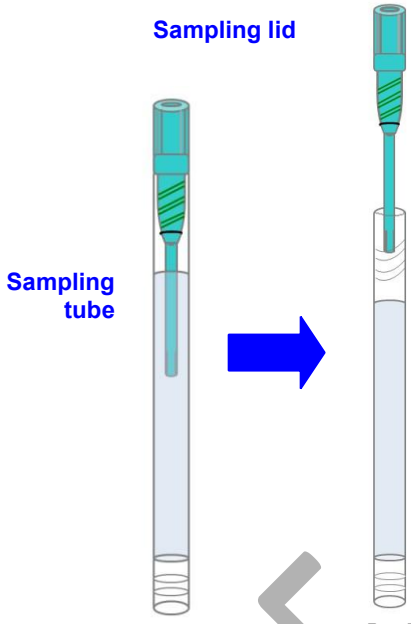
EpiTuub® Fecal Rotavirus and Adenovirus DUO Antigen Rapid Test - Instructions for Fecal Sample Collection

Qualitative detection of Rotavirus and Adenovirus antigens in human feces.

Version 8

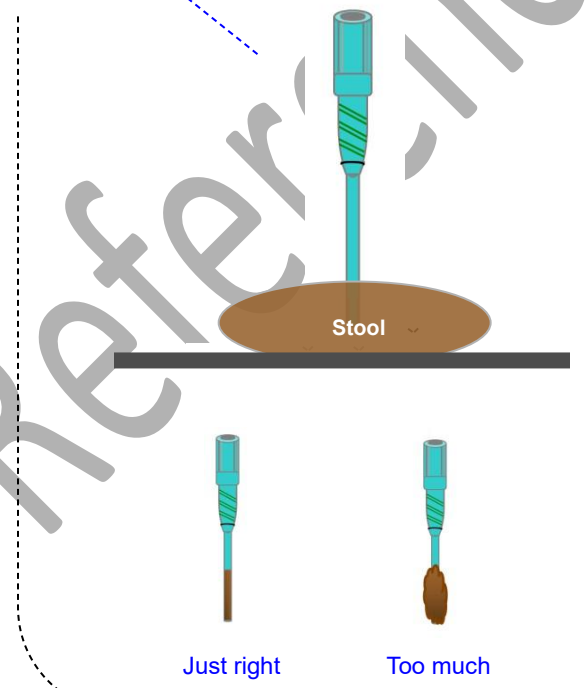
1

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.



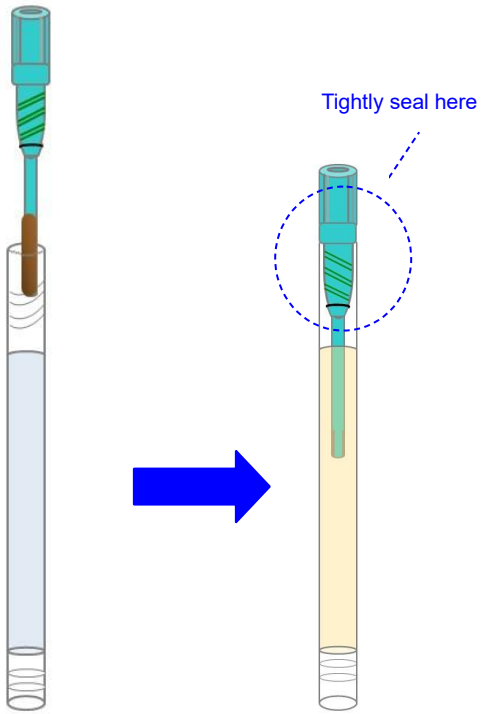
2

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

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

EC REP

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

Qualitative detection of Rotavirus and Adenovirus antigens in human feces.

