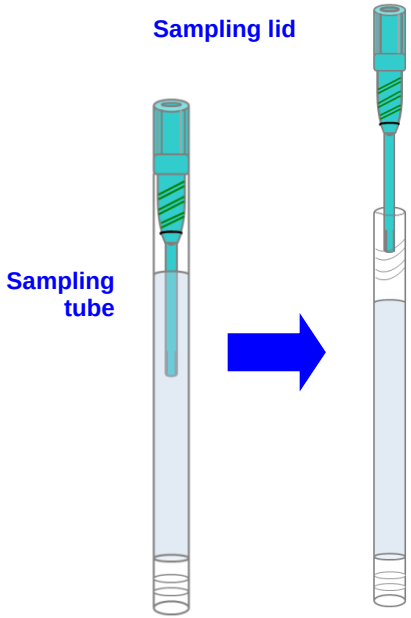
EpiTuub® Fecal Rotavirus Antigen Rapid Test Kit - Instructions for Test Procedures

Qualitative detection of Rotavirus antigen in human feces.

FOR REFERENCE USE ONLY

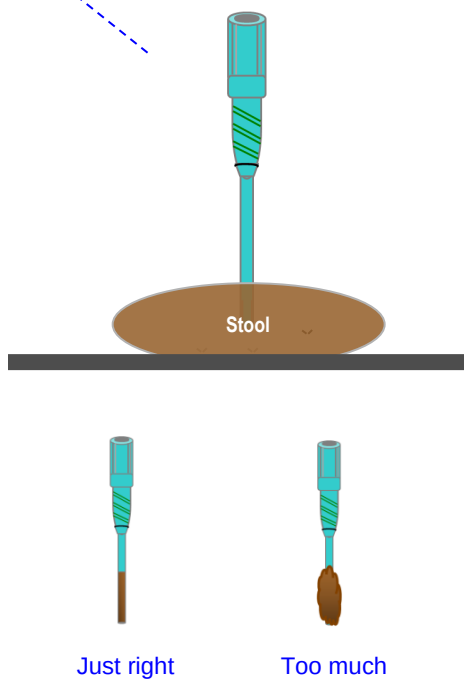
1

1. Collect a stool sample using the enclosed stool sampling paper:
   a. Clean the bowl and flush the toilet two times. Unfold and lay the Sample Collection Paper directly on the top of the water in the toilet bowl (the paper should float above the water).
   b. After bowel movement, take the sampling tube and unscrew the sampling lid, keeping the sampling tube in a **vertical position** to prevent loss of solution.



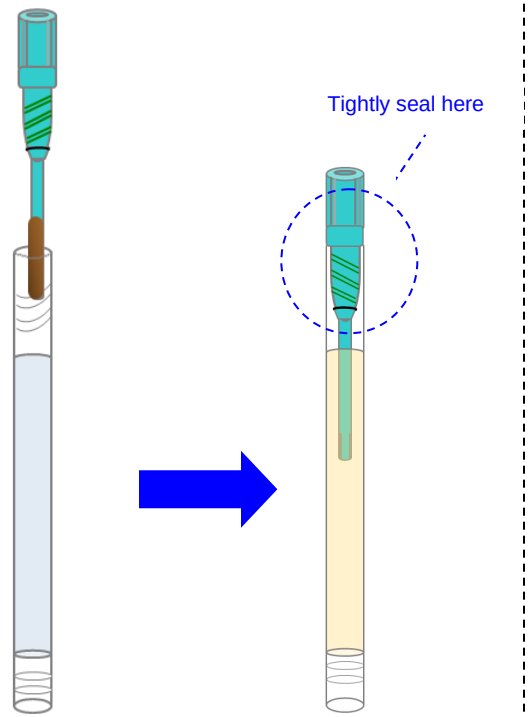
2

1. Hold the sampling lid by the **Thumb Grip**.
2. Use the tip of the sampling lid to collect a small amount of fecal sample at two or more sites. Only take the fecal sample that sticks to the sampling lid tip (never intentionally place any separate piece of fecal sample into the tube). The total amount of stool collected should be less than one grain of cooked rice. For liquid stool, collect 0.1mL into the sampling tube.



3

1. Insert and screw the sampling lid back into the sampling tube **in a vertical position**. Do not spill any solution from the tube.
2. Tightly seal the lid with the tube.
3. Flush toilet.



READ ALL THE INFORMATION IN THIS LEAFLET BEFORE SAMPLING

Store at 2-8°C. Do not freeze. Keep out of reach of children. For in-vitro diagnostic use. Not to be taken internally. Not to be sampled directly from anus.

If you have any questions, please contact your physician or laboratory staff or call Epitope Diagnostics at 858-693-7877 from 8:00 a.m. to 5:00 p.m. PST

EU: IVD CE +2 +8 °C

Manufactured by Epitope Diagnostics, Inc. San Diego CA 92121, USA (V10/2019-06)

EC REP MDSS GmbH Schiffgraben 41 30175 Hannover Germany

US Patent: 7,780,915

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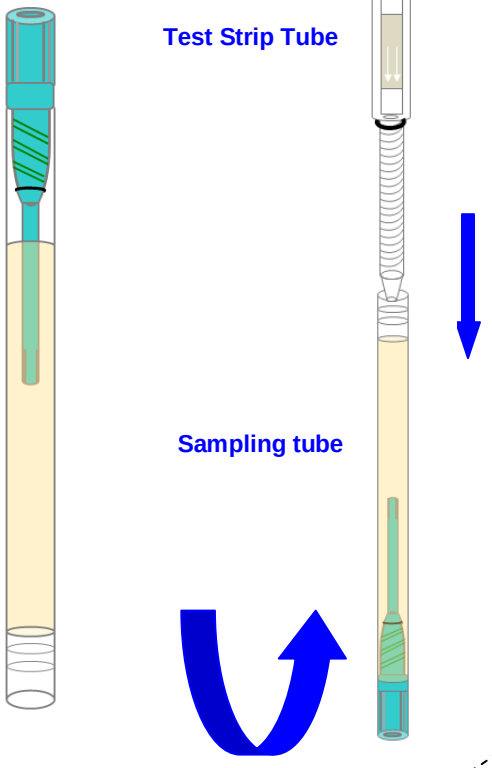
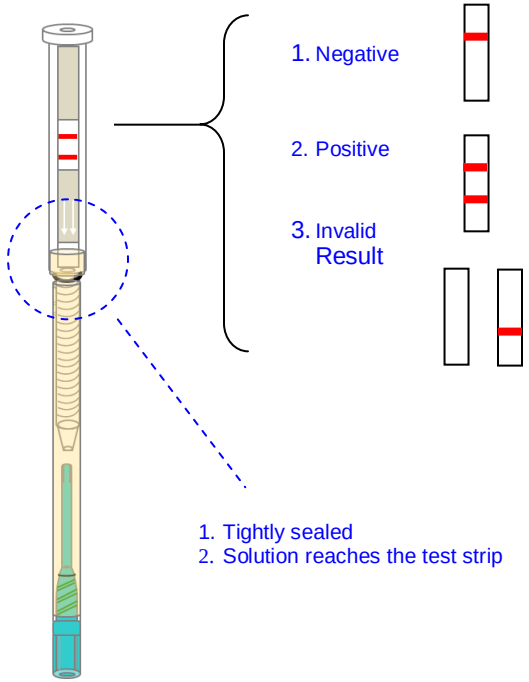
A

1. Shake to dissolve the stool into solution.
2. **Turn the sampling tube upside down vertically.**
3. Remove the test strip from foil pouch.



B

1. Insert and screw the test strip **in a vertical position** into the sampling tube by breaking the bottom seal of the sampling tube.
2. Allow the solution to flow into the bottom space of test strip, keeping the device **in a vertical position**.
3. You may soon see a red fluid moving across the white area of the test strip. Read test result after 5 minutes.



For In-Vitro Diagnostic Use

Catalog Number: KT917 (30T/Kit)
KT917.10(10T/Kit)

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 faeces 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 are 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 faeces. Following extraction, the only step required is to screw the rotavirus test strip into the sample collection device. As the sample extraction flows through the chamber and reaches 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

1. Fecal specimen collection device (30159):containing sampling tube, sampling lid and pre-added extraction solution in the sampling tube. This device should be stored at 2 to 8°C. Do not freeze.

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MDSS GmbH
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2. Test strip tube (30162): dipstick for the Rotavirus test assembled in a transparent housing and sealed in a foil pouch with desiccant. It should remain in its original sealed pouch until ready for use. The test strip should be stored at 2 to 8ºC. Do not freeze.
3. Single use green pipette.
4. Patient label for sample collection device.
5. Instruction for use.

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Timer or clock

PRECAUTIONS

1. For in-vitro diagnostic use only. Not to be taken internally.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Do not reuse the test.

PATIENT PREPARATION

1. Dietary restrictions are not necessary.

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 at 2-8 ºC for 1 to 2 days. For longer storage they must be kept frozen at -20ºC. 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 pipette 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.

TEST PROCEDURE

1. Bring the sealed foil pouch test strips and collected specimens to room temperature.
2. Shake the sampling tube vigorously to ensure a good liquid suspension.
3. Position the sampling tube upside down vertically and let it settle for about 1 minute.
4. Remove the test strip from the sealed foil pouch.
5. Screw the test strip tube into the sampling tube by **breaking** the bottom seal of the sampling tube. Secure tightly! (Figure A)
6. Allow the solution to flow into the bottom space of the test strip and keeping the device **in a vertical position**.
7. Read test result at 5 minutes. Do not interpret test result after 10 minutes.

PROCEDURAL NOTES

1. After the test strip tube is screwed completely into the sampling tube, you should see a minimum 5 mm extraction buffer liquid in the bottom of the strip tube.
2. You should see liquid migrating across the membrane area right after the screw in process. If not, take the tube and tap against the table several times, and the migration of the liquid should be observed.

INTERPRETATION OF RESULTS

- **Positive:**
  If two red/pink colored bands are visible within 5 minutes, the test result is positive and valid (Figure B).
- **Negative:**
  If test area has no red/pink colored band and the control area displays a red colored band, the test result is negative (Figure B).
- **Invalid:**
  If a colored band does not form in the control area regardless of there being any band in the test area, the test result is invalid (Figure B) and needs to be retested.

QUALITY CONTROL

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

1. **Internal procedural control:** Each EpiTuub® Rotavirus test has a built-in procedural control. It will appear if the test has been performed correctly, sample wicking has occurred and the reagents are reactive. It does not ensure that the test line antibody is accurately detecting the presence or absence of rotavirus 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.

Follow local, state, and 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. 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*™ Fecal Rotavirus antigen test is designed for the aid of clinical diagnosis and should not replace other diagnostic procedures.

PERFORMANCE CHARACTERISTICS

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.

REFERENCES

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 Detectiono 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 Congresso Nacional de Virologia, Madrid, 26th Oct. 99

	Manufacturer	IVD	For *in vitro* diagnostic use only
EC REP	Authorized representative		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by
DIL	Sample diluent		