IVD

Rapid-VIDITEST

Astrovirus Card

One step Astrovirus Card Test.

Instruction manual

INTENDED USE:

The Rapid-VIDITEST Astrovirus Card is a one step coloured chromatographic immunoassay for the qualitative detection of Astrovirus in stool samples.

INTRODUCTION:

Astrovirus is a cause of infectious gastroenteritis in infants and young children, also observed in adults. It is transmitted by fecal-oral contact. The main symptoms of viral gastroenteritis are watery diarrhoea 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 Astrovirus that causes gastroenteritis and may last for 3 days.

PRINCIPLE:

The Rapid-VIDITEST Astrovirus Card is a qualitative immunochromatographic assay for the determination of Astrovirus in feces samples. The membrane is pre-coated with mouse monoclonal antibodies, on the test band region, against viral antigens.
During testing, the sample is allowed to react with the coloured conjugate (anti-astrovirus mouse monoclonal antibodies-red microspheres) which was pre-dried on the test. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a GREEN coloured band always appears. The presence of this GREEN band serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

MATERALS PROVIDED:

- Rapid-VIDITEST Astrovirus Card tests
- Instructions for use
- Stool collection tubes-sample diluent

MATERIALS REQUIRED BUT NO PROVIDED:

- Specimen collection container
- Disposable gloves
- Timer

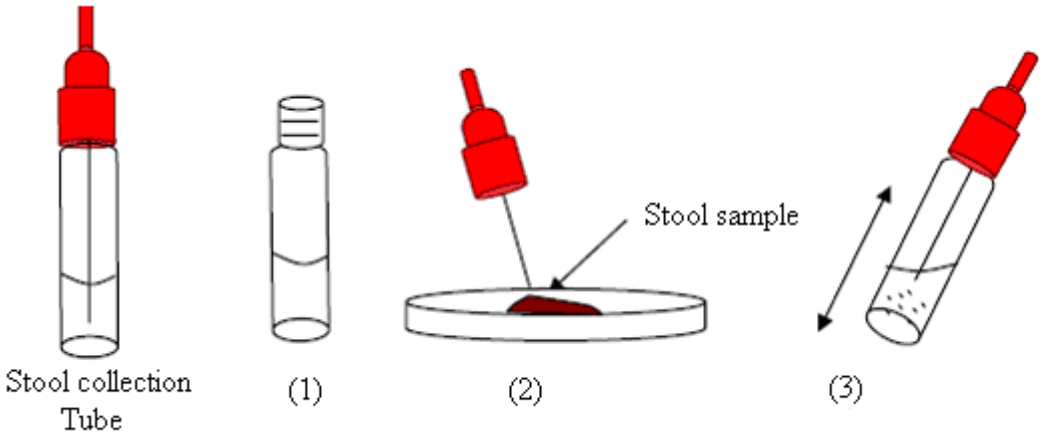
SPECIMEN COLLECTION AND PREPARATION:

Stool samples should be collected in clean containers and the assay should be done right after collection. The samples can be stored in the refrigerator (2-4ºC) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at –20ºC. In this case, the sample will be totally thawed, and brought to room temperature before testing.

PROCEDURES:

To process the collected stool samples:

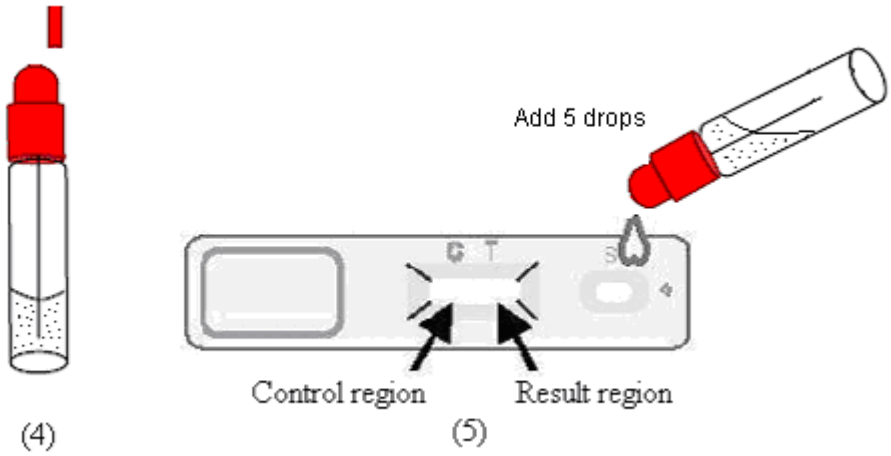
Unscrew the tap (1) and use the stick to pick up a little sample (2). Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion (3).