For In-Vitro Diagnostic Use

Catalog Number: KT926 (30T/Kit)
KT926.10 (10T/Kit)

INTENDED USE

This rotavirus and adenovirus Duo antigen test kit is intended for the direct qualitative detection of the presence of rotavirus and/or adenovirus antigens in patient fecal samples. The test might be used as an aid for detecting patients with acute gastroenteritis infected with rotavirus and/or adenovirus. 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. 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. Adenoviruses are one of the main causes of acute gastroenteritis and diarrhea, especially in children under the age of two years. 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 individualsDiagnosis of gastroenteritis with rotavirus and/or adenovirus 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

This is a two-in-one test including a rotavirus antigen test strip and an adenovirus antigen test strip that are back-to-back positioned in one test tube.
The rotavirus and adenovirus DUO antigen rapid test strips employ two group paired monoclonal antibodies for either rotavirus antigen or adenovirus antigen. Dye-conjugated monoclonal antibodies against antigen VP6 of group A of rotavirus, and solid-phase specific rotavirus are one of the antibody pair

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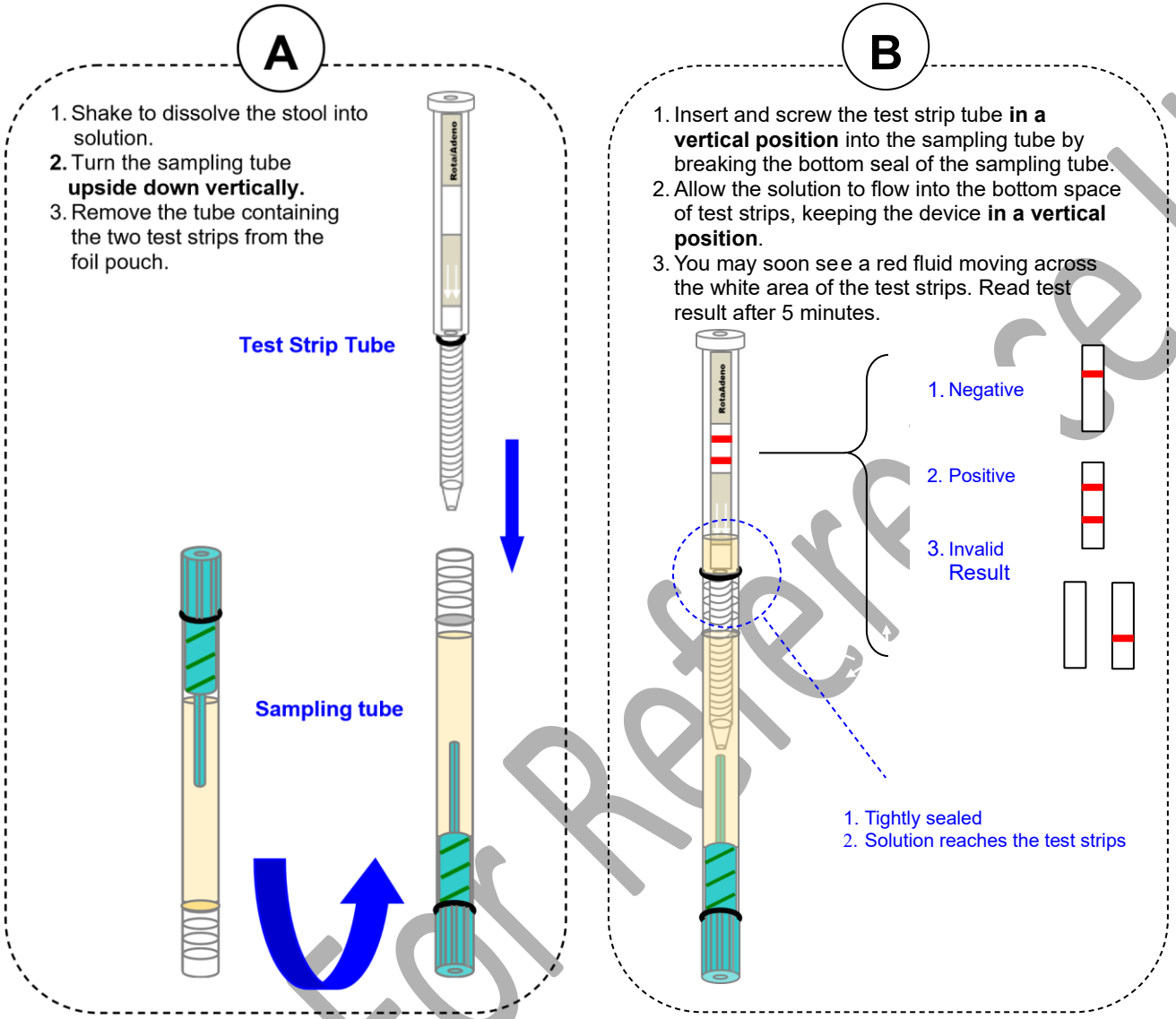
REAGENTS: Preparation and Storage

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



READ ALL THE INFORMATION IN THIS INSERT BEFORE TESTING
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, call customer information staff of Epitope Diagnostics at 1-858-693-7877, 8:00 a.m. to 5:00 p.m. PST.

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EC REP

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2. Test strip tube (30168 and 30164): one dipstick for the Rotavirus/Adenovirus DUO test is assembled as a two-in-one test containing 1 Rotavirus antigen test strip and 1 Adenovirus antigen test strip that are back-to-back positioned in this tube. This tube is 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. 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

1. Stool specimens can be collected at any time of the day.
2. Collect a random sample of feces in a clean, dry cup or toilet paper or as indicated in the Figure 1.
3. Unscrew the sampling lid and keep the sampling tube in a vertical position to prevent the loss of any extraction solution.
4. Insert and twist the tip of the sampling lid into the stool specimen at two or more different sites (Figure 2).
5. Collect fecal sample that is stuck to the surface of the sampling lid. The total amount of stool sample should be less than one grain of cooked rice. Do not intentionally collect any separate and large pieces of fecal sample into the tube.
6. Replace the sampling lid into the tube and secure tightly (Figure 3).
7. The specimen is ready for testing, transportation or storage. It can be stored at 2-8ºC for up to 21 days and at room temperature for up to 14 days.

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)

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/pink 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 and Adenovirus DUO test, the internal procedural control and external controls.

1. **Internal procedural control:** Each EpiTuub® Rotavirus and Adenovirus DUO 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 Rotavrius and/or Adenovirus 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 Rota virus and/or Adenovirus antigens 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

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.

Manufactured by Epitope Diagnostics, Inc. San Diego CA 92121, USA

techniques (ELISA) was satisfactory. However, interferences in the performance of the tests should not be excluded.

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EpiTuub® Fecal Rotavirus and Adenovirus DUO Antigen

Rapid Test - Instructions for Test Procedures *Qualitative detection of Rotavirus and Adenovirus antigens in human feces.*

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 and Adenovirus DUO antigen test is designed for the aid of clinical diagnosis and should not replace other diagnostic procedures.

PERFORMANCE CHARACTERISTICS Sensitivity
The sensitivity and specificity of this adenovirus antigen test device are studied with 212 clinical samples and compared with an adenovirus antigen ELISA test. **Sensitivity:** 98% (61/62 = 98.4%)
Specificity: 99% (149/150 = 99.3%)
Accuracy: 99% (210/212 = 99.1%)
Inter-series and intra-series accuracy: 100 % **Sensitivity**
The sensitivity and specificity of this rotavirus antigen test device are studied with 206 clinical samples and compared with a rotavirus antigen ELISA test **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 and Giardia *lamblia*

REFERENCES

1. Nishio O, Ooseto M, Takagi K, Yamasita Y, Ishihara Y, Isomura S. Enzyme-linked immunosorbent assay employing monoclonal antibodies for direct identification of enteric adenoviruses (Ad40,41) in feces. Microbiol Immunol. 1990;34(10):871-7.
2. Vizzi E, Ferraro D, Cascio A, Di Stefano R, Arista S. Detection of enteric adenoviruses 40 and 41 in stool specimens by monoclonal antibody-based enzyme immunoassays. Res Virol. 1996 Nov-Dec;147(6):333-9.

	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		

US Patent: 7,780,915