Viral diarrhea (Norovirus+Rotavirus+Adenovirus+Astrovirus) Combo Rapid Test

Package Insert

REF	IMVD-N647H-01/IMVD-N647H-02/ IMVD-N647H-05/IMVD-N647H-10	English

【INTENDED USE】

The test is a rapid chromatographic immunoassay for the qualitative detection of norovirus, rotavirus, adenovirus and astrovirus antigens in human fecal specimens to aid in the diagnosis of norovirus, rotavirus, adenovirus and astrovirus infection.
The test is for self-testing use. It is not automated. For *in vitro* diagnostic use only.

【MATERIALS】

Materials Provided

	Kit size	1T/kit	2T/kit	5T/kit	10T/kit
Components	Package insert	1	1	1	1
	Stool collection paper(s)	1	2	5	10
	Dropper(s)	1	2	5	10
	Test cup(s) (with dilution buffer) 2 mL (0.02% Proclin 300, ≤0.02% NaN_3)	1	2	5	10

Materials Required But Not Provided

- Timer

【WARNINGS AND PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For self-testing *in vitro* diagnostic use only.
- Do not use after the expiration date. Do not reuse the test.
- Store in a dry place at 2-30°C (36-86°F). Do not use if any of the test kit content or packaging is damaged or opened.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not drink the buffer in the kit. Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.
- Keep the kit out of the reach of children. Test for children should be used with an adult.
- Handle all specimens as if they contain infectious agents. The used tests and specimens may be infectious and should be discarded according to local regulations.
- Wash hands thoroughly before and after handling.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.
- **Keep the test cup upright while testing. Do not move or turn the test cup upside down.**
- Components provided in the kit are approved for use in the test. Do not use any other commercial kit component.
- This test provides only a preliminary test result, it could not replace medical advice. Always seek guidance from a qualified healthcare provider before making any health-related decisions.

【SPECIMEN COLLECTION AND PREPARATION】

- The fecal specimen should be collected in a clean and dry container or stool collection paper.
- No dietary restrictions are necessary before using the test.
- Test should be performed immediately after the feces have been collected.

Collected with stool collection paper as follows:


Unfold the stool collection paper and peel off the liner covering the adhesive tape on each end of the collection paper.


Lift toilet seat and secure the adhesive tabs of the stool collection paper to the sides of the toilet rim.


Make bowel movement onto stool collection paper. Avoid urinating on the paper. If needed, urinate in the front of the bowl, missing the collection paper.

【DIRECTIONS FOR USE】

Before performing the test, allow the test cup to equilibrate to room temperature (15-30 °C).

- Wash your hands with soap and rinse with clean water.
- Remove the test cup from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.

1

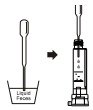


Unscrew the cap of the test cup and take out the sampling stick.

2



Solid feces:
Randomly stab the sampling stick into the fecal specimen in **3 different sites**. Do not scoop the fecal specimen.



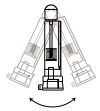
liquid feces:
Hold the dropper vertically, aspirate fecal specimens, and then transfer **2 drops** of the liquid specimen into the test cup containing the dilution buffer.

3



Insert the sampling stick back into the test cup and tighten the cap.

4



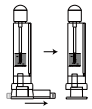
Shake the test cup for about **10-15 seconds** to mix well.

5



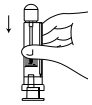
Leave the cup for reaction for **2 minutes**.

6



Tear off the plastic seal from the base of test cup.

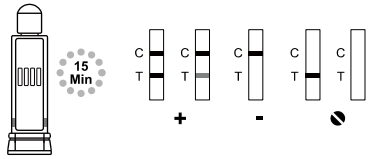
7



Put the test cup on a clean and level surface, press the cup body from the top to the bottom and start the timer.

8

Keep the test upright while testing.
Do not move or turn the test upside down.



Read results at 15 minutes. Do not read results after 20 minutes.

【READING THE RESULTS】



There are 4 test windows, which are Noro, Rota, Adeno, and Astro (shown on the left), and correspond to Norovirus, Rotavirus, Adenovirus, and Astrovirus, respectively.
The results for each test window are interpreted as follows:



POSITIVE

Two lines appear in the Noro/Rota/Adeno/ Astro window. One colored line should be in the control region (C) and the other colored line should be in the test region (T).
This result means that there is the presence of the correlative antigens in feces and that you should consult a physician.
NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of antigens (norovirus or rotavirus or adenovirus or astrovirus) present in the specimen.



NEGATIVE

One colored line appears in the control line region (C). No colored line appears in the test line region (T).
This result means that the presence of the antigens (norovirus or rotavirus or adenovirus or astrovirus) in feces was not detectable.



INVALID

Control line fails to appear.
Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact the local distributor.

