CE

IVD

Rapid-VIDITEST

Rotavirus Card

One step Rotavirus Card Test

Instruction manual

INTENDED USE:

The Rapid-VIDITEST Rotavirus Card test is a rapid chromatographic immunoassay for the qualitative detection of Rotavirus antigens in human faeces specimens to aid in the diagnosis of Rotavirus infection.

INTRODUCTION:

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. Rotavirus is the more frequent cause of acute diarrhea in children under two years of age.

PRINCIPLE:

The Rapid-VIDITEST Rotavirus Card is a qualitative lateral flow immunoassay for the detection of Rotavirus antigen in human faeces samples. The membrane is pre-coated with monoclonal antibodies against Rotavirus antigens on the test line region. During testing, the sample reacts with the particle coated with anti-Rotavirus 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.

MATERALS PROVIDED:

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

MATERIALS REQUIRED BUT NO PROVIDED:

- Specimen collection container
- Disposable gloves
- Timer

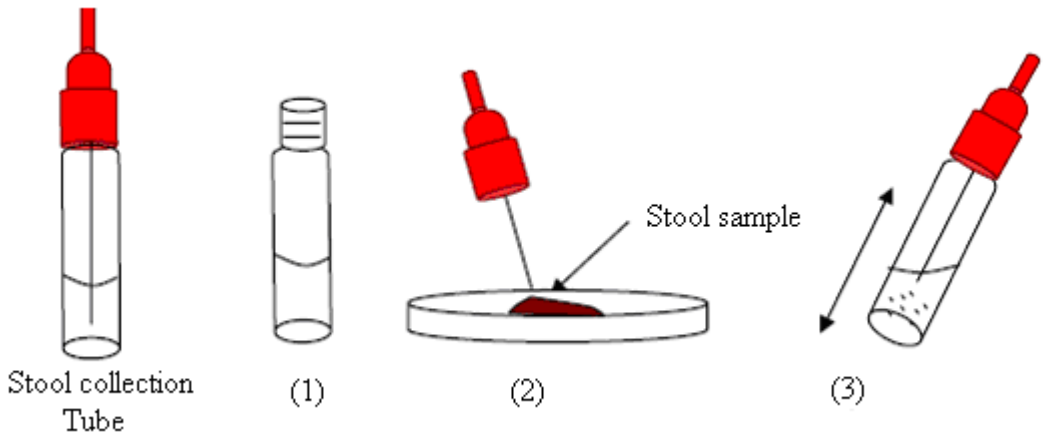
SPECIMEN COLLECTION AND PREPARATION:

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.

PROCEDURES:

To process the collected stool samples:

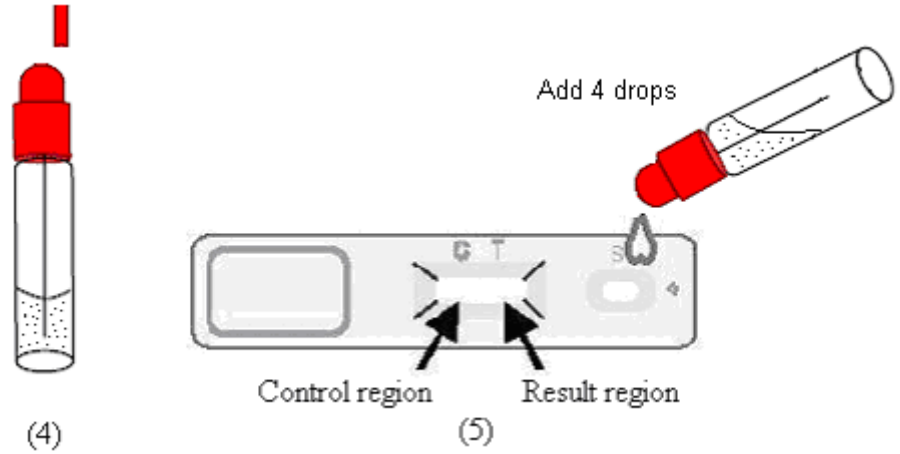
Use a separate specimen collection vial/testing tube for each sample.. Dispense exactly 1mL of the buffer into a vial/testing tube (1). Introduce the swab or stick two times into the faecal specimen to pick up a little sample (100 mg) (2) and put into the testing tube or vial with buffer. Shake the testing tube or vial in order to assure good sample dispersion (3). For liquid stool samples, aspirate the faecal specimen with a dropper and add 100 µL into the testing tube or vial with buffer.



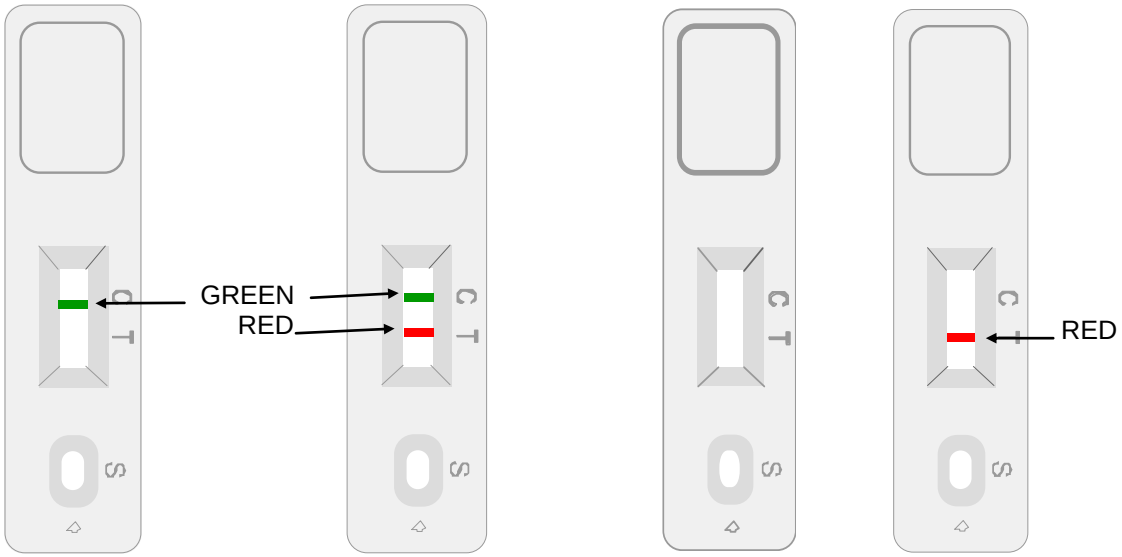
Test Procedure:

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. Remove the Rapid-VIDITEST Rotavirus Card from its sealed pouch and use it as soon as possible. Shake the specimen collection vial to assure a good sample dispersion. Break off the tip of the vial (4).
2. Use a separate device for each sample. Dispense exactly 4 drops into the specimen well (S) (5). Start the timer.
3. Read the result at **10 minutes** after dispensing the sample.



INTERPRETATION OF RESULTS:



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

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

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. Rapid-VIDITEST Rotavirus Card will only indicate the presence of Rotavirus in the specimen (qualitative detection) and should be used for the detection of Rotavirus antigens in faeces specimens only. Neither the quantitative value nor the rate of increase in Rotavirus 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 Rotavirus infection.
5. This test provides a presumptive diagnosis of Rotavirus infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES:

Each year in the U.S., Rotavirus infection results in the hospitalization of an estimated 70,000 children, 160,000 emergency room visits in children younger than 5, and half a million visits to doctor's offices. It is estimated that 100 children die each year in the U.S. from complications of Rotavirus infection. Rotavirus affects populations in all socioeconomic groups and is equally prevalent in industrialized and developing countries, so differences in sanitation practices or water supply are not likely to affect the incidence of the infection. In the U.S., Rotavirus infections usually peak in the fall months in the southwest and spread to the northeast by spring, so infections are most common during the winter months. However, infection with Rotavirus can occur at any time of the year.

PERFORMANCE CHARACTERISTICS:

Sensitivity and Specificity

An evaluation was conducted comparing the results obtained using the Rapid-VIDITEST Rotavirus Card to a commercial available Rotavirus ELISA assay.
Rapid-VIDITEST Rotavirus Card was highly specific (>98%) and also highly sensitive (>99%) compared with the results of that ELISA assay.

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of Rapid-VIDITEST Rotavirus Card . There is not cross reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in feces (Astrovirus, Adenovirus, *Escherichia coli*, *Campylobacter*, *Giardia lamblia*, Human Hemoglobin).

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.

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.

REFERENCES:

1. SILVA DE OLIVEIRA, CONSUELO; LINHARES, ALEXANDRE C. et al., “Rotavirus: clinical features and prevention”, Jornal de Pediatria - Vol. 75, Supl.1, 1999.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS:

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

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