



# Rapid Test for Detection of Norovirus antigen (Colloidal Gold)

Catalog No.: BG1701C

## NAME AND INTENDED USE

Bioneovan Rapid Test for Detection of Norovirus antigen (Colloidal Gold) is an in vitro immunoassay for the qualitative determination of the detection of norovirus in human feces specimens in one step. As an auxiliary diagnosis of acute viral gastroenteritis, it quickly diagnoses the pathogen for disease, avoids the spread of hospitals or communities and reduces the need for unnecessary antibiotic therapy.

## SUMMARY

Norovirus (NoV), also known as Norovirus, belongs to the family Calicivirus. It is mainly transmitted through contaminated water, food, etc., and is transmitted by contact or aerosol formed by pollutants. It has been recognized as the primary pathogen causing viral diarrhea and gastroenteritis in adults in Europe and the United States, and is the second pathogen secondary to rotavirus in children with viral diarrhea. In the outbreak of non-bacterial gastroenteritis, Norovirus occupies an important position, 30% to 50% of aseptic gastroenteritis is related to it, and 90% of viral gastroenteritis caused by food is Caused by the virus [4]. Norovirus is mainly divided into five genomes (GI, GII, GIII, GIV and GV). The main infections are GI, GII and GIV. The Norovirus of GII genome is the most common strain in the world. There are three methods for clinical or laboratory diagnosis of Norovirus infection, such as electron microscopy, molecular biology and immunological detection.

## PRINCIPLES OF THE ASSAY

The kit utilizes the principle of colloidal gold immunochromatography to sequentially coat goat anti-mouse IgG antibody (C line), mouse anti-Norovirus monoclonal antibody (GII-2) and mouse anti-Norovirus on nitrocellulose membrane. Monoclonal antibody (GI-2); a gold-labeled mouse anti-norovirus antibody (GII-1) and a mouse anti-Norovirus monoclonal antibody (GI-1) were simultaneously immobilized on a gold standard pad. When a positive sample is detected, the Norovirus antigen (GII) and/or Norovirus antigen (GI) in the sample and the mouse anti-Norovirus antibody (GII-1) and/or the mouse anti-Norovirus single on the gold pad The cloned antibody (GI-1) binds to form a complex and moves along the membrane under chromatography. After the detection line, a sandwich complex is formed with the pre-coated antibody to form a sandwich complex, and the color is developed by binding to the goat anti-mouse IgG antibody at the quality control line, and the negative sample is only developed at the quality control line.

## MATERIALS PROVIDED

20 tests Norovirus rapid test Cassette

Each box contains as below:

1. Test card: 20 tests
2. Sample dilution: 1ml /bottle × 20
3. Instruction manual: 1 piece

The components in different batches and different varieties of kits may not be mixed.

## SAMPLE REQUIREMENTS

The collected samples are tested within three months and stored at -20 °C. Save for more than three months at - 70 ° C. If transportation is required, it should be carried out at low temperatures. The feces to be preserved should be treated aseptically during collection and storage. Thoroughly thaw before use and return to room temperature before testing.

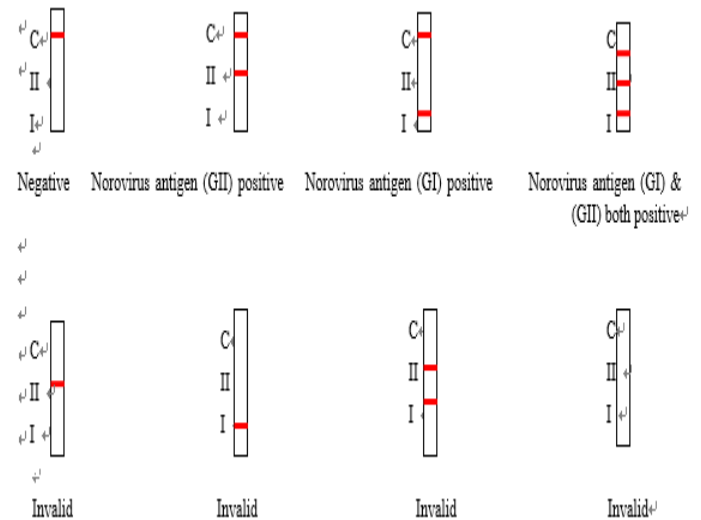
## TEST PROCEDURE

If the kit is kept in the refrigerator, return the kit to room temperature before use.

1. Unscrew the cap, remove the picking screw, take the sample from the feces (about 100mg), place it in the picker with the sample diluent, and tighten the cap.
2. Shake and mix, and screw the top cap of the toilet.
3. Place the test card on a flat surface, vertically and slowly add 2-3 drops of the mixed sample (about 80 μl) to the center of the test card loading end.

5-15 minutes of interpretation. After 15 minutes, the interpretation is invalid.

## INTERPRETATION OF RESULTS



C-line color development only: negative; C line, II line color development: Norovirus antigen (GII) positive; C line, I line color development: Norovirus antigen (GI) positive; C line, II line, I line color development: Norovirus antigen (GII) and Norovirus antigen (GI) are positive at the same time; only R line or A line color: invalid; C line, R line A line are not color: invalid.

### LIMITATION

1. Only detect Norovirus antigen (GII) and Norovirus antigen (GI) in stool samples.
2. This kit cannot be used as a quantitative detection reagent.
3. Any positive results need to be determined after contacting the clinical information.
4. All highly sensitive immunoassay systems are inevitably non-specification and may cause biological false positives.

### PRECAUTIONS

1. For in vitro diagnostic use only;
2. After the kit is opened, store it in a dry environment and try to use it within 9 weeks. Do not mix the components of different batches;
3. The product itself will not cause biosafety problems, but the tested reagents and samples should be treated as infectious substances;
4. Excessive collection of stool samples or excessively thick stool samples may cause the diluted sample to clog the test strips. Please take the diluted sample after standing or centrifuge to take the supernatant for testing;
5. The sample added to the test strip should not be too much, otherwise it will cause erroneous results.

### STORAGE AND STABILITY

Sealed at 4-30 ° C in the dark & dry condition.

### EXPIRATION

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



*In vitro* diagnostic device



Lot code



Consult instructions for use



Catalogue number



Keep dry



Contains sufficient for <n> tests



Temperature limitation



Manufacturer



Use by



Do not use if package damaged