VITASSAY

Influenza A+B+ RSV+Adenovirus Resp.

Rapid test for the qualitative detection of Influenza type A, Influenza type B, RSV and Adenovirus from nasal swabs.

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CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only. EN

INTENDED USE

Vitassay Influenza A+B+RSV+Adenovirus Resp. is a rapid, immunochromatographic assay for the simultaneous qualitative detection of Influenza type A, Influenza type B, RSV and Adenovirus from nasal swabs.

Simple, non-invasive and highly sensitivity immunoassay to make a presumptive diagnosis of Influenza type A, influenza type B, RSV and/or Adenovirus infection.

INTRODUCTION

Acute Respiratory Diseases (ARD) are transmittable diseases, among which viruses are the leading cause (1). Among these, the most common ones are influenza, parainfluenza, rhinovirus and respiratory syncytial virus (2), and the family of SARS-CoV have recently become sheer relevant for the global population.

ARDs are the main causes of mortality worldwide, especially in children under five (3). The high morbidity, of which these infections are responsible, has a big socio-economic impact as well (4). Fast and accurate diagnosis is essential to select the appropriate treatment and diminish the impact on the population and health systems. Since all viruses already mentioned can cause upper and lower respiratory tract infections, and clinical manifestations can overlap, diagnoses need to be based on laboratory analysis.

Influenza virus

Influenza in humans is caused by influenza A and influenza B viruses, which presents a broad spectrum of clinical features: from mild respiratory symptoms like sore throat, runny nose, cough, fever, headache, myalgia and fatigue, to severe (and sometimes life threatening) pneumonia or non-respiratory complications (5). Both viruses are a significant cause of global morbidity and mortality, and it is especially important along elderly and immunocompromised population due to the high risk of presenting complications. Transmission is usually through droplets and aerosols or by direct or indirect contact with an infected person.

These enveloped negative-sense single-strand RNA viruses, belong to the family of Orthomyxoviridae. Influenza B usually cause localised outbreak, while influenza A produces epidemics and pandemics (6). The latter one can be classified into different subtypes depending on the glycoproteins located on its surface: hemagglutinin (HA) and neuraminidase (NA). Up to date, eighteen HA (H1-18) and eleven NA (N1-11) subtypes have been identified (7).

Regarding the diagnosis, viral culture is the gold standard for diagnosing influenza viral infections, however the technique is time consuming. Hence, other methods have been more commonly used in clinical practice, including real-time PCR and immunochromatographic rapid tests.

Respiratory Syncytial Virus

The human respiratory syncytial virus (RSV) is an enveloped, single stranded linear RNA genome virus. RSV, which belongs to the genus *Orthopneumovirus*, is divided into two major groups, A and B, based on antigenic and genomic differences. RSV infection most commonly causes a cold-like illness. But it can also cause bronchitis, croup, and lower respiratory infections like bronchiolitis and pneumonia. Of every 100 infants and young children with RSV infection, 25 to 40 (25% to 40%) will show signs of pneumonia or bronchiolitis (8).

RSV is transmitted via large nasopharyngeal secretion droplets coming from infected individuals. These droplets enter via the mucus membranes of the eyes, nose and mouth following close contact, or self-inoculation after touching contaminated surfaces (9).

Adenovirus

Adenoviruses are members of a non-enveloped and double-stranded DNA virus family: *Adenoviridae* family. This family contains more than 50 immunologically distinct human Adenovirus serotypes, which are classified in 6 species (A-F) (10). These species can cause different disorders in humans: Adenovirus -B and C are responsible for respiratory infections, Adenovirus -B and D cause conjunctivitis, and Adenovirus-F serotypes 40 and 41 produce gastroenteritis. In terms of respiratory infections, clinical manifestations are common cold, fever, pharyngitis, bronchitis, and pneumonia.

Transmission can take place by air due to cough and sneezes, or close contact with an infected person. Interestingly, around 95% of 6 years-old children are seropositive for adenovirus and in up to 5% of overall respiratory infections and 4-10% of acquired pneumonia adenovirus infection is source (11) (12). Thus, Adenovirus plays an important role in paediatric respiratory tract infections.

PRINCIPLE

Vitassay Influenza A+B+RSV+Adenovirus Resp. is a qualitative immunochromatographic assay to make a presumptive diagnosis of Influenza type A, Influenza type B, RSV and/or Adenovirus infection.

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

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

Strip C: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against RSV.

Strip D: The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against Adenovirus.

