Noroviruses Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

A lateral flow immunochromatographicassay for the qualitative rapid detection of Norovirus antigen in feces sample

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTRODUCTION

Noroviruses are a genetically diverse genus of single-stranded RNA, non-enveloped viruses in the Caliciviridae family. The known viruses in the genus are all considered to be the strains of a single species called Norwalk virus. The viruses are transmitted by fecally contaminated food or water; by person-to-person contact; and via aerosolization of the virus and subsequent contamination of surfaces. Noroviruses are the most common cause of viral gastroenteritis in humans, and affect people of all ages.

SUMMARY AND PRINCIPLE OF THE TEST

Norovirus, sometimes referred to as the winter vomiting bug, is the most common cause of gastroenteritis. Infection is characterized by diarrhea, vomiting, and stomach pain. Blood is not usually present. Fever or headaches may also occur. This usually develops 12 to 48 hours after being exposed. Recovery typically occurs within 1 to 3 days. Complications may include dehydration.

The virus is usually spread by the fecal–oral route. This may be by contaminated food or water or person-to-person contact. It may also spread via contaminated surfaces or through the air. Risk factors include unsanitary food preparation and sharing close quarters. Diagnosis is generally based on symptoms. Confirmatory testing may be done for public health purposes.

Norovirus results in about 685 million cases of disease and 200,000 deaths globally a year. It is common both in the developed and developing world. Those under the age of five are most often affected and in this group it results in about 50,000 deaths in the developing world. Disease more commonly occurs in winter months. It often occurs in outbreaks, especially among those living in close quarters. In the United States, it is the cause of about half of foodborne disease outbreaks. The disease is named after Norwalk, Ohio, where an outbreak occurred in 1968.

The Norovirus Rapid Test Kit (Colloidal Gold) is designed to detect Norovirus GⅠ and GⅡ by visual inspection of the color change of the internal strip. The membrane is immobilized with anti-norovirus GⅠ antibodies and anti-norovirus GⅡ antibodies on the test region. During the test, the sample reacts with a colored anti-norovirus GⅠ antibodies colloidal gold conjugates and anti-norovirus GⅡ antibodies colloidal gold conjugate pre-coated on a test sample pad. The mixture then moves across the membrane by capillary action and interacts with the reagents on the membrane. If there were enough norovirus GⅠ in specimens, a colored band will form at the T1 region of the membrane. Similarily, If there were enough norovirus GⅡ in specimens, a colored band will form at the T2 region of the membrane. The presence of a color band indicates a positive result and the absence of a color band indicates a negative result. The presence of a color band in the control region serves as a program control. This indicates that the appropriate volume of sample has been added and a membrane lick has occurred.

REAGENTS AND MATERIALS

Test devices. Each cassette is pouched with a dropper and a package of desiccant.
Extraction diluents
Instruction for use.

PRECAUTIONS

1. For in-vitro diagnostic use only.
2. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
3. Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
4. Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
5. Avoid contact between hands and eyes or nose during specimen collection and testing.

STORAGE AND STABILITY

The Norovirus Rapid Test Cassette can be stored at any temperature between 2-30°C. **Do not freeze.** The stability of the kit under these storage conditions is 24 months. Use up the reagents as soon as possible after the kit is unpacked.

SPECIMEN COLLECTION AND HANDLING

• The Norovirus Rapid Test Device (Feces) is intended only for use with human fecal specimens.
• Collect sufficient quantity of feces (1-2 g or 1-2 ml for liquid samples). Stool samples should be collected in clean and dry containers (without preservatives or transport media).
• Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored in the refrigerator (2-8°C) for 1~2 days prior to testing. For longer storage (maximum 1 year) samples must be kept frozen at -20°C .
• Bring specimens to room temperature prior to testing.
• Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

TEST PROCEDURE

Preparations:

Specimen collection and pre-treatment:

1) Use the specimen collection container for specimen collection. Best results will be obtained if the assay is performed within 6 hours after collection.

2) **For solid specimens:** Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 3 different sites of the feces to collect approximately 125 mg of feces .