【SUMMARY】

The test comprises of 4 parts, viz., norovirus, rotavirus, adenovirus and astrovirus. The details for each part are given below.
For Norovirus: Noroviruses are a major cause of acute gastroenteritis worldwide, often causing explosive outbreaks in institutions. The illness is acute, usually mild.The symptoms of Norovirus illness usually include nausea, vomiting, diarrhea, and some stomach cramping. The illness often begins suddenly, and the infected person may feel very sick. In most people the illness is self-limiting with symptoms lasting for about 1 or 2 days.[1]
For Rotavirus: Rotavirus is the most common agent responsible for acute gastroenteritis, mainly in young children.[2] Rotavirus is transmitted by oral-fecal route with an incubation period of 1-3 days. Rotaviral gastroenteritis may result in mortality for populations at risk such as infants, the elderly and immunocompromised patients.[3] In temperate climates, rotavirus infections occur mainly in the winter months. With hospitalized children suffering from acute enteric disease up to 50% of the analyzed specimen were positive for rotavirus.[4]
For Adenovirus: Research has shown that enteric adenoviruses, primarily Ad40 and Ad41, are a leading cause of diarrhea in many of these children, second only to the rotaviruses.[5]
For Astrovirus: Astrovirus is a type of virus that was first discovered in 1975 using electron microscopes following an outbreak of diarrhea in humans.[6] Human astroviruses have been shown in numerous studies to be an important cause of gastroenteritis in young children worldwide.

【LIMITATIONS】

1. The test should be used for the detection of norovirus, rotavirus, adenovirus and astrovirus in human fecal specimens only. Neither the quantitative value nor the rate of increase in norovirus, rotavirus, adenovirus and astrovirus concentration can be determined by this qualitative test.
2. The test will only indicate the presence of norovirus, rotavirus, adenovirus and astrovirus in the specimen and should not be used as the sole criteria for the confirming norovirus, rotavirus, adenovirus and astrovirus to be etiological agent for diarrhea.
3. 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, rotavirus, adenovirus and astrovirus infection with low concentration of virus particles.
4. Fecal specimen from infant under one year old can produce a false norovirus positive result.
5. Some nonspecific reactions were documented by the newborns: the presence of both adenovirus and rotavirus lines should be interpreted carefully.[7]

【PRINCIPLE】

The **test** is a qualitative, lateral flow immunoassay for the detection of norovirus, rotavirus, adenovirus and astrovirus in human feces. During testing, the specimen reacts with the conjugate antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with corresponding specific monoclonal antibodies coated on the membrane and generates a colored line at the level of the T line. The presence of a colored line in T region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control reaction zone (C) indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The Combo Test comprises of four parts and details of each part are given here.

The norovirus rapid test contains mouse IgG, norovirus Genogroup 1 and Genogroup 2 monoclonal antibodies coated particles, Norovirus Genogroup 1, Genogroup 2 and goat anti mouse IgG monoclonal antibodies coated on the membrane.

The rotavirus rapid test contains mouse IgG,and anti-rotavirus antibody coated particles, goat anti mouse IgG and anti-rotavirus antibody coated on the membrane.

The adenovirus rapid test contains mouse IgG and anti-adenovirus antibody coated particles, goat anti mouse IgG and anti-adenovirus antibody coated on the membrane.

The astrovirus rapid test contains mouse IgG and anti-astrovirus antibody coated particles, goat anti mouse IgG and anti-astrovirus antibody coated on the membrane.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

NOTE: It is suggested to use the test cup within one hour after removing it from the foil pouch.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms the test cup is working well.

【PERFORMANCE CHARACTERISTICS】

	Sensitivity	Specificity	Overall Accuracy
Rota	98.0%	98.0%	98.0%
Adeno	96.0%	99.0%	98.0%
Noro	98.1%	99.2%	99.0%
Astro	95.2%	99.2%	98.3%

Performance data of rotavirus obtained by clinical study with 150 participants enrolled. Performance data of adenovirus obtained by clinical study with 150 participants enrolled. PCR has been utilized as reference method for rotavirus and adenovirus. Performance data of norovirus obtained by clinical study with 302 participants enrolled. Performance data of astrovirus obtained by clinical study with 302 participants enrolled. ELISA has been utilized as reference method for norovirus and astrovirus.

Limit of Detection (LOD)

	Rota	Adeno	Noro	Astro
LOD	50ng/mL	25ng/mL	G1: 25ng/mL G2: 20ng/mL	350 ng/mL

Hook Effect

No high-dose hook effect was detected at the concentration up to 1.32 mg/mL for rotavirus, 1mg/mL for adenovirus, 1.17mg/mL for norovirus G1, 0.51mg/mL for norovirus G2 and 2.54mg/mL for astrovirus.

Precision-Repeatability

No difference was detected in intra lot.

Precision-Reproducibility

No difference was detected between days, sites, lots and operators.

Cross-Reactivity

No cross-reactivity was observed when tested with following organisms:

Acinetobacter calcoaceticus	*Klebsiella pneumonia*
Candida albicans	*Proteus mirabilis*
E. coli	*Salmonella choleraesius*
Group A Streptococcus	*Branhamella catarrhalis*
Hemophilus influenza	*Enterococcus faecium*
Neisseria meningitidis	*Gardnerella vaginalis*
Pseudomonas aeruginosa	*Group C Streptococcus*
Acinetobacter spp	*Neisseria gonorrhea*
Chlamydia trachomatis	*Proteus vulgaris*
Enterococcus faecalis	*Staphylococcus aureus*
Group B Streptococcus	*Coxsackie virus A9*
Coxsackie virus A16	*Coxsackie virus B1-B5*
Enterovirus 68	*Enterovirus 71*
ECHO virus type 6	*ECHO virus type 11*
ECHO virus type 14	*ECHO virus type 30*

Interfering Substances

The following potentially interfering substances does not interfere with the test results.

