

# VITASSAY

## Astrovirus

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

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For professional *in vitro* diagnostic use only.

### INTENDED USE

**Vitassay Astrovirus** is a rapid one step immunochromatographic one step assay for the qualitative detection of astrovirus in human stool samples.

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

### INTRODUCTION

Human astroviruses, first identified in 1975, are now considered an important cause of viral gastroenteritis, predominately infecting children  $\leq 2$  years of age.

Astrovirus, especially classic astrovirus, are considered gastrointestinal pathogens affecting children worldwide, with very few reports of astrovirus-mediated disease in normal healthy adults. Immunocompromised individuals and the elderly also represent high-risk groups. Typically, astrovirus infection induces a mild, watery diarrhea that lasts 2 to 3 days, associated with vomiting, fever, anorexia, and abdominal pain. Vomiting is less prevalent in astrovirus infection than in rotavirus or calicivirus infection, and astrovirus infections also show a longer incubation period. Based on data from adult volunteer studies and outbreaks of gastroenteritis in a child care center, the mean incubation period of astrovirus infections was calculated to be 4.5 days. In general, astrovirus diarrhea is milder than those caused by rotaviruses or noroviruses, and it resolves spontaneously, although in some cases astrovirus infections have required hospitalization. Asymptomatic infections have also been described in children and adults, although astrovirus prevalence as asymptomatic pathogens has yet to be characterized. Studies in immunodeficient patients, including HIV infected individuals, have associated astrovirus infections with symptomatic gastroenteritis, but a recent report has also shown that classic astrovirus infections can also spread systemically and cause severe disseminated lethal infections in highly immunocompromised children.

### PRINCIPLE

**Vitassay Astrovirus** is a qualitative immunochromatographic assay for the detection of astrovirus in human stool samples.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against astrovirus. During the process, the sample reacts with the antibodies against astrovirus, 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.
- 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 Astrovirus**. 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 (2-30°C/35.6-86°F).

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
<ul style="list-style-type: none"><li>• 25 tests/kit <b>Vitassay Astrovirus</b></li><li>• Instructions for use.</li><li>• 25 vials with diluent for the sample dilution.</li></ul>	<ul style="list-style-type: none"><li>• Specimen collection container.</li><li>• Disposable gloves.</li><li>• Timer.</li></ul>

### SPECIMEN COLLECTION

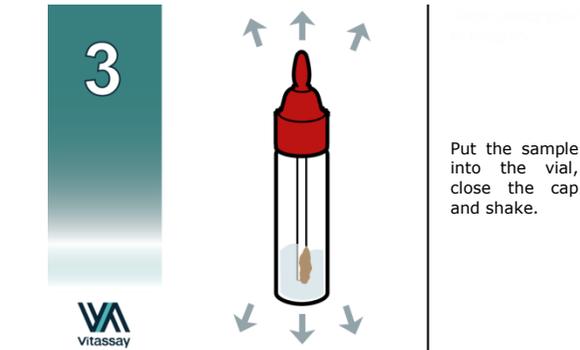
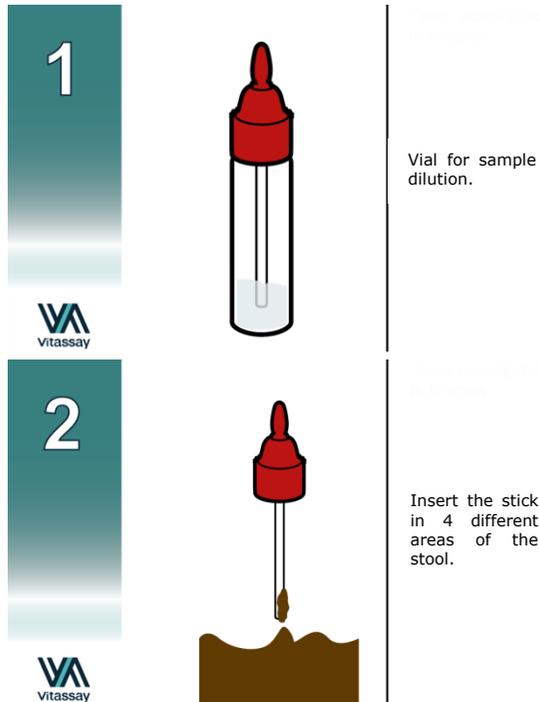
Collect sufficient quantity of feces: 1-2g or mL for liquid samples. Stool samples should be collected in clean and dry containers.

Samples can be stored in the refrigerator (2-8°C/35.6-46.4°F) for 1-2 days prior to testing. For longer storage, maximum 1 year, the

specimen must be kept frozen at -20°C/4°F. Samples must be brought to room temperature before testing.

