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## Astrovirus Rapid Test

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Cat. No.:DTS604

Pkg.Size:

### Intended use

TheAstrovirus Deviceis a rapid chromatographic immunoassay for the qualitative detection of Astrovirus antigens in human faeces specimens to aid in the diagnosis of Astrovirusinfection.

### General Description

Viral gastroenteritis is an infection caused by a variety of viruses thatresults 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 Of The Test

TheAstrovirus Device is a qualitative immunoassay for the detection of Astrovirus antigen in human faeces samples. The membrane is precoated 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.

### Reagents And Materials Provided

Devices  
Instruction for use  
Specimen collection vial with buffer

### Materials Required But Not Supplied

Specimen collection container  
Disposable gloves  
Timer

### Storage

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/36-86°F). 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.

### 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 (2-4°C/36-40°F) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at -20°C/-4°F. In this case, the sample will be totally thawed, and brought to room temperature before testing.

## Assay Procedure

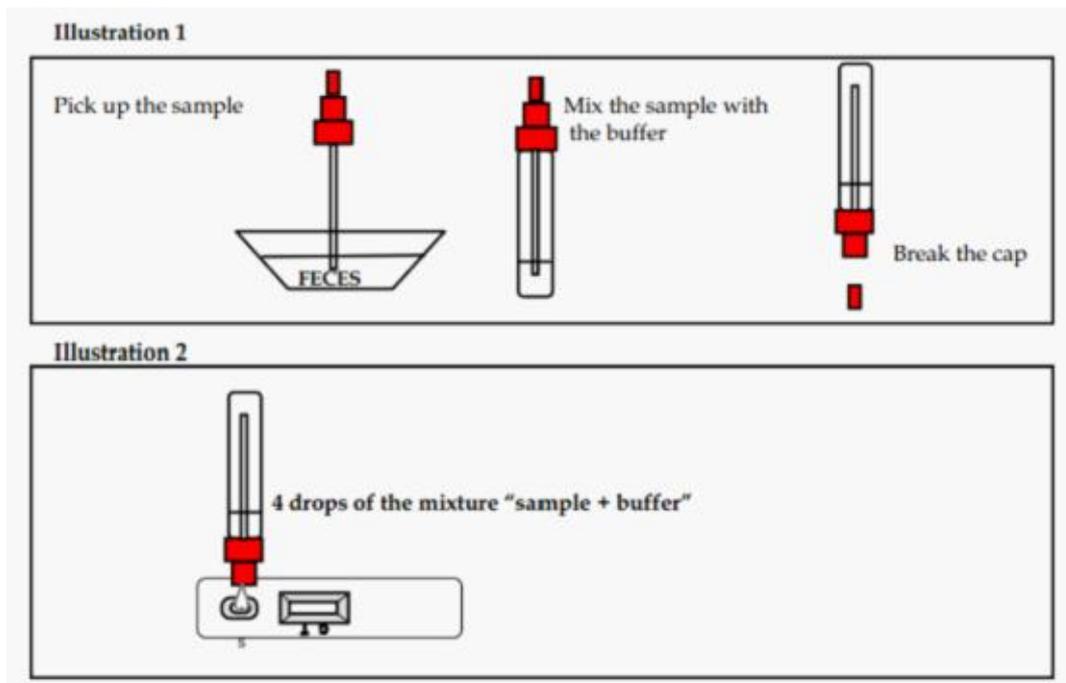
To process the collected stool samples (see illustration 1):

Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick two times into the faecal specimen to pick up quite a lot of sample (200- 300mg). Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 200-300µL into the specimen collection vial with buffer.

Test Procedure (see illustration 2)

Allow the tests, stool samples and buffer to reach to room temperature (15-30°C/59-86°F) 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.



## 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.

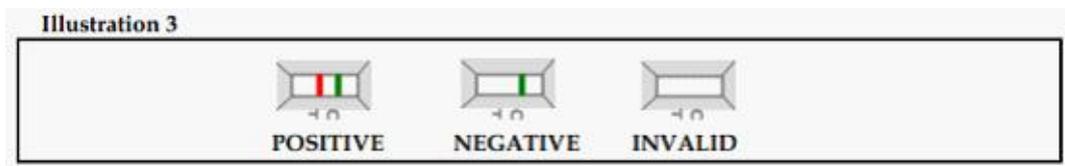
## Interpretation of Results

**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 your local distributor.

**NOTE:** 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.



## Expected Values

A study of intestinal disease in the UK, published in 1999 determined incidence as 3.8/1000 patient years in the community (95%CI, range 2.3-6.4), the fourth most common known cause of viral gastroenteritis. Studies in the USA have detected astroviruses in the stools of 2-9% of children presenting symptoms; illness is most frequent in children of less than two years, although outbreaks among adults and the elderly have been reported. Early studies carried out in Glasgow demonstrated that a significant proportion of babies excreting virus particles, 12%, did not exhibit gastrointestinal symptoms, and seroprevalence studies carried out in the US have shown that 90% of children have antibody to HastV-1 by age 9, suggesting that (largely asymptomatic) infection is common. There is, as with most viral causes of gastroenteritis, a peak of incidence in the winter.

## Sensitivity

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.

## 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 >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

## Precautions

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.

## 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.

## 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.