For liquid specimens: Hold the pipette vertically, aspirate fecal specimens, and then transfer 125 µL into the specimen collection tube containing the extraction buffer.

3) Place the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.

4) Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.

Procedure:

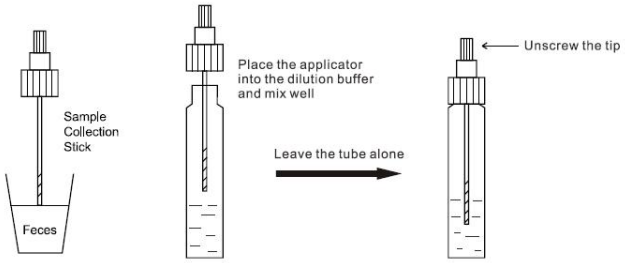
1) Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. To obtain a best result, the assay should be performed within one hour.

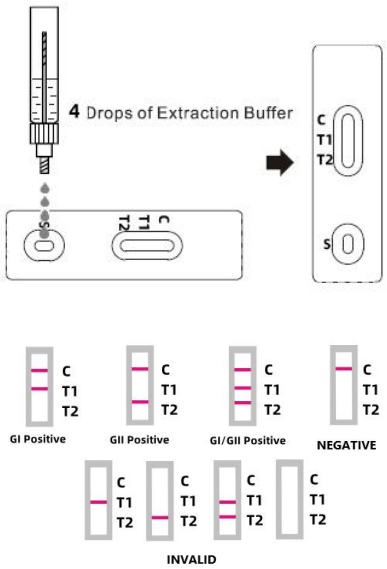
2) Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and dispense 4 drops of solution into the specimen well (S) of the test device.

Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.

As the test begins to work, you will see color move across the membrane.

Wait for the colored band(s) to appear. The result should be read at 10 minutes.





INTERPRETATION OF RESULTS

Negative:
One colored band appears in the control band region (C). No band appears in the test band region (T1/T2).

Positive:
Norovirus GⅠ Positive: * A colored band appears in the control band region (C) and another colored band appears in the T1 band region.

Norovirus GⅡ Positive: * A colored band appears in the control band region (C) and another colored band appears in the T2 line region.

Norovirus GⅠ and GⅡ Positive: * A colored band appears in the control line region (C) and two other colored bands appear in T1 line region and T2 line region respectively.

Invalid: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:
1. The intensity of the color in test region (T1/T2) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

PERFORMANCE

Norovirus GⅡ:

Evaluation Method		Commercial Test	
		Positive	Negative
Norovirus Rapid Test	Positive	102	6
	Negative	3	870

Specificity: 99.32% (98.52%～99.75%)
Sensitivity: 97.14% (91.88%～99.41%)

Norovirus GⅠ:

Evaluation Method		Commercial Test	
		Positive	Negative
Norovirus Rapid Test	Positive	28	2
	Negative	1	450

Specificity: 99.56% (98.76%~99.96%)
Sensitivity: 96.55% (91.03%~98.82%)

Cryptosporidium parvum	Enterovirus	Rotavirus
Listeria monocytogenes	Staphylococcus aureus	Clostridium difficile
Adenovirus	Yersinia	Shigella
Hepatitis A	Escherichia coli	RSV
Astrovirus	Salmonella	Giardia lamblia
Helicobacter pylori	Campylobacter	

Specificity:
Cross reactivity with following organisms has been studied at 1.0 x 10^9 organisms/ml. The following organisms were found negative when tested with the Noroviruses Rapid Test Cassette (Colloidal Gold).

LIMITATION OF PROCEDURE

1. The test should be used only for the detection of norovirus antigen in feces samples.
2. The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line, when reporting the result
3. More than 800 samples were evaluated to assure the correct performance of the test. The correlation of the results with other techniques was excellent. However, interferences in the performance of the tests should not be excluded.
4. No cross-reactions with other viruses or substances were observed during the evaluation of the test. A negative result does not totally exclude a possible norovirus infection. The significance of the results must be evaluated in relation to the patient's clinical symptoms.

Code:GKPD039-1 Effective date: May 28, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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