During the process, the sample reacts with the antibodies against Influenza A (strip A) and/or Influenza B (strip B) and/or RSV (strip C), and/or Adenovirus (strip D) 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

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(test line) capture the conjugate complex and a red line will be visible in the strip A, 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, if the sample is RSV positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in strip C and if the sample is Adenovirus positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible in strip D. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears (for all the 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* diagnostic use only.
- Do not use after expiration date.
- Do not use the kit without having read and understood the information on procedures, precautions, and limitations provided in the instructions for use.
- Do not use the kit if the label sealing the outer carton is torn or damaged.
- Do not use the product if the outer carton or the aluminium pouches are open or damaged on arrival.
- Do not use the test (and positive/negative controls if applicable) if the desiccant material is missing or broken inside the aluminium pouch.
- Do not use the vial with sample diluent if it is opened or damaged upon arrival.
- It is recommended to protect the reagents from moisture.
- Components provided in the kit are approved for use with the **Vitassay Influenza A+B+RSV+Adenovirus Resp.** Do not mix components from different kits and/or lots. Do not use any other commercial kit component.
- Do not reuse. This is a single-use device.
- For the correct traceability of the sample, each vial with sample diluent and test used must be perfectly recognisable including patient identification.
- Specimens and material in contact with samples should be considered as potentially hazardous and handle in the same manner as an infectious agent, in accordance with local/national safety regulations. Use appropriate infection control practices when collecting and handling samples.
- Do not touch the head of the sterile swab provided when removing it from its primary packaging to avoid contamination.
- A new test must be used for each sample to avoid contaminations errors.
- Follow Good Laboratory Practices. These practices should include, but are not limited to, personal protective equipment (PPE), such as lab coat, surgical or appropriate mask or face shield, disposable gloves, and eye protection. Take the necessary precautions during sample collection, transport, storage, handling, and disposal. Each sample must be correctly and unequivocally identified to ensure proper traceability of samples.
- Do not eat, drink, smoke or apply cosmetic products in the workplace. Once the test is completed wash your hands thoroughly.
- Avoid handling solvents near the kit to prevent possible deterioration to the labelling and pouch printing information.
- In case of spillage, clean thoroughly with a suitable disinfectant.
- The material of the kit used should be disposed of in an appropriate biohazard container after testing. These containers must be disposed of in accordance with local or national regulations.
- Reagents contain preservatives (<0.1% sodium azido). Avoid any contact with the skin or mucous membrane. In accordance with Regulation (EC) No 1907/2006 (REACH), **Vitassay Influenza A+B+RSV+Adenovirus Resp.** do not contain substances and/or mixtures which meet the hazard classification criteria available in Regulation (EC) No 1272/2008 (CLP) or which are in concentrations higher than the value established in the mentioned regulation for their declaration.
- The presence of yellow lines in the result window (control line area and test line area), before using the test, is completely normal and does not imply a failure in the functionality of the test.
- The interpretation of the results is visual, using coloured lines. The interpretation of the results should be performed by a professional user without problems of visualisation and colour interpretation.
- Perform the interpretation of results in a well-lit place.
- A statement declaring no requirement for Material Safety Data Sheet, and certificate of analysis, can be provided on request (not included).

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC). 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
▪ **10** Tests/kit **Vitassay Influenza A+B+RSV+Adenovirus Resp.** ▪ 10 Vials with sample diluent. ▪ 10 Swabs. ▪ Instructions for use.	▪ Disposable gloves. ▪ Timer. ▪ Vortex

SPECIMEN COLLECTION

Samples should be collected following proper infection control practices.

Samples should be processed as soon as possible after collection. If this is not possible, the samples can be stored in the refrigerator (2-8ºC) for maximum 8 hours prior testing.

Samples must be brought to room temperature before testing.

Homogenize the samples as thoroughly as possible prior to testing.

SPECIMEN PREPARATION

Use a sterile swab and a separate device for each sample. Please ensure that samples from different patients have been correctly identified.

Nasal swab method:

Recommended blow your nose once using a tissue before collection of the specimen.

1. Remove the swab from its packing.
2. Use the sterile swab to collect the specimen from one nostril. Insert the swab into the nostril (approx. 2 cm), rotate against the nasal wall several times (5 times) to ensure that the swab contains cells as well as mucus.
3. Carefully remove the swab from the nostril and repeat the same procedure from the other nostril.
4. Process the swab as soon as possible after collecting the specimen.

