Accu-Screen Adenovirus/Rotavirus Combo Rapid Test Device

Package Insert

A rapid,one step test for the qualitative detection of adenovirus and rotavirus antigens in human stool specimen.
For professional in vitro diagnostic use only.

INTENDED USE

Adenovirus/Rotavirus Combo Rapid Test Device is an in vitro qualitative immunochromatographic assay for the rapid detection of adenovirus and rotavirus antigens in human stool specimen.The test results are intended to aid in the diagnosis of rotavirus infection and to monitor the effectiveness of therapeutic treatment.

PRINCIPLE

Adenovirus/Rotavirus Combo Rapid Test Device is a sandwich solid phase immunochromatographic assay.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 pad containing antibodies against adenovirus and rotavirus coupled to red-colored colloidal gold.If the sample contains adenovirus or rotavirus antigens,the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes.These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which adenovirus and rotavirus specific antibodies are immobilized separately.As the complexes reach the test line, they will bind to the antibody corresponding to the virus on the membrane to form of a line.A 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 virus is not present or lower than the detection limit of the test,only the control line will be visible.If the control line dose not developed, the test is invalid.

SPECIMEN COLLECTION AND PREPARATION

SPECIMEN COLLECTION

Stool samples must be taken as soon as the symptoms appear.Viral particles decrease in number after one week.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 Rotavirus Antigen Test.Specimens may be stored at 2-8℃ for 2 days without interfering with the assay performance.For long-term storage of specimens,20℃ 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.Bring all reagents, including test device,to room temperature (15-30℃) before use.

SPECIMEN PREPARATION

- Unscrew the sample bottle,use the attached applicator stick attached on the cap to transfer small piece of stool (4-6mm in diameter;approximately 50mg–200mg) into the sample bottle containing specimen preparation buffer.For liquid or semi-solid stools,add 100µL of stool to the vial with an appropriate pipette.
- Replace the stick in the bottle and tighten securely.Mix stool sample with the buffer thoroughly by shaking the bottle for a few seconds.

MATERIALS

Materials Provided

- Test Devices
- Droppers
- Specimen collection tube with extraction buffer
- Package Insert

Materials required but not provided

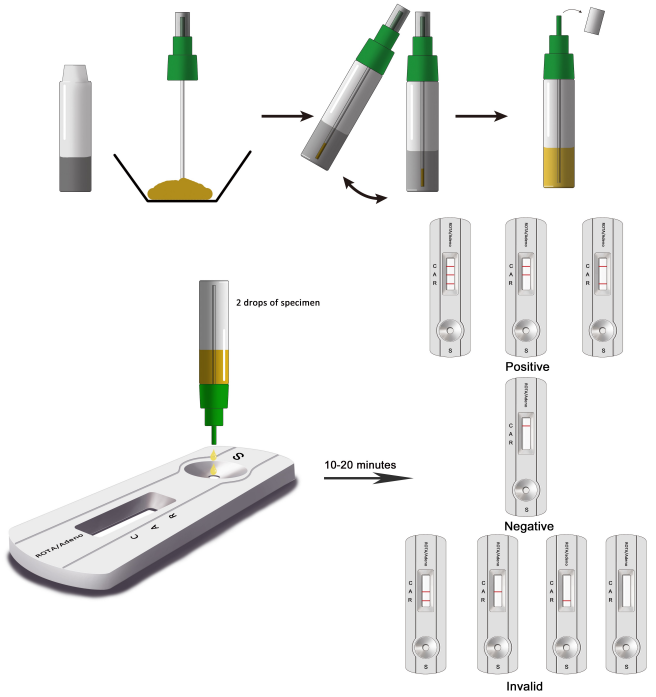
- Specimen collection containers
- Timer
- Centrifuge and pipette to dispense 80ul if required

DIRECTIONS FOR USE

Allow the test cassette,specimen,and buffer to reach room temperature(15-30℃) prior to testing.

1. To **collect fecal specimens:**
   Collect sufficient quantity of feces (1-2ml or 1-2g) in a clean,dry specimen collection container to obtain enough virus particles.Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8℃ if not tested within 6 hours.For long-term storage,specimen should be kept below -20℃.
2. To **press fecal specimens:**
   For **Solid Specimen**:
   - Unscrew the cap of the specimen collection tube,then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50mg of feces (equivalent to 1/4 of a pea).Do not scoop the fecal specimen.

