Rotavirus+Adenovirus+ Norovirus Antigen Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

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

PRODUCT NAME

Rotavirus+Adenovirus+ Norovirus Antigen Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 tests/kit

INTENDED USE

The Rotavirus+Adenovirus+ Norovirus Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of Rotavirus/Adenovirus/ Norovirus in human Fecal specimen. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Rotavirus/Adenovirus/Norovirus. Any reactive specimen with the Rotavirus/Adenovirus/ Norovirus antigen Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION THE TEST

Rotavirus,Adenovirus and Norovirus are most common and major causes of severe gastroenteritis in infants and young children.Pattern also observed in adults.They are transmitted by faecal-oral contact.The main symptoms of viral gastroenteritis are watery diarrhoea and vomiting.The affected person may also have headache,fever and abdominal cramps("stomach ache").In general,the symptoms begin 1 to 2 days following infection with a virus that causes gastroenteritis and may last for 1 to 10 days, depending on which virus causes the illness(Rotavirus 3 days, Adenovirus 5-8 days and Norovirus 3 days).

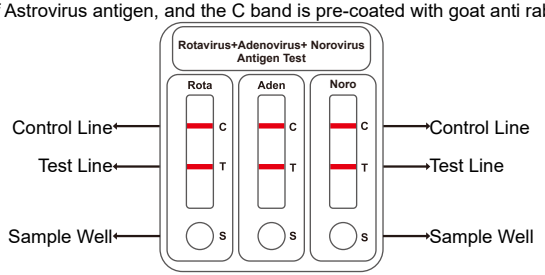
PRINCIPLE

The Rotavirus, Adenovirus and Norovirus antigen Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of Rotavirus, Adenovirus and Astrovius strips.

Rotavirus strip:1) a burgundy colored conjugate pad containing monoclonal anti-rotavirus antibody conjugated with colloidal gold (anti-rotavirus conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with another monoclonal anti-rotavirus antibody, and the C line is pre-coated with a control line antibody.

Adenovirus strip:1) a burgundy colored conjugate pad containing recombinant antigen conjugated with colloid gold (monoclonal mouse anti-Adenovirus antibody conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing test band (T bands) and a control band (C band). The T band is pre-coated with monoclonal mouse anti- Adenovirus antibody for the detection of Adenovirus antigen, and the C band is pre-coated with goat anti rabbit IgG.

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



Rotavirus strip:When an adequate volume of extracted specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Rotavirus Ag, if present in the specimen, will bind to the anti-rotavirus conjugates. The immunocomplex is then captured on the membrane by the pre-coated rotavirus antibody forming a burgundy colored T line, indicating a rotavirus positive test result.Absence of the T line suggests that the concentration of rotavirus Ag in the specimen is below the detectable level, indicating a rotavirus negative result. The test contains an internal control (C line), which should exhibit a burgundy colored line of the immunocomplex of the control antibodies, regardless of color development on the T line. Otherwise, the test result is invalid and the specimen must be retested with another device.

Adenovirus strip: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. Adenovirus if present in the specimen will bind to the monoclonal mouse anti-Adenovirus antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-Adenovirus antibody, forming a burgundy colored T band, indicating a Adenovirus antigen positive test result. Absence of test band (T) 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 rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid, and the specimen must be retested with another device.

Norovirus Strip: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 if present in the specimen will bind to the monoclonal mouse anti-Norovirus GI and GII antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated mouse anti-Norovirus GI and GII antibody, forming a burgundy colored T band, indicating Norovirus GI and GII antigens positive test result. Absence of test band (T) 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 rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid, and the specimen must be retested with another device.

COMPONENTS

Materials Provided

Components	25 tests/kit	5 tests/kit	1 tests/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution	1mL/bottle, 25pcs	1mL/bottle, 5pcs	1mL/bottle, 1pcs
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

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

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.

2.Do not open the sealed pouch, unless ready to conduct the assay.

3.Do not use expired devices.

4.Bring all reagents to room temperature (15°C-30°C) before use.

5.Do not use the components in any other type of test kit as a substitute for the components in this kit.

6.Do not use hemolized blood specimen for testing.

7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.

8.Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.

9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.

10.Dispose of all specimens and materials used to perform the test as biohazardous waste.

11.Handle the Negative and Positive Control in the same manner as patient specimens.

12.The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.

13.Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

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

To prepare specimens using solid stool samples follow Procedure A below. To prepare specimens using watery stool samples follow Procedure B below.

Procedure A: Solid stool samples

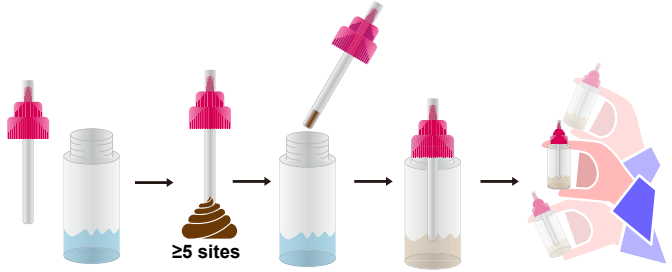
Step 1: Collect a random stool sample in a clean, dry receptacle.

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.



Procedure B: Watery 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.

Step 3: Fill the plastic dropper with the sample; dispense 2 drops (70-85uL) into the stool collection device.

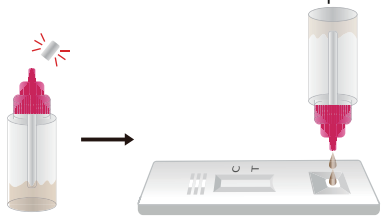
Step 4: Replace the collection stick and tighten securely to close the stool collection device.

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.



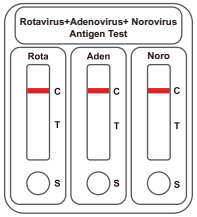
Step 5: Set up timer.
Step 6: Results can be read after 15 minutes. Positive results can be visible in as short as 1 minute.
Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

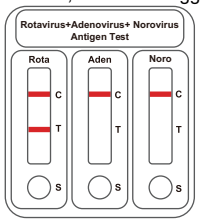
Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.
External Control: Good Laboratory Practice recommends using the external controls, positive 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℃ -30℃ .
e.The temperature of the test area falls outside of 15℃ -30℃ .

INTERPRETATION OF ASSAY RESULT

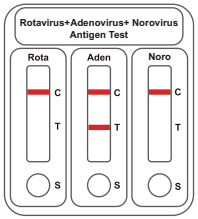
Negative Control
If only the C band is present, the absence of any burgundy color in the T bands, indicates that no Rotavirus,Adenovirus and Astrovirus antigen are detected.
The result is negative or non-reactive.



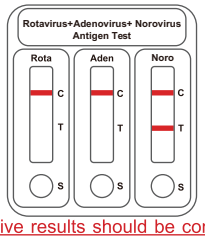
Positive Control:
Rota Positive: In addition to the presence of C band, if T band is developed, indicates for the presence of Rotavirus ; the result suggeststt infection of Rotavirus.



Adenovirus Positive: In addition to the presence of C band, if T band is developed, the test indicates for the presence of Adenovirus antigen. The result suggests fresh infection of Adenovirus.

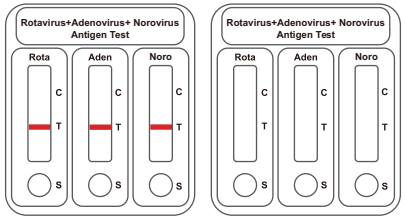


Norovirus Positive: In addition to the presence of C band, if T band is developed, indicates for the presence of Norovirus. The result suggests fresh infection of Norovirus.



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.

INVALID:
If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands(Rota,ADV and Astrovirus) as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance For Rotavirus Test:
107 fecal samples collected from subjects with symptomatic diarrhea and non-diarrheal symptoms were tested with the Rotavirus Ag Rapid Test and with a reference rotavirus antigen rapid test. Comparison for all subjects is shown in the following table:

	Rotavirus+Adenovirus+ Norovirus Antigen Rapid Test		
Reference	Positive	Negative	Total
Positive	36	0	36
Negative	2	69	71
Total	38	69	107
Relative Sensitivity: 100%, Relative Specificity: 97.2%, Overall Agreement: 98.1%.			

2.Clinical Performance For Adenovirus Test
A total of 354 patient samples from susceptible subjects were test by the ELISA test. Comparison for all subjects is showed in the following table:

Rotavirus+Adenovirus+ Norovirus Antigen Rapid Test	ELISA Test		
Reference	Positive	Negative	Total
Positive	150	4	154
Negative	2	198	200
Total	152	202	354
Relative Sensitivity: 97.4%; Relative Sp ecificity:99%; Overall agreement: 98.31%.			

3.Clinical Performance For Norovirus Test
A total of 437 patient samples from susceptible subjects were test by the ELISA test. Comparison for all subjects is showed in the following table:

Rotavirus+Adenovirus+ Norovirus Antigen Rapid Test	ELISA Test		
Reference	Positive	Negative	Total
Positive	237	5	242
Negative	10	185	195
Total	247	190	437
Relative Sensitivity: 97.93%; Relative Specificity:94.87%; Overall agreement: 96.57%.			

LMITATIONS OF TEST

1.The Rotavirus/Adenovirus/Norovirus Antigen Rapid Test Kit (Fecal Specimen) is for in vitro diagnostic use only. This test should be used for the detection of Rotavirus/ Adenovirus/Norovirus antigens in human Fecal specimens.
2.The Rotavirus/Adenovirus/Norovirus Antigen Rapid Test Kit (Fecal Specimen)will only indicate the presence to Rotavirus/Adenovirus/Norovirus in the specimen and should not be used as the sole criteria for the diagnosis of Rotavirus/Adenovirus/ Norovirus infections.
3.If the symptom persists, while the result from Rotavirus/Adenovirus/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 Rotavirus/Adenovirus/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.

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		Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

EC REP

SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.