QuickStripe™ Rotavirus

One-Step Test for Determination of Rotavirus in Human Feces

Instruction Manual

Test kit for 25 determinations

(Catalog No.41205)

For In Vitro Diagnostic Use
For professional use only
Store at 4-30°C. **Do Not Freeze**

***Savyon®* Diagnostics Ltd.**
3 Habosem St. Ashdod 77610
ISRAEL
Tel.: +972.8.8562920
Fax: +972.8.8523176
E-mail: support@savyondiagnostics.com

INTENDED USE

QuickStripe Rotavirus is a rapid immunochromatographic test for use in the qualitative screening of human faecal samples for detection of the presence of rotavirus antigen.

SUMMARY AND EXPLANATION

Rotaviruses are one of the major causes of pediatric gastroenteritis and diarrhea. Untreated, rotavirus infection may result in severe illness with dehydration and disturbances of the body's normal electrolyte balance, especially in babies and preschool children [1]. Rotavirus is the cause of up to 50% of the hospitalized cases of diarrheal illness in infants and young children [2]. Rotavirus induced dehydration is a major cause of infant morbidity in both developed and underdeveloped countries, and a major cause of infant mortality in the latter regions (up to 4% per year) [3].

The highest prevalence of the disease is experienced in temperate climates during the cooler months of the year [4]. In tropical climates rotavirus infection can occur year round [2]. The age groups most susceptible to the disease are that of infants and children [4] and geriatric patients [9,12].

Diagnosis of rotavirus gastroenteritis is based on the identification of rotavirus particles in the feces. These particles, shed in large numbers during infection, may be observed by electron microscopy (EM) or detected by immunological methods, such as the immunochromatographic method used in the *QuickStripe Rotavirus* assay.

PRINCIPLE OF THE PROCEDURE

The *QuickStripe Rotavirus* lateral flow test combines anti-*rota* antibody-dye conjugates and solid phase antibodies to selectively identify rotavirus. As the test sample flows through the test stick, the labeled antibody-dye conjugate binds to the rotavirus antigen forming an antibody-antigen complex. The complex binds to the anti-*rota* antibodies in the test zone producing a color band. A red color band appears if the sample is positive for rotavirus. In the absence of rotavirus antigens there is no line in the test zone. The reaction mixture continues flowing through the test stick, producing a green color band in the control zone. The green control line serves as verification that sufficient volume of specimen has been added and as an internal control for the integrity of the reagents.

KIT CONTENTS (25 determinations)

25 *QuickStripe Rotavirus* dipstick tests placed in individual pouches with desiccant;
25 sample dilution tubes, each containing 0.5 ml dilution buffer and placed into a plastic stand;
1 Instructions For Use sheet

WARNINGS AND PRECAUTIONS

1. Do not use kit or components beyond expiration date.
2. All components of the kit are for in-vitro diagnostic use only, not for internal or external use in humans or animals.
3. Infectious agents may be present in test specimens. Therefore all specimens should be regarded and handled as potential biohazards. Never pipette by mouth and avoid contact with open wounds.
4. Do not mix reagents from kits of different lots.
5. Incubation times or temperatures other than those specified may give erroneous results.
6. After use the product should be discarded into a suitable biological waste container. Sterilize used test strips, strip holder, and test tubes before releasing into the environment.

STORAGE OF REAGENTS

The test stick should be stored at 4-30^{0}C in its sealed pouch and under dry conditions. Expiration date for each assay lot is indicated on the pouch. Do not use if foil pouch seal is not intact!

SPECIMEN COLLECTION AND HANDLING

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) 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.

SAMPLE PREPARATION

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

Use a separate swab, stick and testing tube for each sample. Introduce the swab or stick two times into the faecal specimen to pick up a little sample (~50 mg) and put into the testing tube with buffer. Shake the testing tube in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 50 µL into the testing tube with buffer.

TEST PROCEDURE (see illustration 2)

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

1. Remove a dipstick test from the pouch.
2. Label the test with a patient name or ID number. Insert the dipstick test vertically (with the arrows pointing downwards) into the test tube containing the diluted sample.
3. Leave the test strip to stand vertically taking care that the sample volume does not exceed the indicated arrows. Start the timer.
4. Read the result at **10 minutes**.

