CE IVD

Norovirus Antigen Rapid Test Kit (Fecal Specimen)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Human Norovirus antigen in human fecal specimens.For professional medical institutions use only,Not for self testing.

PRODUCT NAME

Norovirus Antigen Rapid Test Kit (Fecal Specimen)

SPECIFICATION

40 tests/kit, 25 tests/kit, 5 tests/kit

INTENDED USE

The Norovirus Antigen Rapid Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of Norovirus in human Fecal Specimen. It is suitable for the auxiliary diagnosis of Norovirus infection.

INTRODUCTION

Norovirus are the leading cause of epidemic gastroenteritis,including foodborne outbreak,in the united states. Noroviruses belong to the family Caliciviridae and can be grouped into five genogroups(GI through GV),which are further divided into at least 34 genotyoes. Genotypes GI,GII and GIV infect humans,causing gastroenteritis,whereas GIII and GV typically infect animals.

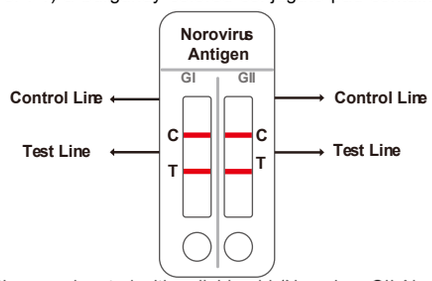
The symptoms of Norovirus related diseases are those typical of gastroenteritis,that is,vomiting,watery diarrhea and abdominal cramps. Vomiting is a characteristic symptom in the majority of Norovirus infections(64% of adults and 81% od children). Other symptoms such as general malaise,low grade fever,nausea and fatigue are also present in over 90%of cases.The incubation period of the disease is generally between 12 and 48 hours,while infection lasts between 12 and 60 hours.Infection may also be asymptomatic,and thus contribute to the spread of the virus in the community. As a rule,the disease does not have serious consequences,and most patients recover within 1-2 days without complications. Debilitated patients and persons with weaker immune system such as children,elderly or chronic patients may be affected by more serious forms of disease. Specially,dehydration may represent a serious complication for children,the elderly and persons with a precarious metabolic balance or cardio circulatory instability.

PRINCIPLE

The Norovirus Antigen Rapid Test Kit is a lateral flow chromatographic immunoassay.

Strip I consists of: 1) a burgundy colored conjugate pad containing mouse anti-Norovirus GI antigen conjugated with colloid gold (Norovirus GI Ab conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with rabbit anti-Norovirus GI antigen, and the C band is pre-coated with goat anti-mouse IgG antibody.

Strip II consists of : 1) a burgundy colored conjugate pad containing mouse anti-



Norovirus GII antigen conjugated with colloid gold (Norovirus GII Ab conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with rabbit anti-Norovirus GII antigen, and the C band is pre-coated with goat anti-mouse IgG antibody.

Strip I:When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Norovirus GI Ag if present in the specimen will bind to the Norovirus GI Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated rabbit anti-Norovirus GI antibody, forming a burgundy colored T band, indicating a Norovirus GI Ag positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the presence of colored T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

Strip II:When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the test cassette. Norovirus GII Ag if present in the specimen will bind to the Norovirus GII Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated rabbit anti-Norovirus GII antibody, forming a burgundy colored T band, indicating a Norovirus GII Ag positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the presence of colored T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

COMPONENTS

Materials Provided

Components	40 tests/kit	25 tests/kit	5 tests/kit
Cassettes	40 cassettes with dependent sealed foil pouch	25 cassettes with dependent sealed foil pouch	5 cassette with dependent sealed foil pouch
Specimen vial with buffer	1mL/bottle, 40pcs	1mL/bottle, 25pcs	1mL/bottle, 5pcs
Transfer tube	40 pcs	25 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

Main ingredients of test cassettes:

Mouse anti-Human Transferrin antibody, Goat anti-rabbit IgG polyclonal antibody, Human Transferrin antibody, rabbit IgG, Colloidal gold conjugate, Other test device support; one desiccant.

Main ingredients of Sample Diluent Solution:

Neutral salt buffer

Reagents of different batch numbers cannot be used interchangeably.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer for timing use

PRECAUTIONS

- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- For in-vitro diagnostic use only
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C

STORAGE AND STABILITY

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Procedure A: Solid stool samples

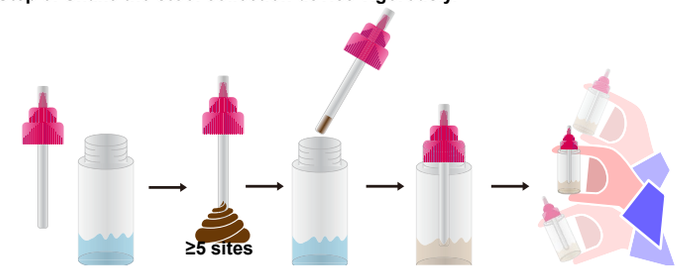
Step 1: Collect a random stool sample in a clean, dry receptacle.

Step 2: Open the stool collection device by unscrewing the top and use the collection stick to randomly pierce the stool sample in at least five different sites. Do not scoop stool sample as this may lead to an invalid test result.

Step 3: Ensure stool sample is only in the grooves of the collection stick. **Excess stool sample may lead to an invalid test result.**

Step 4: Replace the collection stick and tighten securely to close the stool collection device.

Step 5: Shake the stool collection device vigorously.



Note: Specimens extracted may be stored at 2-8°C for up to 3 days. If longer storage is required, freezing at ≤-20°C is recommended.

