IVD

Asan Easy Test® ROTA Strip

ASAN

Diagnostic Kit for Rotavirus Antigen Detection in Human Feces

Immunochromatography

EXPLANATION OF THE TEST

Asan Easy Test® ROTA Strip is an Immunochromatographic assay for the detection of Group A rotaviruses in fecal specimen.The test uses a polyclonal antibody to detect group specific proteins including major inner capsid proteins(VP6), present in Group A rotaviruses.

The membrane is pre-coated the specific polyclonal antibody to the rotavirus on the test line region of the membrane. During the test, the sample is allowed to react with the colloidal gold conjugated by another specific antibody to the rotavirus antigen. The reactant moves upward on the membrane by capillary action. For positive result, a visible line with high sensitivity and specificity as forming antigen-antibody-gold complex appears in the test line region. Regardless of the presence of rotavirus antigen, the mixture continuously moves across the membrane to pre-dried control line. Therefore, the control line will always appear and verify proper performance of the test.

MATERIALS PROVIDED

Asan Easy Test® ROTA Strip contains following items to perform the assay.

1. Test strip in aluminium pouch with a desiccant.
2. Sample collection tubes with assay buffer.
3. Sample collection sticks.
4. Instruction manual for use

PRECAUTIONS

1. For *in-vitro* diagnostic use only
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

1. Specimens should be obtained and handled by specialist in accordance with standard feces collection method.
2. Fecal specimens should be collected as soon as possible following the onset of symptoms.
3. The test should be performed using fresh human feces.
4. Specimens must be tested as soon as they are collected. If necessary, they may be stored at 2~8℃ for up to 48hours or at -20 for longer periods.

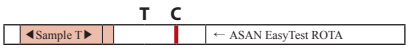
TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing the test.
2. Take a portion of feces (about 12.5mg or 12.5㎕) from inside and surface of specimens at 3~4 different sites thoroughtly.
3. Put collected specimen into a tube containing assay buffer.
4. Mix the specimen until the feces is dissolved in the assay buffer. (If the mixture have many solid materials, centrifuge can be used at 2000g for 15~20 seconds.)
5. Remove the test strip from its protective pouch.
6. Immerse the test strip in the tube in the direction indicated by the arrow for 2~15minutes..
7. Let them react for 15minutes and read the result.

INTERPRETATION OF THE TEST

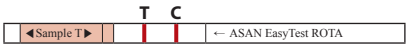
A. Negative result:

The presence of only one red color band ("C" band) within the result window indicates a negative result.



B. Positive result:

The presence of two red color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result.



C. Invalid result:

If If no band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

STORAGE & EXPIRATION

1. Asan Easy Test® ROTA Strip should be stored at 4 ~ 30℃ (39.2 ~ 86°F).
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

This clinical test was performed using a total of 329 specimens. Each specimen was tested with Asan Easy Test® Rota Strip and commercial EIA kit. The results are summarized in the following tables.

n= 329		Commercial EIA		Total
		Positive	Negative	
Asan Easy Test® Rota Strip	Positive	188	8	196
	Negative	12	121	133
Total		200	129	329

※ Relative Sensitivity : 94 %, Relative Specificity : 93.8 %

※ Detection limit : $10^3 TCID_{50}$/ml

LIMITATIONS OF THE TEST

1. A negative result does not exclude the possibility of rotavirus infection in the patient. Failure to detect rotavirus may be a reult of factors such as collection of specimen at an improper time in the disease when too few virions are present and improper sampling or handling of the specimen.
2. The Asan Easy Test® ROTA Strip detects group specific viral proteins present in human serotypes of Group A rotavirus. The test cannot be used to differentiate between serotypes of group A rotavirus, or to detect other rotavirus serogroups (B~F).
3. A positive result does not preclude the presence of other enteric pathogens. While the relation between rotavirus and gastroentieritis is well established, concurrent infection with other microbial pathogens is possible. Additional microbiological tests should be performed in parallel with Asan Easy Test® ROTA Strip in order to exclude other possible causes of the illness.
4. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be made by the physician after all clinical and laboratory findings have been evaluated.

ASAN
ISO13485:2003

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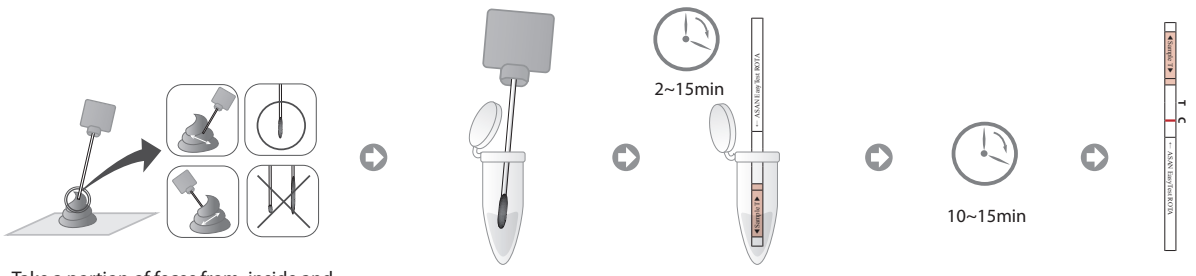
REF Code No.: 22401, 22402
Document Code: ROTA0-S0E00



Take a portion of feces from inside and surface of specimen at 3~4 different sites

Mix well

Reading