BandiCheck Rotavirus, Adenovirus & Norovirus 3-in-1 Rapid Test Kit

1. Product Contents

This product contains a test device packaged in a sealed aluminium foil bag, which includes 3 test strips to detect the presence of the following in the stool sample, including Rotavirus antigen (RVAg),Adenovirus antigen (AdAg), Norovirus GI antigen (NoV(GI) Ag) and Norovirus GII antigen (NoV(GII) Ag). The product also includes: 1 buffer solution, 2 disposable stool collection paper, 1 product instruction manual and 1 biohazard waste disposal bag.

2. Intended Use

2.1 The purpose of this product is to provide a preliminary test for the user's reference. If the test result is positive, the user should seek the opinion of medical personnel as soon as possible together with the test result. If the result is negative, it does not mean the user does not have the above-mentioned diseases. If the symptoms or physical discomfort persist, the user should also seek the opinion of professional medical personnel as soon as possible. Banitore, BandiCheck and its distributors will not be responsible for any differences between the product and routine medical diagnostic test results.
2.2 Users can choose to use the disposable stool collection paper included with the product, or the collection method provided on the website of the Departmentof Health of Hong Kong Special Administrative Region (please scan the QR code below). After following the instructions to perform the subsequent steps, the test device will check whether the stool contains the target viral antigens. If present, the result will be positive, and vice versa.

Suggested stool collection method accordingly to Department of Health of HKSAR

2.3 This product helps to accurately identify the root cause of infection, enabling targeted treatment. By identifying the specific type of pathogen, specific treatment methods can be selected, improving the effectiveness of the treatment.

3. Warnings and Precautions

3.1 Please read the following instructions and follow each step in order to obtain accurate test results.
3.2 Thoroughly wash your hands before and after the test.
3.3 This product is for in vitro diagnostic use only.
3.4 All components inside the test kit are for single use only, do not use them for multiple tests or reuse.
3.5 Do not mix components from different test kits.
3.6 Do not use expired products.
3.7 Do not use if the product packaging is damaged, poorly sealed, or the buffer solution is leaking.
3.8 Avoid testing at high temperatures (above 30℃).
3.9 Test kit stored at low temperatures must be balanced to room temperature (18-28℃) before opening and use.
3.10 Do not perform the test in public places.
3.11 Do not touch the test strip area on the test device.
3.12 When handling samples, all samples should be considered as potentially infectious.
3.13 The test result should be read within the specified time after adding the buffer solution to the test device.

3.14 Appropriate biosafety procedures should be followed to handle used products, such as placing all components in the waste bag included in the product and disposing it in a non-public place.
3.15 If the buffer solution contacts the skin or eyes, please rinse with plenty of water. If you feel unwell, please seek help from professional medical personnel.
3.16 If the test result is positive, you should wear personal protective equipment such as disposable gloves and a mask before handling the used product. You should also notify any cohabitants or close contacts.
3.17 The used test device, stool collection papers, and other accessories that have been used may contain and transmit viruses, all used components should be disposed as biohazardous waste.
3.18 Whether the collection paper can be flushed without causing a blockage is highly depending on the design of each different drainage system.

