VITASSAY

Astrovirus

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

IUE-7355011 Ed01 October 2023

CE IVD EN

Vitassay

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 ≤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 diarrhoea 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 childcare center, the mean incubation period of Astrovirus infections was calculated to be 4.5 days. In general, Astrovirus diarrhoea 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.
- Read the instructions for use carefully before using the test.
- Do not use the kit if the label sealing the outer carton is torn or if the bags are open or damaged on arrival.
- Do not use the tests if the desiccant material is missing or broken inside the aluminium pouch.
- Specimens should be considered potentially hazardous and should be handled in the same manner as an infectious agent, following local/national regulations. A new test should be used for each sample to avoid contamination errors.
- Material exposed to the samples should also be considered potentially hazardous and should be handled in the same manner as an infectious agent, following local/national regulations.
- Do not reuse. This is a single-use device.
- Tests and used material should be disposed of in an appropriate 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 or components from other batched.
- 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.
- In case of spillage, clean thoroughly with a suitable disinfectant.
- Do not eat, drink or smoke in the workplace.
- 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 visual interpretation of the results is done by coloured lines, the interpretation of the results should be done by a professional user without problems of visualisation and colour interpretation.

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- A certificate of analysis can be provided on request (not included).

STORAGE AND STABILITY

The storage temperature of the kits should be 2-30ºC.

Do not freeze.

Under these conditions, they can be used until the expiry date indicated on the kit label.

All kit components are for single use only and must remain in their primary packaging until use. The test must remain in the sealed pouch until use.

MATERIALS

MATERIAL PROVIDED	MATERIAL REQUIRED BUT NOT PROVIDED
▪ **25** tests/kit **Vitassay Astrovirus** ▪ Instructions for use. ▪ **25** vials with diluent for the sample dilution.	▪ PPE, such as disposable gloves ▪ Specimen collection container ▪ Timer ▪ Micropipette (in case of liquid stool)

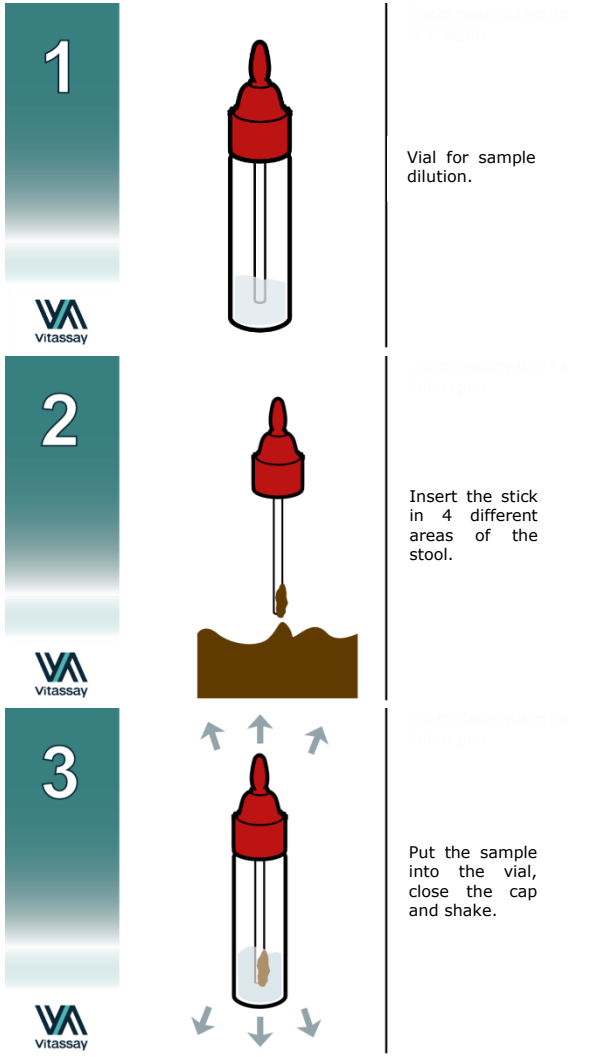
SPECIMEN COLLECTION

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) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20ºC. 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).

