Diagnostic Kit for Rotavirus Group A Antigen

（Immunochromatography）

Product Name

Diagnostic Kit for Rotavirus Group A Antigen（Immunochromatography）

Intended Use

The reagent is used to detect the rotavirus group A antigen in inInfants and young children's feces qualitatively.

Rotavirus (Rotavirus, Rov) 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 Rov A 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 Rov A has important clinical value in the early diagnosis and identification of Rov A infection.

Test Principle

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

Main Components

The testing kit is in the form of strip and cassette. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with mouse anti-Rov monoclonal antibody, nitrocellulose membrane coated with mouse anti-Rov monoclonal antibody， control line coated with goat anti mouse IgG antibody. The sample dilution is made of PBS-Tween.

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.

Sample Requirement

1. Fecal supernatant is required for the detection.

2. The excretion peak of Rov 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 sample 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 by the swab on the tube, put the sample into the 2mL distilled water and mix sufficiently.

5. Samples 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 Procedure

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℃)

Strip and Cassette:

1. Take off the outer packing, put the strip/cassette onto the desk with the sample adding area of the strip/ sample hole of the cassette up.

2. Break off the top of the sample tube, drop 2-3 drops of diluted sample (about 80~100μl) vertically into the sample adding area of the strip /sample hole of the cassette.

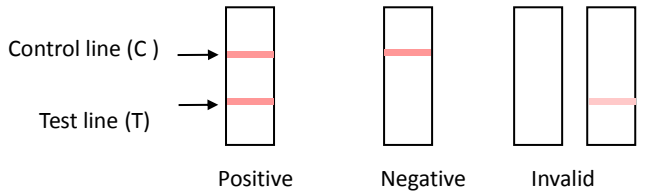
3. Observe the test results immediately within 5~10 minutes, the result is invalid over 10 minutes.

Result Judgment

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. Verify the test procedure and repeat the test with a new testing device.



Limitations

1. This reagent is designed for the qualitative screening test. Concentration of Rov 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 infection is still suspected, the sample should be collected later and carry the detection again.

Performance Characteristics

1. Using internal quality control samples:

Negative specificity: The results should all be negative when detecting 10 kits of Rov negative quality control samples.

Positive specificity: The results should all be positive when detecting 10 kits of Rov positive quality control samples.(Including strong, medium and weak positive samples)

Limit of detection: The results should all be positive when detecting diluted Rov positive quality control samples with the diluent rate at 1:32.

Precision: The results should be consistent and the coloration degree should be consistent when detecting the precision control samples by 10 kits of the same batch.

2. Clinical trial results

A clinical evaluation was conducted on 1040 samples comparing the results obtained using the Diagnostic Kit for Enteric Adenovirus Antigenand other commercially available Adv tests. The results demonstrated a 97.45% positive agreement, 99.22% negative agreement, and a 98.75% overall agreement of the Diagnostic Kit for Rotavirus Group A Antigen compared to the other Rov tests.

3. Analytical sensitivity: 600 mol/L bilirubin, 5g /L triglyceride, 10g/L hemoglobin and 10g/L oxalic acid can affect the background color, but has no effect on the detection result. 10^7 cuf/mL staphylococcus aureus, pseudomonas aeruginosa, enterococcus faecalis , group C streptococcus , klebsiella pneumonia, branhamella catarrhalis, haemophilus influenza, monilia albican , neisseria meningitidis , shigella, neisseria gonorrhoeae , group B streptococcus, bacillus proteus vulgaris , S. faecium , bacillus mirabilis, acinetobacter , bacillus ex pneumoenteritidis suis, gardnerella vaginalis, acinetobacter calcoaceticus, escherichia coli, pathogenic escherichia coli, salmonella enteritidis, chlamydozoa trachomatis, adenovirus and rotavirus group B,C samples showed no cross-reactivity.

4. Hook effect: the hook effect will not occur when detecting 9.73×10^6PFU/mL of rotavirus group A antigen.

Precaution

1. For IN VITRO diagnose 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 test 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 sample may occur according to too much or too sticky sample. Diluted samples should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing.

7. All samples 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.

9. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.