

Five Infectious Diarrhea Virus Nu-
cleic Acid Test Kit

(PCR-Fluorescent Probe Method)

1 【Product Name】

Five Infectious Diarrhea Virus Nucleic Acid Test Kit
(PCR-Fluorescent Probe Method)

2 【Specification】

10 tests/ kit (10200145A), 50 tests/ kit (10200145B)

3 【Intended Use】

This kit is used for in vitro qualitative test of nucleic acids of Norovirus (Type GI and GII), Sapovirus (Type I, II and V), Rotavirus (Group A, B and C), Astrovirus and Enteric adenovirus in rectal swab and unformed stool (liquid or semi-liquid).

Diarrheal disease is one of the global public health problems. Infectious diarrhea, as a classification of the etiology of diarrheal disease, has a high incidence and wide prevalence, and is an important disease that harms human health. Diarrheal viruses that cause acute intestinal infectious diseases are mainly Norovirus, Sapovirus, Rotavirus, Astrovirus, Enteric adenovirus and so on.

The test results of this product are for clinical reference only and should not be used as the sole criterion for clinical diagnosis. It is recommended to comprehensively analyze the patient's condition by integrating clinical manifestations, other laboratory tests, and relevant diagnostic criteria.

4 【Principle of the Procedure】

The Five Infectious Diarrhea Virus Nucleic Acid Test Kit (PCR-Fluorescent Probe Method) is an automated in vitro diagnostic test that uses real-time fluorescent PCR for the qualitative detection of Norovirus (Type GI and GII), Sapovirus (Type I, II and V), Rotavirus (Group A, B and C), Astrovirus and Enteric adenovirus. Primers and probes target conserved regions of each pathogen to enable specific amplification and fluorescent detection.

This assay is performed on the iFIND® Full-Automatic Nucleic Acid Detection and Analyzer system, which automates and integrates sample purification, nucleic acid extraction, amplification, and detection. The iFIND system consists of an instrument, a PAD controller with pre-installed software, and pre-configured testing workflows. The system uses single-use, self-contained iFIND cartridges that contain the ultrasonic

buffer and amplification reagents, and function as the reaction chamber for nucleic acid extraction and PCR.

The assay is designed for rectal swab and unformed stool (liquid or semi-liquid). Each cartridge contains an internal control to monitor sample processing efficiency and the presence of PCR inhibitors. During testing, the iFIND instrument measures real-time fluorescence and generates amplification curves for qualitative identification of each target pathogen.

All reactions occur within the sealed cartridge. Because all processing steps are fully contained and isolated within the cartridge, the risk of cross-contamination between samples is effectively minimized.

5 【Reagents】

5.1 Materials Provided

The Five Infectious Diarrhea Virus Nucleic Acid Test Kit contains sufficient reagents to process 10 (10200145A) or 50 (10200145B) samples respectively.

Table 1. Components of Kit A

Cartridges	10 per kit	50 per kit
1. Bead 1, Bead 2, and Bead 3 (freeze-dried)	1 of each per cartridge	1 of each per cartridge
2. Wash Reagent	3 mL per cartridge	3 mL per cartridge
3. Elution Reagent	2 mL per cartridge	3 mL per cartridge
Sample Preservation Solution	2 mL×10 tubes	2 mL×50 tubes
Disposable Transfer Pipettes	10 per kit	50 per kit
Disposable Sampling Swab	10 per kit	50 per kit
Instructions for Use	1 per kit	1 per kit

Note: The disposable transfer pipettes and swab in Kit A are externally sourced, and their shelf life is indicated on their labels.

5.2 Materials Available but Not Provided

Table 2. Contents of Kit B

Positive Control	Components
Lyophilized powder of standard strains containing Norovirus, Sapovirus, Rotavirus, Astrovirus, Enteric adenovirus and internal standard gene fragments	1 test per kit
Negative Control	1 test per kit
Lyophilized powder containing internal standard gene fragments	
Diluent	2 tubes per kit
Nuclease-free water 2 mL	

Kit B provides positive and negative controls designed to confirm proper kit function and to assess the testing environment and operator performance. The controls are recommended to

be used in the following situations:

1. Initial verification: Run both positive and negative controls when using the kit for the first time.
2. Troubleshooting: If questionable or inconsistent results are obtained, run both controls to evaluate the kit, the environment, and operator handling.
3. Environmental monitoring: If contamination of the testing environment is suspected, run both controls to verify result reliability.

