Adenovirus-Rotavirus-Norovirus Detection Kit

IP-Triple I

Instructions for use

[Intended use]

Detection of adenovirus, rotavirus and, norovirus in stool specimen.

[Contents of the kit]

1) Test device
   - Anti-norovirus antibody (Test line 1)
   - Anti-rotavirus antibody (Test line T)
   - Anti-adenovirus antibody (Test line 2)
   - Anti-norovirus, anti-rotavirus, anti-adenovirus antibody-conjugated gold colloid
   - Anti-mouse IgG antibody (Control line)
2) Extraction buffer
3) Sample collector
4) Sample collection swab
5) Instructions for use

[Equipment required for pretreatment of sample or assessment]

Micropipette, tips, mixer and timer

[Principle of assessment]

IP-Triple I is a lateral flow immunochromatographic assay for the qualitative detection of norovirus, rotavirus and adenovirus in stool specimen. The viral antigen forms a complex with the specific monoclonal antibody-conjugated gold colloid in the pad and moves onto the membrane by capillary action within the test plate. At this time, the complex goes to react with the specific monoclonal antibody coated on the test line and, with the polyclonal anti-mouse antibody coated on the control line of the membrane to generate a reddish violet line. In absence of viral antigen, test line does not emerge. Thus, the presence of norovirus in the specimen can be evaluated by appearance of the test line. Control line is used for procedural control and, indicate test is working correctly.

[Notes of assessment]

(1) Bring the kit at room temperature prior to assessment.
(2) In the case of sample with high amount of feces or viscosity, centrifugation procedure should be doing at 3000xg for 10 minutes.

[Operational procedure]

1. Method of sample preparation

(1) Add 0.8mL of Extraction buffer to Sample collector and add 50 mg of stool specimen (about 50 µL in the case of liquid stool specimen).
(2) Mix sample well by a mixer or similar and leave for 3 minutes.

2. Assessment method

(1) Remove the test device from foil pouch.
(2) Transfer by drop 80µL of specimen supernatant into the sample well (S).
(3) At 15 minutes, determinate by visual examination the test result. Do not determinate test result after 15 minutes.

[Determination of test result]

After reaction according to the operational procedure, determination of test result is based on the line that emerges on the result window at 15 minutes.

〈 Positive 〉

‣When a reddish violet lines are observed in the **control line (C)** and **test line (1)** on the result window, the sample is determined **Norovirus positive.**

‣When a reddish violet line is observed in the **control line (C)** and a black line is observed in the **test line (T)** on the result window, the sample is determined **Rotavirus positive.**

‣When a reddish violet lines are observed in the **control line (C)** and **test line (2)** on the result window, the sample is determined **Adenovirus positive.**

♦ The thickness of the line varies depending on the concentration of virus in the sample. Even when a test line is pale, a sample with observable line by visual examination should be evaluated as positive.

〈 Negative 〉

When a line is observed on the control line (C) but not on test line (1, T or 2) on the result window, the sample is determined negative.
♦ Negative result can be obtained by no presence of antigen in the sample or antigen is inferior to limit of detection of the kit

〈 Invalid → re-measure 〉

When a line cannot be observed on the control line (C) on the result window, the test is determined as invalid. The test should be performed again in a new test plate.

[Handling of sample]

(1) Stool specimens should be diluted and used for assessment as soon as possible after collection.
(2) Maintain stool specimens at 2-8℃ until perform the test within 3 days after collection. For longer time, stool specimen should be kept below -20℃ (bring specimens to room temperature prior to testing).
(3) Stool specimen that has been diluted in extraction buffer cannot be stored and used for test later.
(4) Handle all samples with caution and regard them as contagious.

[Performance]

1. Reactivity
   IP-Triple detected norovirus, group A rotavirus and, adenovirus from stool specimen.
2. Cross-reactivity
   Cross-reactivity is not observable with virus such as astrovirus genotype 1 and, sapovirus.
3. Interfering substances
   5mg/mL hemoglobin does not affect test result.
4. Correlation data

Norovirus		RT-PCR		
		+	-	Total
IP-Triple I	+	50	0	50
	-	2	48	50
	Total	52	48	100

Sensitivity: 96.2% (50/52), Specificity:100% (48/48)

Rotavirus		Commercial Rapid Test 1		
		+	-	Total
IP-Triple I	+	49	1	50
	-	0	62	62
	Total	49	63	112

Sensitivity: 100% (49/49), Specificity:98.4% (62/63)

Adenovirus		Commercial Rapid Test 2		
		+	-	Total
IP-Triple I	+	6	0	6
	-	0	106	106
	Total	6	106	112

Sensitivity: 100% (6/6), Specificity:100% (106/106)

[Precaution and Warnings]

(1) Kit should be stored at 1 – 30℃
(2) Do not use kit beyond the expiration date.
(3) Test plate cannot be re-used.
(4) Decontaminate all instruments and materials by autoclave or sodium hypochlorite, and dispose it in accordance with laws and local regulations.

