English VER 4.0

Nucleic Acid Extraction Kit (Spin Column)

Instruction for Use CE IVD

Basic UDI **697089547NAEK01R4**

REF

Type A	P08202T2024, 24 Tests/Kit	Applicable for serum, plasma, stool, oropharyngeal swab, nasopharyngeal swab and nasal swab.
	P08202T2050, 50 Tests/Kit	
	P08202T2100, 100 Tests/Kit	
Type B	P08201T2024, 24 Tests/Kit	Applicable for stool, oropharyngeal swab, nasopharyngeal swab and nasal swab.
	P08201T2050, 50 Tests/Kit	
	P08201T2100, 100 Tests/Kit	

INTENDED USE

This kit can be manually used to extract viral DNA and RNA from a variety of liquid samples such as stool, swab, serum, plasma, sputum, etc. The purified nucleic acid can be used in downstream analysis, such as PCR amplification. This kit is for *in vitro* diagnostic use and the operator must be professional personnel.

TEST PRINCIPLE

Guanidinium lysis buffer can release the nucleic acid from the virus particles or cells. After centrifuging, the nucleic acid is adsorbed by the silica gel membrane, then purify the nucleic acid by washing buffer and elute nucleic acid from the membrane by elution buffer.

REAGENT PROVIDED

Nucleic Acid Extraction Kit (spin column) includes the following components:

Type A

No.	Labels	Main Contents	24tests	50 tests	100 tests
1	Lysis Buffer L	Guanidine salt	5 mL/bottle (1 bottle)	12 mL/bottle (1 bottle)	23 mL/bottle (1 bottle)
2	Washing Buffer A (WA)	Guanidine salt	6.5 mL/bottle (1 bottle)	13 mL/bottle (1 bottle)	26 mL/bottle (1 bottle)
3	Washing Buffer B (WB)	Tris Buffer	4.5 mL/bottle (1 bottle)	9.5 mL/bottle (1 bottle)	19 mL/bottle (1 bottle)
4	Elution Buffer	Tris Buffer	5 mL/bottle (1 bottle)	10 mL/bottle (1 bottle)	15 mL/bottle (1 bottle)
5	Column	——	24 pcs/bag (1bag)	50 pcs/bag (1bag)	100 pcs/bag (1bag)
6	Collection Tube	——	24 pcs/bag (1bag)	50 pcs/bag (1bag)	100 pcs/bag (1bag)
7	Proteinase K	Proteinase K	1.3 mL/tube (1tube)	2.6 mL/tube (1tube)	5.2 mL/tube (1tube)
8	RNA Carrier	RNA	120 μg/tube (1tube)	225 μg/tube (1tube)	450 μg/tube (1tube)

Type B

No.	Labels	Main Contents	24tests	50 tests	100 tests
1	Lysis Buffer L	Guanidine salt	5 mL/bottle (1 bottle)	12 mL/bottle (1 bottle)	23 mL/bottle (1 bottle)
2	Washing Buffer A (WA)	Guanidine salt	6.5 mL/bottle (1 bottle)	13 mL/bottle (1 bottle)	26 mL/bottle (1 bottle)
3	Washing Buffer B (WB)	Tris buffer	4.5 mL/bottle (1 bottle)	9.5 mL/bottle (1 bottle)	19 mL/bottle (1 bottle)
4	Elution Buffer	Tris buffer	5 mL/bottle (1 bottle)	10 mL/bottle (1 bottle)	15 mL/bottle (1 bottle)
5	Column	——	24 pcs/bag (1bag)	50 pcs/bag (1bag)	100 pcs/bag (1bag)
6	Collection Tube	——	24 pcs/bag (1bag)	50 pcs/bag (1bag)	100 pcs/bag (1bag)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Reagents needed in the laboratory: ethanol (96%-100%, analytical reagents).
2. Centrifuges whose speed could reach 12000 rpm.
3. Consumables used in laboratory such as gloves, masks, pipette etc.

STORAGE AND SHELF-LIFE

This kit is valid for 12 months when stored at room temperature (15-30°C) in dry condition. This kit can be transported at room temperature (15-30°C). RNA carrier should be stored at -(20±5) °C after dissolved. 6 times repeated freeze-thaw cycles of resolvent RNA carrier have no effect on the performance of the kit (the performance has not been verified when more than 6 times). After adding ethanol, Washing Buffer A(WA) and Washing Buffer B(WB) should be used within 3 months. Lysis Buffer L and Washing Buffer A(WA) may appear white crystals when the temperature is lower than 15 °C. It can be dissolved in 50°C-60°C water bath which has no effect on the performance of the kit.

