ASTROVIRUS-DIPSTICK

For professional *in Vitro* **diagnostic use only.**

Immunochromatographic test strip for the detection of Astrovirus antigens in human faeces

I. INTRODUCTION AND INTENDED USE

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, adenoviruses, astroviruses and noroviruses.
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 5-8 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.
Astrovirus Dipstick is a screening immunochromatographic assay to detect Astrovirus antigen in stool samples.

II. PRINCIPLE

Astrovirus Dipstick strip is a non-invasive lateral flow assay, rapid, precise and easy to perform.
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.

III. REAGENTS AND MATERIALS

Each kit contain:
1. Astrovirus Dipstick (25 test): tube containing 25 reactive strips and dissecant.
2. Extraction buffer (25): 25 vial containing 1 mL of extraction solution.
3. Instruction for use (1)

Required materials (not supplied)
Specimen collection container, Disposable gloves, Plastic pipettes, testing tubes or vials, Timer or clock.

IV. PRECAUTIONS

- For *in* vitro and professional use only
- Do not use after expiration date.
- Stool specimen can be potentially infectious. Safety measures for handling as well as storing the collected specimen must be fixed by the operators.
- *As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.*

V. STORAGE

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC). 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.

VI. SAMPLES 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 (2-8ºC) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20ºC. In this case, the sample will be totally thawed, and brought to room temperature before testing. Specimens may be frozen and thawed twice.

Liquid or Semi-Solid Stools
Using a separate pipette for each stool, draw stool of the sample itself. Dispense 200-300 µL of each stool into a separate extraction tube. Mix carefully, then vortex 15 seconds.
Care should be taken when pipetting semi-solid stool. The addition of less than indicated of stool may cause a false-negative test. The addition of more than indicated of stool may cause invalid results due to restricted sample flow.

Formed / Solid Stools
Unscrew the top of the extraction tube. Collect the stool sample with the tip of the collection device by dipping in three different places of the same stool specimen.. Verify to transfer a small portion (200-300 mg) of stool. Put the collection device back into the plastic test tube. Shake the extraction tube in order to get an homogeneous solution. Wait at least 3 minutes. Repeat the operations just to obtain a dark yellow-brown solution, if necessary.
The transfer of too little stool, or failure to mix and suspend the stool in extraction tube completely may result in a false-negative test results. Care should be taken to transfer no less and no more than the amount indicated. The sample should be thoroughly mixed with a vortex before testing. The addition of excessive amount of stool may cause invalid results due to restricted sample flow.

VII. PROCEDURE

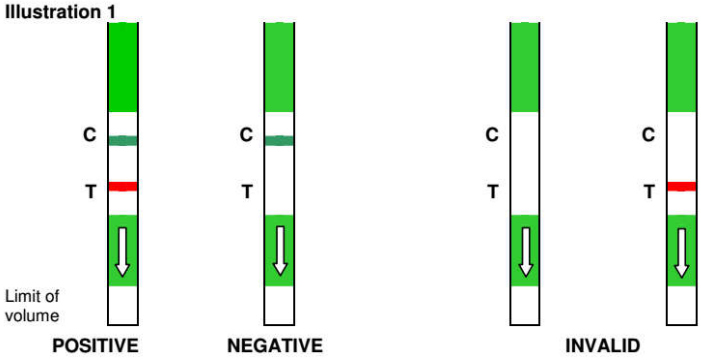
Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the tube with strips until ready to perform the assay.

1. Use Astrovirus strip as soon as possible when opening the tube.
2. Shake thoroughly to homogenize the solution the vial with sample and extraction buffer.
3. Break the dropper of the vial and dispense 5-6 drops (150 µL) into a testing tube.
4. Leave the test strip to stand vertically taking care of not surpassing the limit of immersion indicated with the arrows. Start the timer.
5. Start the timer and read the result at 10 minutes after dispensing the sample.

VIII. INTERPRETING THE RESULTS

Negative test: only one line appears in the control line region (green control line).
Positive test: two lines appears: in the Result Line Region (red test line) and in the control line region (green control line).
Invalid test: The absence of the migration control line, which is the upper line, makes the result invalid. In this case, the sample must be retested.

Illustration 1



NOTES OF INTERPRETATION OF RESULTS

The intensity of the red coloured band in the result line region 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.

XI. PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The kit was validated comparing the results obtained with Astrovirus Dipstick versus those ones obtained with an ELISA test (Ridascreen®Astrovirus, r-Biopharm).
Sensitivity and specificity of kit have been determined on 28 stool samples. The results are the following:
Sensitivity > 94 % Specificity > 99 % ; PPV > 99%; NPV > 92%.

Interference

No cross-reactions have been found with bacteria normally present in the gastro-intestinal tract and those ones generally infecting the same area such as *Enterococcus, Klebsiella, Proteus, Candida, Campylobacter, Shigella, Salmonella, E.Coli as well as yeasts strains and Adeno-Rotavirus.* Leukocytes, whole blood, were found not to have any effect if present in stool specimens.

X. LIMITS OF THE TEST

- Astrovirus Dipstick is screening test for determination of presence of Astrovirus in human faeces. A definitive clinical diagnosis should be made by the physician after all clinical and laboratory findings have been evaluated.
- A positive result does not rule the possibility that other pathogens may be present.
- 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.
- The components of this I.v.D. were always tested together without compatibility with components from other manufacturers. While not excluding the possibility that these components can be used with components of the same formulation but produced by other companies, there is no experimental evidence of such compatibility.

XI. BIBLIOGRAPHIC REFERENCES

1. CUKOR G., and BLACKLOW N. R., "Human Viral Gastroenteritis", Microbiological Reviews, Vol. 48 No 2, June 1984, pp. 157-179.
2. NEEL K. KRISHNA, B. A, "Identification of Structural Domains Involved in *Astrovirus* Capsid Biology", Viral Immunol. 2005; 18(1): 17-26.
3. BON, F. et al. "Prevalence of group A rotavirus, human calicivirus, *Astrovirus* type 40 and 41 infections among children with acute gastroenteritis in Dijon, France. "J. Clin. Microbiol. 37 No 9 3055-3058 (199).

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (25 tests) **Ref. VC1020**

Astrovirus Disptick	25 items
Extraction solution (1,0 mL)	25 items
Instruction for use	1 item

DMA (EDMS) CODE 15709090 CE IVD