

5. After the automatic purification is over, transfer the Elution Buffer in columns 5 and 11 to a clean nuclease-free 0.5mL centrifuge tube; if not using it immediately, please store at -20 degrees.

【Symbol Description】

	CE MARK		CATALOGUE NUMBER
	IN VITRO DIAGNOSTIC MEDICAL DEVICE		BATCH CODE
	CAUTION		MANUFACTURER
	CONSULT INSTRUCTIONS FOR USE		DATE OF MANUFACTURE
	TEMPERATURE LIMITATION		USE BY DATE
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		DO NOT REUSE

【Basic Information】



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【Effective Date】 2020-12-01

MagaBio plus Virus DNA /RNA Purification Kit III

【Product Name】 MagaBio plus Virus DNA /RNA Purification Kit III

【Packing Size】 32 Tests/box; 50 Tests/box; 100 Tests/box

【Usage】 Used for nucleic acid extraction, enrichment, purification and other steps. The isolated product is used for clinical in vitro testing.

【Principle and Advantage】

Nucleic acid in swabs, tissue, stool, blood, serum, plasma and other body fluid samples is released by using Lysis Buffer. Released virus DNA/ RNA is bound exclusively and specifically to the Magnetic beads. The virus DNA/ RNA bound to magnetic particles is captured by magnetic material; contaminants are removed by washing with Wash Buffer. The nucleic acid is then eluted from the particles with an Elution Buffer.

【Kit Components】

Cat#	BSC86S1E	BSC86S1B	BSC86M1B	Components
Components Name	32 T	50 T	100 T	
Lysis Buffer	96 well	25 mL	50 mL	Surfactant and Tris buffer
Wash Buffer I		※ 15 mL	※ 30 mL	High-salt solution
Wash Buffer II	pre- loaded plates	※ 6 mL×2	※ 12 mL×2	Low-salt solution
Elution Buffer	2 pieces	10 mL	20 mL	DNase/RNase free H ₂ O
MagaBio Reagent		1.25 mL	1.25 mL×2	Magnetic particles coated with silicon
Handbook	1	1	1	/

Notes : Buy BSC86S1B , add 15mL Absolute ethanol to ※15mL Wash Buffer I before use; add 24mL Absolute ethanol to ※6mL Wash buffer II before use ;

Buy BSC86M1B , add 30mL Absolute ethanol to ※30mL Wash Buffer I before use; add 48mL Absolute ethanol to ※12mL Wash buffer II before use.

【Reagents to be prepared by the user】

Buy BSC86S1B and BSC86M1B, please prepare the absolute ethanol (analytical grade) by yourself.

【Storage and transportation】

- The kit can be transported at room temperature (2~25°C) .
- The kit should be stored at room temperature (2~25°C) .
- All reagents are valid for 12 months if stored properly.

【Applicable instrument】

- Magnetic rack or Bioer NPA-32P purification instrument;
- Water bath or dry bath;
- Vortex mixer.

【Sample Requirements】

If the sample volume is less than 300μL, you can add an appropriate volume of PBS buffer or Normal saline to make the total volume reach 300μL.

【Procedure】

Buy BSC86S1B and BSC86M1B , please follow the manual extraction method below.

A. Sample preparation

- Processing of different samples:

- (1) Virus in whole blood, serum, plasma, ascites and other liquid samples virus: Add 300µL sample to a 1.5mL nuclease-free centrifuge tube.
 - (2) Virus in Animal /plant tissue: Grind sample fully with normal saline or PBS, centrifuge at 12,000g for 5-10min. Take 300µL supernatant to a 1.5mL nuclease-free centrifuge tube.
 - (3) Virus in feces sample: Grind the feces sample fully with normal saline or PBS, centrifuge at 12,000g for 5-10min. Take 300µL supernatant to a 1.5mL nuclease-free centrifuge tube.
 - (4) Virus in saliva or other viscous liquid: Add 200µL sample to a 1.5mL nuclease-free centrifuge tube.
 - (5) Swab samples: Put the swab into tube with sample preservative fluid, and shake the tube vigorously for 1 min. Take 300µL immersion solution to a 1.5mL nuclease-free centrifuge tube.
 - (6) For alveolar lavage fluid, sputum and other viscous liquid samples: Take 150µL of samples to a sterile 1.5mL nuclease-free centrifuge tube. Add 150µL of sputum liquefier (Cat. # BSC83M1). After shaking and mixing, incubate the sample at 37°C for 10 min. Centrifuge for a few seconds.
2. Add 500µL Lysis Buffer to the 1.5mL nuclease-free centrifuge tube, shake and mix well.
 3. Incubate at 70°C for 2 minutes.