APPLICABLE SPECIMENS

1. The applicable samples for each specification are listed in the REF part.
2. If the samples are not processed in time, they should be stored at refrigerator ranging from -80 °C to -20 °C. Transport samples at 0~8°C to avoid the repeat of freeze-thawing.

TEST PROCEDURE

1. Type A

1.1. Preparation

1.1.1. Prepare RNA carrier

Centrifuging at 3000-4000rpm for 30s, then add 120 μL Elution Buffer (24 tests), 225 μL Elution Buffer (50 tests) or 450 μL Elution Buffer (100 tests), mix and centrifuge, label the tubes. The RNA carrier solution should be stored at -(20±5) °C.

1.1.2. Prepare lysis solution

Configure the lysis solution according to the following ratio, and mix thoroughly by vortex:

Sample Number	RNA Carrier	Lysis Buffer L	Proteinase K
n	4 μL×(n+1)	200 μL×(n+1)	50μL ×(n+1)

If the number of samples is n, it is recommended to prepare n+1 lysis solution.

1.1.3. Prepare Wash Buffer A(WA)

Add 6.5 mL ethanol (24tests), 13 mL ethanol (50tests) or 26 mL ethanol (100tests) to the Washing

Buffer A(WA), mix ups and downs for 6 times and mark the bottle.

1.1.4. Prepare Wash Buffer B(WB)

Add 18 mL ethanol (24tests), 38 mL ethanol (50tests) or 76 mL ethanol (100tests) to the Washing Buffer B(WB), mix ups and downs for 6 times and mark the bottle.

1.1.5. Preprocess stool samples

Take 0.2 g stool sample into a nuclease-free microcentrifuge tube, add 1mL physiological saline, vortex for 1min, centrifuge at 12000 rpm for 10 min, use the supernatant as the material to be extracted.
Note: Other sample types do not need pre-processing and can be used directly in extraction process.

1.2. Extraction process

1.2.1. If the centrifuge has a refrigeration function, set the temperature to 25°C.
1.2.2. Take n 1.5 mL microcentrifuge tubes, label the tubes and add 254 µL lysis solution (prepared in 1.1.2) into each tube.
1.2.3. Add 200 µL sample, vortex thoroughly.
1.2.4. Centrifuge briefly, stay at room temperature (15°C-30°C) for 5 min.
1.2.5. Place column on collection tube and label the column, transfer all liquid into the column, centrifuge at 12000 rpm for 30 s.
1.2.6. Discard the liquid in the collection tube, add 500 µL Washing Buffer A(WA) to column, and centrifuge at 12000 rpm for 30 s.
1.2.7. Discard the liquid in collection tube, add 450 µL Washing Buffer B (WB) to column, and centrifuge at 12000 rpm for 30 s.
1.2.8. Repeat 1.2.7.
1.2.9. Discard the liquid in collection tube and centrifuge at the maximum speed for 2 min.
1.2.10. Discard the collection tube and place the column on 1.5 mL centrifuge tube. Carefully add 40~100 µL Elution Buffer to the center of the column membrane, and stay for 1 min and centrifuge at 12000 rpm for 2 min.
1.2.11. Discard the column and temporarily store the nucleic acid at 2-8 °C for inspection. The nucleic acid extracted is suggested for immediate detection or store them at-70 °C for long time.

2. Type B

2.1. Preparation

2.1.1. Prepare Wash Buffer A(WA)

Add 6.5 mL ethanol (24tests), 13 mL ethanol (50tests) or 26 mL ethanol (100tests) to the Washing Buffer A(WA), mix ups and downs for 6 times and mark the bottle.

2.1.2. Prepare Wash Buffer B(WB)

Add 18 mL ethanol (24tests), 38 mL ethanol (50tests) or 76 mL ethanol (100tests) to the Washing Buffer B(WB), mix ups and downs for 6 times and mark the bottle.

2.1.3. Preprocess stool samples

Take 0.2 g stool sample into a nuclease-free microcentrifuge tube, add 1mL physiological saline, vortex for 1min, centrifuge at 12000 rpm for 10 min, use the supernatant as the material to be extracted.
Note: Other sample types do not need pre-processing and can be used directly in extraction process.

2.2. Extraction process

2.2.1. If the centrifuge has a refrigeration function, set the temperature to 25°C.
2.2.2. Take n 1.5 mL microcentrifuge tubes, label the tubes and add 200 µL Lysis Buffer L to each tube.
2.2.3. Add 200 µL sample to the tube with Lysis Buffer L, vortex thoroughly.
2.2.4. Centrifuging briefly, stay at room temperature (15°C-30°C) for 5 min.
2.2.5. Place column on collection tube and label the column, transfer all liquid into the column, centrifuge at 12000 rpm for 30 s.
2.2.6. Discard the liquid in the collection tube, add 500 µL Washing Buffer A(WA) to column, and centrifuge at 12000 rpm for 30 s.
2.2.7. Discard the liquid in collection tube, add 450 µL Washing Buffer B (WB) to column, and centrifuge at 12000 rpm for 30 s.
2.2.8. Repeat 2.2.7.
2.2.9. Discard the liquid in collection tube and centrifuge at the maximum speed for 2 min.
2.2.10. Discard the collection tube and place the column on 1.5 mL centrifuge tube. Carefully add 40~100 µL Elution Buffer to the center of the column membrane, and stay for 1 min and centrifuge at 12000 rpm for 2 min.
2.2.11. Discard the column and temporarily store the nucleic acid at 2-8 °C for inspection. The nucleic acid extracted is suggested for immediate detection or store them at-70 °C for long time.

LIMITATIONS OF THE TEST

1. The purity and quality of nucleic acid extracted by this kit are affected by the instrument and personnel.
2. All the performances described in the instruction for use were evaluated by a specific pathogen and the related PCR detection kit, it is recommended to assess the performance according to a specific application.

PERFORMANCE CHARACTERISTICS

1. The PCR detection kit for Hepatitis A virus (HAV) and Hepatitis B virus (HBV) were used to evaluate the precision, limit of detection and interference of this kit in serum and plasma specimens. The results show the intra-batch coefficients of variation are less than 5% and inter-batch coefficients of variation are less than 5%, the limit of detection is 30IU•mL-1 and 800g•L^{-1} hemoglobin, 7mmol•L^{-1} blood fat, 0.1g•L^{-1} lamivudine and 0.01g•L^{-1} of adefovir dipivoxil have not affected the performance.
2. The PCR detection kit for *Enterovirus and Adenovirus* were used to evaluate the precision, limit of detection and interference of this kit in oropharyngeal swab, anterior nasal swab and stool specimens. The results show the intra-batch coefficients of variation are less than 5% and inter-batch coefficients of variation are less than 5%, the limit of detection is 500 copies•mL^{-1} and 10% blood, 0.1g•L^{-1} ribavirin and 0.1g•L^{-1} of acyclovir have not affected the performance.
3. The PCR detection kit for Influenza A virus and *Adenovirus* were used to evaluate the precision, limit of detection and interference of this kit in nasopharyngeal swab and nasal swab specimen. The results show the intra-batch coefficients of variation are less than 5% and inter-batch coefficients of variation are less than 5%, the limit of detection is 500 copies•mL^{-1}, and 10% blood, 1mg•mL^{-1} mucoprotein, 0.15mg•L^{-1} dexamethasone and 0.5mg•mL^{-1} of oxymetazoline have not affected the performance.

WARNING AND PRECAUTIONS

a. The purification function of this kit is limited, so try to avoid inhibitors like mucus when sampling nasopharyngeal swab, oropharyngeal swab, and nasal swab. These inhibitors might interfere with the downstream analysis and cause false results.
b. Most viruses are highly contagious. Take various defense measures before operation. Use biological safety cabinets when processing samples.
c. During the operation, please pay attention to preventing RNA degradation by RNase, and avoid contamination of other nucleic acids which might lead to false positives. Microcentrifuge tubes, pipette tips, and other lab consumables must be sterilized. Operators should wear masks and powder-free gloves. Instruments and equipment such as operating tables and pipettes etc. should be wiped and disinfected with 10% sodium hypochlorite or 70% ethanol regularly. The

experiment room and ultra-clean workbench should be treated with UV light regularly and at the end of each experiment.

d. Before the experiment, prepare reagents according to the instruction.
e. Lysis Buffer L and Washing Buffer A (WA) contain irritating compounds. Must be careful to avoid contacting of skin, eyes, and clothes, and prevent inhalation into mouth and nose. If it is contaminated with skin or eyes, rinse immediately with plenty of water or saline, and seek medical advice if necessary.
f. Exceed repetitions of RNA carrier freezing and thawing should be avoided.
g. If there are no special instructions for different batches of reagents, please do not mix them.
h. Please use this kit within the validity period.
i. Dispose of the waste according to biosafety procedures issued by local authorities.

If there is any serious incident occurs in relation to the device, please report to the manufacturer and the competent authority in your country immediately.

Manufacturing date and expiration date: view on label

INDEX OF SYMBOLS

Consult Instructions for Use	Contain <n> tests	Do not use if package is damaged and consult instruction for use
In vitro diagnostic medical device	Use-by date	Authorized Representative in the European Community
Catalogue #	Lot Number	Temperature limit 15 to 30 ℃
Manufacture Date	Manufacturer	CE conformity marking
Unique device identifier		

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Number: 301100053300
Effective Date: 2023-06-09