VITASSAY

Influenza A+B

Rapid test for the simultaneous qualitative detection of Influenza type A and type B from nasal swab, nasopharyngeal wash or aspirate specimens.

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CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay Influenza A+B is a rapid, immunochromatographic, one step assay for the simultaneous qualitative detection of Influenza type A and Influenza type B from nasal swabs, nasopharyngeal wash or aspirate specimens.

Simple and highly sensitivity immunoassay to make a presumptive diagnosis of Influenza type A and/or type B respiratory infection.

INTRODUCTION

The clinical presentation of the respiratory infections caused by different viral pathogens can be very similar, making etiological diagnosis difficult.

Influenza A, B and C viruses, respiratory syncytial viruses (RSV) and adenovirus are of primary importance since infections produced by them range from mild respiratory illness to fatal pneumonia, and cause considerable morbidity and excess deaths in children, elderly people, and in immunocompromised individuals throughout the world.

Influenza A and B are two types of influenza viruses that cause epidemic human disease.

Uncomplicated influenza illness is characterized by the abrupt onset of constitutional and respiratory signs and symptoms (e.g. fever, myalgia, headache, malaise, nonproductive cough, sore throat, and rhinitis). Among children, otitis media, nausea, and vomiting are also commonly reported with influenza illness.

PRINCIPLE

Vitassay Influenza A+B is a qualitative immunochromatographic assay for the detection of Influenza type A and Influenza type B from nasal swabs, nasopharyngeal wash or aspirate specimens.

Strip A: The test line zone of the membrane is pre-coated with monoclonal antibodies against Influenza type A.

Strip B: The test line zone of the membrane is pre-coated with monoclonal antibodies against Influenza type B.

During the process, the sample reacts with the antibodies against Influenza type A (strip A) and/or Influenza Type B (strip B), forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is Influenza type A positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in the strip A, and if the sample is Influenza type B positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in strip B. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears (for both strips).

The presence of these green lines (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Do not use the test if its pouch is damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay Influenza A+B**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/35.6-86ºF).

The test is stable until the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use.

Do not freeze.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
▪ 25 tests/kits **Vitassay Influenza A+B**. ▪ 1 Reagent B (sample diluent). ▪ 25 Swabs. ▪ 25 Disposable pipettes. ▪ 25 Testing tubes. ▪ Instructions for use. ▪ Vitassay **Influenza A Positive Control** swab and **Vitassay Influenza B** Positive Control swab + Instructions for use.	▪ Specimen collection container. ▪ Disposable gloves. ▪ Timer. ▪ Vortex

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SPECIMEN COLLECTION

Samples should be collected in clean and dry containers.

Samples should be process as soon as possible after collection. If this is not possible, the samples can be store in the refrigerator (2-8ºC/35.6-46.4ºF) for 8 hours prior testing.

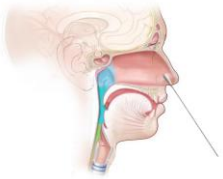
Samples must be brought to room temperature before testing.

Homogenize the samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

- Nasal swab method:

1. Remove the swab from its packing.
2. Use the sterile swab to collect the specimen from the nostril, rotating against the nasal wall (ensuring that swab contains cells as well as mucus).
3. Repeat the same procedure from the other nostril.
4. Process the swab as soon as possible after collecting the specimen.



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

For adults:

1. Place the irrigator up to the nose.
2. Let the sterile saline water run into the nose (2.5mL). It will run out the opposite side.
3. Collect the wash in a clean specimen container, tilt the head forward and allow the water with mucus to run out of the nostril into the specimen container. Repeat the mucus collection for the other nostril and collect it into the same container.

For children:

1. Use an aspiration bulb or bulb syringe to instil the saline water into one nostril, leaning the children head.
2. Aspirate the mix of mucus-saline water into the bulb and transfer it into a clean container.
3. Repeat for the other nostril and transfer the fluid into the same specimen container.