Illustration 1

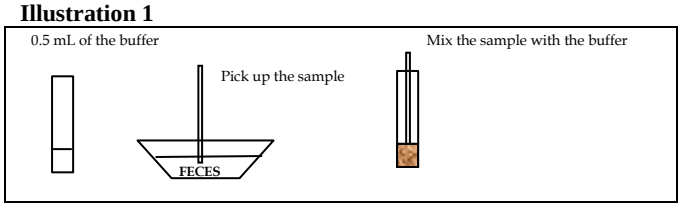
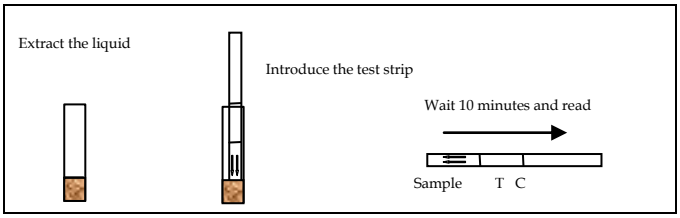
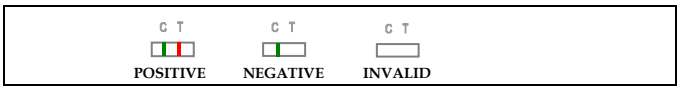


Illustration 2



INTERPRETATION OF RESULTS



POSITIVE: Two lines appear on the test membrane. A **red** test line (marked in the illustration with the letter T) in the test zone and a **green** control line (marked in the illustration with the letter C) in the control zone.

NEGATIVE: Only one **green** band appears across the control line region marked in the illustration 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.

NOTES: 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

Each test strip contains a built in procedural control. Correct device performance is confirmed when a green line appears in the control zone of the strip (C). It confirms sufficient specimen volume and correct procedural technique. Good laboratory practice requires running a known positive control sample when a new lot of strips is used. If a positive result is not obtained, test results are not valid and the kit should not be used.

LIMITATIONS OF THE PROCEDURE

1. *QuickStripe Rotavirus* 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.
6. Do not use samples containing preservatives or detergents.
7. Infrequently a diluted stool sample may fail to diffuse up the stick. In such a case transfer 0.3 ml (about half the volume) of the liquid from the diluted sample to another of the provided dilution tubes, mix vigorously, and test again with a new *QuickStripe Rotavirus*.
8. A negative result does not exclude the possibility of rotavirus infection. The quantity of virus or antigen may be too small, or the sampling may be inadequate or improper.

EXPECTED RESULTS

Age of patient, geographical location, season of the year, weather and general health environment are all factors influencing the prevalence of rotavirus. In temperate climates, viral gastroenteritis is more prevalent during the winter months and infection is less common in the summer.

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.

SENSITIVITY AND SPECIFICITY

Sensitivity and Specificity

An evaluation was conducted comparing the results obtained using the *QuickStripe Rotavirus* to a commercially available Rotavirus ELISA assay.

QuickStripe Rotavirus was highly specific (>98%) and also highly sensitive (>99%) compared with the results of that ELISA assay.

Cross-Reactivity

An evaluation was performed to determine the cross reactivity of *QuickStripe Rotavirus*. There is no cross reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in feces.

- *Astrovirus*
- *Adenovirus*
- *Escherichia coli*
- *Campylobacter*
- *Giardia lamblia*
- *Human Hemoglobin*

BIBLIOGRAPHY

1. Cukor, G and Blacklow, NR. 1984. Microbiol. Rev. 48:157-179.
2. Kapikian, AZ, et al. in Viral, Rickettsial and Chlamydial Infections, 5th Edition (Lennette, EH and Schmidt, NJ, editors). 1979. Am. Public Health Assoc., pp. 927-996.
3. Kapikian, AZ, et al. in Viral Infections of Humans, 2nd Edition (Evans, AS, editor). 1982. Plenum Books, pp. 283-326.
4. Barnett, B. 1982. Med. Clin. North Amer. 67:1031-1058.
5. Brandt, CD, et al. 1983. J. Clin. Microbiol. 18:71-78.
6. Chrystie, IL, et al. 1978. Lancet, pp. 1176-1178.
7. Bryden, AS, et al. 1982. J. Infection 4:43-48.
8. Wenman, WM, et al. 1979. N. Engl. J. Med. 301:303-306.
9. Marrie, TJ, et al. 1982. Arch. Internal Med. 142:313-316.
10. Rodriquez, WJ et al. 1977. J. Pediatrics 91:188-193.
11. Kapikian, AZ, et al. 1976. N. Engl. J. Med. 294:965-972.
12. Cubbit, WD. 1982. Medicine Today 1:33-38.
13. Blacklow, NR and Cukor, G. 1985. Man. Clin. Microbiol., 4th Edition, pp. 805-812.
14. Brandt, CD, et al. 1982. J. Clin. Microbiol. 16:478-482.
15. Blacklow, NR and Cukor, G. 1981. N.Engl. J. Med. 304:397-406.
16. Nagayoshi, S, et al. 1980. Eur. J. Pediatrics 134:99-102.

CE

European Authorized Representative: Obelis s.a.
Boulevard Général Wahis 53, B-1030 Brussels
Tel: +32.2.732.59.54 Fax: +32.2.732.60.03
E-mail:mail@obelis.net