   For **Liquid Specimens**:
   - Hold the dropper vertically,aspirate fecal specimens,and then transfer 2 drops (approximately 50µL) into the specimen collection tube containing the extraction buffer.
   - Tighten the cap onto the specimen collection tube,and then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.
3. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour.Best result will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the specimen collection tube upright and unscrew the tip of the specimen collection tube.Invert the specimen collection tube and **transfer 2 full drops of the extracted specimen (approximately 80µL)** to the specimen well(S) of the test cassette,and start the timer.Avoid trapping air bubbles in the specimen well(S).See illustration below.
5. **Read the results at 10 minutes after dispensing the specimen.**Do not read results after 20 minutes.
   Note:If the specimen does not migrate (presence of particles),centrifuge the extracted specimen contained in the extraction buffer vial.Collect 80µL of supernatant,dispense into the specimen well(S).Start the timer and continue from step 5 onwards in the above instructions for use.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

Positive result:
Rotavirus Positive:A red line appears in the control line region (C) and another red line appears in the T2 line region.
Adenovirus Positive:A red line appears in the control line region (C) and another red line appears in the T1 line region.
Rota and Adeno Positive:A red line appears in the control line region (C) and two other red lines appears in T1 line region and T2 line region respectively.
NOTE: The intensity of the color in the test line region(T1/T2) will vary depending on the concentration of rotavirus or adenovirus antigens present in the specimen. Therefore, any shade of color in the test line region(T1/T2) should be considered positive.
Negative result: No red line appears in the test line region (T1/T2). A distinct pink line shows on the control line region (C).
Invalid: The control line next to the test line does not become visible within 10 minutes after the addition of the sample.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control.It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device.Control materials which is not provided with this test kit may be commercially available.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The performance of Adenovirus/Rotavirus Combo Rapid Test Device has been evaluated with 605 clinical specimens collected from children and young adults in comparison with latex agglutination method.The results show that Adenovirus/Rotavirus Combo Rapid Test Device has high sensitivity and specificity for rotavirus and adenovirus.

Method		Latex Agglutination		Total Results
	Result	Positive	Negative	
Rotavirus rapid test	Positive	191	2	193
	Negative	0	168	168
Total result		191	170	361

Relative Sensitivity: >99.9% (98.4%-100%) Relative Specificity: 98.8% (95.8%-99.9%) Relative Accuracy:99.4%(98.0%-99.9%) *95% Confidence Intervals

Method		Latex Agglutination		Total Results
	Result	Positive	Negative	
Adenovirus rapid test	Positive	60	1	61
	Negative	0	183	183
Total result		60	184	244

Relative Sensitivity: >99.9% (95.1%%-100%) **Relative Specificity:** 98.8% (97%-100%)
Relative Accuracy: 99.4% (97.7%-100%) *95% Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of seven specimens:a negative,a rotavirus low positive,an adenovirus low positive,a rotavirus medium positive,an adenovirus medium positive,a rotavirus high positive and an adenovirus high positive.The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent on the same seven specimens:a negative,a rotavirus low positive,an adenovirus low positive,a rotavirus medium positive,an adenovirus medium positive,a rotavirus high positive and an adenovirus high positive.The specimens were correctly identified >99% of the time.

LIMITATIONS

1. The test is for qualitative detection of adenovirus and rotavirus antigens in stool sample and do not indicate the quantity of the antigens.
2. The test is for in vitro diagnostic use only.
3. 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 finding have been evaluated.

EXPECTED VALUES

Adenovirus/Rotavirus Combo Rapid Test Device detects the presence of adenovirus and rotavirus antigens in stool specimens.Expected values for any given population should be determined for each laboratory.The positivity rate of any given laboratory may vary depending on geographic ation, season,and living environment.

PRECAUTIONS

1. For in vitro diagnostic use.
2. Wear protective glove while handling kit components and test specimens.
3. Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed of as potential bio-hazards.
4. Do not use kit components beyond expiration date.
5. Dispose all used materials in appropriate container. Treat as potential biohazard.
6. The expiration date is indicated on the package label.
7. Store Sample Collection Tubes at 2-30℃.Store test device at 2-30℃.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community /European Union
	Date of Manufacture		Use-by date
	Do not re-use		Consult instructions for use or consult electronic instructions for use
LOT	Batch code		Do not use if package is damaged and consult instructions for use
REF	Catalogue number	Σ	Contains sufficient for <n> tests

Hangzhou Realy Tech Co., Ltd.
#2 Building, No. 763, Yuansha Village, Xinjie Street, Xiaoshan District, 311200 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
Website: www.realytech.com

EC REP
Luxus Lebenswelt GmbH
Kochstr.1,47877, Willich, Germany

Number:1100029602
Version:1.2
Effective Date:2021-07-01