CE IVD

Rotavirus Antigen Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

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

PRODUCT NAME

Rotavirus Antigen Rapid Test Kit (Colloidal Gold)

SPECIFICATION

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

INTENDED USE

The Rotavirus Ag Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of rotavirus antigen in fecal specimens. This device is intended to be used as a screening test and as an aid in the diagnosis of infection with rotavirus. Any reactive specimen with the Rotavirus Ag Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION THE TEST

Diarrhea is one of the principle causes of childhood morbidity and mortality worldwide, resulting in 2.5 million deaths annually. Rotavirus infection is the leading cause of severe diarrhea in infants and children under the age of five, accounting for 40%-60% of acute gastroenteritis and causing an estimated 500,000 childhood deaths each year. By the age of five, nearly every child in the world has been infected with rotavirus at least once. With subsequent infections, a broad, heterotypic antibody response is elicited; therefore, adults are rarely affected.

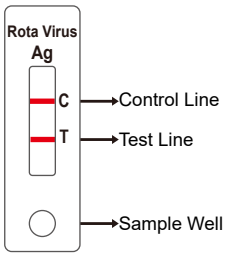
To date seven groups of rotaviruses (groups A-G) have been isolated and characterized. Group A rotavirus, the most common rotavirus, causes more than 90% of all Rotavirus infections in humans. Rotavirus is transmitted primarily by the fecal-oral route, directly from person to person. Virus titers in stool reach a maximum shortly after the onset of illness, then decline. The incubation period of a rotavirus infection is usually one to three days and it is followed by gastroenteritis with an average duration of three to seven days. Symptoms of the disease range from mild, watery diarrhea to severe diarrhea with fever and vomiting.

Diagnosis of an infection with rotavirus can be made following diagnosis of gastroenteritis as the cause of severe diarrhea in children. Recently, specific diagnosis of an infection with rotavirus has become available through the detection of virus antigen in stool by immunoassay methods such as latex agglutination assay, EIA, and lateral flow chromatographic immunoassay.

The Rotavirus Ag Rapid Test is a lateral flow chromatographic immunoassay which utilizes a pair of specific antibodies to qualitatively detect the rotavirus antigen in fecal specimen. The test can be performed without cumbersome laboratory equipment, and the results are available within 15 minutes.

PRINCIPLE

The Rotavirus Ag Rapid Test is a lateral flow chromatographic immunoassay. The test strip consists of: 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.



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.

REAGENTS AND 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

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.

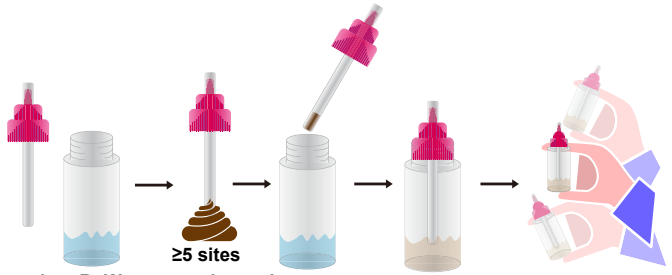
SPECIMEN COLLECTION AND HANDLING

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.



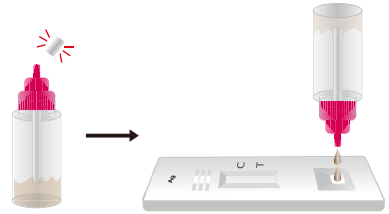
Procedure B: Watery stool samples

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 line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.

External Control: Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:

A.New operator uses the kit, prior to performing testing of specimens.
B.A new lot of test kits is used.
C.A new shipment of kits is used.
D.The temperature used during storage of the kit falls outside of 2-30°C.
E.The temperature of the test area falls outside of 15-30°C.
F.To verify a higher than expected frequency of positive or negative results.
G.To investigate the cause of repeated invalid results.

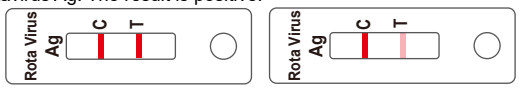
INTERPRETATION OF ASSAY RESULT

Negative Control

If only the C line is developed, the test indicates that the level of rotavirus Ag in the specimen is undetectable. The result is negative.

Positive Control:

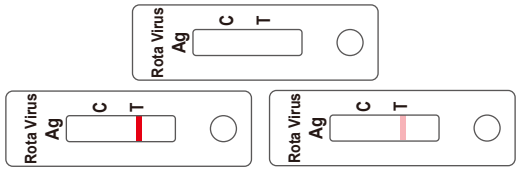
If both the C line and the T line are developed, the test indicates that the specimen contains rotavirus Ag. The result is positive.



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 line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance For Rota 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 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.Serotype Detection:

The Rotavirus Ag Rapid Test detects Group A rotavirus:

3.Cross-reactivity:

The cross-reactivity of the Rotavirus Ag Rapid Test was assessed by testing fecal specimens collected from patients with other gastro-intestinal infectious diseases.

Fecal specimens	Sample size	Rotavirus Ag Reactivity
Typhoid fever	6	Negative
Adenovirus	10	Negative
H. pylori	10	Negative
Cholera (spiked)	3	Negative
Relative Sensitivity:98.15% , Relative Specificity:100%, Overall Agreement: 99.6%		

LMITATIONS OF TEST

1.The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of rotavirus Ag in feces. Failure to follow the procedure may give inaccurate results.
2.The Bestest Rotavirus Ag Rapid Test is limited to the qualitative detection of rotavirus Ag in human fecal specimen. The intensity of the test line does not have linear correlation with antigen concentration in the specimen.
3.A negative result for an individual subject indicates absence of detectable rotavirus antigen. However, a negative test result does not preclude the possibility of infection with rotavirus.
4.A negative result can occur if the quantity of the rotavirus antigen present in the specimen is below the detection limits of the assay or the antigens that are detected are not present in the fecal sample collected.
5.If the symptoms persist and the result from the Bestest Rotavirus Ag Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with alternative test methods.
6.The use of meconium stools in this assay is not recommended, as their performance characteristics have not been evaluated.

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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