Name	Concentration	Name	Concentration
Ascorbic acid	20 mg/dL	Oxalic acid	60 mg/dL
Uric acid	60 mg/dL	Aspirin	60 mg/dL
Glucose	2000 mg/dL	Urea	2000 mg/dL
Bilirubin	100 mg/dL	Albumin	6000 mg/dL
Caffeine	40 mg/dL	Montmorillonite powder	60mg/mL
Racecadotril	6mg/L	Loperamide capsules	0.3mg/L

【ADDITIONAL INFORMATION】

1. How does the test work?

Noroviruses are a major cause of acute gastroenteritis worldwide. Rotavirus is the most common agent responsible for acute gastroenteritis, mainly in young children. Adenovirus primarily Ad40 and Ad41, are a leading cause of diarrhea in many of these children, second only to the rotaviruses. Human astrovirus have been shown in numerous studies to be an important cause of gastroenteritis in young children worldwide.

The test is for the qualitative detection of norovirus/rotavirus/ adenovirus/astrovirus antigens in self-collected fecal specimens. A positive result indicates norovirus and/or rotavirus/adenovirus/ astrovirus antigens present in the specimen.

2. When should the test be used?

You can do this test at home as an early diagnosis of rotavirus and/or adenovirus and/or norovirus and/or astrovirus infection when you have the symptoms such as repeated stomach and intestinal troubles (acute gastroenteritis, diarrhea etc.).

3. Can the result be incorrect?

The results are accurate as far as the instructions are carefully respected. Nevertheless, the result can be incorrect if the test gets wet before performing the test or if the quantity of feces dispensed in the dilution buffer is too much or not sufficient.

Besides, due to immunological principles involved, there exist the chances of false positive or false negative results in rare cases under proper use and normal conditions. A consultation with the doctor is always recommended for such tests based on immunological principles.

4. How to interpret the test if the color and the intensity of the lines are different?

The color and intensity of the lines have no importance for result interpretation. The test should be considered as positive whatever the color intensity of the test line is.

5. What is the line that appears under the mark C (control) for?

When this line appears, it only means that the test unit is performing well.

6. What is a false positive result?

A false positive test result means the rotavirus and/or adenovirus and/or norovirus and/or astrovirus antigen is not present but shows detected by the device. The most common causes of a false positive test are cross reactants or unknown interference in the sample.

7. What is a false negative result?

A false negative test means the rotavirus and/or adenovirus and/or norovirus and/or astrovirus antigen is present but is not detected by the device. False negative results may occur if the specimen is improperly collected or handled.

8. What do I have to do if the result is positive?

If the result is positive, it means that the norovirus and/or rotavirus and/or adenovirus and/or astrovirus antigens were detected in feces and that you should consult a doctor to show the test result. Then, the doctor will decide whether additional analysis should be performed.

9. What do I have to do if the result is negative?

If the result is negative, it means that it was not possible to detect the norovirus or rotavirus or adenovirus or astrovirus antigens. However, if the symptoms persist, it is recommended to see a doctor.

【BIBLIOGRAPHY】

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2. Wilhelmi I, Roman E, Sanchez-Fauquier A. (2003). Viruses Causing Gastroenteritis. Clin Microbiol Infect. 9: 247-262.
3. Hung T, et al. (1984). Waterborne Outbreak of Rotavirus Diarrhoea in Adults in China caused by a Novel Rotavirus. Lancet. 1(8387): 1139-1142.
4. Cukor G, Perron DM, Hudson R, Blacklow NR. (1984) Detection of Rotavirus in Human Stools by Using Monoclonal Antibody. J. Clin. Microl. 19(6): 888-892.
5. Wood D J, A S Bailey. (1987). Detection of Adenovirus Types 40 and 41 in Stool Specimens by Immune Electron Microscopy. Journal of Medical Virology. 21: 191-199.
6. Brown DW, Gunning KB, Henry DM, et al. (2008). A DNA Oligonucleotide Microarray for Detecting Human Astrovirus Serotypes. Journal of Virological Methods. 147(1): 86–92.
7. Jones NK, Ranellou K, Zhang H, Jalal H. Adenovirus pseudo-outbreak in a large UK neonatal intensive care unit. Am J Infect Control. 2018;46(12):1411-1413.

Index of Symbols

	Consult instructions for use or consult electronic instructions	Σ	Contains sufficient for <n> tests	30°C 2°C	Temperature limit
	for use				
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer	UDI	Unique device identifier

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Germany

Summary of safety and performance is available on website: https://ec.europa.eu/tools/eudamed/

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Number:14604132500
Revision Date:2026-08-24