4. Overview of Viruses

4.1 Those three viruses targeted by the product can all cause viral gastroenteritis, with the main symptoms including diarrhea and vomiting. According to the information from the Centre for Health Protection of the Department of Health of the Hong Kong Special Administrative Region, the most common causes of viral gastroenteritis are norovirus and rotavirus infections. In addition to diarrhea and vomiting, other symptoms include headache, fever, and abdominal pain. Patients typically develop symptoms 1-2 days after infection, and the duration of symptoms can last 1-10 days, depending on the specific virus causing the illness. The following section is written based on the publicly available information from the Centre for Health Protection.
4.2 Norovirus is a common causes of acute gastroenteritis and food poisoning, typically associated with the consumption of undercooked shellfish. The incubation period is usually 12-48 hours. People can become infected with norovirus through contact with infected individuals, consuming contaminated food or water, or by touching contaminated surfaces. Individuals of all age groups are at risk of infection, which is more common in the winter. Symptoms include nausea, vomiting, diarrhea, abdominal pain, mild fever, and general discomfort.
4.3 Rotavirus is one of the most common causes of severe diarrhea in children under the age of 5 globally. The incubation period is typically less than 48 hours, but can be as long as 72 hours. Rotavirus is primarily transmitted through the fecal-oral route, and can also spread through the consumption of contaminated food or water, or contact with contaminated surfaces. Rotavirus infections are more common during cooler seasons, and outbreaks can occur more easily in settings like daycare centers. The main symptoms of rotavirus infection include fever, abdominal pain, vomiting, and watery diarrhea. Young children may occasionally develop severe dehydration as a result of the illness.
4.4 Adenovirus infection can cause respiratory symptoms as well as diarrhea, eye inflammation, and rashes, with an incubation period generally ranging from 2 to 14 days. Adenoviruses are primarily transmitted through respiratory droplets, direct contact with the oral and nasal secretions of infected individuals, or by consuming contaminated food or water. Adenovirus infections can occur year-round and can lead to outbreaks of acute respiratory and eye infections in settings such as schools and hospitals. Symptoms of adenovirus infection may include cough, runny nose, sore throat, and fever, as well as abdominal pain and diarrhea for gastrointestinal infections, along with eye inflammation. Children, the elderly, and individuals with weakened immune systems are more susceptible to infection.

5. Testing Principle

The product uses lateral flow immunoassay technology to detect three types of viral antigens in human stool samples, including Rotavirus antigen, Adenovirus type 40 and 41 antigens and Norovirus (GI) and Norovirus (GII) antigens. The product has 3 test strips, and the specific detection principle is as follows:
5.1 The detection zone of each strip is coated with specific antibodies targeting these three types of viruses.

5.2 The conjugate pad at the bottom of the test strip contains monoclonal antibodies specific to the target viruses, conjugated with latex microbeads.
5.3 If the sample contains any of the target viral antigens, they will form immune complexes with the labeled antibodies on the conjugate pad.
5.4 These immune complexes will then migrate through capillary action to the detection zone, where they will be captured by the specific antibodies, resulting in a pink or light purple test line appearing.
5.5 Each strip also has a control line to ensure the validity of the testing process.

6. Storage and Stability
6.1 The test kit should be stored at 2-30℃. Do not freeze or store above 30℃.
6.2 If stored at 2-8℃, ensure the kit is balanced to room temperature before use.
6.3 The manufacturing date, batch number, and expiry date are printed on the outer packaging. Please use the product before , and do not use after the expiry date.
6.4 The shelf life of this test kit is 24 months from the manufacturing date.
6.5 The test card should be used within 15 minutes after taking it out from the aluminium foil pouch.
6.6 If you have any questions regarding the product quality, please contact customer service using the contact information provided on the packaging.

7. Limitations
7.1 This test kit is for in vitro diagnostic use only, and the results cannot be used as the sole basis for diagnosis.
7.2 Diagnosis should be made based on a comprehensive assessment of clinical symptoms, epidemiological conditions, and further clinical data.
7.3 If the test is not performed according to the correct procedures, the accuracy of the test results may be affected or lead to invalid test.
7.4 This test kit is only for presumptive testing, and confirmatory testing should be performed by a medical laboratory.
7.5 The accuracy of the test depends on the sample collection process.
7.6 Improper sample collection may affect the test results.
7.7 A positive test result does not rule out co-infections with other pathogens or viruses.
7.8 Negative results may be due to:
  7.8.1 Improper sample collection, transfer, or handling, resulting in viral load below the detection limit.
  7.8.2 Viral gene mutations that render the detection antibodies ineffective.
  7.8.3 Product storage issues that render the detection antibodies ineffective.
  7.8.4 Product usage issues that prevent the product from functioning properly.
7.9 A negative result does not mean the patient is not infected. If symptoms appear, the patient should seek medical advice as soon as possible .
7.10 This product can only provide a qualitative detection of the presence of rotavirus antigen, adenovirus type 40 or 41 antigen, and norovirus (GI type) or norovirus (GII type) antigen in the sample, but cannot determine the concentration of the antigens in the sample.
7.11 Like most immunoassays, it may not be able to detect new variant virus antigens, or the sensitivity may be lower for new variant viruses. For the latest information on the effectiveness against new variant viruses, please refer to the updates published on the Banitore® online store website (https://shop.banitore.com.hk/pages/latestnews).
7.12 The test performance in immunodeficient patients has not been evaluated.

