VITASSAY

RSV+Adenovirus Resp.

Rapid test for the simultaneous qualitative detection of RSV and Adenovirus from nasal swab, nasopharyngeal wash or aspirate specimens.

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Vitassay

For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay RSV+Adenovirus Resp. is a rapid, immunochromatographic, one step assay for the simultaneous qualitative detection of respiratory syncytial virus (RSV) and Adenovirus from nasal swabs, nasopharyngeal wash or aspirate specimens.

Simple and highly sensitivity immunoassay to make a presumptive diagnosis of RSV and/or Adenovirus respiratory infection.

INTRODUCTION

Respiratory syncytial virus, RSV, was discovered nearly 60 years ago as the causative agent of human respiratory tract disease and it still remains a serious threat to infants, immunocompromised persons, and the aging adult population. Although infants and young children are still the main target of RSV, pneumonia in the elderly is being found more frequently associated with RSV infection and leads to more deaths in that population than among young children.

Lower respiratory tract infection in infants and children also arise from human adenovirus. There are at least 51 immunologically distinc human adenovirus serotypes associated with infections ranging from respiratory disease, urinary tract disease and keratoconjunctivitis, to gastroenteritis.

PRINCIPLE

Vitassay RSV+Adenovirus Resp. is a qualitative immunochromatographic assay for the detection of RSV and Adenovirus from nasal swabs, nasopharyngeal wash or aspirate specimens.

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

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

During the process, the sample reacts with the antibodies against RSV (strip A) and/or Adenovirus (strip B), forming conjugates. The mixture moves upward on the membrane by capillary action. 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 the strip A, 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 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 RSV+Adenovirus Resp.** 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 RSV+Adenovirus Resp.** ▪ 1 Reagent B (sample diluent). ▪ 25 Swabs. ▪ 25 Disposable pipettes. ▪ 25 Testing tubes. ▪ Instructions for use. ▪ Vitassay **RSV Positive Control** swab and **Vitassay Adenovirus Resp.** 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.

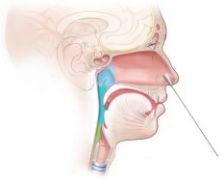
Samples must be brought to room temperature before testing.

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

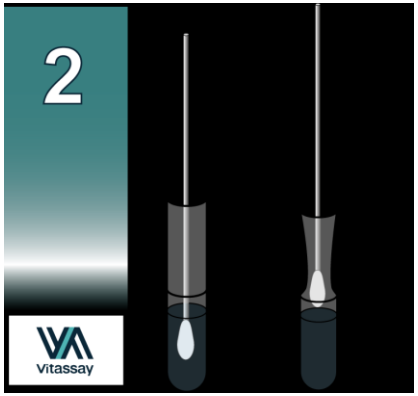
Allow tests, samples, controls and diluent to reach room temperature (15-30ºC/59-86ºF) prior to testing.

Do not open pouches until the performance of the assay.

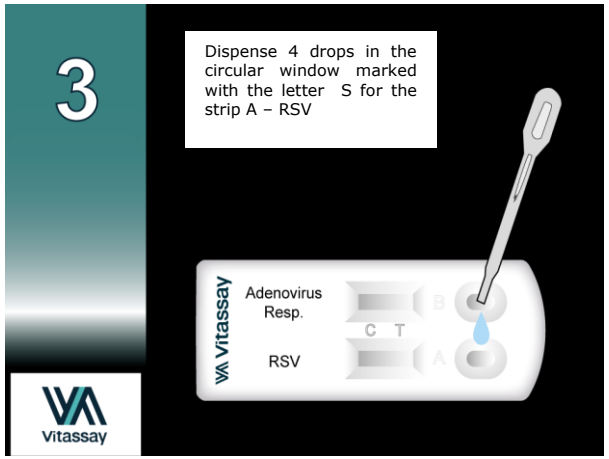
- Nasal swab method:

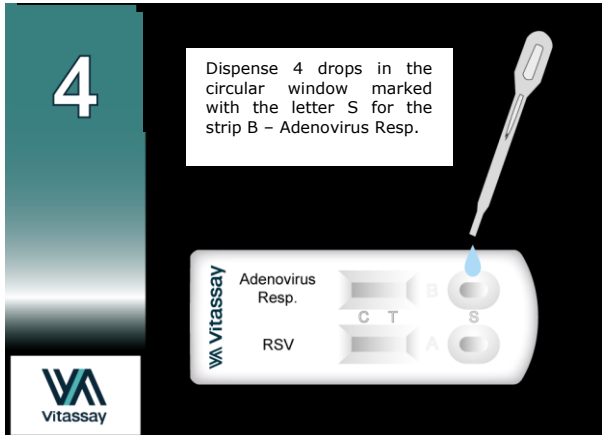
1. Add 15 drops of the reagent B (figure 1) and put the swab into the tube immediately.
2. Mix the solution rotating the swab forcefully against the side of the tube at least 1 minute. Best results are obtained when the specimen is vigorously extracted in the solution (figure 2). Extract as much liquid 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 RSV+Adenovirus Resp.** 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 – RSV (figure 3), and add 4 drops, from the same tube, into the circular window marked with the letter S for the strip B – Adenovirus Resp. (figure 4).
5. Read the results at **10 minutes**. Do not read the test result later than 10 minutes.

Add 15 drops of Reagent B.



Put the swab into the tube, rotating 1 minute and extract the liquid.





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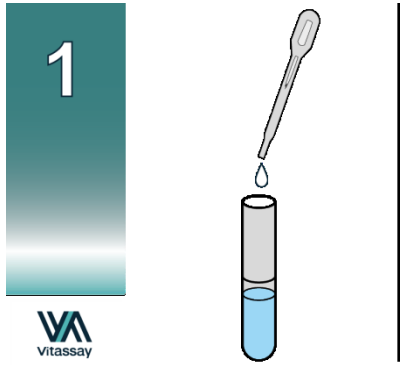
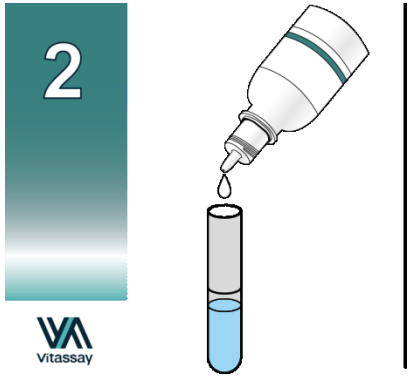
If the test does not run due to the type of sample, stir the sample added in the sample window (S) with the pipette. If it doesn't work, dispense a drop of Reagent B until seeing the liquid running through the reaction zone.

- Nasopharyngeal aspirate method:

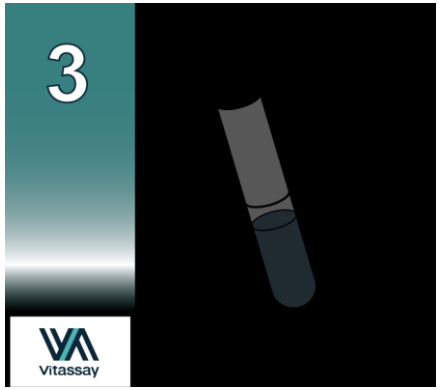
1. Add 6 drops of the nasopharyngeal wash or aspirate samples with a pipette (figure 1) and 9 drops of reagent B in a testing tube (figure 2). Mixer with vortex for at least 1 minute to homogenize. Best results are obtained when the specimen is vigorously extracted in the solution (figure 3).
2. Remove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



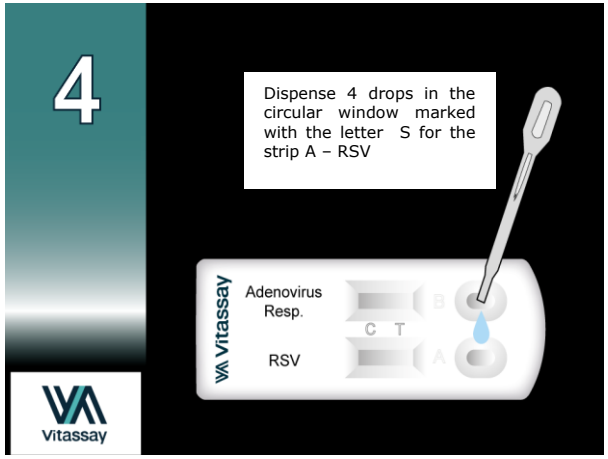
Add 6 drops of nasopharyngeal wash/aspirate.

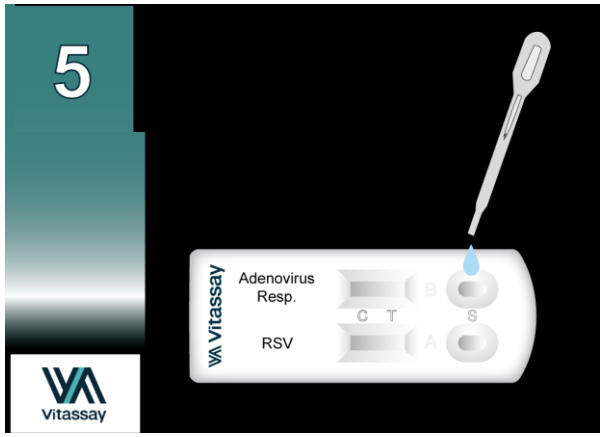


Add 9 drops of Reagent B.