B. Sample Extraction

1. Add 25µL magnetic beads to the centrifuge tube (the magnetic beads should be mixed thoroughly before use), and mix upside down at room temperature for 3 minutes.
2. Place the centrifuge tube on the magnetic rack for 1 minute to allow the magnetic beads in the tube to be adsorbed, use a pipette to remove the liquid in the tube, and remove the centrifuge tube.
3. Add 500 µL of Wash Buffer I to resuspend the magnetic beads, place the centrifuge tube on the magnetic rack for 1 minute, use a pipette to remove the liquid in the tube, and remove the centrifuge tube.
4. Add 500 µL of Wash Buffer II to resuspend the magnetic beads, place the centrifuge tube on the magnetic rack for 1 minute, use a pipette to remove the liquid in the tube, and remove the centrifuge tube.
5. Add 500µL of Wash Buffer II to resuspend the magnetic beads. Place the centrifuge tube on the magnetic stand for 1 minute. Use a pipette to remove the liquid in the tube, allow the magnetic beads to continue to be adsorbed and dry at room temperature for 2 minutes.
6. Remove the centrifuge tube from the magnetic rack, add 70µL of elution buffer to resuspend the magnetic beads, and incubate in water bath at 70 °C for 3 minutes. In the meantime, shake it twice to fully elute the nucleic acid.
7. Place the centrifuge tube on the magnetic rack for 1 minute to adsorb the magnetic beads, and transfer the liquid to a new 1.5 mL nuclease-free centrifuge tube.

Note: If liquid is adhered on the tube wall and tube cover during operation, please centrifuge briefly to gather all liquid into the bottom of the tube, and then place it on the magnetic rack.

If you want to use with automated instruments, the lysis temperature and elution temperature of the deep-well plate need to be adjusted and optimized.

【Explanation of test results】

This kit is suitable for the extraction of viral nucleic acid in swabs, tissue, feces, blood, serum, plasma and other body fluid samples.

【Limitations of the test method】

Sample size: The sample size should be less than 300µL;

Sensitivity: It requires high-sensitivity PCR detection reagents.

【Performance Indicators】

The extracted product is detected by high-sensitivity HBV DNA detection reagent to reach a sensitivity of 10 IU/mL. The extracted product is detected by high-sensitivity HCV RNA detection reagent to reach a sensitivity of 50 IU/mL. The quality control products calibrated by the national standard products are repeatedly tested and statistically determined.

【Notes】

1. The following procedure is suitable for the use of Bioer NPA-32P nucleic acid purification instrument. If other nucleic acid purification systems are used, the operating procedures need to be adjusted according to the performance of different instruments.
2. If the room temperature is too low, you need to preheat the bottled lysis buffer in a 56 °C water bath for 10 minutes to confirm that there is no crystal precipitation before use.
3. After receiving the kit, it should be stored at room temperature (2~25°C) .

Appendix: The automation purification, take Bioer NPA-32P as an example

1. Reagent Preparation

a. For BSC86S1B and BSC86M1B

Add 500µL Lysis Buffer to the column 1 and 7 of the 2.2mL 96-deep-well plate, 500µL Wash Buffer I to the column 2 and 8, 500µL Wash Buffer II to the column 3, 4 and 9, 10; 70µL Elution Buffer to the column 5 and 11, 175µL pure water and 25µL MagaBio Reagent to the column 6 and 12 (the magnetic beads should be mixed thoroughly before use).

b. For BSC86S1E

Put the 96 well pre-loaded reagents at room temperature. Invert 96-well plate upside down for three times, and tear off the plastic bag. Centrifuge the pre-loaded reagent for a few seconds (or swing by hand a few times) to avoid reagent adhering to the wall of the tubes. Tear off the aluminum foil film of 96-well plate and identify the direction of the plate (magnetic beads in column #6 & #12).

2. Add 300µL sample to the 96 well plate columns Lysis Buffer strip (#1 and #7) , please avoid cross-contamination. Note: Please refer to manual extraction method for sample preparation from different sources.
3. Place 96 deep well plate to the instrument, install the 8-strip tips on the instrument.
4. Run the program according to the following procedures:

Step	Well	Name	Waiting Time (min: ss)	Mixing Time (min: ss)	Magnet Time (min: ss)	Adsorption	Speed	Volume (µL)
1	1	Lysis	00 : 00	02 : 00	00 : 00	Normal	F	700
2	6	Beads	00 : 00	00 : 15	00 : 15	Strong	F	200
3	1	Bind	00 : 00	03 : 00	00 : 45	Strong	F	700
4	2	Wash 1	00 : 00	00 : 30	00 : 30	Strong	F	500
5	3	Wash 2	00 : 00	00 : 30	00 : 30	Strong	F	500
6	4	Wash 3	00 : 00	00 : 30	00 : 30	Strong	F	500
7	5	Elution	02 : 00	02 : 30	00 : 30	Normal	F	70
8	6	Discard	00 : 00	00 : 15	00 : 00	Normal	F	200

Temperature settings:

Lysis temperature: 80°C. Lysis heating ends at Step 2;

Elution temperature: 80°C. Elution starts heating at Step 7.