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TECHNICAL DATA SHEET

INFLU A+B

RESPY DIPSTICK

Influenza type A+B Test

Influenza A/New Caledonia/20/99 **(H1N1) strain** (15 µg/mL hemagglutinin)

Influenza A/Fujian/411/2002 **(H3N2) strain** (15 µg/mL hemagglutinin)

Influenza B/**Shanghai/361/2002 strain** (15 µg/mL hemagglutinin))

Cod.VC1012

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Rapid One Step Immunochromatographic Test for the detection of Influenza type A and type B antigens in human nasopharyngeal specimens

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1 INTRODUCTION

A rapid, one step test for the qualitative detection of Influenza type A and type B antigens in human nasopharyngeal specimens.

For professional *in vitro* diagnostic use only.

2 INTENDED USE

The Influenza A&B Strip test is a rapid chromatographic immunoassay for the qualitative detection of Influenza type A and type B antigens in human nasopharyngeal specimens to aid in the diagnosis of Influenza infection.

3 SYNTHESIS

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).

4 PRINCIPLE

The Influenza A&B Strip is a qualitative immunoassay for the detection of Influenza type A and type B antigen 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 (A/B) or two (A and B) coloured lines. A green coloured band 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.

5 REAGENTS AND MATERIALS REQUIRED

MATERIAL REQUIRED	MATERIAL REQUIRED BUT NOT PROVIDED
- Strips/Dipstick	- Specimen collection container
- Instructions for use	- Disposable gloves
- Diluent A/Diluent B	- Timer
	- Testing tubes or vials/Specimen collection tube
	- Droppers

The Reagent A contents saline solution and the Reagent B contents sample diluent that is a detergent. Also contains NaN_3 as preservative at a concentration less than 0.1%.

Nasopharyngeal samples must be observed as potentially infectious. Adopt adequate security practices.

6 STORAGE AND STABILITY

Store as packaged in the sealed pouch/pack either at refrigerated or room temperature (2-30°C/36-86°F). The test is stable through the expiration date printed on the sealed pouch/tube. The test must remain in the sealed pack/pouch until use. Do not freeze.

7 PROCEDURES

7.1 Specimen collection and preparation

7.1.1 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.

7.1.2 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 2°-4°C (36°-40°F) during storage and transport.

7.2 Strip test procedure (see illustration 2)

Allow the tests, samples and buffer to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not open the tube with strips until ready to perform the assay.

To process the collected nasopharyngeal wash or aspirate samples (see illustration 1):

Use a separate pipette and testing tube for each sample. Add the nasopharyngeal wash or aspirate sample (6 drops or 300uL) in a testing tube or vial. Add the diluent B (3 drops or 150uL) and mix. Extract some of the liquid and dispense 150uL in a new testing tube. Remove the Influenza A&B Strip from its sealed pack and use it as soon as possible. Use a separate test strip for each sample. Leave 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 after dispensing the sample.

To process the collected nasopharyngeal swab (see illustration 2):

Use a separate testing tube or vial for each sample (swab). Add the diluent A (10 drops or 500uL) into the testing tube or vial, put the nasopharyngeal swab, mix and extract as much

liquid possible from the swab. Add the diluent B (3 drops or 150uL) and mix. Extract some of the liquid and dispense 150uL in a new testing tube. Remove the *Influenza A&B* Strip from its sealed pack and use it as soon as possible. Use a separate test strip for each sample. Leave 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 after dispensing the sample.