PROCEDURE

Follow appropriate infection control practices. Allow tests, samples, and diluent to reach room temperature (15-30ºC) prior to testing.

Do not open pouches until the performance of the assay.

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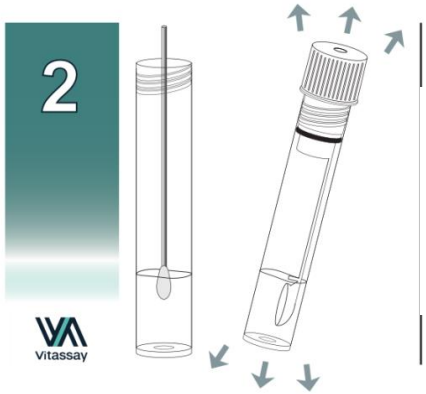
Nasal swab method:

Use a vial with sample diluent and a different test for each sample. Ensure that each sample is correctly identified (sample traceability) throughout the process.

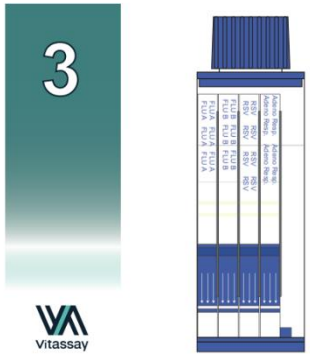
1. Open the cap of the vial for sample dilution with diluent (figure 1).
2. Introduce the swab immediately into the vial for sample dilution (figure 2) and mix the solution by rotating the swab forcefully against the side of the tube at least 1 minute. Best results are obtained when the specimen is vigorously extracted in the solution, avoiding splashes and aerosols. Extract as much liquid as possible from the swab, by 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. Close the vial with sample and diluent. Shake the vial to assure a good sample dispersion, sake during 60 seconds (figure 2).
4. Remove **Vitassay Influenza A+B+RSV+Adenovirus Resp.** from its sealed bag just before using it (figure 3).
5. Take the vial for sample dilution containing the diluted sample (figure 4), place it inside the multitest tube (figure 5). Screw the cap of the multitest tube tighly (figure 6). The bottom of the vial for sample dilution will break and the diluent+sample solution reaches the sample zone of the strips (figure 7).
6. Place the multitest tube vertically on a flat surface and read the results at **10 minutes**. Do not read the test result later than 10 minutes. Any result read after 10 minutes will be considered invalid.

If the test does not run due to solid particles (the sample is not homogenized), migration process can stop on one or more strips. In this case, tap the end of the multitest tube on hard surface to allow migration to start again.

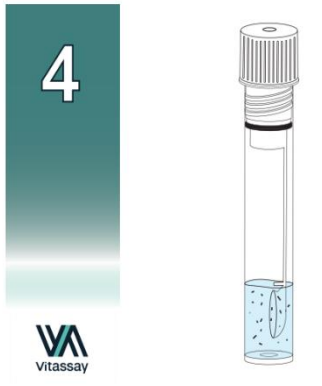
Open the cap of the vial for sample dilution.



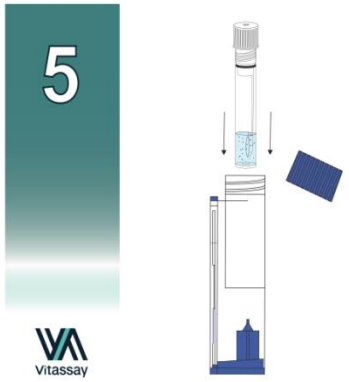
Introduce the swab into the vial for sample dilution and mix the solution by rotating the swab forcefully against the side of the tube. Extract as much liquid as possible from the swab. Mix 60 seconds.



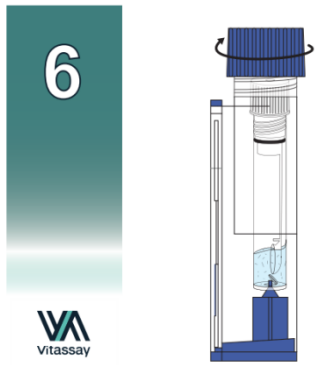
Take the Vitassay Influenza A+B+RSV+ Adenovirus Resp.



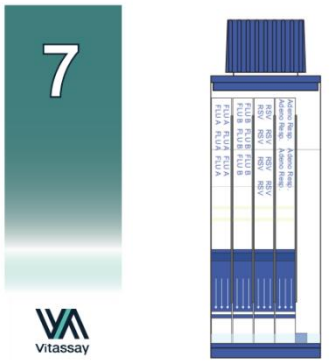
Vial with the diluted sample inside.