8. Product Performance Characteristics
8.1 Clinical Performance
The product has undergone clinical comparative evaluation to confirm the relative sensitivity, specificity, and accuracy of the product can meet the expected requirements.

8.1.1 Norovirus

Reference \ Product	Positive	Negative	Total
Positive	110	1	111
Negative	0	259	259
Total	110	260	370

Relative sensitivity of Norovirus antigen = 100%
Relative specificity of Norovirus antigen = 99.62%
Relative accuracy of Norovirus antigen = 99.73%

8.1.2 Rotavirus

Reference \ Product	Positive	Negative	Total
Positive	111	1	112
Negative	1	246	247
Total	112	247	359

Relative sensitivity of Rotavirus antigen = 99.11%
Relative specificity of Rotavirus antigen = 99.60%
Relative accuracy of Rotavirus antigen = 99.12%

8.1.3 Adenovirus

Reference \ Product	Positive	Negative	Total
Positive	107	1	108
Negative	1	240	241
Total	108	241	349

Relative sensitivity of Adenovirus antigen = 99.07%
Relative specificity of Adenovirus antigen = 99.59%
Relative accuracy of Adenovirus antigen = 99.43%

8.2 Detection Limit

The detection limit (LOD) refers to the minimum concentration of the virus that can be reliably detected in at least 30 repeated tests, with 95% of the repeated test results being positive. The detection limits for each detectable virus or specific viral strain are as follows:

Virus Type	Dilution Concentration	Detection Rate
Rotavirus	4ng/ml	100%
Adenovirus	2.5ng/ml	100%
Norovirus	7ng/ml	97%

8.3 Cross-Reactivity

This test evaluates whether the product will react with other pathogens besides the target substances, which could interfere with the accuracy of the test results. Each pathogen will be tested in 3 replicates, and this test also includes evaluating the cross-reactivity between the target viruses of the product.

Pathogen	Cross-Reactivity		
	Rotavirus (Yes/No)	Adenovirus (Yes/No)	Norovirus (Yes/No)
Rotavirus A	Yes	No	No
Adenovirus	No	Yes	No

Norovirus	No	No	Yes
Sapovirus	No	No	No
Coxsackievirus B5	No	No	No
Enterovirus	No	No	No
EV71 virus	No	No	No
Coxsackievirus A24	No	No	No
Echovirus 6	No	No	No
Rhinovirus A30	No	No	No
Rhinovirus B72	No	No	No
Enterovirus EV70	No	No	No
Coxsackievirus A16	No	No	No
Hepatitis A virus	No	No	No
Astrovirus	No	No	No
Hepatitis E virus	No	No	No
Astrovirus	No	No	No
Staphylococcus aureus	No	No	No
Salmonella Typhi	No	No	No
Salmonella Paratyphi B	No	No	No
Salmonella Paratyphi A	No	No	No
Salmonella Paratyphi C	No	No	No
Salmonella Enteritidis	No	No	No
Salmonella Enteritidis subspecies enteritidis	No	No	No
Salmonella Typhimurium	No	No	No
Yersinia enterocolitica	No	No	No
Yersinia pseudotuberculosis	No	No	No
Group B Streptococcus	No	No	No
Group A Streptococcus	No	No	No
Streptococcus pneumoniae	No	No	No
Enterococcus	No	No	No
Shigella dysenteriae	No	No	No
Campylobacter jejuni subspecies jejuni	No	No	No
Campylobacter coli	No	No	No
ETEC	No	No	No
Escherichia coli	No	No	No
EPEC	No	No	No
EIEC	No	No	No
EAEC	No	No	No
EHEC	No	No	No
Clostridium difficile	No	No	No
Clostridium perfringens	No	No	No
Klebsiella pneumoniae	No	No	No
Vibrio parahaemolyticus	No	No	No
Aeromonas hydrophila	No	No	No
Vibrio vulnificus	No	No	No
Vibrio cholerae	No	No	No