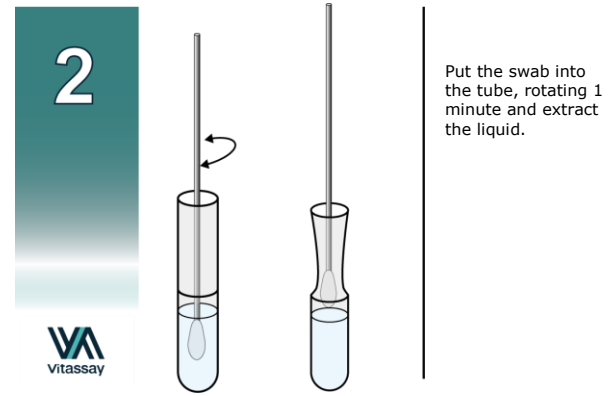
PROCEDURE

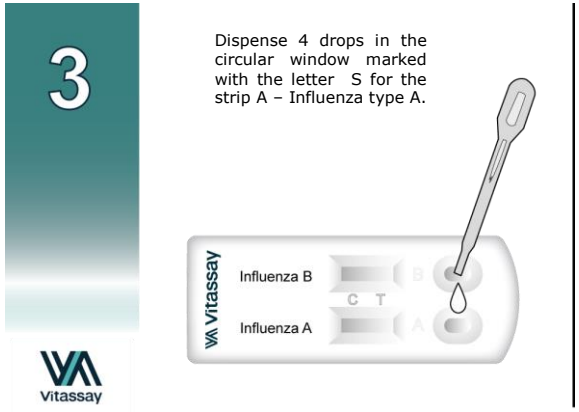
Allow tests, samples, controls and diluent to reach room temperature (15-30ºC/59-86ºF) prior to testing.

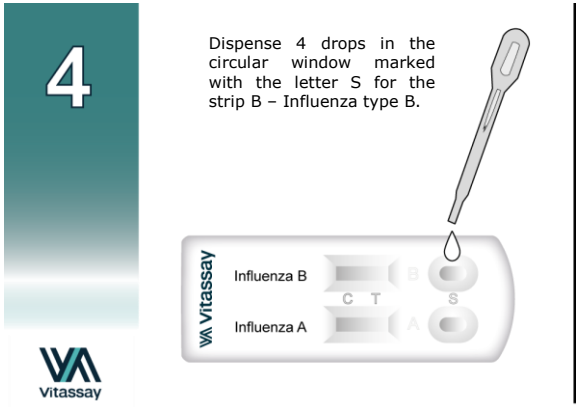
Do not open pouches until the performance of the assay.

- Nasal swab method:

1. Add 15 drops of the reagent B (figure 1) and put the swab into the tube immediately.
2. Mix the solution rotating the swab forcefully against the side of the tube at least 1 minute. Best results are obtained when the specimen is vigorously extracted in the solution (figure 2). Extract as much liquid as possible from the swab, squeezing the sides of the tube or rotating the swab against the side of the tube as the swab is withdrawn. Discard the swab.
3. Remove **Vitassay Influenza A+B** from its sealed bag just before using it.
4. Use a separate pipette and test for each sample or control. Dispense exactly 4 drops from the testing tube, into the circular window marked with the letter S for the strip A – Influenza A (figure 3), and add 4 drops, from the same tube, into the circular window marked with the letter S for the strip B – Influenza B (figure 4).
5. Read the results at **10 minutes**. Do not read the test result later than 10 minutes.







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If the test does not run due to the type of sample, stir the sample added in the sample window (S) with the pipette. If it doesn't work, dispense a drop of Reagent B until seeing the liquid running through the reaction zone.

- Nasopharyngeal aspirate method:

1. Add 6 drops of the nasopharyngeal wash or aspirate samples with a pipette (figure 1) and 9 drops of reagent B in a testing tube (figure 2). Mixer with vortex for at least 1 minute to homogenize. Best results are obtained when the specimen is vigorously extracted in the solution (figure 3).
2. Remove **Vitassay Influenza A+B** from its sealed bag just before using it.
3. Dispense exactly 4 drops from the testing tube, in the circular window marked with the letter S for the strip A – Influenza type A (figure 4), and add 4 drops, with the same tube, in the circular window marked with the letter S for the strip B- Influenza type B (figure 5).
4. Read the results at **10 minutes**. Do not read the test result later than 10 minutes.

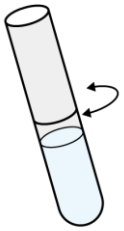
1

Add 6 drops of nasopharyngeal wash/aspirate.

2

Add 9 drops of Reagent B.

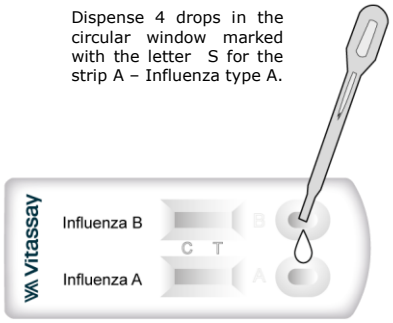
3



Mix the solution with vortex 1 minute.

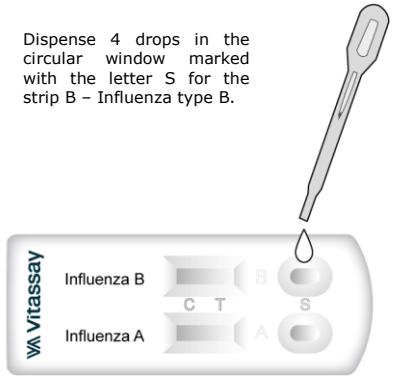
4

Dispense 4 drops in the circular window marked with the letter S for the strip A – Influenza type A.



