IVD

Nucleic Acid Extraction Reagent

Instructions for Use

For Professional Use Only

Product Name

Nucleic Acid Extraction Reagent

Catalogue Reference Number

201001

Model

MEG-96C

Packing Specifications

Specification: 96 Preps /kit

Product Description

The Nucleic Acid Extraction Reagent is designed for rapid and reliable isolation of nucleic acid from bacteria, bacterial cultures, swabs, sputum, bronchoalveolar lavage fluid, fiber brushes, pus, and other specimens. The Nucleic Acid Extraction Reagent provides high-quality nucleic acid, which is suitable for direct use in most downstream application such as amplifications and enzymatic reactions. This system can be easily adapted to automated systems or centrifugation systems. It has the advantages of high automation, fast extraction speed, stable results, and simple operation.

Intended Use

This kit is designed to isolate and purify nucleic acid from bacteria, bacterial cultures, swabs, sputum, bronchoalveolar lavage fluid, fiber brushes, pus, and other specimens.

The kit is "For Professional Use Only" by trained and validated laboratory personnel. Read this Instruction for Use carefully before use.

Kit Storage and Handling

The Nucleic Acid Extraction Reagent can be stored at room temperature (10°C~30°C, which is equivalent to 50°F~86°F) for 12 months from the date of manufacture. Please see label for expiration date.

Specimen Collection and Handling

The specific collection methods of the specimens are subject to the applicable product manual.
The specific storage conditions of the specimens are subject to the applicable product manual.
The specific transportation conditions of the specimens are subject to the applicable product manual.

Principle of the Procedure

The isolation procedure is based on magnetic beads technology and comprises the following steps:

1. Lyse bacteria at high temperature with Lysing Buffer to release nucleic acid from bacterial specimens.
2. Lysed specimens are added to Binding Buffer, and then the Magnetic beads are added, and total nucleic acids can be bound onto the Magnetic beads during incubation.
3. Magnetic beads are separated by centrifugation or magnetic separator, and unbound materials are removed by washing.
4. Nucleic acids are eluted from the Magnetic beads. At this stage, the nucleic acids are ready for use in DNA analysis.

Kit Contents and Preparation of Working Solution

Table 1 MEG-96C Reagent

Name of Component	Amount per Plate/ Tube	No. of Plate/ Tube	Storage Condition
MEG Binding Buffer,	96 Preps /plate	1 plate	Store at 10°C~ 30°C (50°F~86°F)
MEG Magnetic Beads	96 Preps /plate	1 plate	
MEG Washing Buffer	96 Preps /plate	1 plate	
MEG Elution Buffer	96 Preps /plate	1 plate	
MEG Lysing Buffer	25 mL/bottle	1 bottle	

Note: The plates provided in this kit is for single-use only. Do not reuse the plates.
Perform all steps at room temperature (10 to 30 ℃) unless otherwise noted.

Reagents and Materials Required But Not Provided

[Consumables Not Provided]

- Centrifuge tubes

[Equipment Not Provided]

- Vortex mixer
- Incubator
- Centrifuge suitable for tubes
- Centrifuge suitable for deep-well plates
- Auto-Pure 96 Nucleic Acid Purification System (Hangzhou Allsheng Instruments Co., Ltd.)

Note: MEG-96C extraction kit may be compatible with same type of above mentioned automatic

nucleic acid extraction instrument (12 × 8 matrix magnetic bars). Please verify before use.

Procedure

Sample enrichment

Table 2 Different samples enrichment protocol

Sample type	Action
Bacterial culture	Take an appropriate amount of bacterial suspension into a centrifuge tube, centrifuge at 13,000 rpm for 3 minutes, and discard the supernatant.
Swab	The swab sample must be thoroughly shaken and mixed in the sample preservation solution or sterile saline to elute the bacteria adhering to the swab. Take an appropriate amount of preservation solution into a centrifuge tube as required, centrifuge at 13,000 rpm for 3 minutes, and discard the supernatant.
Sputum or tuberculosis-like	Add an appropriate amount of 4% sodium hydroxide to the sample and mix well to make it fully liquefied. Take an appropriate amount of the liquefied sample into a centrifuge tube as required, centrifuge at 13,000 rpm for 3 minutes, and discard the supernatant.

