

EpiTuub™ Fecal Rotavirus Antigen Test Kit

Rapid Immunochromatographic Test Device for the detection of
Rotavirus Antigen in Feces



KT 917



30 Tests



2 – 8°C

US: For In Vitro Diagnostics Use

EU:



INTENDED USE

This rotavirus antigen test kit is intended for the direct qualitative detection of the presence of rotavirus antigen in patient fecal samples. The test might be used as an aid for detecting patients with acute gastroenteritis infected with rotavirus. It is for professional use only.

SUMMARY OF PHYSIOLOGY

Rotaviruses are the main cause of acute gastroenteritis and diarrhea, especially in children under the age of two years. Rotaviruses have been identified in almost 40% of the faces of children with gastroenteritis. Rotavirus is the cause of up to 50% of the hospitalized cases of diarrhea in infant and young children. If not treated, the infection may result in severe dehydration and disorders of body electrolyte balance. Therefore, it can be mortal in risk populations such as children, the elderly or immunosuppressed individuals. Rotavirus is transmitted by oral-fecal contact with an incubation period of 1-3 days. Characteristic symptoms include vomiting, hydrodiarrhoea for between 3 and 8 days, high temperature and stomach pains. A large amount of rotavirus particles is shed during infection.

Diagnosis of gastroenteritis with rotavirus infection can be established based on the detection of the virus particles by electron microscopy or the virus antigen by specific immunoassay methods.

ASSAY PRINCIPLE

The Rotavirus Rapid Test Strip employs dye-conjugated monoclonal antibodies against antigen VP6 of group A of rotavirus, and solid-phase specific rotavirus antibodies. In this test the specimen is first treated with an extraction solution to extract rotavirus antigens from the feces. Following extraction, the only step required is to screw the rotavirus test strip into the sample collection device. As the sample extraction flows through chamber and reach the test strip, the colored particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the colored particles. Different colored lines will be visible, depending upon the virus content of the sample. These lines, after 5 minutes of incubation at room temperature, are used to interpret the result.

REAGENTS: Preparation and Storage

This test kit must be stored at 2 – 8°C upon receipt. For the expiration date of the kit refer to the label on the kit box. All components are stable until this expiration date.

Prior to use allow all reagents to come to room temperature if the kit is stored at refrigerated condition.

1. Rotavirus test strip	30
2. Fecal sample collection device	30
3. Single use green pipet	30
4. Patient label for sample collection device	30
5. Instruction for use	1

SAFETY PRECAUTIONS

The reagents are for professional use only. Source material from which reagents of bovine serum was derived in the contiguous 48 United States. It was obtained only from donor health animals maintained under veterinary supervision and found free of contagious diseases. Wear gloves while performing this test and handle these reagents and patient samples as if they are infectious. Do not get in eyes, on skin, or on clothing. Do not ingest. On contact, flush with copious amounts of water for at least 15 minutes. When the assay procedure is completed, dispose of specimens (biohazard materials) carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal. Use Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Disposable pipette for watery sample collection
2. Positive Control

Both are for internal quality control use only. They are available from Epitope Diagnostics. Please contact your distributor or sales representative.

SPECIMEN COLLECTION

Stool samples must be taken as soon as the symptoms appear. Viral particles decrease in number after one week, making the diagnosis more difficult. The samples can be stored in the refrigerator for 1 to 2 days. For longer storage they must be kept frozen at -20°C. In this case, the sample should be totally thawed, and brought to room temperature and homogenized before testing.

For each solid specimen: Unscrew the sampling lid and keep the sampling tube in a vertical position to prevent the loss of any extraction solution. Insert and twist the tip of the sampling lid into the stool specimen at two or more different sites. Collect fecal sample that is stuck to the surface of the sampling lid. Do not intentionally collect any separate and large pieces of fecal sample into the tube. Replace the sampling lid into the tube and secure tightly.

For each liquid specimen: Unscrew the sampling lid and keep the sampling tube in a vertical position to prevent the loss of any extraction solution. Using the green pipet to collect **three drops** of the liquid stool sample and add to the sampling tube. Replace the sampling lid into the tube and secure tightly.

ASSAY PROCEDURE

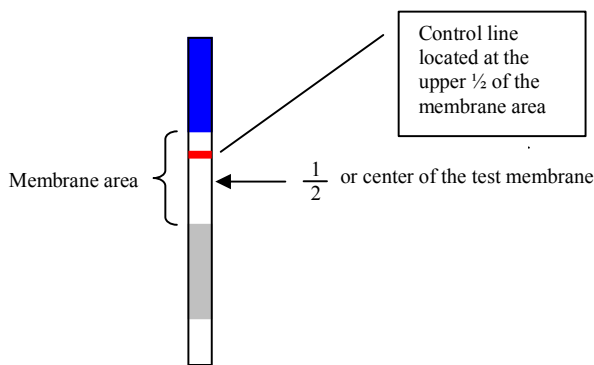
1. Bring foil pouch sealed test strips and collected specimens to room temperature (8 - 30°C).
2. Mix the sampling tube vigorously to ensure a good liquid suspension.
3. Position the sampling tube upper side down in vertical and let it sediment for about 1 minute.

4. Remove the test strip from the sealed foil pouch.
5. Screw the test strip **in a vertical position** into the sampling tube by **breaking into** the bottom seal of the sampling tube. Tighten securely!
6. Allow the solution flow into the bottom space of the test strip and keep the device **in a vertical position**.
7. Read test result at 5 minutes and do not interpret test result after 10 minutes.