Introduce the vial with the diluted sample into the multitest.



Close the cap and the bottom of the diluent vial will break.



Reaction takes place. **Read results at 10 minutes.**

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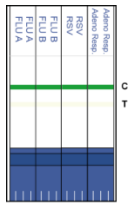
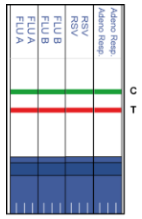
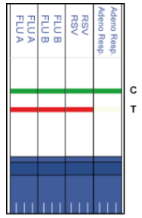
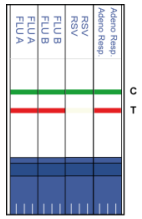
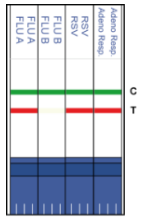
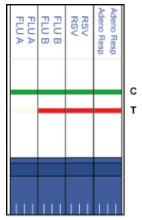
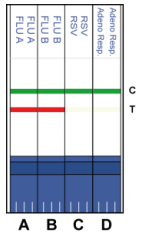
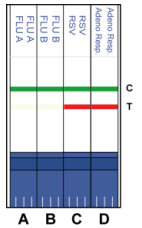
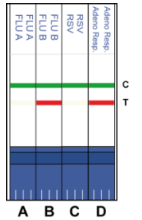
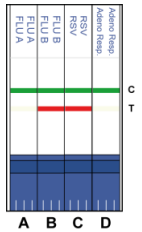
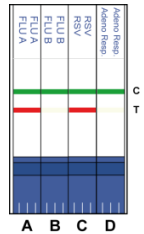
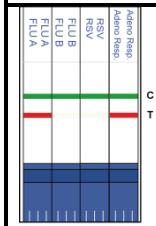
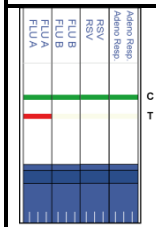
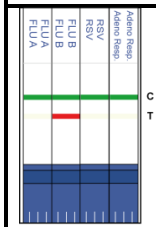
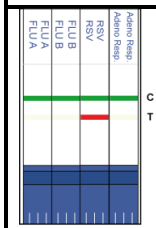
INTERPRETATION OF THE RESULTS