Sample lysing

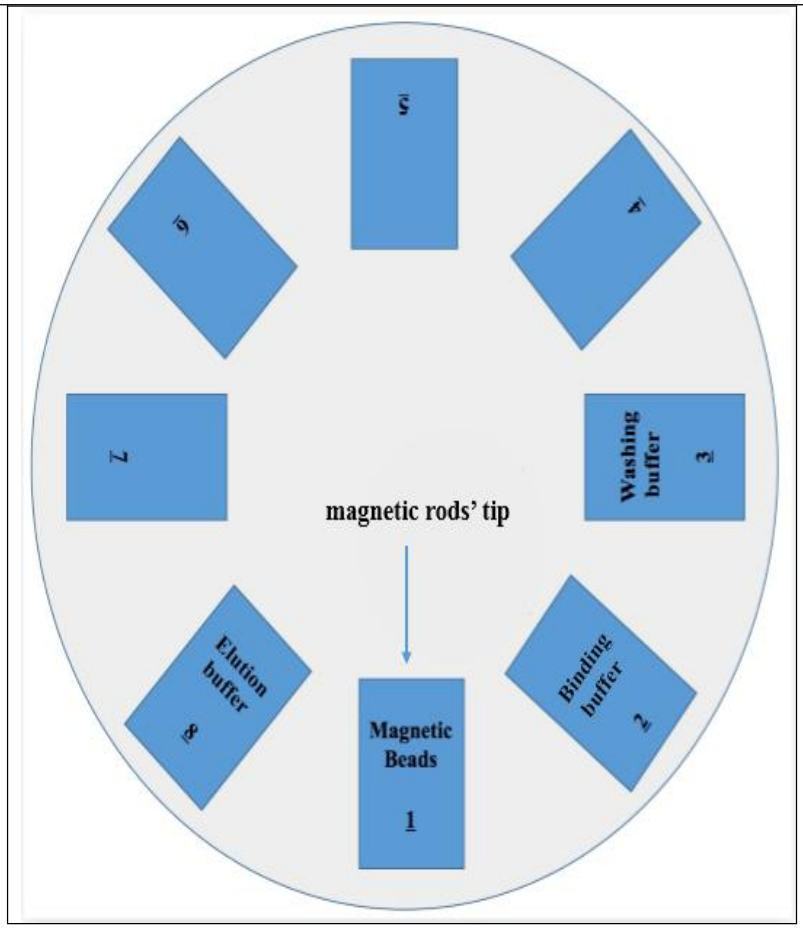
Table 3 Sample lysis protocol

Step	Action
1	Take the sample pellet retained after centrifugation, add 200 μL MEG Lysing Buffer, and mix well.
2	Place the sample on an incubator at 95℃. For gram-negative bacteria samples, heat for 5 minutes; for gram-positive bacteria samples, heat for 10 to 20 minutes.
3	After the heating, centrifuge briefly to allow the wall-mounted liquid to accumulate at the bottom of the tube.

Automatic extraction

Table 4 Automatic extraction protocol

Step	Action
1.Prepare the Plate	a. Mix the reagents and magnetic beads in the plate up and down before opened. b. Centrifuge at 500 rpm for 1 minute to spin down the reagents and magnetic beads. Note: If there is no centrifuge, gently shake the reagents to ensure that the liquids are accumulated at the bottom of the deep well plate. c. Remove the sealing film from the 96 deep-well plate carefully for the next step.
2.Add the Sample	d. Add the lysed samples to MEG Binding Buffer plate.
3.Prepare the instrument	e. Ensure that the instrument is ready for experiment (pre-disinfection). f. Place the plates in the instrument as follows:

	 g. Mount magnetic rods' tip in the MEG Magnetic Beads plate and select the program on the instrument. h. Start to run and load the prepared 96 deep-well plate and magnetic rods' tip in the correct positions when prompted by the instrument (**see Table 5**).
4.Elute the DNA	When prompted by the instrument (20 to 25 minutes after the initial start): i. Remove the 96 deep-well plates from the instrument, and the nucleic acid stayed in MEG Elution Buffer can be directly used or stored at -20 to -80 ℃.

The program of automatic extraction follows the settings below:

Table 5 The program parameters

Step	Position	Plate	Action	Mix Time (min)	Magnet Time (sec)	Wait time (min)	Volume (μL)	Mix Speed	Temp. (℃)
1	1	MEG Magnetic Beads plate	Transfer beads	0	60	0	300	Medium	RT
2	2	MEG Binding	Binding	2	0	2	800	Medium	RT

		Buffer plate							
3	2	MEG Binding Buffer plate	Binding	1	60	0	800	Medium	RT
4	3	MEG Washing Buffer plate	Washing	1	60	0	700	Medium	RT
5	8	MEG Elution Buffer plate	Elution	5	60	0	50	Slow	65
6	3	MEG Washing Buffer plate	Discard beads	0	0	0	700	Medium	RT

Note: RT is short for “Room Temperature”.

Limitations

The product needs to be used together with other molecular detection reagents as an auxiliary reagent for molecular diagnosis.

Performance Characteristics

1. The product can be effectively used for nucleic acid extraction of various samples and can extract GBS bacteria as low as 25 CFU/mL calibrated by Chinese national reference of GBS.

2. The precision is excellent. Use a fluorescent PCR reagent to evaluate the extracted product, and the coefficient of variation of the product Ct value should be less than 5%.

Warnings and Precautions

1. Carefully check whether the reagent components are complete and thoroughly mixed before use.

2. The performance of the kit is only applicable to the specimen types of this product.

3. The detected sample should be deemed as potential infectious substances and should be operated under the requirements of relevant laws and regulations.

4. Sample should be treated in the biosafety cabinet and the operators should wear appropriate work clothes and disposable gloves and use the pipettor. The pipettes used in the experiment

should be directly put into the waste tank containing disinfectant, and discard after being sterilized.

5. It is recommended to perform UV disinfection of the nucleic acid extraction instrument for 20 minutes before and after the experiment.

6. A small number of magnetic beads may remain during elution. Avoid pipetting magnetic beads when transfer the nucleic acid for the subsequent operations.

7. Do not use the expired kits.

8. This kit is only used for *in vitro* diagnosis.

9. The plates provided in this kit are for single use. Do not reuse the plates.

Explanation of Symbols

 In Vitro Diagnostic Medical Device	 Consult instructions for use	 Catalogue number
 Temperature limit	 Manufacturer	 Batch code
 Do not re-use	 Use-by date	 Date of manufacture
 <n> Contains sufficient for <n> tests	/	/

Manufacturer Basic Information

Manufactured for:

Fosun Pharma USA Inc.
104 Carnegie Center, Suite 204
Princeton, NJ 08540
Tel: (866) 611-3762

Manufactured by:
Yaneng BIOscience (Shenzhen) Co., Ltd.
Room 301, 302, 304, 401A1
Building No.1 Bio-Pharmacy Business Accelerator
14 Jinhui Road, Kengzi Street
Pingshan District, Shenzhen, Guangdong, China

Made in China

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The Nucleic Acid Extraction Reagent *Instruction for Use* can be downloaded from the following link: **https://fosunpharmausa.com/in-vitro-diagnostics/reagents/**