(RovA)Rotavirus Group A Antigen/

(EAd)Enteric Adenovirus Antigen

Rapid Test Kit

(Immunochromatography)

Product Name

(RovA)Rotavirus Group A Antigen/(EAd)Enteric Adenovirus Antigen Rapid Test Kit
(Immunochromatography)

Intended Use

Rotavirus (RovA) is an important pathogen of viral diarrhea and enteritis in infants and young children and pathogen of diarrhea in adults over the world. The rotavirus group A is an important antigen in children with diarrhea. Incubation period of RovA infection is 1-3 days with an acute onset. There will be a symptom with diarrhea, vomiting, and even dehydration. The detection methods of adenovirus mainly include electron microscopy, isolation and culture method, immunological technique, nucleic acid detection and so on. The detection of RovA has important clinical value in the early diagnosis and identification of Rova infection.

Adenovirus (EAd) is a large group of viruses that can cause diseases in the respiratory tract, eyes, digestive tract, urethra and bladder. EAd 40/41 is an important pathogen for causing diarrhea in children, which is the second most important pathogen of the infantile diarrhea. Incubation period of EAd infection is 8-10 days, the typical course last for 5-12 days. There will be a symptom with vomit, watery diarrhea and low-grade fever. Compared with rotavirus infection, adenovirus infection has a lighter symptom of diarrhea and dehydration. The detection methods of adenovirus mainly include electron microscopy, isolation and culture method, immunological technique, nucleic acid detection and so on. The detection of adenovirus antigen has important clinical value in the early diagnosis and identification of EAd infection.

The reagent is used to detect the rotavirus group A antigen/ Enteric Adenovirus Antigen (type40/41) in inInfants and young children's feces qualitatively.

Test Principle

ROVA: The test utilizes antibodies including a mouse anti-Rov monoclonal antibody 2 and goat anti-mouse IgG antibody on the nitrocellulose membrane with colloidal gold marked mouse anti-Rov monoclonal antibody 1 as an mark tracer. The reagent is used to detect the Rov antigen in feces according to the principle of double antibody sandwich method and gold immunochromatography assay.

The specimen mixing up mouse anti-Rov monoclonal antibody 1–marker move along the membrane to the T line, and form the T line when the specimen contains Rov, which a positive result. Conversely, it is a negative result.

EAd: The test utilizes antibodies including a mouse anti-EAd monoclonal antibody 2 and goat anti-mouse IgG antibody on the nitrocellulose membrane with colloidal gold marked mouse anti-EAd monoclonal antibody 1 as an mark tracer. The reagent is used to detect the EAd antigen in feces according to the principle of double antibody sandwich method and gold immunochromatography assay.

The specimen mixing up mouse anti-EAd monoclonal antibody 1–marker move along the membrane to the T line, and form the T line when the specimen contains EAd, which a positive result. Conversely, it is a negative result.

Main Components

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. The sample dilution is made of PBS-Tween. Different components of different batches cannot be used at the same time to avoid erroneous results

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

Sample Requirement

1. Fecal supernatant is required for the detection.
2. The excretion peak of RovA from gastroenteritis patients' feces is 3-5 days after symptom appears. Positive results will not occur if the feces are collected long time after the diarrhea appears.
3. A specimen must be collected in a clean and dry container.
4. The samples were collected from different parts (at least six, about 50mg) of the feces, and the 2mL distilled water was added to the mixture.
5. Specimens may be stored at 20~37℃ for 12 hour, 2-8℃ for 3 days, and at -20 ℃ for 1 year. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly mixed. Repeat freeze and thaw for no more than 3 times.

Test Methods

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

1. Take off the outer packing, put the cassette onto the desk with the sample window up.

2. Drop 2~3 drops of diluted specimen (about 80~100μl) vertically into the sample hole of cassette.

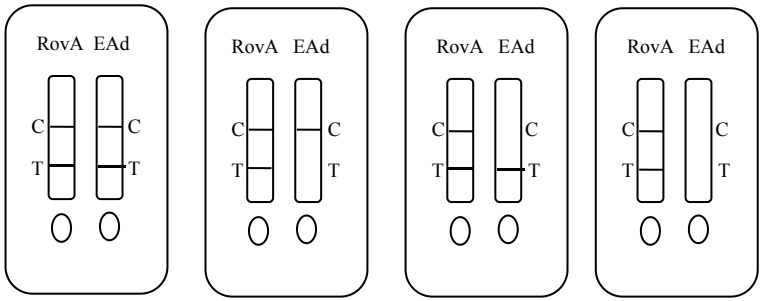
3. Observe the test results immediately within 5~10 minutes, the result is invalid over 10 minutes.

Interpretation of Results

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure.



Limitations

1. This reagent is designed for the qualitative screening test. Concentration of RovA/EAd cannot be determined by this qualitative test.

2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

3. Abnormal results may occur according to operator error or drug use. If RovA/EAd infection is still suspected, the specimen should be collected later and carry the detection again.

Attentions

1. For *IN VITRO* diagnostic use only.

2. Do not use after the expiration date.

3. Reagents should be used as soon as possible after opened.This reagent cannot be reused for disposable.

4. The result is invalid over 10 minutes.

5. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

6. Reagent blocking by specimen may occur according to too much or too sticky specimen. Diluted specimens should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

7. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

8. Patients used to receive monoclonal antibodies therapy may have human anti-mouse antibodies in blood, which will infect the detection result of this reagent.