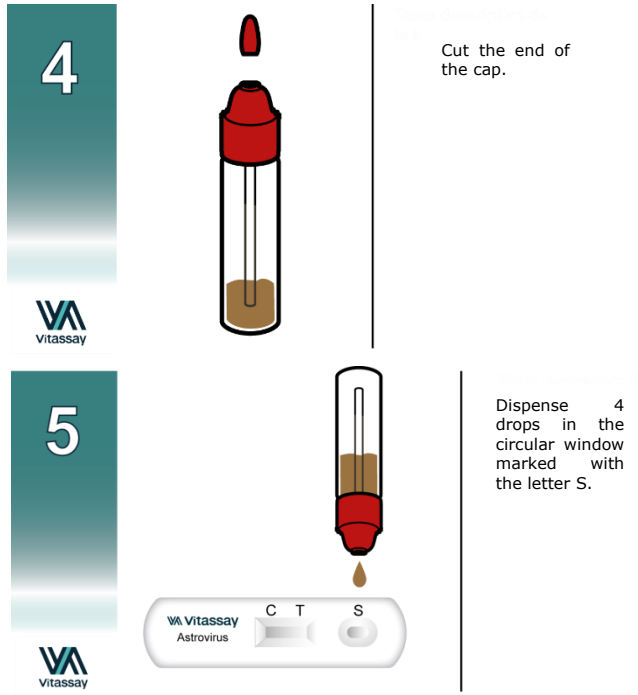


PROCEDURE

Allow the test, stool sample, controls and diluent to reach room temperature (15-30ºC) 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.



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INTERPRETATION OF THE RESULTS

	**NEGATIVE** Only one green line in the control zone **(C)**	There is no Astrovirus presence. No apparent infection caused by Astrovirus.
	**POSITIVE** In addition to the green line (**control line C**), a red line appears, (**test line T**)	There is Astrovirus presence. Possible infection caused by Astrovirus.
ANY OTHER RESULTS		Invalid result, we recommend repeating the assay using the sample with another test. **Note**: Wrong procedural techniques, insufficient sample volume 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 coloured 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

- 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.
- After one week of infection, the number of viruses in faeces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
- The quality of **Vitassay Astrovirus** depends on the quality of the sample. Proper faecal specimens must be obtained.
- Positive results determine the presence of Astrovirus in faecal samples. A positive result should be followed up with additional laboratory techniques (biochemical methods or PCR) to confirm the results.
- Negative results should not be considered as conclusive; it is possible that the concentration of antigens in the faecal sample 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 PCR).
- **Bloody stool** samples and/or **mucous** stool samples can cause non-specific reactions in the test. Such positive samples should be followed up with other diagnostic techniques to confirm the result.

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 diarrhoea 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 faecal 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

Table 1. Results of **Vitassay Astrovirus** compared to a commercial kit.

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

Table 2. Sensitivity, specificity, positive predictive values, and negative predictive values of the **Vitassay Astrovirus** compared to a commercial kit.

Furthermore, A clinical study with **Vitassay Astrovirus** was performed using remnants of 137 faecal samples from patients with symptoms of Astrovirus infection. Discrepant results were confirmed using a commercial real-time PCR.

The results are shown below:

		Ridascreen®*Astrovirus* Test		
		Positive	**Negative**	**Total**
Vitassay Astrovirus	**Positive**	20	2	22
	Negative	1	114	115
	Total	21	116	137

Table 3. Results of **Vitassay Astrovirus** compared to a commercial kit.

Vitassay Astrovirus RIDASCREEN Astrovirus			
Sensitivity	**Specificity**	**PPV**	**NPV**
95.2% (76.2-99.9%)	98.3% (96.9 – 100.0%)	90.9% (70.8–98.9%)	99.1% (95.3 – 100.0%)

Table 4. Sensitivity, specificity, positive predictive values, and negative predictive values of the **Vitassay Astrovirus** compared to a commercial kit.

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 hystolitica	*Salmonella paratyphi*	*Yersinia enterocolitica*
Escherichia coli O157:H7	*Salmonella typhi*	

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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	Σ n	Contains sufficient for <n> test
DIL	Sample diluent	REF	Catalogue number
CE	CE Marking		

Changes control		
Nº Version	**changes**	**Date**
IUE-7355011 Ed00 Noviembre 2016	Original version	11/2016
IUE-7355011 Ed01 October 2023	Addition of a new evaluation. The format has been updated. The limitations section has been updated. Grammatical and editorial changes have been made to Precautions, Limitations, Sample Collection, Preservation and Stability. Required but not included material updated with minor changes.The wording has been changed under Interpretation of results.	03/10/2023

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