INTERPRETATION OF RESULTS

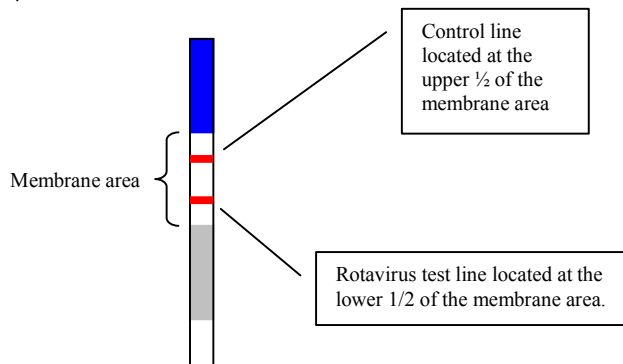
- **Valid Test:**

The appearance of control line on the test reading membrane area indicates the test is valid. The control line located at the upper half of the test membrane area.



- **Positive:**

If two red/pink colored bands are visible within 10 minutes, the test result is positive and valid.

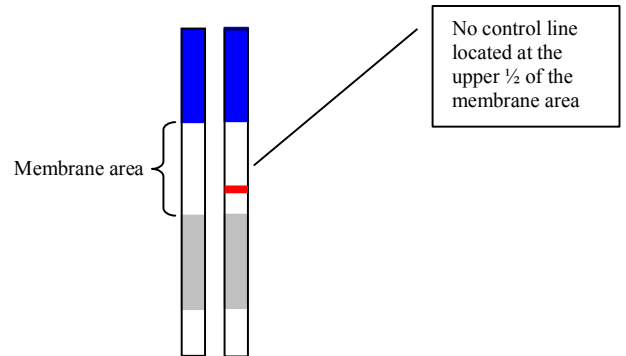


- **Negative:**

If test area has no colored band and the control area displays a red/pink colored band, the test result is negative (see figure as Valid Test).

- **Invalid:**

If a colored band does not form in the control area regardless there is any band in the test area, the test result is invalid.



Note: The control line located at the upper half of the test membrane area and the test line located at the lower half of it.

QUALITY CONTROL

Good laboratory practices recommend the use of appropriate controls. There are two types of controls for the *EpiTuub*TM Rotavirus antigen test, the internal procedural control and external controls.

1. **Internal procedural control:** Each *EpiTuub*TM fecal rotavirus antigen test consists a build in procedural control. It will appear if the test has been performed correctly and the reagents are reactive. It does not ensure that the test line antibody is accurately detecting the presence or absence of viral antigen in the test fecal sample.
2. **External controls:** It is recommended to use external positive controls. The external positive controls are not provided with this kit, but are commercially available from Epitope Diagnostics. External controls are used to assure that the test line antibody is reactive. However, external controls will not detect an error in performing the patient sample test procedure. It is recommended that the external control be tested once per kit.

You should always follow local, state, federal guidelines for running quality control.

LIMITATION OF THE PROCEDURE

1. The test should be used only for the detection of rotavirus antigen in fecal samples.
2. The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line, when reporting the result
3. Two hundred samples were evaluated to assure the correct performance of the test. The correlation of the results with other techniques (ELISA) was satisfactory. However, interferences in the performance of the tests should not be excluded.
4. No cross-reactions with other viruses or substances were observed during the evaluation of the test. A negative result does not totally exclude a possible rotavirus infection. The significance of the results must be evaluated in relation to the patient's clinical symptoms.
5. As with all diagnostic tests, the definitive clinical diagnosis must not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated. *EpiTuub*TM fecal rotavirus antigen test is designed for the aid of clinical diagnosis and should not replace other diagnostic procedures.

PERFORMANCE

The sensitivity and specificity of this rotavirus antigen test device are studied with 206 clinical samples and compared with a rotavirus antigen ELISA test. The date is showed as below.

ELISA	Positive	Negative	Total
EpiTuub™			
Positive	68	2	70
Negative	2	134	136
Total	70	136	206

Specificity: 98.5 % (134/136)

Sensitivity: 97.1 % (68/70)

Accuracy: 98.1% (202/206)

Inter-series and intra-series accuracy: 100 %

Interference: Cross reactivity has been evaluated and found to be negative compared to positive specimens of *Cryptosporidium parvum*, to the Adenovirus group and to the 40/41 strain of Adenovirus.

LITERATURES

1. Set-up of a new rapid immunochromatographic diagnostic test for a Rotavirus detection. *D. Van Beers , M. DE Foor , R. Viehoff , D. Col , M. Venuti and T. Leclipteux.* Progress in Clinical Virology III , Bologne , Septembre 1997.
2. Detection of rotavirus in faecal specimens with a monoclonal antibody enzyme-linked immunosorbent assay : comparison with polyclonal antibody enzyme-immunoessays and a latex agglutination test. *Sneyers et al.* Comp. Immun. Microbiol. Infect. Dis. , vol 12 , n°4 , pp 95-104 , 1989
3. Comparison of Three Rapid Immunoassays for the Detection of Rotavirus Antigen in Stool Samples *I. Van der Donck et al.* ESCV Winter Meeting 1999, Rotterdam, the Netherlands
4. Evaluacion de tres Metodos de Deteccion de Rotavirus en Heces *I. Wilhelmi et al.* 6th Congreso Nacional de Virologia, Madrid, 26th Oct. 99

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For technical assistance or place an order, please contact Epitope Diagnostics, Inc. at (858) 693-7877 or fax to (858) 693-7678. www.epitopediagnostics.com



This product is produced by
Epitope Diagnostics, Inc.
 San Diego, CA 92126, USA



MDSS
 Schiffgraben 41
 30175 Hannover, Germany

Manufacturer	No. of tests
Catalog Number	Keep away from heat and direct sun light
Concentrate	Store at
In Vitro Diagnostic Device	Use by
Read instructions before use	Lot No.
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