VITASSAY

Adenovirus

Rapid test for the qualitative detection of adenovirus in human stool samples.

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CE IVD EN

Vitassay

For professional *in vitro* diagnostic use only.

INTENDED USE

Vitassay Adenovirus is a rapid one step immunochromatographic assay for the qualitative detection of adenovirus in human stool samples.

Simple, non-invasive and highly sensitive screening assay to make a presumptive diagnosis of adenovirus infection.

INTRODUCTION

Human adenovirus is a double stranded DNA virus, non-enveloped, that belongs to the *Mastadenovirus* genus within *Adenoviridae* family. The infections caused by human adenovirus may be asymptomatic, or may induce common diseases such as respiratory distress, gastroenteritis and hemorrhagic cystitis.

Rotavirus, adenovirus and norovirus are often related with both diarrhea and subclinical infections. These viruses are shed in the feces of infected (symptomatic and asymptomatic) individuals, and acquired through the fecal-oral route by the consumption of contaminated water, food, direct contact and aerosols. The enteric viruses are a special concern in public health due to their wide distribution, rapid transmission, high prevalence, and resistance under environmental conditions.

Risk of outbreaks is higher in Adenovirus infections because fecal viral breakthrough continue for a long time after diarrhea is over.

PRINCIPLE

Vitassay Adenovirus is a qualitative immunochromatographic assay for detection of adenovirus in human stool samples.

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**. 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/kit **Vitassay Adenovirus** ▪ Instructions for use. ▪ 25 vials with diluent for sample dilution.	▪ Specimen collection container. ▪ Disposable gloves. ▪ Timer.

SPECIMEN COLLECTION

Collect sufficient quantity of feces: 1-2g or mL for liquid samples. Stool samples should be collected in clean and dry containers.

Samples can be stored in the refrigerator (2-8ºC/35.6-46.4ºF) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20ºC (-4ºF). Samples must be brought to room temperature before testing.

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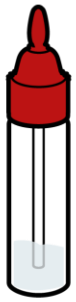
SPECIMEN PREPARATION

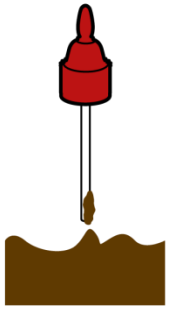
1. Remove the cap of the vial with diluent for sample dilution (figure 1).
2. Use the stick to collect sufficient sample quantity. For solid stool, insert the stick once in 4 different areas of the stool sample, taken approx. 125mg, (figure 2), and add it into the vial with diluent for the sample dilution. For liquid stool, take 125µL of the sample using a micropipette and transfer it into the vial with diluent for the sample dilution.
3. Close the vial with the diluent and stool sample. Shake the vial vigorously in order to assure good sample dispersion (figure 3).

1



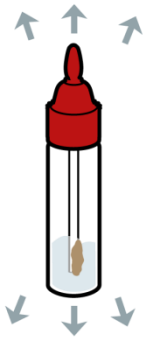
Vial for sample dilution.

2



Insert the stick in 4 different areas of the stool.

3



Put the sample into the vial, close the cap and shake.

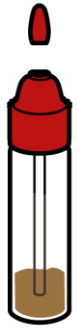
PROCEDURE

Allow the test, stool sample, controls and diluents to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until the performance of the assay.

1. Shake the vial with the sample vigorously to obtain a good sample dilution.
2. Remove the **Vitassay Adenovirus** from its sealed bag just before using it.
3. Take the vial for sample dilution containing the diluted sample, cut the end of the cap (figure 4) and dispense 4 drops in the circular window marked with the letter S (figure 5).
4. Read the results at **10 minutes**. Do not read the results later than 10 minutes.

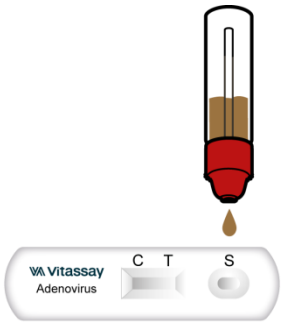
If the test does not run due to solid particles, stir the sample added in the circular window with the stick. If it does not work, dispense a drop of diluent until seeing the liquid running through the reaction zone.

4



Cut the end of the cap.

5



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

INTERPRETATION OF THE RESULTS

	**NEGATIVE** Only one green line in the control zone **(C)**	There is no adenovirus presence. No infection caused by adenovirus.
	**POSITIVE** In addition to the green line (**control line C**), a red line appears, **test line(T)**	There is adenovirus presence. Viral infection caused by adenovirus.
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 still 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**. Green line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

- **Vitassay Adenovirus** must be carried out within 2 hours of opening the sealed bag.
- An excess of stool sample could cause wrong results (brown bands appear). Dilute the sample with the diluent and repeat the test.

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- The intensity of test line may vary depending on the concentration of antigens.
- The use of other samples different from human samples has not been established.
- The quality of **Vitassay Adenovirus** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Positive results determine the presence of adenovirus in fecal samples. A positive result should be followed up with additional laboratory techniques (biochemical methods or microscopy) to confirm the results. 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 antigens in the fecal sample is lower than the detection limit value. If symptoms or situation still persist, an adenovirus determination should be carried out with another technique (for example microscopy).

EXPECTED VALUES

Infectious diarrhea is one of the most common diseases affecting children <5 years old, leading to significant morbidity and mortality worldwide, especially in developing countries. Diarrhea causes >1.8 million deaths each year. Although many pathogens can cause diarrhea, >75% of cases are caused by viruses. Rotavirus are the leading cause of severe diarrhea among children <5 years of age. Sapoviruses, astroviruses, and adenoviruses have also been reported to cause diarrhea in children.

Adenovirus usually accounts for 3.2 to 12.5% of acute diarrhea cases, and the detection ratio is higher in developing countries than in developed countries.

PERFORMANCE CHARACTERISTICS

Clinical sensitivity and specificity

An evaluation with fecal samples was performed using **Vitassay Adenovirus** and confirmed by PCR.

Results were as follows:

		PCR		
		Positive	Negative	Total
Vitassay Adenovirus	Positive	7	0	7
	Negative	0	52	52
	Total	7	52	59

Vitassay Adenovirus vs PCR			
Sensitivity	Specificity	PPV	NPV
>99%	>99%	>99%	>99%

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

Cross reactivity

No cross reactivity was detected against gastrointestinal pathogens that are occasionally present in feces:

Astrovirus	*Giardia lamblia*	*Salmonella typhi*
Campylobacter coli	*Helicobacter pylori*	*Shigella boydii*
Campylobacter jejuni	*Listeria monocytogenes*	*Shigella dysenteriae*
Clostridium difficile	*Norovirus*	*Shigella flexneri*
Cryptosporidium parvum	*Rotavirus*	*Shigella sonnei*
Entamoeba hystolitica	*Salmonella enteritidis*	*Staphylococcus aureus*
Enterovirus	*Salmonella paratyphi*	*Yersinia enterocolitica*
Escherichia coli O157:H7	*Salmonella typhimurium*	

REFERENCES

1. MICHELE REGINA VETTER, RODRIGO STAGGEMEIER, ANDRIA DALLA VECCHIA, ANDREIA HENZEL, CAROLINE RIGOTTO, FERNANDO ROSADO SPILKI. "Seasonal variation on the presence of adenoviruses in stools from non-diarrheic patients". Brazilian Journal of Microbiology 46, 1, 749-752 (2015).

2. YASIN TUGRUL KARAKUS, BIRCAN SAVRAN, SAIME ERGEN DIBEKLIOGLU. "Incidence of rotavirus and adenovirus 40/41 in children and infants". European Journal of Medical Sciences, 2014 Mar; 1(1): 22-25.

3. ZENGZHI REN; YUANMEI KONG; JUN WANG; QIANQIAN WANG; AILONG HUANG; HONGMEI XU. "Etiological study of enteric viruses and the genetic diversity of norovirus, sapovirus, adenovirus and astrovirus in children with diarrhea in Chongquing, China". BMC Infectious Diseases, 2013 13: 412.

4. LIYING LIU; YUAN QUIAN; YOU ZHANG, JIE DENG; LIPING JIA; HUIJIN DONG. "Adenoviruses Associated with acute Diarrhea in children in Beijing, China". PloS ONE 9(2): e88791.

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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