ACCU-TELL®
Rotavirus Cassette (Feces)
For in vitro diagnostic use only

For Feces Samples

This package insert is applied to the below products:

Catalog No.	**Product Name**
ABT-IDT-B63	Rotavirus Cassette (Feces)

Intended Use

ACCU-TELL® Rotavirus Cassette (Feces) is a rapid test for the qualitative detection of group A rotaviruses (antigen assay) in faecal specimens.

PRECAUTIONS

1. **For in vitro diagnostic use** (not for internal use).
2. The procedures should be followed precisely for accurate results
3. Do not use this test past the expiration date.
4. The test device should remain in the sealed pouch until use.
5. Do not use if pouch is damaged or opened.
6. The test cannot be reused. Discard it in the dustbin after single use.
7. Do not touch the membrane located within the windows.
8. Examine if the Specimen collection tube exists before usage.
9. Dispose all used materials in an appropriate container. Treat as potential biohazard.

TEST PRINCIPLE

The test is a qualitative, solid phase, double antibodies sandwich immunochromatographic assay .

The faecal sample must be diluted in the dilution buffer that is supplied with the test.

To perform the test, an aliquot of diluted stool sample is added to the sample well of the test cassette. The sample flows through a label pad containing rotavirus antibody coupled to red-colored colloidal gold. If the sample contains rotavirus antigens, the antigen will bind to the antibody coated on the colloidal gold particles to form “rotavirus antigens”-“antibody-gold ”complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which rotavirus specific antibodies are immobilized. As the complexes reach the test line, they will bind to the antibody on the membrane in the form of a line.

A second red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly.

If rotavirus antigen is not present or lower than the detection limit of the test, only the control line will be visible. If the control line does not develop, the test is invalid.

REAGENTS AND MATERIALS

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Each kit contains Rota- Cassettes, a dilution buffer:

1. Rota –Cassette

Each strip is sensitized with a mouse monoclonal antibody directed against the VP6 Rotavirus antigen and goat anti-mouse IgG polyserum.

The anti-Rotavirus conjugate is produced with a mouse monoclonal antibody directed against the human Rotavirus Group A VP6 antigens. This purified antibody is conjugated to **colloidal gold** particles.

These Cassettes come in a pouch with a desiccant.

2. Specimen collection tubes with 2 mL dilution buffer each for sample collection and dilution

--inoculating loops for taking the faecal samples

--Dilution Buffer (2 mL):Saline solution buffered to pH 7.5 with TRIS and containing EDTA, NaN3 (<0.1%),a detergent, and charged proteins.

3. Instruction for use

MATERIALS NEEDED BUT NOT PROVIDED

(1)Timer，

(2)disposable gloves.

No other equipment or reagents are needed.

STORAGE AND STABILITY

1.The test kit can be Stored at 2℃～30℃ in the sealed pouch .It is stable through the expiration date printed on the pouch label. Do not freeze.

2.Preferably open the pouch only shortly before the test.

SPECIMEN COLLECTION AND STORAGE

1.Stool specimens should be collected during the acute phase of the infection,preferably the first 3 to 5 days of illness. Viral particles decrease in number after one week.

2.Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the Rapid Rotavirus Antigen Test.

3.Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.

4.The stool specimens must be tested as soon after they are collected as possible. If necessary, they may be stored at 2-8°C for 3 days without interfering with the assay performance.

For long-term storage of specimens, -20°C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.

ASSAY PROCECURE

Preparation

1.Test device, patient’s sample, and controls should be brought to room temperature (15-30℃) prior to testing.

2.Do not open the pouch until you are ready to perform the test.

