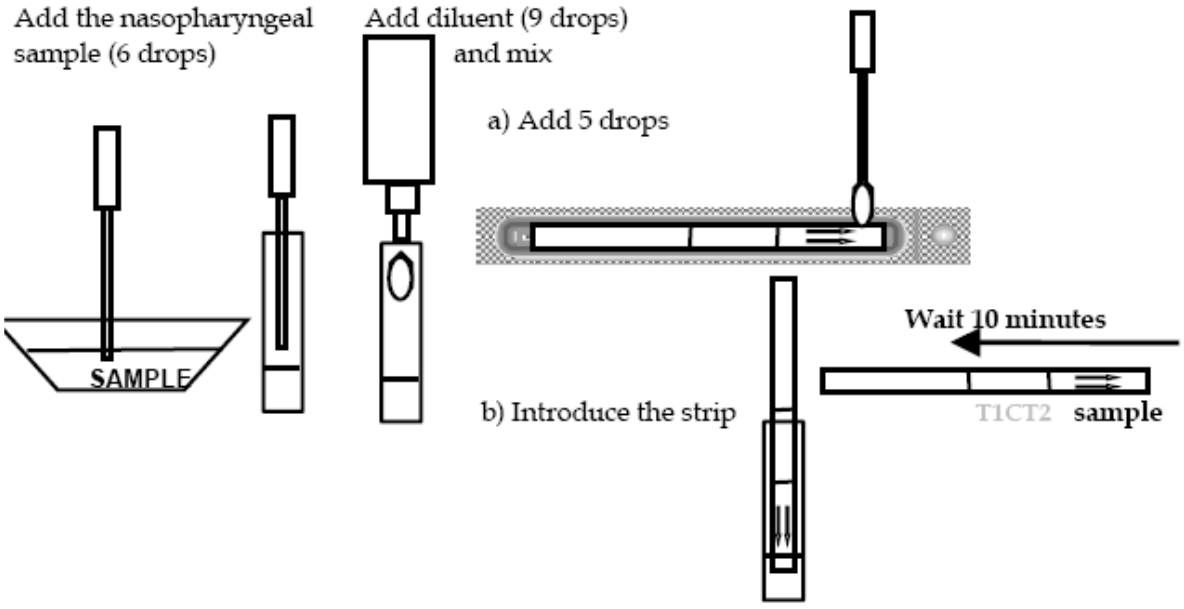
Allow the tests, samples and buffer to reach to room temperature (15 – 30 °C) prior to testing. Do not open the package until ready to perform the assay. Only bring to room temperature the number of tests required to assay before opening it.

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. Discard the swab. Cut the blister to obtain a test single pack, hold the non sealed side and open it peeling off the upper foil.
Don't remove the Strip from the blister cavity and use it as soon as possible. Place the test on a flat surface. Dispense exactly 5 drops on the white end of the test. Read the result at 10 minutes.

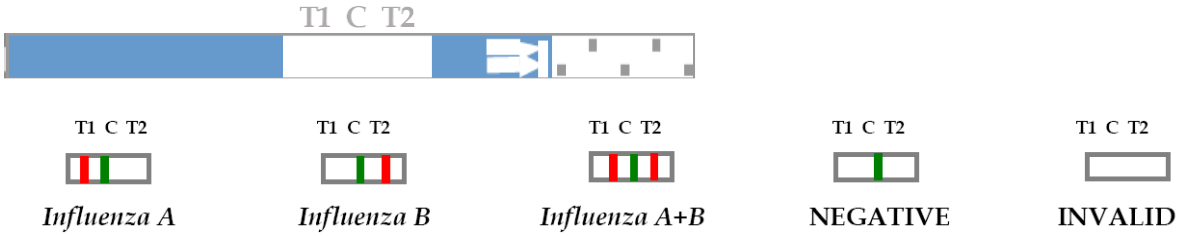
Place the test strip to stand vertically taking care of not surpassing the limit of immersion indicated with the arrows. Start the timer. Read the result at 10 minutes.



<u>To process the collected nasopharyngeal wash or aspirate samples:</u>
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). Cut the blister to obtain a test single pack, hold the non sealed side and open it peeling off the upper foil.
a) Don't remove the strip from the blister cavity and use it as soon as possible. Place the test on a flat surface. Dispense exactly 5 drops on the white end of the test. Read the result at 10 minutes.
b) Place the test strip to stand vertically taking care of not surpassing the limit of immersion indicated with the arrows. Start the timer. Read the result at 10 minutes.



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



***Influenza* A positive**: Two lines appear across the result zone, a **red** test line marked in the illustration 3 with the letter T1 and a **green** control line marked in the illustration 3 with the letter C.

***Influenza* B positive**: Two lines appear across the central window, a **red** test line marked in the illustration 3 with the letter T2 and a **green** control line marked in the illustration 3 with the letter C.

***Influenza A+B* positive**: Three lines appear across the central window, two **red** test lines marked in the illustration 3 with the letters (T1 and T2) and a **green** control line marked in the illustration 3 with the letter C.

NEGATIVE: Only one **green** line appears across the control line region marked in the illustration 3 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. See illustration 3.

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. Rapid-VIDITEST Influenza A+B Blister 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.

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 Blister 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 Influenza Rapid-VIDITEST Influenza A+B Blister. 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 pack either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pack. Do not freeze.

PRECAUTIONS :

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pack 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 pack.

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
	Number of tests		

Last Revision: September 2014/A