[Storage and available period]

Storage : 1 – 30℃
Useable period: expiry date is as described in the outer package.
♦ Avoid high temperature and humidity condition.

[Reference]

1. Shiota.T., et al. J. Virol. 81:12298-12306(2007)
2. Nguyen.T.A., et al. J. Trop. Pediatr. 53:264-269(2007)
3. Okame.M., et al. J. Med. Virol. 79:1180-1186(2007)
4. Pattara K., et al. J. Trop. Pediatr. 56:368-369(2010)

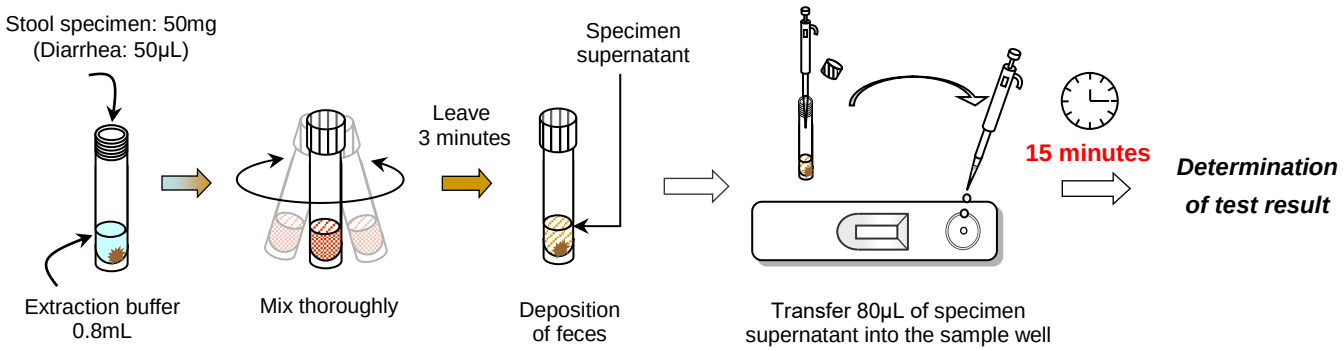
Manufacturer
Immuno Probe Co., Ltd.
1331-3 Kamagata Ranzan-machi
Hiki-gun, Saitama 355-0225 Japan
E_mail: info@immuno-probe.com

IP-Triple I

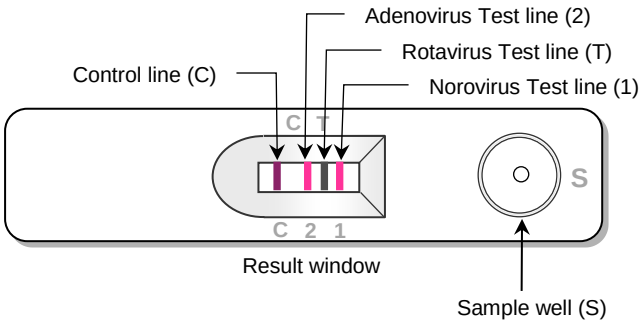
Ag Detection
Adenovirus-Rotavirus-Norovirus

Operational Procedure

Method of sample preparation and assessment method:

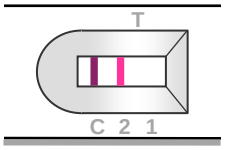


Determination of Test Result

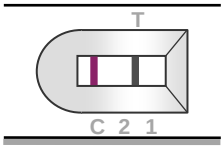


Positive

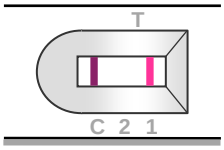
Adenovirus



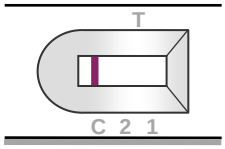
Rotavirus



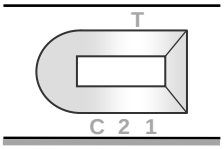
Norovirus



Negative



Invalid



Immuno Probe Co., Ltd.

Method of sample preparation and assessment method: