VITASSAY

Adenovirus Resp.

Rapid test for the qualitative detection of Adenovirus from nasal swabs, nasopharyngeal wash or aspirate specimens.

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CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay Adenovirus Resp. is a rapid, immunochromatographic, one step assay for the qualitative detection of Adenovirus from nasal swabs, nasopharyngeal wash or aspirate specimens.

Simple and highly sensitivity immunoassay to make a presumptive diagnosis of Adenovirus respiratory infection

INTRODUCTION

Human adenoviruses (AdVs; Genus Mastadenovirus, Family Adenoviridae), which were first isolated from the respiratory tract by tissue culture are known to cause a wide range of human diseases, including respiratory, gastrointestinal, ocular, urinary, and central nervous system infections. Although AdV infections are typically acute, self-limiting and not fatal, they may have severe consequences for both immunocompromised patients and on rare occasions previously healthy infants. AdV can also cause localized epidemics in small and crowed populations, such as schools and military facilities.

The incubation period usually ranges from 4 to 8 days but has been demonstrated to be as long as 10 days. Adenovirus may be transmitted by a wide variety of routes including droplet, fomites (including improperly sterilized medical equipment and contaminated ophthalmic solution), fecal-oral, and auto-inoculation, including in healthcare settings.

Community dwellings, such as military barracks, daycare centers, and nursing homes, have been associated with an increased risk for exposure, including outbreaks. Furthermore, inadequately chlorinated swimming pools and natural bodies of water have been linked to Adenovirus conjunctivitis outbreaks.

In addition to fever, patients with respiratory infection often present with pharyngitis, such as fever, tonsillar exudates (in as many as 52% of children) and leukocytosis.

In addition to the aforementioned respiratory symptoms, accompanying non-respiratory manifestations such as malaise, myalgias, conjunctivitis, and abdominal pain may also be observed.

PRINCIPLE

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

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 Adenovirus, forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears.

The presence of this green line (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 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) on the sealed pouch.

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/kit **Vitassay Adenovirus Resp.** ▪ 1 Reagent B (sample diluent). ▪ 25 Swabs. ▪ 25 Disposable pipettes. ▪ 25 Testing tubes. ▪ Instructions for use. ▪ **Vitassay Adenovirus 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.

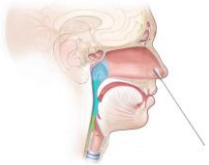
Samples must be brought to room temperature before testing.

Homogenize the samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

- **Nasal swab:**

1. Remove the swab from its packing.
2. Collect specimen with a sterile swab from one nostril.
3. Insert the swab into the nostril to the nasopharynx, rotating against the nasal wall (to ensure swab contains cells as well as mucus).
4. Repeat procedure using other nostril.
5. Process the swab as soon as possible after collecting the specimen.



- **Nasopharyngeal aspirate:**

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. Tilt and twist the irrigator side to side and up and down directing the water flow into all portions of the nasal cavity.
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 instill 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.

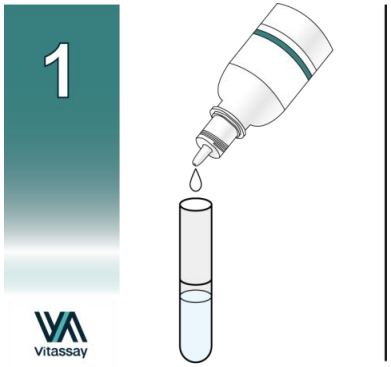
PROCEDURE

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

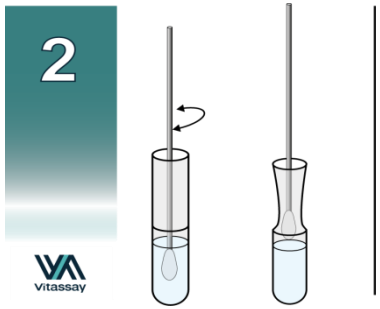
Do not open pouches until the performance of the assay.