8.4 Interference Substances

Interference substance testing is used to evaluate whether substances that are naturally present or artificially introduced along with the sample may affect the accuracy of the product at a certain concentration. The evaluated concentration of potential interfering substances is equivalent to three times the detection limit. The test method involves transferring 50 μL of the interfering substances at the specified concentrations listed below into the sample, and then using the product to perform the interference test. When the interfering substances were tested at the concentrations shown in the table below, the listed substances did not interfere with the test results of the product.

Interference Substances	Concentration
Hemoglobin	0.5mg/mL
Triglycerides	40mg/mL
Intestinal mucus (mucoproteins)	0.8mg/mL
White blood cells	$5.0x10^8$cells/L
Antinuclear antibodies	1:100dilution
Rheumatoid factor	250IU/mL
Anti-mitochondrial antibodies	1:100dilution
Human anti-mouse antibodies	322ng/mL
Compound Coptis powder	2.4mg/L
Norfloxacin	8mg/L
Montmorillonite powder	0.3mg/mL
Lactobacillus preparation (Mammy Love)	2mg/mL
Hydrochloride loratadine	1mg/L
Levofloxacin	4mg/L
Azithromycin	10mg/L
Penicillin	200,000U/L
Ceftriaxone sodium	40mg/L
Meropenem	40mg/L
Interferon	200,000U/L

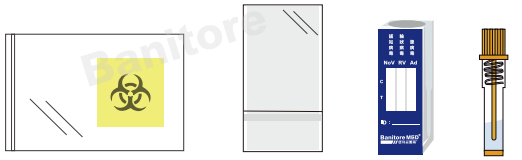
9. Test Procedure

9.1 First, check components and quantities contained in the product are correct.

Components	Quantity
Test Device	1
Disposable Stool Collection Paper	2
Buffer Solution	1
Product Instruction Manual	1
Biohazard Waste Disposal Bag	1

Note: Do not mix components from different batches when using.

9.2 Take out all the components from the test kit at room temperature (18-28℃) and ensure they are balanced to room temperature before use.



Biohazard waste disposal bag | Disposable stool collection paper | Test device | Buffer

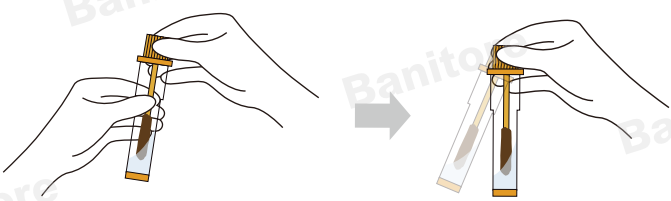
9.3 Steps 9.4-9.8 below describe the sampling procedure for individuals who defecate in a toilet. If the user needs to collect sample from a person who requires assistance with incontinence products like diapers, user can collect the sample directly from the diaper after ensure the stool sample is not contaminated by urine. Then, further proceed based on the instruction in Step 9.9.
9.4 Lift the toilet seat.
9.5 Open the packaging of the disposable stool collection paper and take it out.
9.6 According to the diagram below, put the collection paper in the toilet seat, ensuring the middle part of the paper is suspended over the toilet opening.
9.7 Close the toilet seat to ensure the collection paper is sandwiched between the seat and the toilet.

9.8 Pass stool gently, without excessive force or hurry. Ensure there is stool collected on the paper.

9.9 Unscrew the cap of the buffer solution. Using the sampling stick attached to the cap, swab the surface of the stool from side to side.