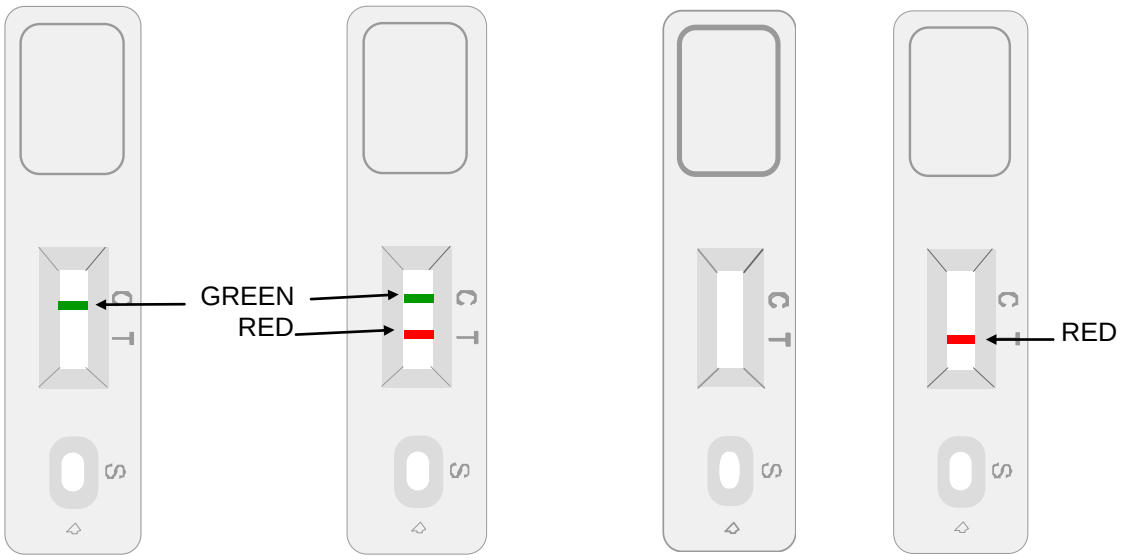
Test Procedure:

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

1. Proceed to shake the stool collection tube in order to assure good sample dispersion. Cut the end of the top (4).
2. Remove the Rapid-VIDITEST Astrovirus Card device from its sealed bag just before using.
3. Use a separate stool collection tube and device for each sample or control. Dispense exactly 5 drops or 150 µL into the circular window marked with an arrow (5).
4. Read the result at **10 minutes** (the coloured bands appear).



INTERPRETATION OF RESULTS:



NEGATIVE: Only one GREEN band appears across the central window in the site marked with the letter C (control line).

POSITIVE: In addition to the GREEN control band, a RED band (test line) also appears in the site marked with the letter T (result line).

INVALID: A total absence of the control coloured band (GREEN) regardless the appearance or not of the result line (RED). 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.

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 region (C) is an internal control. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS:

1. The test must be carried out within 2 hours of opening the sealed bag.
2. An excess of stool sample could cause wrong results (brown bands appear).
3. After one week of infection, the number of viruses in feces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
4. This test provides a presumptive diagnosis for Astrovirus infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS:

The evaluation was conducted comparing the results obtained using the Rapid-VIDITEST Astrovirus Card to a commercial available Astrovirus ELISA assay.

Sensitivity

The detection of Astrovirus showed >94% of concordance in sensitivity.

Specificity

The detection of Astrovirus showed a >99% of concordance in specificity.

The use of mouse monoclonal antibodies in the elaboration of Rapid-VIDITEST Astrovirus Card assures high degree of specificity for the detection of this virus.

STORAGE AND STABILITY:

Store as packaged in the sealed pouch at 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.

PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The tests should be discarded in a proper biohazard container after testing.

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 (1999).

SYMBOLS FOR IVD COMPONENTS AND REAGENTS:

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer

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