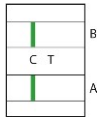
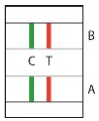
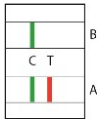
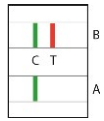
Mix the solution with vortex 1 minute.





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 RSV	B Adenovirus Resp.	INTERPRETACIÓN
	**Negative** GREEN	**Negative** GREEN	There is no RSV and Adenovirus Resp. presence. No infection caused by RSV and Adenovirus Resp.
	**Positive** GREEN-RED	**Positive** GREEN-RED	There is RSV and Adenovirus Resp. presence. Simultaneous infection caused by RSV and Adenovirus Resp.
	**Positive** GREEN-RED	**Negative** GREEN	There is RSV presence. Infection caused by RSV.
	**Negative** GREEN	**Positive** GREEN-RED	There is Adenovirus Resp. presence. Infection caused by Adenovirus Resp.
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 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 RSV+Adenovirus Resp.** 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 RSV and/or adenovirus respiratory infection. 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.
- Negative results 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 negative results undergo confirmatory testing using other method and/or virus identification by cell culture or PCR.

EXPECTED VALUES

Approximately 3.4 million people throughout the world are hospitalized every year with pneumonia or bronchitis attributed to RSV infection and nearly 17,000 die in the USA alone.

In Mediterranean areas RSV outbreaks happen mainly in winter whereas in tropical countries they happen in rainy months.

Endemic adenovirus in infants is responsible of 10% of respiratory tract infections, and of 10% of cases of acute gastritis.

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity of RSV

Nasal samples were used in order to evaluate the results obtained by **Vitassay RSV + Adenovirus Resp.** and BINAXNow® RSV, Alere.

Results were as follows:

		BinaxNOW® RSV		
		Positive	**Negative**	**Total**
Vitassay RSV + Adenovirus Resp. RSV	**Positive**	18	0	18
	Negative	1	10	11
	Total	19	10	29

Vitassay RSV + Adenovirus Resp. (RSV) **vs BinaxNOW® RSV**			
Sensitivity	**Specificity**	**PPV**	**NPV**
95%	>99%	>99%	91%

Clinical sensitivity and specificity of Adenovirus

Nasal samples were used in order to evaluate the results obtained by **Vitassay RSV + Adenovirus Resp.** and other two commercial test (Adenovirus Respi, CorisBioConcept) and (PathoDx®Adenovirus, Remel).

Results were as follows:

		Adenovirus Respi		
		Positive	**Negative**	**Total**
Vitassay *RSV* + *Adenovirus Resp.* Adenovirus	**Positive**	20	0	20
	Negative	0	5	5
	Total	20	5	25

		PathoDx®Adenovirus		
		Positive	**Negative**	**Total**
Vitassay *RSV* + *Adenovirus Resp.* Adenovirus	**Positive**	20	0	20
	Negative	0	5	5
	Total	20	5	25

Vitassay RSV + Adenovirus Resp. (Adenovirus) **vs Adenovirus Respi** and **PathoDx®Adenovirus**			
Sensitivity	**Specificity**	**PPV**	**NPV**
>99%	>99%	>99%	>91%

The results showed that **Vitassay RSV + Adenovirus Resp.** has a high sensitivity and specificity to detect RSV and adenovirus.

Cross reactivity

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

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

REFERENCES

1 PAUL SHAPSHAK; JOHN T. SINNOTT; CHARURUT SOMBOONWIT; JENS H. KUHN. "Respiratory Syncytial Virus". Global Virology I – Identifying and Investigating Viral Diseases, 2015, pp. 73-92.

2. SALVATORE BARBERI; MARIO BARRETO; FRANCESCO LA PENNA; BERNARDINA MAZZARELLA; MARIA –ELENA LIVERANI; OTTAVIA DE LUCA; MAURIZIO SIMMACO; MARIA PIA VILLA. "Respiratory syncytial virus and adenovirus in acute lower respiratory infections in hospitalized infants and children". Open Journal of Pediatrics, 2012, 2, pp. 31-37.

3. GUILLERMO BERNAOLA; WALTER LUQUE. "Fisiopatología de las Infecciones por Adenovirus". Pediatrica, Oct. 2001-Mar. 2002, Vol. 4, No. 2, pp. 41-47.

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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