Atlas Medical

**Astrovirus Device**

**One Step Astrovirus Antigen Test Device**

A rapid, one step test for the qualitative detection of *Astrovirus* antigens in human feces.

IVD *For In-Vitro diagnostic and professional use only*

Store at 2-30 ºC

CE

**Intended use**

The *Astrovirus* Device is a rapid chromatographic immunoassay for the qualitative detection of *Astrovirus* antigens in human faeces specimens to aid in the diagnosis of *Astrovirus* infection.

**synthesis**

Viral gastroenteritis is an infection caused by a variety of viruses that results in vomiting or diarrhea. Many different viruses can cause gastroenteritis, including rotaviruses, noroviruses, adenoviruses, sapoviruses, and astroviruses.

The main symptoms of viral gastroenteritis are watery diarrhea and vomiting. The affected person may also have headache, fever, and abdominal cramps ("stomach ache"). In general, the symptoms begin 1 to 2 days following infection with a virus that causes gastroenteritis and may last for 1 to 10 days, depending on which virus causes the illness. Some research studies have shown that the duration of the symptoms are approximately three to four days. Astrovirus infection is not usually a severe situation and only in some rare cases leads to dehydration. Adenoviruses and astroviruses cause diarrhea mostly in young children, but older children and adults can also be affected.

**PRINCIPLE**

The *Astrovirus* Device is a qualitative immunoassay for the detection of *Astrovirus* antigen in human faeces samples. The membrane is pre-coated with monoclonal antibodies against *Astrovirus* antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*Astrovirus* antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A green coloured band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

**precautions**

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

**Materials**

**materials provided**

- Devices.
- Buffer.
- Instruction for use.

**materials required but no provided**

- Specimen collection container.
- Disposable gloves.
- Timer.
- Specimen collection vial/testing tube.

**SPECIMEN COLLECTION AND PREPARATION**

Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-4ºC/36-40ºF) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20ºC/-4ºF. In this case, the sample will be totally thawed, and brought to room temperature before testing.

**PROCEDURE**

**To process the collected stool samples (see illustration 1):**

Use a separate specimen collection vial/testing tube for each sample. Dispense exactly 1mL of the buffer into a vial. Introduce the swab or stick two times into the faecal specimen to pick up quite a lot of sample (200-300mg). and put into the testing tube or vial with buffer. Shake the testing tube or vial in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 200-300 µL into the testing tube or vial with buffer.

**Test Procedure (see illustration 2)**

**Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until ready to perform the assay.**

1. Remove the *Astrovirus* Device from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure a good sample dispersion. Break off the cap of the vial.
3. Use a separate device for each sample. Dispense 4 drops into the specimen well (S). Start the timer.
4.- Read the result at **10 minutes** after dispensing the sample.

*Illustration 1:*

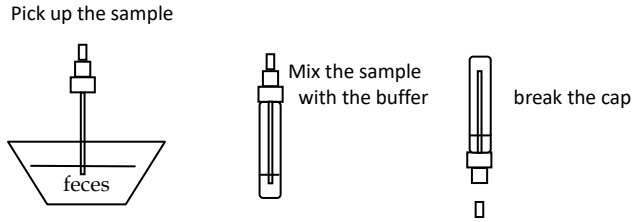
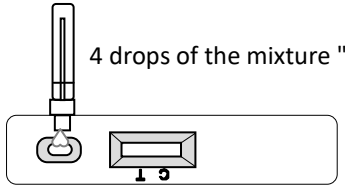



*Illustration 2:*



## INTERPRETATION OF RESULTS

*Illustration 3*

Positive Negative Invalid

**POSITIVE:** Two lines appears across the central window in the result line region (**red** test line marked in the illustration 3 with the letter T) and in the control line region (**green** control line marked in the illustration 3 with the letter C).

**NEGATIVE:** Only one **green** band appears across the control line region marked in the illustration 3 with the letter C (control line).

**INVALID**: A total absence of the green control coloured band regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact you local distributor.

### Notes on the interpretation of results

The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

### Quality Control

Internal procedural controls are included in the test:

- A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

### limitations

1. *Astrovirus* Device will only indicate the presence of *Astrovirus* in the specimen (qualitative detection) and should be used for the detection of *Astrovirus* antigens in faeces specimens only. Neither the quantitative value nor the rate of increase in *Astrovirus* antigens concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *Astrovirus* infection.
5. This test provides a presumptive diagnosis of *Astrovirus* infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

## PERFORMANCE CHARACTERISTICS

### SENSITIVITY AND SPECIFICITY

The evaluation was conducted comparing the results obtained using the *Astrovirus* Device to a commercial available *Astrovirus* ELISA assay.
The detection of *Astrovirus* showed >94% of concordance in sensitivity and >99% of concordance in specificity.

### CROSS-REACTIVITY

It was performed an evaluation to determine the cross reactivity of *Astrovirus* Device. There is not cross reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in faeces.

- Rotavirus
- Adenovirus
- Escherichia coli
- Campylobacter
- Giardia lamblia
- Human Hemoglobin

## REFERENCES


1. SUNITA SHASTRI et al., “Prevalence of Astroviruses in a Children’s Hospital”, JOURNAL OF CLINICAL MICROBIOLOGY Sept. 1998, p. 2571–2574 Vol. 36, No. 9.
2. ASHLEY et al., “Astrovirus-associated gastroenteritis in children”, Journal of Clinical Pathology,. 1978, 31, 939-943.



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**PPI1837A01**
**Rev A (02.09.2019)**


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|---|---|---|---|
| REF | Catalogue Number | | Temperature limit |
| IVD | In Vitro diagnostic medical device | | Caution |
| | Contains sufficient for <n> tests and Relative size | | Consult instructions for use (IFU) |
| LOT | Batch code | | Manufacturer |
| | Do not re-use | | Use-by date |
| | Manufacturer fax number | | Do not use if package is damaged |
| | Manufacturer telephone number | | Date of Manufacture |
| | Keep away from sunlight | | Keep dry |