Strip A: Influenza A, Strip B: Influenza B, Strip C: RSV and Strip D: Adenovirus

	**NEGATIVE** Only one green line in the control zone (C) in the four strips (A,B,C and D)	There is no Influenza A, Influenza B, RSV and Adenovirus presence.
	**POSITIVE** In addition to the green line (control line C), a red line appears in each strip, test line (T)	There is Influenza A, Influenza B, RSV and Adenovirus presence.
	**NEGATIVE** Strip D (Adenovirus)→ green line **POSITIVE** Strip A (Influenza A)→ green/red lines Strip B (Influenza B)→ green/red lines Strip C (RSV)→ green/red lines	There is Influenza A, B and RSV presence. Possible infection caused by Infuenza A, B and RSV.
	**NEGATIVE** Strip C (RSV)→ green line **POSITIVE** Strip A (Influenza tipo A)→ green/red lines Strip B (Influenza tipo B)→ green/red lines Strip D (Adenovirus)→ green/red lines	There is Influenza A, B and Adenovirus presence. Possible infection caused by Infuenza A, B and Adenovirus.
	**NEGATIVE** Strip B (Influenza B)→ green line **POSITIVE** Strip A (Influenza A)→ green/red lines Strip C (RSV)→ green/red lines Strip D (Adenovirus)→ green/red lines	There is Influenza A, RSV and Adenovirus presence. Possible infection caused by Infuenza A, RSV and Adenovirus.
	**NEGATIVE** Strip A (Influenza A)→ green line **POSITIVE** Strip B (Influenza B)→ green/red lines Strip C (RSV)→ green/red lines Strip D (Adenovirus)→ green/red lines	There is Influenza B, RSV and Adenovirus presence. Possible infection caused by Infuenza B, RSV and Adenovirus.
	**NEGATIVE** Strip C (RSV)→ green line Strip D (Adenovirus)→ green line **POSITIVE** Strip A (Influenza A)→ green/red lines Strip B (Influenza B)→ green/red lines	There is Influenza A and B presence. Possible infection caused by Infuenza A and B.
	**NEGATIVE** Strip A (Influenza A)→ green line Strip B (Influenza B)→ green line **POSITIVE** Strip C (RSV)→ green/red lines Strip D (Adenovirus)→ green/red lines	There is RSV and Adenovirus presence. Possible infection caused by RSV and Adenovirus.
	**NEGATIVE** Strip A (Influenza A)→ green line Tira C (RSV)→ green line **POSITIVE** Strip B (Influenza tipo B)→ green/red lines Strip D (Adenovirus)→ green/red lines	There is Influenza B and Adenovirus presence. Possible infection caused by Infuenza B and Adenovirus.
	**NEGATIVE** Strip A (Influenza A)→ green line Strip D (Adenoviurs)→ green line **POSITIVE** Strip B (Influenza B)→ green/red lines Strip C (RSV)→ green/red lines	There is Influenza B and RSV presence. Possible infection caused by Infuenza B and RSV.
	**NEGATIVE** Strip B (Influenza B)→ green line Strip D (Adenovirus)→ green line **POSITIVE** Strip A (Influenza A)→ green/red lines Strip C (RSV)→ green/red lines	There is Influenza A and RSV presence. Possible infection caused by Infuenza A and RSV.
	**NEGATIVE** Strip B (Influenza B)→ green line Strip C (RSV)→ green line **POSITIVE** Strip A (Influenza A)→ green/red lines Strip D (Adenovirus)→ green/red lines	There is Influenza A and Adenovirus presence. Possible infection caused by Infuenza A and Adenovirus.
	**NEGATIVE** Strip B (Influenza B)→ green line Strip C (RSV)→ green line Strip D (Adenovirus)→ green line **POSITIVE** Strip A (Influenza A)→ green/red lines	There is Influenza A presence. Possible infection caused by Infuenza A.
	**NEGATIVE** Strip A (Influenza A)→)→ green line Strip C (RSV)→ green line Strip D (Adenovirus)→ green line **POSITIVE** Strip B (Influenza B)→ green/red lines	There is Influenza B presence. Possible infection caused by Infuenza B.
	**NEGATIVE** Strip A (Influenza A)→ green line Strip B (Influenza B→ green line Strip D (Adenovirus)→ green line **POSITIVE** Tira C (RSV)→ green/red lines	There is RSV presence. Possible infection caused by RSV.

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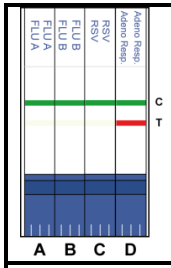	**NEGATIVE** Strip A (Influenza A)→ green line Strip B (Influenza B)→ green line Strip C (RSV)→ green line **POSITIVE** Strip D (Adenovirus)→ green/red lines	There is Adenovirus presence. Possible infection caused by Adenovirus.
Any other results	Invalid result either A, B, C and/or D. We recommend repeating the assay using the same sample with another test. Any result read after more than 10 minutes has elapsed will be considered invalid.	

Notes: The intensity of the red coloured test line in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, this is a qualitative test, so neither the quantitative value nor the rate of increase of the antigen can be determined using this test.

NEGATIVE: The presence of only one green line (green control line) should be considered a negative result.

POSITIVE: The presence of both lines (green control line and red test line), regardless of the intensity of the red line, should be considered a positive result.

Results detailed in the above table should be followed up with additional confirmatory diagnostic procedures.

A single or double viral infection is more common than a triple or quadruple infection.

Invalid results: Total absence of any control coloured lines (green) indicates an invalid result, regardless of the appearance or not of the test lines (red**).** Wrong procedural techniques, deterioration of the reagents or insufficient sample volume are mostly the main reasons for an invalid result. Review the procedure and repeat the assay with a new test. If the problem persists, discontinue using the kit and contact your local distributor.

QUALITY CONTROL

Internal procedural control is included in **Vitassay Influenza A+B+RSV+Adenovirus Resp**. 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+RSV+Adenovirus Resp.** must be carried out within 2 hours of opening the sealed bag.
- The intensity of the test lines may vary depending on the concentration of antigens.
- The use of the test on samples other than nasal swabs has not been determined.
- The quality of the test depends on the quality of the sample. Samples must be obtained appropriately.
- Positive results determine the presence of Influenza type A, Influenza type B, RSV and/or Adenovirus respiratory antigens. A confirmed infection should only be made by a physician after all clinical and laboratory findings have been evaluated and must be based in the correlation of the results with further clinical observations.
- Positive test results do not rule out co-infections with other pathogens.
- The sensitivity of the test may be reduced when transport media are used due to greater dilution of the sample. The use of transport media is not recommended.
- Negative results should not be considered as conclusive; it is possible that the concentration of antigen in the sample 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 methods, and/or virus identification by cell culture, PCR or another technique.
- For accurate results, do not use bloody samples.
- Highly viscous samples may cause a non-specific reaction in the test.

EXPECTED VALUES

Influenza virus types A and B circulate and cause seasonal epidemics of the disease. Seasonal influenza is an acute respiratory infection common throughout the world. According to the WHO, there are approximately one billion cases of seasonal influenza each year; of these, between three and five million are severe.

Most people recover without treatment. However, the disease causes between 290,000 and 650,000 respiratory deaths each year. In industrialised countries, most influenza-related deaths occur in people aged 65 and older. 99% of deaths among children under five with influenza-related lower respiratory tract infections occur in developing countries. Vaccination is the best way to prevent the disease (13).

Each year, respiratory syncytial virus causes approximately 3.6 million hospitalisations and around 100,000 deaths among children under five worldwide. Most of these deaths (97%) occur in low- and middle-income countries, where access to supportive medical care is limited. In adults, it is estimated that in the United States alone, this virus causes up to 160,000 hospitalisations and 10,000 deaths among adults over 65 years of age. The hospitalisation rate for infected adults is higher among people with underlying conditions such as asthma, chronic obstructive pulmonary disease or congestive heart failure (14).

Adenoviruses account for at least 5–10% of respiratory tract infections (RTIs) in children and 1–7% in adults. In immunocompromised individuals, dissemination and/or severe respiratory failure develop in 10-30% of cases, and mortality rates from severe AdV pneumonia can exceed 50% (15).

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

An evaluation was performed to compare the results obtained by **Vitassay Influenza A + B + RSV + Adenovirus Resp.** with other immunochromatographic tests ((BinaxNOW® Influenza A&B (Alere), BinaxNOW® RSV (Alere) and Adenovirus Respi, (CorisBioConcept) and a immunofluorescence test (PathoDx®Adenovirus, Remel).

Results were as follows:

		BinaxNOW® Influenza A&B		
		Positive	Negative	Total
Vitassay Influenza A + B + RSV + Adenovirus Resp. (Influenza A+B)	Positive	5	0	5
	Negative	0	6	6
	Total	5	6	11

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

		BinaxNOW® RSV		
		Positive	Negative	Total
Vitassay Influenza A + B + RSV + Adenovirus Resp. (RSV)	Positive	18	0	18
	Negative	1	10	11
	Total	19	10	29

Vitassay Influenza A + B + RSV + Adenovirus Resp. vs **BinaxNOW® RSV**			
Sensitivity	Specificity	PPV	NPV
95%	>99%	>99%	91%

		PathoDx®Adenovirus		
		Positive	Negative	Total
Vitassay Influenza A + B + RSV +Adenovirus Resp. (Adenovirus)	Positive	20	0	20
	Negative	0	5	5
	Total	20	5	25
		Adenovirus Respi		
		Positive	Negative	Total
Vitassay Influenza A +B +RSV + Adenovirus Resp. (Adenovirus)	Positive	20	0	20
	Negative	0	5	5
	Total	20	5	25

Vitassay Influenza A +B +RSV + Adenovirus Resp. vs PathoDx®Adenovirus Test and **Adenovirus Respi Test**			
Sensitivity	Specificity	PPV	NPV
>99%	>99%	>99%	>99%

Vitassay
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Ctra. N.330, Km.566
22197-Cuarte (Huesca, SPAIN)
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The results showed that **Vitassay Influenza A + B + RSV + Adenovirus Resp.** has a high sensitivity and specificity to detect Influenza type A, Influenza type B, RSV and/or Adenovirus.

Cross reactivity

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

Influenza type A (Strips B, C and D)	Influenza type B (Strips A, C and D)
Adenovirus (Strips A, B and C)	RSV (Strips A, B and D)

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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
CE	CE Marking		

Change control		
Nº Version	**Changes**	**Date**
IUE- 7715043 Ed00 January 2017	Original version	01/2017
IUE- 7715043 Ed01 September 2025	Updated format, error correction, updated introduction, addition of precautions and limitations, correction of material not provided, improved wording on specimen collection, specimen preparation and procedure more detailed, addition of clarifications on interpretation of results, updated expected values and bibliography.	05/09/2025

Vitassay