6 【Storage, Transport and Handling】

1. Kit A should be stored and transported at 2°C to 28°C, protected from light, and free from freezing. The kits have a shelf life of 12 months when stored under the recommended storage conditions.
2. Production date and expiration date: refer to the outer packaging.

7 【Applicable Instrument】

The Kit is compatible with the Full-Automatic Nucleic Acid Detection and Analyzer (Models: iFIND S2, iFIND S4, iFIND S8; Medical Device Registration Certificate No.: 20233221927) manufactured by RocGene (Xuzhou) Technology Co., Ltd.

8 【Specimen Collection, Handling and Storage】

8.1 Specimen Type

Rectal swab and unformed stool (liquid or semi-liquid)

8.2 Specimen Collection

8.2.1 Rectal swab

Take the lateral decubitus position or the knee-thoracic position. Moisten a sterile swab (provided in the kit) with normal saline (Do not use the provided sample preservation solution). Gently insert the swab 3–4 cm into the rectum along the anal wall, rotate it twice, and withdraw gently. Immediately place the swab into the tube containing the sample preservation solution.

8.2.2 Unformed stool (liquid or semi-liquid)

Collect the unformed stool specimen in a clean container following the laboratory's standard specimen collection procedures. Immerse a sterile swab (provided in the kit) in the stool sample for 2–4 seconds; complete saturation is not required. Insert the swab into the provided sample preservation solution.

8.3 Specimen Storage

1. Maintain recommended storage conditions to preserve specimen integrity.
2. Test specimens as soon as possible after collection.
3. Storage conditions:
 - Room temperature (10–30 °C): 12 hours
 - Refrigerated (2–8 °C): 3 days
 - Frozen (–20 ± 5 °C): 12 months
4. Frozen specimens must be completely thawed and mixed before use.
5. Avoid more than three freeze–thaw cycles.

9 【Assay Procedure】

9.1 Specimen Pre-processing

Mix the sample thoroughly by shaking the tube about 20 times or vortex for approximately 10 seconds. Centrifuge the sample at 5,000 rpm for 5 minutes. Use the supernatant for subsequent testing.

9.2 Cartridge Preparation

1. Open the cartridge lid and remove the aluminum seal.
2. Using the provided pipette, transfer 1 mL of the supernatant (prepared according to Section 9.1) into the sample chamber (large opening) of the cartridge.

Note: Dispense the sample slowly along the chamber wall to avoid bubbles.

3. Close the cartridge lid firmly.

Note: If repeat testing is needed, store the remaining sample at 2–8 °C for up to 3 days.

10 【Run the Test】

1. Power on the RocGene iFIND® System.
2. Log in with your username and password.
3. Wait for the system to complete the self-check. Once finished, click “OK” to enter the “Running” window and select the desired instrument unit.
4. Scan or manually enter the **Cartridge ID**; When the Cartridge ID is entered correctly, the corresponding test project will be selected automatically.
5. Scan or manually enter the **Sample ID**. The Sample ID will be inserted into the middle of the default Experiment Name.

Example: If the default name is 20250907-165208 and Sample ID 888888 is entered, the name becomes 20250907-888888-165741.

6. By default, the Experiment Name is generated from the date and time the system was powered on. Edit if needed; the name will be linked to the test results in the “Analyze” window.
7. Click “Open Door” to open the module.
8. Insert the cartridge with the amplification tube facing the inside of the module.
9. Close the door.
10. Click “Start Run” to initiate the assay.
11. During the run, the green indicator flashes. When complete, it remains solid.
12. After the run finishes, click “OK” in the prompt box.
13. Navigate to the **Analyze** window to review and confirm test results.