Nasal swab procedure:

1. Add 15 drops (figure 1) Reagnt B and immediately put the swab into the tube.
2. 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 (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 the **Vitassay Adenovirus Resp.** from its sealed bag and using the pipette, dispense 4 drops from the testing tube into the circular window marked with letter S (figure 3).
4. Read the results at **10 minutes**. Do not read the test results later than 10 minutes.



Add 15 drops of Reagent B.

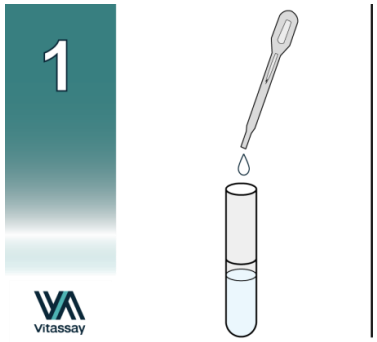


Put the swab into the tube, rotating 1 minute and extract the liquid.

Dispense 4 drops in the circular window marked with the letter S.

Nasopharyngeal wash or aspirate procedure

1. Add 6 drops (figure 1) of the nasopharyngeal wash or aspirate samples with a pipette and 9 drops (figure 2) of Reagent B in testing tube. Mixer with vortex at least 1 minute to homogenize. Best results are obtained when the specimen is vigorously extracted in the solution (figure 3).
2. Remove **Vitassay 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 (figure 4).
4. Read the results at **10 minutes**. Do not read the test results later than 10 minutes.



Add 6 drops of nasopharyngeal wash/aspirate.

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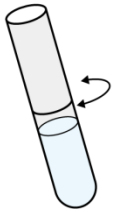
Add 9 drops of Reagent B.

3



Mix the solution with vortex 1 minute.

4

Dispense 4 drops in the circular window marked with the letter S.

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

	**NEGATIVE** Only one green line in the control zone (**C**)	There is no Adenovirus Resp. presence. No infection caused by Adenovirus Resp.
	**POSITIVE** In addition to the green line (**control line C**), a red line appears, (**test line T**)	There is Adenovirus Resp. presence. Infection caused by RSV.
ANY OTHER RESULTS		Invalid result, we recommend repeating the assay using the sample with another test. **Note:** Wrong procedural techniques or deterioration of the reagents are mostly the main reasons for 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.

QUALITY CONTROL

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

LIMITATIONS

- **Vitassay Adenovirus Resp.** must be carried out within 2 hours of opening the sealed bag.
- It should only be used with nasal swabs, nasopharyngeal wash and aspirate samples. The use of other samples has not been established.
- The quality of **Vitassay Adenovirus Resp.** depends on the quality of the sample; Proper throat swab specimens must be obtained.
- The intensity of test line may vary from very strong (high antigens concentration) to faint (antigens concentration is close to the detection limit).
- Positive results determine the presence of Respiratory Syncytial Virus infection. A positive result should be followed up by a physician 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 antigens concentration in nasal samples 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

Adenovirus (Ad) infections account for about 4-10% of viral pneumonia and bronchiolitis in children, and an alarming number of fatal illnesses and long-term pulmonary complications have been reported worldwide.

In the United States, epidemiologic studies have shown that 1-5% of all respiratory infections are caused by Adenovirus. This virus particularly causes problems among children younger that 5 years who may get 61% of all Adenovirus documented infections.

Lower tract respiratory infections are a major cause of death in less than 5 years old children, mainly in developing countries. In less than 2 years old children, 70-90% are viral and from the total of the infections, 2-5% are Adenovirus, with a high moratlity associated with intrahospitals outbreaks. Adenovirus is the resposible of endemic infections during the year.

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

An evaluation, with nasal samples, was performed comparing **Vitassay Adenovirus Resp** and another rapid commercial test (Adenovirus Respi, CorisBioConcept) and an immunofluorescent commercial test (PathoDx®Adenovirus, Remel).

Results were as follows:

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

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

Vitassay Adenovirus Resp vs PathoDx®Adenovirus and Adenvoirus Respi Test			
Sensitivity	**Specificity**	**PPV**	**NPV**
>99%	>99%	>99%	>99%

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

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Cross reactivity

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

Influenza type A	Influenza type B	Respiratory Syncytial Virus

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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

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