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QuickStripe™ Adeno/Rota

One-Step Test for Determination of
Adenovirus and Rotavirus in Human Feces

Instruction Manual

Test kit for 10/25 determinations
(Catalog No. 41207)

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

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Intended Use

QuickStripe™Adeno/Rota is a rapid immunochromatographic test for use in the qualitative screening of human fecal samples for detection of the presence of rotavirus or adenovirus antigen.
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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 [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 occur year round [2]. The age groups most susceptible to the disease are that of infants and children [4].
Adenoviruses have been implicated in a wide range of clinical diseases affecting mainly the respiratory, ocular and the gastrointestinal systems of the human [5,6]. Some adenovirus serotypes are enteric and have emerged as a major source of pediatric gastroenteritis [7,8].
Diagnosis of rotavirus and adenovirus gastroenteritis is based on the identification of virus 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™Adeno/Rota* assay.

Principle of the Procedure

The *QuickStripe™Adeno/Rota* lateral flow test employs two antibody-dye conjugates (anti-rotavirus and anti-adenovirus) and two solid phase antibodies to selectively identify rotavirus and adenovirus. As the test sample flows through the test stick, the labeled antibody-dye conjugate binds to the rotavirus/adenovirus antigen forming an antibody-antigen complex. The complex binds to the anti-*rota* or anti-*adeno* antibodies in the test zone producing a color band. A red color band appears if the sample is positive for rotavirus and a blue color band appears if the sample is positive for adenovirus. In the absence of rotavirus and adenovirus 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

10/25 *QuickStripe™Adeno/Rota* tests placed in individual pouches with desiccant;
10/25 sample dilution tubes, each containing 0.5 ml dilution buffer
1 instruction sheet

Warnings and Precautions

1) Do not use kit or components beyond expiration date.
2) All components in 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

Store the test kit from 4 - 30°C for the duration of the shelf life. Open container only to remove strips, otherwise keep tightly closed.

Specimen Collection and Handling

Fecal samples should be collected in clean, dry containers, free of calf or bovine serum (which may contain antibodies to rotavirus) or detergents. Approximately 0.05 g (0.05 ml) is sufficient to perform the test. Swab samples are acceptable provided that this amount of feces can be collected. For best results samples should be collected 3-5 days after appearance of symptoms of rotavirus infection. Samples collected eight days or more after symptoms are first noted may not contain sufficient antigen or virus particles to be detected.
Refrigerate all specimens until ready for testing. If specimens are not going to be tested within 48 hours, they should be stored at -20°C or below. Avoid repeated freezing and thawing. Storage in a self-defrosting freezer is not recommended. Samples diluted in Sample Diluting Solution should be discarded after use.

SAMPLE PREPARATION

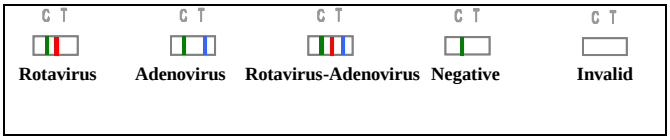
1. Open a sample tube.
2. Add a small portion of feces (about 0.05 g) to the sample tube. Screw on the cap tightly.
3. Shake tube vigorously until sample dissolves into test fluid.
4. Wait until the large particles settle to the bottom of the tube.

Test Procedure

1. Remove a test strip from the container.
2. Label the test with a patient name or ID number. Insert the test strip 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**.

Interpretation of Results

INTERPRETATION OF RESULTS



Rotavirus 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.
Adenovirus positive: Two lines appear on the test membrane. A **blue** 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 control zone.
Rotavirus-Adenovirus positive: Three lines appear on the test membrane. Two lines in the test zone (a **red** test line and a **blue** test line marked with the letter T) and one line in the control zone (**green** control line marked with the letter C).
Negative: Only one **green** band appears in the control region marked with the letter C (control line).
Invalid: A total absence of the green colored control band regardless of the appearance or not of the red and blue test lines. 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 strip. If the problem persists, discontinue using the test kit and contact your local distributor. See illustration.

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. Rotavirus and some adenoviruses have been identified as causes of gastroenteritis. The specificity of this test does not preclude the possibility of bacterial gastroenteritis. It is advisable, therefore, to test the fecal sample for bacterial diarrheal pathogens as well.
2. Do not use samples containing preservatives or detergents.
3. A negative result does not exclude the possibility of rotavirus or adenovirus infection. The quantity of virus or antigen may be too small, or the sampling may be inadequate or improper.
4. Infrequently a diluted stool sample may fail to diffuse up the stick. In such a case transfer 0.5 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™Adeno/Rota* test strip.

Expected Results

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

Specific Performance Characteristics

The performance of the *QuickStripe™Adeno/Rota* test was compared to the RIDA®QUICK Rotavirus/Adenovirus immunochromatographic assay.

QuickStripe™ Adeno/Rota test strip adenovirus line	RIDA®QUICK Rotavirus/Adenovirus *adenovirus* line		
	+	-	Total
+	8	2	10
-	0	28	28
Total	8	30	38

QuickStripe™ Adeno/Rota test strip rotavirus line	RIDA®QUICK Rotavirus/Adenovirus *rotavirus* line		
	+	-	Total
+	16	0	16
-	0	22	22
Total	16	22	38

Correlation between the *QuickStripe™Adeno/Rota* test strip and the RIDA®QUICK Rotavirus/Adenovirus test:
Adenovirus – 95% correlation
Rotavirus – 100% correlation

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