11 【Quality Control】

Table 3. Fluorescent Channels and Targets

Channel	Target
ATTO	Enteric adenovirus (EADV)
FAM	Norovirus (NV)
VIC	Rotavirus (RV)

ROX	Sapovirus (SaV)
CY5	Astrovirus (AstV)
CY55	Internal Control

Each test includes an internal quality control (IC), which verifies that the cartridge and test process are functioning properly. If the quality control criteria are not met, the test results shouldn't be interpreted.

Internal Control (IC):

The internal control confirms that:

- the sample was added correctly,
- reagents are functioning as intended,
- the procedure was performed correctly, and
- no interfering substances prevented amplification.

External Controls:

External quality controls (see Section 5.2) are available but not provided. They may be used in accordance with local, state, or federal regulations, as applicable

12 [Cut-off Values]

Based on clinical sample testing, the positive cutoff values for Norovirus, Sapovirus, Rotavirus, Astrovirus, Enteric adenovirus were established using the ROC curve method. A result is considered positive when the Ct value is ≤ 40 in the corresponding detection channel.

13 [Interpretation of Results]

When the instrument is operating normally and the internal control test results meet all requirements, test sample results are analyzed and interpreted. Results are automatically generated by the instrument.

Table 4. Interpretation of Results

Result	Interpretation of results & action
Positive for Norovirus	There is Norovirus virus in the sample.
Positive for Rotavirus	There is Rotavirus virus in the sample.
Positive for Astrovirus	There is Astrovirus virus in the sample.
Positive for Sapovirus	There is Sapovirus virus in the sample.
Positive for Enteric adenovirus	There is Enteric adenovirus virus in the sample.
Negative	There are no above viruses or the content is below the detection limit in the sample.
Invalid	Repeat test using the original sample. If the repeat result remains invalid, consider collecting a new specimen.

14 [Limitations]

1. The test results of this product are for clinical reference only and should not be used as the sole criterion for clinical diagnosis.
2. The primer or probe binding region is a conserved region of the pathogen, and mutations rarely occur, but genetic mutations in the epidemic process of the pathogen cannot be ruled out, resulting in false negatives.
3. Inappropriate sample collection, transportation, handling, experimental procedures, or experimental conditions, may all lead to false negative and/or false positive results.
4. Only common mutations have been validated in clinical trials. Rare or novel strains have not been clinically validated.
5. Contamination by microorganisms and amplification products may cause erroneous results. Strict attention should be paid to laboratory division and the PCR standard laboratory operation method should be followed.

15 [Analytical Performance Characteristics]

1. **Limit of Detection (LoD)**
500 copies/ml.
2. **Analytical specificity**
No cross reactivity with other enteric pathogens.

16 [Warnings and Precautions]

1. For in vitro diagnostic use only. Please read the product manual carefully before operation.
2. All samples for detection should be handled as potentially infectious. Wear laboratory coats, protective disposable gloves and change the gloves often to avoid cross-contamination between samples. Handling of samples and waste must meet relevant requirements outlined in local, state and national regulations.
3. This kit does not contain active substances of human or animal origin.
4. Product performance is verified only for sputum sample and the sample collection and processing method described in section 8 [Specimen Collection, Handling and Storage]. If other sample types or sample collection and processing methods are used, product performance cannot be guaranteed.
5. The kit still has a certain amount of biological load and pollutants after use, handle the reagent with appropriate precautions and good laboratory practice.
6. Note: Improper operation during the storage, transportation and use of the reagent may affect the test results. For example, improper storage and transportation, sample collection, sample processing and test process are not standardized. Please strictly follow the instructions.

17 [Key to symbols]

Symbols	Title	Symbols	Title
	CE Marking		In vitro diagnostic medical device
	Temperature Limitation		Keep away from sunlight

Symbols	Title	Symbols	Title
	Do not use if package is damaged		Do not re-use
	Consult Instruction for Use		Caution
	Manufacturer		Authorized representative in the European Community/ European Union
	Reference	/	/

18 【Basic information】



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