9.10 Filling stool on the spiral groove on the tip of the sampling stick is enough. Overfilling or underfilling may affect the test results. Please refer to the diagram below for details.

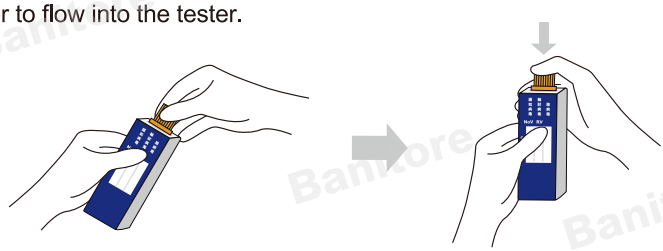
9.11 Place the stool collection swab back into the buffer solution, tighten the cap, and shake it gently about 10 times to mix the stool with the buffer.



9.12 Flush the collection paper and stool, and thoroughly wash your hands after. (If sampling from a diaper, properly dispose the diaper and thoroughly wash your hands before proceeding to the next step.)

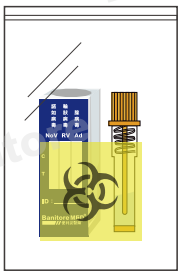
9.13 Tear open the aluminum foil pouch containing the test device, and taking out the test device.

9.14 Insert the buffer into the round opening of the test device and apply firm pressure to allow the protruding part at the bottom of the device's round opening to pierce the aluminum seal at the bottom of the buffer, enabling the buffer to flow into the tester.



9.15 The test results should be read 15 minutes after the buffer has flowed into the test device; any results observed after 20 minutes are considered invalid.

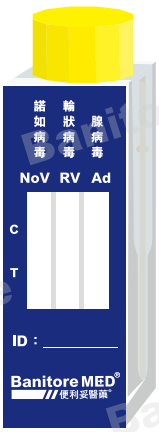
9.16 After completing the test, place all accessories into the biohazard waste disposal bag, seal it securely, and dispose it according to local regulations.



9.17 Wash your hands thoroughly again after disposal.

10. Interpreting Test Results

The product has one test device with 3 test papers. When the test device is facing towards the user (as shown in the picture below), the leftmost test paper is for norovirus antigen, the middle one is for rotavirus antigen, and the rightmost one is for adenovirus antigen.



10.1 Interpreting the Norovirus Antigen Test Results

The test strip has a total of 1 control line and 1 test line. The test line is represented by the letter T, and the control line is represented by the letter C.

10.1.1 If both the control line (C) and the test line (T) appear as a pink or light purple color, it indicates that the stool sample has tested positive for norovirus antigen. This means you have a high chance of being infected with norovirus, and it is recommended that you seek medical attention promptly.

10.1.2 If only the control line (C) appears as a pink or light purple color, it indicates that the stool sample did not contain any detectable norovirus antigen, and the test result is negative.

10.1.3 If there is no control line (C) displayed, regardless of the result of the test line (T), it means the test is invalid. Please review the procedure of each step and repeat the test using a new test kit.

Positive result

Negative result

10.2 Interpreting the Rotavirus Antigen Test Results

The test strip has a total of 1 control line and 1 test line. The test line is represented by the letter T, and the control line is represented by the letter C.

10.2.1 If both the control line (C) and the test line (T) appear as a pink or light purple color, it indicates that the stool sample has tested positive for rotavirus antigen. This means you have a high chance of being infected with rotavirus, and it is recommended that you seek medical attention promptly.

10.2.2 If only the control line (C) appears as a pink or light purple color, it indicates that the stool sample did not contain any detectable rotavirus antigen, and the test result is negative.

10.2.3 If there is no control line (C) displayed, regardless of the result of the test line (T), it means the test is invalid. Please review the procedure of each step and repeat the test using a new test kit.

Positive result

Negative result

10.3 Interpreting the Adenovirus Antigen Test Results

The test strip has a total of 1 control line and 1 test line. The test line is represented by the letter T, and the control line is represented by the letter C.