Illustration 1 Nasopharyngeal aspirate or wash

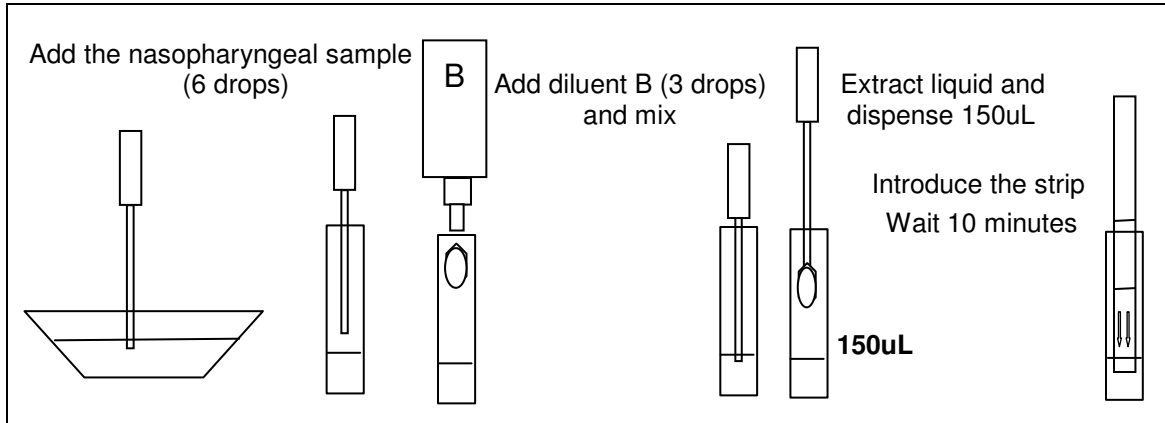
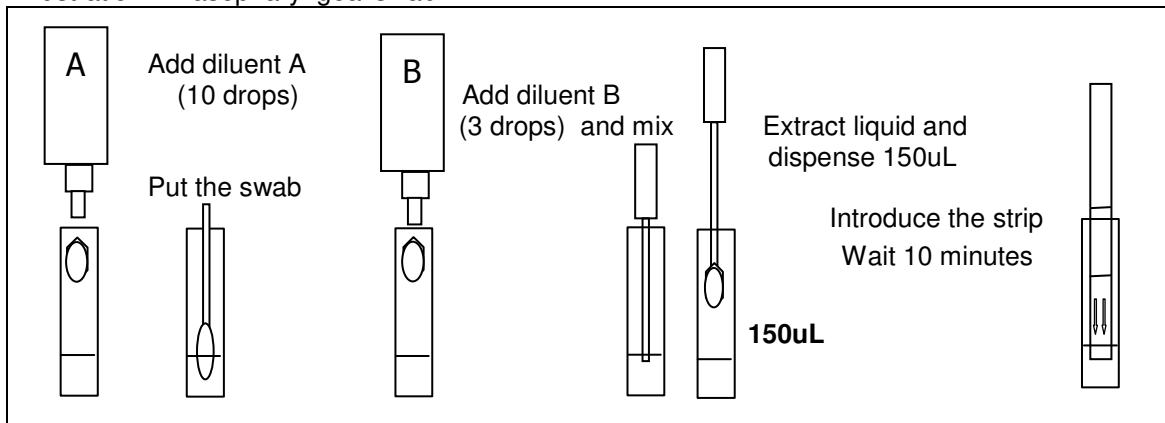
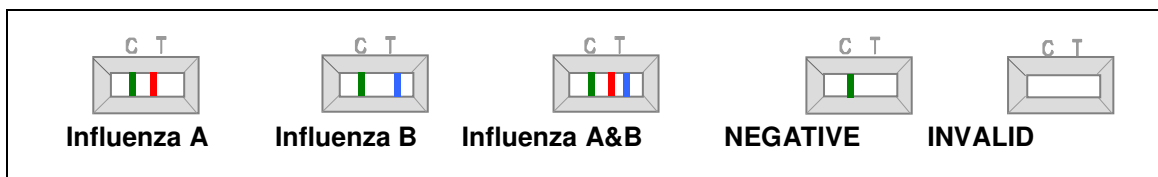


Illustration 2 Nasopharyngeal swab



8 INTERPRETATION OF RESULTS

Illustration 3



POSITIVES:

Influenza A positive: Two lines appear across the central window, in the result line region (**red** test line marked in the illustration 3 with the letter T) and in the control line region (**green** control line marked in the illustration 3 with the letter C).

Influenza B positive: Two lines appear across the central window, in the result line region (**blue** test line marked with the letter T) and in the control line region (**green** control line marked with the letter C). See illustration 5.

Influenza A&B positive: Three lines appear across the central window, in the result line region two lines (**red** test line and **blue** test line marked with the letter T) and in the control line region (**green** control line marked with the letter C). See illustration 3.

NEGATIVE: Only one **green** band appears across the control line region marked with the letter C (control line). See illustration 3.

INVALID: A total absence of the green control coloured band regardless the appearance or not of the red and blue 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.

8.1 NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the red and blue coloured bands in the result line region 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.

8.2 QUALITY CONTROL

8.2.1 Internal procedural controls

The green line appearing in the control region is the internal procedural control. It confirms a sufficient specimen volume and a correct procedural technique.

8.2.2 External quality control testing

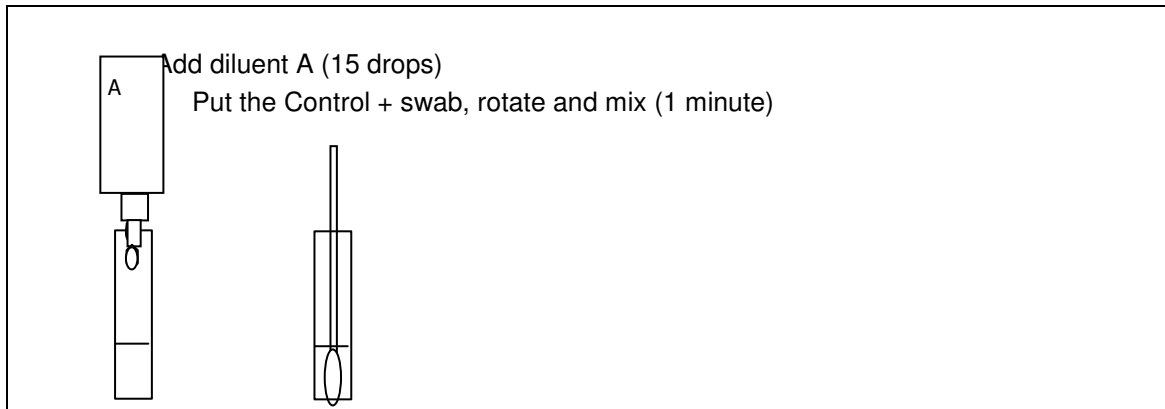
Each kit contains a positive control material. Use the control to test that the extraction reagents and the test are working properly. Also use the control to test that you are able to correctly perform the test procedure.

Quality Control Testing Procedure

Remove the Influenza A&B positive control from its sealed pouch. Add the diluent A (15 drops) into the testing tube or vial, put the positive control swab, mix (1 minute) and extract as much liquid possible from the swab. Discard the swab.

Continue as instructed in the section 7.2 .

Illustration 4. Positive Control Swab



8.3 LIMITATIONS

1. Influenza A&B Strip/Device 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.

9 PERFORMANCE CHARACTERISTICS

9.1 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.

9.2 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.

Virus extract:

Influenza A/New Caledonia/20/99 (H1N1) strain,
Influenza A/Fujian/411/2002 (H3N2) strain and
Influenza B/Shanghai/361/2002 strain.

The detection of Influenza type A and/or type B with Influenza A&B Test showed >99% of sensitivity compared with other commercial rapid tests (QUIDEL Influenza A&B and BINAXNow Influenza A&B).

Detection limit

Different virus extract preparation:

Influenza A/New Caledonia/20/99 (H1N1) strain (15 µg/mL hemagglutinin)

Influenza A/Fujian/411/2002 (H3N2) strain (15 µg/mL hemagglutinin)

Influenza B/Shanghai/361/2002 strain (15 µg/mL hemagglutinin))

was diluted in the sample diluent and tested (with 4 different lots) in accordance with the kit instructions for use.

We found that, under such conditions, the detection limit using the reference antigen preparation of Influenza A and B is 4.7 ng/mL HA for Influenza A and 18.75 ng/mL HA for Influenza B.

The use of mouse monoclonal antibodies in the elaboration of Influenza A&B assures high degree of specificity for the detection of Influenza type A and type B antigens.

9.3 Stability of the test

Stability in Extreme Conditions

Influenza A&B Strip/Device has been designed to be stored at room temperature during the whole validity period. The recommended store temperature is between 2 and 30 °C/36-86°F.

To check the tests performance after a certain period under extreme temperature conditions a few reaction strips from three different Influenza A&B Strip/Device lots were exposed to a temperature of 45°C/113°F during 5 days.

As data showed Influenza A&B Strip/Device maintains its properties even to stand extreme temperature conditions.

From data gathered developing other immunochromatographic test we have established some correlation between this 45°C/113°F stress and longevity of the test.











9.4 Cross-reactivity

It was performed an evaluation to determine the cross reactivity of Influenza A&B Strip/Device . There is not cross reactivity with common respiratory pathogens, other organisms and substances occasionally present in nasopharyngeal samples:

- *Respiratory syncytial virus*
- *Adenovirus*

10 REFERENCES

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 IVD	<i>In vitro</i> diagnostic device	 LOT	Batch code (Exxx)
 i	Consult instructions for use	 REF	Catalogue number
	Keep dry		Contains sufficient for <n> tests
	Temperature limitation		Manufacturer
	Use by (yyyy-month)		Do not use if package damaged

CONTENTS

COD. VC1012

Test Strip/dipstick	25 pieces
Dilution A (Saline)	5.0 mL
Dilution B (Extraction Buffer)	5.0 mL
Instruction for use	1 piece