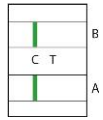
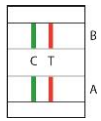
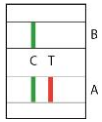
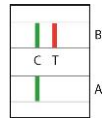
5

Dispense 4 drops in the circular window marked with the letter S for the strip B – Influenza type B.



If the test does not run due to the type of sample, stir the sample added in the sample window (S) with the pipette. If it does not work, dispense a drop of Reagent B until seeing the liquid running through the reaction zone.

INTERPRETATION OF THE RESULTS

RESULTATS	A Influenza A	B Influenza B	INTERPRETATIÓN
	**Negative**	**Negative**	There is no Influenza type A and type B presence. No infection caused by Influenza type A and type B.
	GREEN	GREEN	
	**Positive**	**Positive**	There is Influenza type A and type B presence. Simultaneous infection caused by Influenza type A and type B.
	GREEN-RED	GREEN-RED	
	**Positive**	**Negative**	There is Influenza type A presence. Infection caused by Influenza type A.
	GREEN-RED	GREEN	
	**Negative**	**Positive**	There is Influenza type B presence. Infection caused by Influenza type B.
	GREEN	GREEN-RED	
Any other result			Invalid result either A or B, we recommend repeating the assay using the same sample with another test. **Note:** Wrong procedural techniques or deterioration of the reagents are the main reasons of control line failure. If the symptoms or situation persist, discontinue using the test kit and contact your local distributor.

Notes: The intensity of the red colored test line in the result line zone (T) will vary depending on the concentration of antigens in the specimen.

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QUALITY CONTROL

Internal procedural control is included in **Vitassay Influenza A+B**. Green line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

- **Vitassay Influenza A+B** must be carried out within 2 hours of opening the sealed bag.
- The intensity of test line may vary depending on the concentration of antigens.
- The use of other specimens different should be used only with nasal swab, nasopharyngeal wash and aspirate samples has not been stablished.
- Positive results determine the presence of Influenza type A and/or B. A confirmed infection should only be made by a physician after the evaluation of all clinical and laboratory findings and must be based in the correlation of the results with further clinical observations.
- A negative result should not be considered as conclusive; it is possible that the concentration of antigen is lower than the detection limit value. If symptoms or situation still persist, it is recommended that all negative results undergo confirmatory testing using other method and/or virus identification by cell culture or PCR.

EXPECTED VALUES

Respiratory infections caused by influenza virus type A, influenza virus type B, respiratory syncytial virus (RSV), parainfluenza virus are major causes of upper and lower respiratory tract diseases in infants and young children, causing croup, bronchiolitis, and pneumonia. Additionally, these viruses have all been identified as important causes of severe lower respiratory tract disease, with significant morbidity and mortality, in elderly and immunocompromised patients.

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

An evaluation was performed using **Vitassay Influenza A+B** and these results were compared using an immunochromatographic test (BinaxNOW® Influenza A&B, Alere).

Results were as follows:

		BinaxNOW® Influenza A&B		
		Positive	Negative	Total
Vitassay Influenza A+B	Positive	5	0	5
	Negative	0	6	6
	Total	5	6	11

Vitassay Influenza A+B vs BinaxNOW® Influenza A&B			
Sensitivity	Specificity	PPV	NPV
>99%	>99%	>99%	>99%

The results showed that **Vitassay Influenza A+B** has a high sensitivity and specificity to detect Influenza type A and type B.

Cross reactivity

No cross reactivity was detected against organisms that cause other respiratory infections:

Adenovirus	*Influeneza type B (strip A)*
Influenza type A (strip B)	*Respiratory Syncytial Virus*

REFERENCES

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2. SCOTT A. HARPER, M.D., KEIJI FUKUDA, M.D., TIMOTHY M. UYEKI, M.D., NANCY J. COX, PhD, CAROLYN B. BRIDGES, M.D., "Prevention and Control of Influenza – Recommendation of the Advisory Committee on Immunization Practices (ACIP)", April 30, 2004 / Volume 53;1-40

3. KATE E. TEMPLETON, SITHA A. SCHELTINGA, MATTHIAS F. C. BEERSMA, ALOYS C. M. KROES, and ERIC C. J. CLAAS, "Rapid and Sensitive Method Using Multiplex Real-Time PCR for Diagnosis of Infections by Influenza A and influenza B Viruses, Respiratory Syncytial Virus, and Parainfluenza Viruses 1, 2, 3, and 4", Journal of Clinical Microbiology, Apr. 2004, p. 1564-1569.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

IVD	*in vitro* diagnostic device		Keep dry
	Consult instructions for use		Temperature limitation
	Use by		Manufacturer
LOT	Batch code	Σ n	Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number

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