### SPECIMEN PREPARATION

1. Remove the cap of the vial with diluent for the sample dilution (figure 1).
2. Use the stick to collect sufficient sample quantity. For solid stool, insert the stick 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 125 µL 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 vigorously the vial in order to assure good sample dispersion (figure 3).

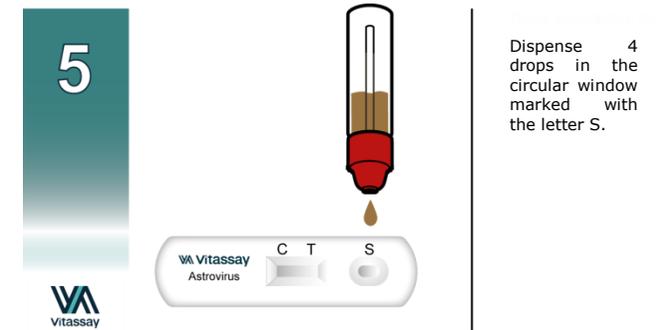
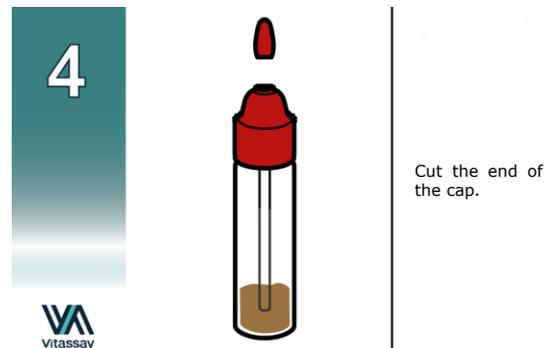


### PROCEDURE

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

1. Shake the vial vigorously to obtain a good sample dilution.
2. Remove the **Vitassay Astrovirus** from its sealed bag just before using it.
3. Take the vial 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 sample window with the stick. If it does not work, dispense a drop of diluent until seeing the liquid running through the reaction zone.



### INTERPRETATION OF THE RESULTS

	NEGATIVE	
	Only one <b>green</b> line in the control zone ( <b>C</b> )	There is no astrovirus presence. No infection caused by astrovirus.
	POSITIVE	
	In addition to the <b>green</b> line ( <b>control line C</b> ), a <b>red</b> line appears, ( <b>test line T</b> )	There is astrovirus presence. Viral infection caused by astrovirus.
<b>ANY OTHER RESULTS</b>		Invalid result, we recommend repeating the assay using the sample with another test. <b>Note:</b> 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 Astrovirus**. **Green** line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

### LIMITATIONS

- **Vitassay Astrovirus** 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.

- 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 Astrovirus** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Positive results determine the presence of astrovirus 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 is lower than the detection limit value. If symptoms or situation still persist, a astrovirus determination should be carried out with another technique (for example microscopy).

#### EXPECTED VALUES

Human astrovirus have been identified as one of the most frequent causes of infantile gastroenteritis, second in incidence only to rotavirus. Astrovirus occur worldwide accounting for about 2% - 16% of diarrhea in the community.

The occurrence of astrovirus infection varies depending on the season. In temperate climates infection is during the rainy season. The variations in the seasonal infection rate particularly in temperate regions is not clearly understood.

#### PERFORMANCE CHARACTERISTICS

##### Clinical sensitivity and specificity

An evaluation with fecal samples was performed using **Vitassay Astrovirus** and comparing the results with another assay (Ridascreen@Astrovirus, r-Biopharm).

Results were as follows:

		Ridascreen@Astrovirus Test		
		Positive	Negative	Total
Vitassay Astrovirus	Positive	16	0	16
	Negative	1	11	12
	Total	17	11	28

Vitassay Astrovirus vs Ridascreen@Astrovirus Test			
Sensitivity	Specificity	PPV	NPV
>94%	>99%	>99%	>92%

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

##### Cross reactivity

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

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

#### REFERENCES

1. YONGXIA WANG; YUNING LI; YU JIN; DAN-DI LI; XIAOLE LI; ZHAO-JUN DUAN. "Recently Identified Novel Human Astroviruses in Children with diarrhea, China". Emergency Infectious Diseases, Vol. 19, N°8, August 2013, pp. 1333-1335.
2. ALBERT BOSCH; ROSA M. PINTÓ; SUSANA GULX. "Human Astroviruses". Clinical Microbiology Reviews, October 2014, Vol. 27, Number 4, pp. 1048-1074.
3. F.A. KUTA; D. DAMISA; N.U. ADABARA; R. ABDULSALAM. "Prevalence of Astrovirus Infection in Children in Nasarawa State, Nigeria". Global Advanced Research Journal of Microbiology, Vol. 3(6), pp. 102-105, July, 2014.

#### 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		Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number