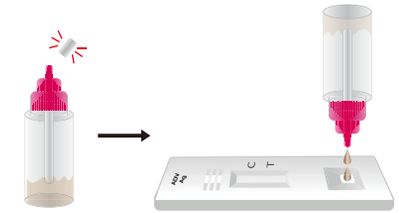
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen.

Step 2: When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.

Step 3: Shake the stool collection device vigorously to ensure an effective liquid suspension.

Step 4: Position the stool collection device upright and twist off the dispenser cap. Holding the stool collection device vertically, dispense 2 drops of the solution (85-95uL) into the sample well of the test device. Do not overload sample.



Step 5: Set up timer.

Step 6: Results can be read after 15 minutes. Positive results can be visible in as short as 1 minute.

Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.

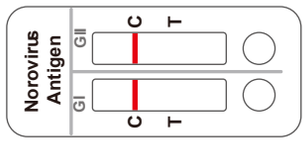
External Control: Good Laboratory Practice recommends using the external controls,

positive and negative, to assure the proper performing of the assay, in particularly, under the following circumstances:
a. New operator uses the kit, prior to performing testing of specimens.
b.A new lot of test kit is used.
c.A new shipment of kits is used.
d.The temperature used during storage of the kit fall outside of 2°C -30°C.
e.The temperature of the test area falls outside of 15°C -30°C.

INTERPRETATION OF ASSAY RESULT

Negative Control

If only the C band is developed, the test indicates that no detectable Giardia antigen is present in the specimen. The result is non-reactive.



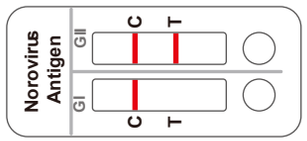
Positive Control:

Norovirus GI antigen positive

If both C and Norovirus GI lines are developed, the test indicates the presence of Norovirus GI antigen in the specimen. The result is positive.

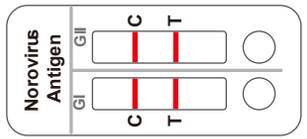
NOROVIRUS GII ANTIGEN POSITIVE

If both C and Norovirus GII lines are developed, the test indicates the presence of Norovirus GII antigen in the specimen. The result is positive.



Norovirus GI and GII antigen positive

If both C, Norovirus GI and GII lines are developed, the test indicates the presence of Norovirus GI and GII antigen in the specimen. The result is positive.



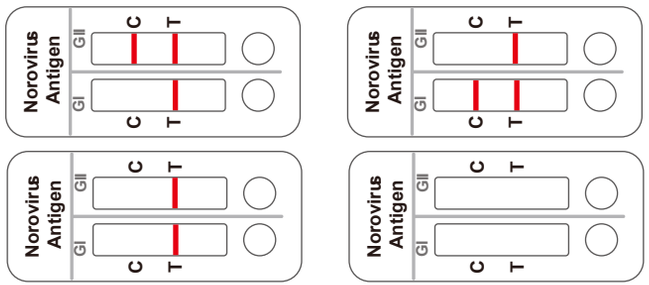
INVALID:

If no C line is developed, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new test device.

Excess fecal specimen can lead to invalid test results; if this is the cause, re-sample and re-test (see instructions for collection of specimen).

The appearance of any burgundy color in the test bands, regardless of intensity, must be considered as presence of the band.

Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.



PERFORMANCE CHARACTERISTICS

1.Sensitivity, Specificity and Accuracy

1.1 Norovirus GI

A total of 513 patient samples from susceptible subjects were test by the ELISA test. Comparison for all subjects is showed in the following table:

Norovirus GI Antigen Test	ELISA Test		
BESTest	Positive	Negative	Total
Positive	108	5	113
Negative	2	398	400
Total	110	403	513
Relative Sensitivity: 95.57%; Relative Sp ecificity:99.5%; Overall agreement: 98.64%			

1.2 Norovirus GII

A total of 534 patient samples from susceptible subjects were test by the ELISA test. Comparison for all subjects is showed in the following table:

Norovirus GII Antigen Test	ELISA Test		
BESTest	Positive	Negative	Total
Positive	121	6	127
Negative	5	402	407
Total	126	408	534
Relative Sensitivity: 95.28%; Relative Specificity:98.77%; Overall agreement: 97.94%			

2.Cross-reactivity

An evaluation was performed to determine the cross reactivity of BESTest Norovirus GI and Norovirus GII ,no cross reactivity against gastrointestinal pathogens occasionally present in faeces.

3.Interfering Substances

This kit has no interference with HAMA, Human serum Albumin, Antinuclear antibody, Antimitochondrial antibody, Cholesterol, Bilirubin conjugated, Lipids, Hemoglobin, Bilirubin unconjugated, Rheumatoid factor, et al.

QUALITY CONTROL

1.Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
2.External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST LIMITATIONS

1.The Norovirus Antigen Rapid Test Kit (Fecal Specimen) is for in vitro diagnostic use only. This test should be used for the detection of Norovirus antigen in human Fecal specimens.
2.The Norovirus Antigen Rapid Test Kit (Fecal Specimen)will only indicate the presence to Norovirus in the specimen and should not be used as the sole criteria for the diagnosis of Norovirus infections.
3.If the symptom persists, while the result from Norovirus Antigen Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few hours later.
4.As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5.If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Norovirus infection.
6.The potential impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated in the test.
7.Due to inherent differences between methodologies, it is highly recommended that, prior to switching from one technology to the next, method correlation studies are undertaken to qualify technology differences. One hundred percent agreement between the results should not be expected due to differences between technologies.
8.Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

CAUTION

1.This product is used for in vitro diagnosis only.
2.Must strictly follow the instructions for operation and interpretation of the results.
3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.should be tested using reagents within the validity period.
4.The cassetes, collectors,droppers,and tubes are for single person one-time use, cannot be reused.
5.Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.
6.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.
7.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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