10.3.1 If both the control line (C) and the test line (T) appear as a pink or light purple color, it indicates that the stool sample has tested positive for adenovirus antigen. This means you have a high chance of being infected with adenovirus, and it is recommended that you seek medical attention promptly.

10.3.2 If only the control line (C) appears as a pink or light purple color, it indicates that the stool sample did not contain any detectable adenovirus antigen, and the test result is negative.

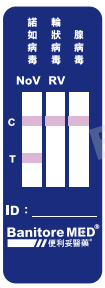
10.3.3 If there is no control line (C) displayed, regardless of the result of the test line (T), it means the test is invalid. Please review the procedure of each step and repeat the test using a new test kit.

Positive result

Negative result

10.4 Definition of Positive Results

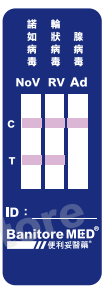
A positive result indicates that the sample being tested contains the antigen or antibody of the corresponding virus, which suggests a high likelihood of viral infection. The user should consider the history of exposure, medical history, and other clinical diagnostic information, and seek the professional judgment of a doctor to determine whether a viral infection has occurred. Users with positive test results should seek medical help as soon as possible. Please note that a positive result does not rule out the possibility of concurrent infection with other viruses or bacteria.



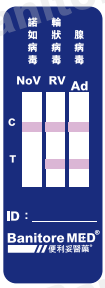
Positive with Norovirus

Positive with Rotavirus

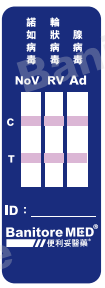
Positive with Adenovirus



Positive with Norovirus and Rotavirus



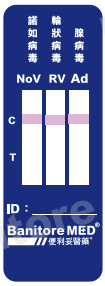
Positive with Rotavirus and Adenovirus



Positive with Norovirus, Rotavirus and Adenovirus

10.5 Definition of Negative Results

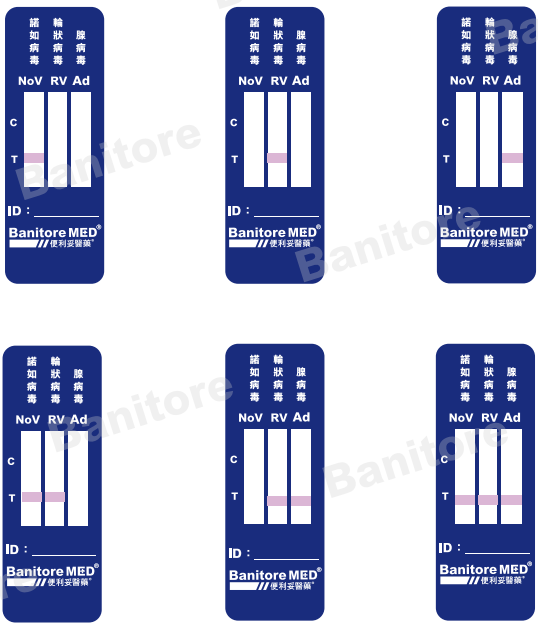
If only the control line (C) appears, and none of the test lines show any color, it indicates that the sample being tested does not contain the antigen or antibody of the corresponding virus. However, this does not completely rule out the possibility of the aforementioned viral infection. Users with negative test results who still have symptoms of viral infection should seek medical help as soon as possible.



Negative result

10.6 Definition of Invalid Results

If there is no control line displayed, it means the test is invalid. In most cases, this is due to not properly following the test procedure and instructions. Please review the procedure of each step and repeat the test using a new test kit.



Invalid result

IVD	In Vitro Diagnostic Use
	Tests per Kit
LOT	Batch number
	Manufacturer
	Expiry Date
	Keep Dry
	Store between 2~30 ℃
	Do not use if packaging is damaged
	See Instruction for Use
	Manufacturing Date
	Do Not Reuse
	Keep away from Sunlight
REF	Model No.

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Customer Service: cs@banitore.com.hk

Manufactured under the commission of Banitore®

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