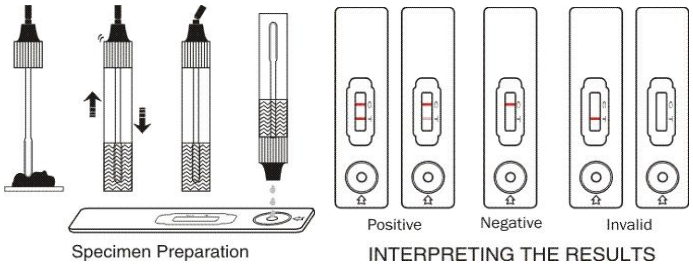
Specimen pre-treatment

1.Unscrew the sample bottle, use the attached applicator stick attached on the cap to transfer a small piece of stool.The dilution ratio must be at most 10% w/v.

--For liquid samples, take **2 loops of 100 µL,**

--for solid samples, take 1 loop, approx.40-100 mg.

2.Replace the stick in the bottle and tighten securely. Stir to homogenize the solution and let stand for **1-2 minutes**.



Testing

1.Remove the test CASSETTE from the sealed foil pouch.

2.Shake the collection tube thoroughly to ensure proper mixing of the fecal sample with the extraction solution.

3.Hold the sample bottle upright with the tip pointing away from the test performer, snap off the tip.

4.Hold the bottle in a vertical position over the sample well of the test card ,**deliver 2 drops (60 -100 µL)** of diluted stool sample to the sample well.

5.Read the result between 5 - 10 minutes. A strong positive sample may show results earlier.

Note: Results after 15 minutes may not be accurate.

INTERPRETING THE RESULTS

For the interpretation of the test result the line(s) that has(ve) appeared in the test result window are visually interpreted.

• Negative result

Only one colored line appears in the control line region (C). No line appears in the test line region (T).The absence of the test result line (T) indicates that no Rotavirus has been detected by the assay.

• Positive Result

Two distinct colored lines appear on the membrane. One colored line forms in the control line region (C) and another apparent colored line appears in the test result line region (T).

NOTE: The intensity of the color in test line regions may vary depending on the concentration of aimed substances present in the specimen. Therefore,any shade of color in the test region should be considered positive. Besides,the substances level can not be determined by this qualitative test.

• Invalid Result

The control line (C) fails to appear. Results from any test that has not produced a control line at the specified reading time should be discarded. Insufficient specimen volume, insufficient specimen migration, or incorrect procedural techniques are the most likely reasons for control line failure.

LIMITATIONS

1.The test is for qualitative detection of rotavirus antigen in stool sample and does not indicate the quantity of the antigens.

2.The test result should be used only to evaluate with patient with signs and symptoms of the disease. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1.Clinical Comparison

The ACCU-TELL® Rotavirus Cassette (Feces) has shown 98.57% sensitivity and 99.58% specificity comparing to the ELISA results.

2.Reproducibility

Reproducibility of the ACCU-TELL® Rotavirus Cassette (Feces)was determined using Ten negative fecal samples, 10 samples of rotavirus low to high positive responses, and 10 samples of adenovirus low to high positive responses. These samples were tested in replicates of 10 days in a blind study by 3 operators working independently in the same laboratory. No change in intensity of result color was detected upon repeated testing of the same sample. The agreement of the expected result was 100%.

3.Interference

The anti-rotavirus antibodies employed in this kit were found not to recognize the following common intestinal pathogens and viruses found in feces:

(1)Adenovirus I, II	(2)Entamoeba histolytica
(3)Ascaris lumbricoides	(4)Campylobacter jejuni
(5)Vibrio cholerae	(6)Clostridium difficile
(7)Echo virus 3, 7	(8)Escherichia coli
(9)Giardia lamblia	(10)Picornavirus
(11) Polio virus I,II,III	(12) Salmonella B, C
(13) Salmonella infantis	(14) Salmonella typhi
(15) Shigella sonnei	(16) Shigella flexneri
(17) Shigella dysenteriae	(18) Vibrio parahemolytica
(19) Trichuris trichiura	(20) Corona-like virus

The anti-adenovirus antibodies detect a genus specific hexon antigen that is present in all human serotypes. The test can not be used to differentiate serotypes. The antiadenovirus antibodies do not cross-react with any other common intestinal pathogens (viruses, bacteria or parasites).

A sample containing a protein A producing strain of S.aureus could cause a false positive reaction.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse