Nucleic Acid Extraction-Purification Kit

Product Identification

Product Name:Nucleic Acid Extraction-Purification Kit

Catalogue Number: S50016E-12A, S50016E-48, S50016E-96, S50016E-24A, S50016E-24B, S50016E-32-A, S50016E-32-T, S50016E-32-S, S50016E-64-A, S50016E-64-T, S50016E-48A, S50016E-48B, S50016E-48C, S50016E-96A, S50016E-96B

Packaging Specification:

1. Specification for manual operation: 48 tests/kit; 96 tests/kit
2. Specification for the nucleic acid extraction system: 12 tests/kit (12A), 24 tests/kit (24A), 24 tests/kit (24B), 32 tests/kit (32-A), 32 tests/kit (32-T), 32 tests/kit (32-S), 64 tests/kit (64-A), 64 tests/kit (64-T), 48 tests/kit (48A), 48 tests/kit (48B), 48 tests/kit (48C), 96 tests/kit (96A), 7200 tests/kit (96B)

Intended Use

The Nucleic Acid Extraction-Purification Kit is used for nucleic acid extraction, collection, purification and other steps, and the processed product can be used for clinical *in vitro* diagnostic test.

Test Principle

After the sample to be separated containing the target nucleic acid is lysed, DNA/RNA molecule is specifically identified and effectively combined with the magnetic beads, which are absorbed on the tube walls by the magnetic separator afterwards, and then the high-purity DNA/RNA is obtained through the process of washing, elution and purification.

Materials Provided

1. The components of specification for manual operation are as follows:

No.	Reagent Name	Specification & Qty. (48T)	Specification & Qty. (96T)
1	S50016E-Lysis and Binding Solution	40 mL/vial × 1 vial	40 mL/vial × 2 vials
2	S50016E-PW 1	14 mL/vial × 1 vial	28 mL/vial × 1 vial
3	S50016E-PW 2	35 mL/vial × 1 vial	70 mL/vial × 1 vial
4	S50016E-Elution Buffer S	4 mL/tube × 2 tubes	16mL/vial × 1 vial
5	S50016E-Magnetic Beads Solution	1.8 mL/tube × 1 tube	3.5 mL/tube × 1 tube
6	Proteinase K	1.2 mL/tube × 1 tube	2.5 mL/tube × 1 tube

2. The components of specification for the nucleic acid extraction system are as follows:

Specification & Qty. (12A)		
No.	Reagent name	Specification (12T)
1	S50016E-Lysis and Binding Solution (12A)	530 μL/well × 1 well × 12 sets
2	S50016E-PW 1 (12A)	400 μL/well × 1 well × 12 sets
3	S50016E-PW 2 (12A)	700 μL/well × 1 well × 12 sets
4	S50016E-Elution Buffer S (12A)	300 μL/well × 1 well × 12 sets
5	S50016E-Elution Buffer S (12A)	600 μL/well × 2 wells × 12 sets
6	Proteinase K (12A)	30 μL/well × 1 well × 12 sets
7	Transfer Pipet	12 pcs × 1 bag
8	Specimen Bag	12 pcs

Specification & Qty. (24A)		
No.	Reagent name	Specification (24T)
1	S50016E-Lysis and Binding Solution (24A)	500 μL/well × 24 wells × 1 plate
2	S50016E-PW (24A)	800 μL/well × 24 wells × 1 plate
3	S50016E-Elution Buffer S (24A)	80 μL/well × 24 wells × 1 plate
4	Proteinase K (24A)	0.6 mL/tube × 1 tube

Specification & Qty. (24B)		
No.	Reagent name	Specification (24T)
1	S50016E-Lysis and Binding Solution (24B)	750 μL/well × 24 wells × 1 plate
2	S50016E-PW (24B)	800 μL/well × 24 wells × 1 plate
3	S50016E-Elution Buffer S (24B)	80 μL/well × 24 wells × 1 plate
4	Proteinase K (24B)	0.6 mL/tube × 1 tube

Specification & Qty. (32-A)		
No.	Reagent name	Specification (32T)
1	S50016E-Lysis and Binding Solution (32-A)	500 μL/well × 8 wells × 4 plates
2	S50016E-Magnetic Beads Solution (32-A)	130 μL/well × 8 wells × 4 plates
3	S50016E-PW (32-A)	800 μL/well × 8 wells × 4 plates
4	S50016E-Elution Buffer S (32-A)	80 μL/well × 8 wells × 4 plates
5	Proteinase K (32-A)	0.8 mL/tube × 1 tube

Specification & Qty. (32-S)		
No.	Reagent name	Specification (32T)
1	S50016E-Lysis and Binding Solution (32-S)	500 μL/well × 8 wells × 4 plates
2	S50016E-Magnetic Beads Solution (32-S)	130 μL/well × 8 wells × 4 plates
3	S50016E-PW (32-S)	800 μL/well × 8 wells × 4 plates
4	S50016E-Elution Buffer S (32-S)	80 μL/well × 8 wells × 4 plates
5	Proteinase K (32-S)	0.8 mL/tube × 1 tube

Specification & Qty. (32-T)		
No.	Reagent name	Specification (32T)
1	S50016E-Magnetic Beads Solution (32-T)	130 μL/well × 8 wells × 4 plates
2	S50016E-Lysis and Binding Solution (32-T)	500 μL/well × 8 wells × 4 plates
3	S50016E-PW (32-T)	800 μL/well × 8 wells × 4 plates
4	S50016E-Elution Buffer S (32-T)	80 μL/well × 8 wells × 4 plates
5	Proteinase K (32-T)	0.8 mL/tube × 1 tube

Specification & Qty. (64-A)		
No.	Reagent name	Specification (64T)
1	S50016E-Lysis and Binding Solution (64-A)	500 μL/well × 16 wells × 4 plates
2	S50016E-Magnetic Beads Solution (64-A)	130 μL/well × 16 wells × 4 plates
3	S50016E-PW (64-A)	800 μL/well × 16 wells × 4 plates
4	S50016E-Elution Buffer S (64-A)	80 μL/well × 16 wells × 4 plates
5	Proteinase K (64-A)	1.5 mL/tube × 1 tube

Specification & Qty. (64-T)		
No.	Reagent name	Specification (64T)
1	S50016E-Magnetic Beads Solution (64-T)	130 μL/well × 16 wells × 4 plates
2	S50016E-Lysis and Binding Solution (64-T)	500 μL/well × 16 wells × 4 plates
3	S50016E-PW (64-T)	800 μL/well × 16 wells × 4 plates
4	S50016E-Elution Buffer S (64-T)	80 μL/well × 16 wells × 4 plates
5	Proteinase K (64-T)	1.5 mL/tube × 1 tube

Specification & Qty. (48A)		
No.	Reagent name	Specification (48T)
1	S50016E-Lysis and Binding Solution (48A)	500 μL/well × 48 wells × 1 plate
2	S50016E-PW (48A)	800 μL/well × 48 wells × 1 plate
3	S50016E-Elution Buffer S (48A)	80 μL/well × 48 wells × 1 plate
4	Proteinase K (48A)	1.2 mL/tube × 1 tube

Specification & Qty. (48B)		
No.	Reagent name	Specification (48T)
1	S50016E-Lysis and Binding Solution (48B)	500 μL/well × 6 wells × 8 plates
2	S50016E-PW (48B)	800 μL/well × 6 wells × 8 plates
3	S50016E-Elution Buffer S (48B)	80 μL/well × 6 wells × 8 plates
4	Proteinase K (48B)	1.2 mL/tube × 1 tube

Specification & Qty. (48C)		
No.	Reagent name	Specification (48T)
1	S50016E-Lysis and Binding Solution (48C)	500 μL/well × 8 wells × 6 plates
2	S50016E-PW (48C)	800 μL/well × 8 wells × 6 plates
3	S50016E-Elution Buffer S (48C)	80 μL/well × 8 wells × 6 plates
4	Proteinase K (48C)	1.2 mL/tube × 1 tube

Specification & Qty. (96A)		
No.	Reagent name	Specification (96T)
1	S50016E-Lysis and Binding Solution (96A)	500 μL/well × 96 wells × 1 plate
2	S50016E-PW (96A)	800 μL/well × 96 wells × 1 plate
3	S50016E-Elution Buffer S (96A)	80 μL/well × 96 wells × 1 plate
4	Proteinase K (96A)	2.5 mL/tube × 1 tube

Specification & Qty. (96B)		
No.	Reagent name	Specification (7200T)
1	S50016E-Lysis and Binding Solution (96B)	500 μL/well × 96 wells × 75 plates
2	S50016E-PW (96B)	800 μL/well × 96 wells × 75 plates
3	S50016E-Elution Buffer S (96B)	80 μL/well × 96 wells × 75 plates

Materials Required but not provided

- Vortex.
- Magnetic separator.
- Centrifuge and centrifuge tubes.
- Precision pipettes and corresponding tips.
- Heater.

Warnings and Precautions

Warnings

1.Do not mix or exchange components from different kit lots.

Precautions

1.The solution containing magnetic beads must be thoroughly mixed before use. For instantaneous centrifugation at low-speed, it is recommended to centrifuge at 800 rpm for 10 s, to avoid the agglomeration of magnetic beads due to excessively high centrifugal speed.

2.When eluting nucleic acids, the efficiency can be improved by heating at 56 °C .

3.After the addition of the sample in the tube the resulting solution is to be considered potentially biohazardous, handle the reagent with appropriate precautions and good laboratory practice.

4.The safe disposal of the reagents supplied must be carried out according to the instruction contained in the specific Safety Data Sheets and in compliance with the national regulations on disposal of potentially hazardous waste.

5.Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established; If you have any questions about the test or the results, please contact Sansure's customer service hotline +86-731-88883176-6116 or send an email to info@sansure.com.cn/support@sansure.com.cn.

IVD storage, operating conditions and stability

1.This kit should be stored at 2℃ to 25℃ and the shelf life of the kit is 12 months.

2.Please refer to the date of manufacture and expiry date on the outer package.

Specimen Requirements

Specimen types: oropharyngeal swabs, nasopharyngeal swabs, alveolar lavage fluid, sputum, saliva, plasma, serum, stool, anal swabs and exfoliated cells from females' cervix, urine.

Compatible Instrument

It is widely compatible to magnetic bead based nucleic acid extraction system.

Test Method

1. Preparation

1.1 Take out all the components out off the kit and equilibrate them at room temperature.

1.2 According to the quantity of test specimens, pipette appropriate quantity of Proteinase K (20 μL/test) and S50016E-Magnetic Beads Solution (30 μL/test), and mix them thoroughly by a vortex to make a Proteinase K-Magnetic Beads Mixture, then instantaneous centrifuge it at a low speed (**800 rpm for 10 s is recommended**).

2. Manual operation process

2.1 Prepare certain 1.5 mL centrifuge tubes according to the quantity of test samples, and add 300 μL sample into each tube.

2.2 Add 500 μL S50016E-Lysis and Binding Solution and 50 μL Proteinase K-Magnetic Beads Mixture into above centrifuge tubes. Cover the tube lids, and mix them by a vortex for 30 s, then heat at 60 °C for 10 min.

2.3 Keep the centrifuge tubes at room temperature for 1 min, and centrifuge them at a low speed, then put them on the magnetic separator. Slowly aspirate and discard the waste liquid after 5 min (* Be careful not to encounter the magnetic beads adsorbed on the inside of the tube wall).

2.4 Add 200 μL S50016E-PW 1 and 600 μL S50016E-PW 2 into above centrifuge tubes, then mix them by a vortex for 30 s. Place the centrifuge tubes on the magnetic separator again after a low-speed instantaneous centrifugation, and the liquid should be completely sucked out and discarded after magnetic absorption for 3 min.

2.5 Place above tubes into a centrifuge for low-speed instantaneous centrifugation, then place the tubes again on the magnetic separator for magnetic absorption. 3 min later, completely suck out the waste liquid from the bottom of the tubes.

2.6 Add 30-100 μL (80 μL is recommend) S50016E-Elution Buffer S into the above tubes, then mix them by a vortex for 30 s. Elute the magnetic beads on the centrifugal tube wall to the bottom of the tube and keep it at room temperature for 3 min. After low-speed instantaneous centrifugation, place the centrifuge tubes on the magnetic separator again for magnetic absorption. 3 min later, transfer the eluted nucleic acids to 1.5 mL clean centrifuge tubes.

3. The nucleic acid extraction system is operated according to the set procedure. For specific operations, please refer to the operating instructions of the nucleic acid extraction system.

3.1 Operation process of nucleic acid extraction system for 24A/24B, 48A/48B/48C, 96A specification

3.1.1 Take out all the components out off the kit and equilibrate them at room temperature. Shake the liquid that may adhere to the wall of the hole to the bottom, and let it stand for 3 to 5 min.

3.1.2 Take out the required components of the kit, remove the sealing bags and parafilms, and insert them into a 48/96 channel instrument.

3.1.3 Take out the sample plate, then add 300-750 μL test sample and 20 μL Proteinase K to each well.

3.1.4 Turn on the instrument and start the corresponding program.

3.1.5 Place the 48/96-well plate in the well corresponding to the program of the instrument.

3.1.6 The extraction procedure ends after about 15 to 30 min.

3.1.7 Take out the 48/96-well plate containing the nucleic acids solution and transfer the nucleic acids.

3.2 Operation process of nucleic acid extraction system for 32-A, 32-T ,32-S specification

3.2.1 Take out all the components out off the kit and equilibrate them at room temperature. Shake the liquid that may adhere to the wall of the hole to the bottom, and let it stand for 3 to 5 min.

3.2.2 Remove the sealing bags and parafilms; the amount of Proteinase K (32-A) and Proteinase K (32-T) and Proteinase K (32-S)added is 20 μL/well and the sample amount is 300 μL/well. According to the number of samples, add Proteinase K (32-A) and sample to the first hole of 32-A specifications, and add Proteinase K (32-T) and sample to the second hole of 32-T specifications,and add Proteinase K (32-S) and sample to the second hole of 32-S specifications.

3.2.3 Turn on the instrument and start the corresponding program. Put the reagent tube, carrier and magnetic sleeve into the corresponding position of the instrument.

3.2.4 The extraction procedure ends after about 15 to 30 min.

3.2.5 Take out the deep-well plate and transfer the nucleic acids.

3.3 Operation process of nucleic acid extraction system for 64-A, 64-T specification

3.3.1 Take out all the components out off the kit and equilibrate them at room temperature. Shake the liquid that may adhere to the wall of the hole to the bottom, and let it stand for 3 to 5 min.

3.3.2 Remove the sealing bags and parafilms; the amount of Proteinase K (64-A) and Proteinase K (64-T) added is 20 μL/well, and the sample amount is 300 μL/well. According to the number of samples, Proteinase K (64-A) and samples are added to 64-A specifications in A1~H1 and A7~H7, and Proteinase K (64-T) and samples are added to 64-T specifications in A2~H2 and A8~H8.

3.3.3 Turn on the instrument and start the corresponding program. Put the deep-well plate, magnetic sleeve, etc. into the corresponding position of the instrument.

3.3.4 The extraction procedure ends after about 15 to 30 min.

3.3.5 Take out the deep-well plate and transfer the nucleic acids.

3.4 Operation process of nucleic acid extraction system for 96B specification

3.4.1 Take out the required components of the kit, remove the sealing bags and parafilms, and insert them into a 96 channel instrument.

3.4.2 Take out the sample plate, then add 300 μL test sample each well.

3.4.3 Turn on the instrument and start the corresponding program.

3.4.4 Place the 96-well plate and magnetic sleeve in the well corresponding to the program of the instrument.

3.4.5 The extraction procedure ends after about 15 to 30 min.

3.4.6 Take out the 96-well plate containing the nucleic acids solution and transfer the nucleic acids.

3.5 Operation process for 12A specification

3.5.1 Load the amplification reagent component assembly into the extraction reagent component to compose the test reagent cartridge.

3.5.2 Open the seal plug of the sample loading hole, add 300-750 μL test sample into it by transfer pipet (When sample enter the lower bubble of transfer pipet indicating enough sample has been taken). After adding and screwing, place the cartridge into Portable Molecular Diagnostic System (S-Q37A/B).

3.5.3 Turn on the instrument and start the corresponding program.

3.5.4 Place the cartridge in the corresponding place to the program of the instrument.

3.5.5 The procedure ends after about 50 to 60 min.

Explanation of Detection Result

The nucleic acids extracted by this kit can be used for nucleic acids detection, sequence analysis, PCR amplification, molecular hybridization and fluorescence PCR, and is widely used in nucleic acid molecular detection and other related fields.

Limitations of Detection Method

The kit should be used together with the magnetic separator or suitable nucleic acid extraction system.

Performance Index

The extraction kit can be matched with most nucleic acid detection kits in the market, and the extracted nucleic acid can meet the sensitivity and precision requirements of the nucleic acid detection kit.

List of References

[1] SARS-CoV-2 RNA Extraction Using Magnetic Beads for Rapid Large-Scale Testing by RT-qPCR and RT-LAMP. Viruses, 2020.

[2] Magnetic bead-based nucleic acid purification kit: Clinical application and performance evaluation in stool specimens. J Microbiol Methods, 2016.

Symbols Key

Symbols	Meanings	Symbols	Meanings	Symbols	Meanings
IVD	*In vitro* diagnostic medical device		Date of manufacture		Use-by date
	Consult Instructions for use		Temperature Limitation		Manufacturer
LOT	Batch code	REF	Catalogue number	Σ	Contains sufficient for <n> tests
EC REP	Authorized representative in the European	CE	This product fulfills the requirements of Regulation (EU) 2017/746 for *in vitro* diagnostic medical devices.		Caution
	Importer		Keep dry		Keep away from sunlight
	Recycling		Fragile, handle with care		This way up
	Stacking limit by mass is 15kg		PAP21: Not corrugated cardboard	Magnetic Beads	Magnetic Beads Solution
Lysis and Binding	Lysis and Binding Solution	Proteinase K	Proteinase K	PW	PW
PW 1	PW 1	PW 2	PW 2	ELUTION BUFFER S	Elution Buffer S
VERSION	Version	UDI	Unique device identifier	Transfer Pipet	Transfer Pipet
PRE	Prepackaging	SPECIMEN BAG	Specimen Bag		Biological risks
	Do not re-use				

Contact Information

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