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Group A Rotavirus Antigen Rapid Test Kit

Catalog No.: BG301C BG301S

NAME AND INTENDED USE

Bioneovan Group A Rotavirus Antigen Rapid Test Kit is an in vitro immunoassay for the qualitative determination of the detection of Group A Rotavirus in human faecal specimens in one step. It is for diagnosis of early infection and epidemic survey. The kit is intended only for an initial screening test and reactive samples should be confirmed by a supplemental assay such as commercial anzyme immunoassay (ELISA) or RT-PCR.

SUMMARY

Rotavirus (RV) belongs to Rotavirus genus in family Reoviridae and recognized as the major etiology agents of severe, dehydrating diarrhea and acute gastroenteritis in infants and young children worldwide. Enteral Rotavirus infections are transmitted via the fecal-oral route from person to person or contaminated objects can be the source of infection. It was said that about 600～800 thousand people died each year from rotaviruses. Even in the developed countries in which the mortality is much lower than developing countries, rotavirus is responsible for 30～60% of all cases of acute gastroenteritis reported each year. Scientist has described seven rotavirus groups (A to G). Only groups A, B, and C infect humans. Group A, which has multiple strains, causes the majority of childhood intections. The golden standard for the diagnosis of Rotavirus infections is direct virus detection by electron microscopy.

PRINCIPLES OF THE ASSAY

The kit uses a sandwich solid phase immunochromatographic assay to detect group A rotavirus antigen in human stool specimen. Nitrocellulose-based membrane pre-coated with Goat polyclonal anti-rotavirus antibodies and the gold labeled specially-selected mouse monoclonal anti-rotavirus antibodies are used as detector materials, respectively. Add an aliquot of diluted stool sample to the sample well of the test cassette. If the sample contains rotavirus antigens, a antigen-antibody-gold complexes will form. 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 pink 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 dose not developed, the test is invalid. The test results are intended to aid in the diagnosis of rotavirus infection and to monitor the effectiveness of therapeutic treatment. The test is fast and easy to operate.

MATERIALS PROVIDED

25x1 tests (strip), 20x1 tests (Cassette)
Group A Rotavirus test Cassette /strip

Each cassette/strip contains a test strip with Goat polyclonal anti-rotavirus antibodies on the test region of the membrane and colored mouse monoclonal anti-rotavirus antibodies-gold conjugate pad.

SAMPLE COLLECTION AND PRESERVATION

1. Sample collection swab
• To take a portion of feces(about 100mg) , insert the sterile swab into a stool sample that presents the most secretion under visual inspection.• Open the sample collection tube and then insert the swab into the sample collection tube containing assay diluents. Swirl the swab at least 10 times until the samples has been dissolved into the assay diluents and discard the swab while squeezing the swab against the wall of tube, replace the cap. Specimen extracted in assay diluents may be stored at 2-8℃ for up to 1 -2 days prior to testing.
2. Specimen transport and storage
• Specimen should be tested as soon as possible after collection. Do not use any kind of transport media to store or transport specimens.
• Faecal sample may be stored refrigerated (2-8℃) for 48 hours. If longer storage is required, freezing at -20℃ is recommended.

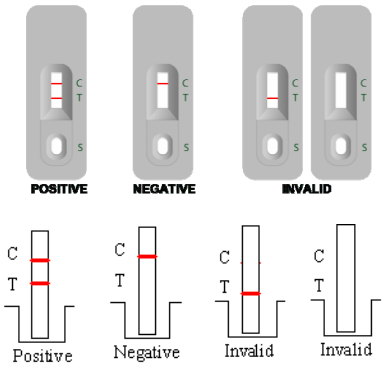
TEST PROCEDURE

1. Bring Membrane Plate and samples to room temperature (20-30℃) before use (approximately 30 minutes).
2. Remove the test cassette/strip from the sealed foil pouch and place the plate on flat desk.
3. Bring all materials and specimens to room temperature (8～30℃).
4.1 **Group A Rotavirus test strip**
1) Add 500µl sample diluents into the test tube.
2) Add proper specimens (S:5 mm in diameter, L: 50µl) into the tube to make the concentration of the solution up to 5%～10% and mix thoroughly.
3) Deliver 100µl (2～3drops) of diluted stool sample to the sample pad of the test strip.
4.2 **Group A Rotavirus test cassette**
1) To take a portion of feces (about 100mg), insert the sterile swab into a stool sample that presents the most secretion under visual inspection.
2) Open the sample collection tube and then insert the swab into the sample collection tube containing assay diluents.
3) Swirl the swab at least 10 times until the samples has been dissolved into the assay diluents and discard the swab while squeezing the swab against the wall of tube, replace the cap.
4) Deliver 100µl (2～3drops) of diluted stool sample to the sample well of the test card.
5. Read the result in 5～10 minutes. A strong positive sample may show result earlier.
Note: Results after 15 minutes may not be accurate.

INTERPRETATION OF RESULTS

Positive Two pink lines appear in both C and T position
Negative Only one pink line appear in C position
Invalid: The control line next to the test line does not become

visible within **10** minutes after the addition of the sample.



LIMITATION

The testing is for qualitative and assistant diagnosis. Confirmation of infection should refer to the clinical and other diagnosis.
A negative result does not exclude the possibility of rotavirus infection in the patient.

PRECAUTIONS

1. Both plate and sample should be with room temperature 20-25 ℃
2. Failure to detect rotavirus may be a result of factors such as collection of specimen at an improper time in the disease when too few virions are present and improper sampling or handling of the specimen.
3. Wrong result might be caused by expired kit or problematic samples.

STORAGE AND STABILITY

Room Temperature.

EXPIRATION

The shelf life is 24 months. Do not use the kit beyond its expiration date.