

Nucleic Acid Extraction Reagent



Instructions for Use

For Professional Use Only

Product Name

Nucleic Acid Extraction Reagent

Catalogue Reference Number

200801

Model

MEB-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 anti-coagulation whole blood. The Nucleic Acid Extraction Reagent provides high-quality DNA, which is suitable for direct use in most downstream applications 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 for the isolation of DNA from anti-coagulation whole blood.

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

Sample collection: peripheral blood is put into the tube that containing anticoagulant as per collection tube instruction. Make sure the blood specimen is legible labelled.

The sample can be stored for 24 hours at room temperature and for a long time below -70°C. It can also be stored in refrigerator at 2 to 8°C or -20°C temporarily.

Samples shall be transported at low temperature in accordance with biosafety regulations.

Principle of the Procedure

The isolation procedure is based on magnetic beads technology and can be divided into the following steps:

1. Lysis and stabilization of the sample with lysis-binding buffer and proteinase K.
2. Magnetic beads are added to specimens lysate, and total nucleic acid are bound onto the magnetic beads during incubation.
3. Magnetic beads are separated by magnetic separator and unbound materials are removed by washing.
4. Nucleic acids are eluted from the magnetic beads. At this stage, the nucleic acids can be used for DNA analysis.

Kit Contents and Preparation of Working Solution

Table 1 MEB-96C Reagent Plate

| Name of Component | Amount per Plate/ Tube | Volume | No. of Plate/ Tube | Storage Condition |
|--------------------------|-------------------------------|---------------|---------------------------|---------------------------------------|
| MEB Lysis-binding Buffer | 96 Preps /plate | 600µL/well | 1 plate | Store at 10°C~ 30°C (50°F~86°F) |
| MEB Magnetic Beads | 96 Preps /plate | 300µL/well | 1 plate | |
| MEB Washing Buffer I | 96 Preps /plate | 800µL/well | 1 plate | |
| MEB Washing Buffer II | 96 Preps /plate | 800µL/well | 1 plate | |
| MEB Elution Buffer | 96 Preps /plate | 100µL/well | 1 plate | |
| MEB Proteinase K | 1.2mL/tube | / | 1 tube | |

Note: The plates provided in this kit are for single-use only. Do not reuse the plates.

Perform all steps at room temperature (10 to 30°C) unless otherwise noted.

Materials and Equipment to be Supplied by User:

Equipment

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

Note: MEB-96C extraction kit may be compatible with same type of above mentioned automatic nucleic acid extraction instrument (12 × 8 matrix magnetic bars). Please do the verification before use.

Procedure

Table 2 Automatic Extraction Protocol

| Step | Action |
|---------------------------------|---|
| 1. Prepare Plate | <p>a. Mix the MEB Magnetic Beads plate up and down to avoid magnetic beads stick to the aluminum film during transportation.</p> <p>b. Centrifuge at 500 rpm for 1 minute to spin down the reagents. Note: If there is no centrifuge, gently fling the reagents to ensure that the liquids are concentrated at the bottom of the deep well plate.</p> <p>c. Remove the aluminum foil seal from the 96 deep-well plate for next step.</p> |
| 2. Prepare Samples | <p>d. Mix the samples thoroughly, and then add 200 μL sample and 10μL MEB Proteinase K to MEB Lysis-binding Buffer plate. Note: If samples are deeply frozen, they need to be prewarmed to 15 to 25°C before use.</p> |
| 3. Set up the Processing Plates | <p>e. Ensure that the instrument is set up for processing.</p> <p>f. Set up the plates in the instrument as follows:</p> <div data-bbox="475 719 1342 1597" style="text-align: center;"> </div> <p>g. Mount magnetic rods' tip in the MEB Magnetic Beads plate and select the program on the instrument.</p> <p>h. Start the run and load the prepared processing 96 deep-well plate and magnetic rods' tip in the right positions when prompted by the instrument (see Table 3).</p> |
| 4. Elute the DNA | <p>When prompted by the instrument (30 to 35 minutes after the initial start):</p> <p>i. Remove the 96 deep-well plate from the instrument, and then take the DNA from MEB Elution Buffer for use or store at -20 to -80°C.</p> |

The program of automatic extraction follows the settings below:

Table 3 The Program Parameters

| Steps | Plate Position | Plate | Action | Mix Time (min) | Magnet Time (sec) | Wait Tme (min) | Mix Speed | Temp. (°C) |
|-------|----------------|--------------------------------|-------------------|------------------|---------------------|------------------|-----------|--------------|
| 1 | 1 | MEB Magnetic Beads plate | Transfer beads | 1 | 60 | 0 | high | RT |
| 2 | 2 | MEB Lysis-binding Buffer plate | Lysis and binding | 15 | 60 | 0 | high | 65 |
| 3 | 3 | MEB Washing Buffer I plate | Washing I | 1 | 60 | 0 | high | RT |
| 4 | 4 | MEB Washing Buffer II plate | Washing II | 1 | 60 | 0 | high | RT |
| 5 | 8 | MEB Elution Buffer plate | Elution | 5 | 60 | 0 | high | 65 |
| 6 | 1 | MEB Magnetic Beads plate | Discard beads | 1 | 0 | 0 | high | RT |

Note: RT is short for “Room Temperature”.

Limitations

As an auxiliary step for molecular detection and used in conjunction with other molecular detection methods, the kit is only used for nucleic acid extraction in clinical institutions, scientific institutions and health systems. This kit is only applicable to the samples mentioned in **Specimen Collection and Handling**. We cannot make sure that the device’ performance would meet the requirements if other types of samples are used. The extraction purity and quality are affected by the testing instruments and operators.

Performance Characteristics

Purity of Nucleic Acid Extraction

The purity of nucleic acid extraction, referring to the value of A260/A280, is not less than 1.6.

Extraction Yield

The nucleic acid concentration of extraction is more than 10 ng/μL.

Repeatability







The CV value is no more than 15%.





Warnings and Precautions

1. Before use, carefully check whether the reagent components are complete and thoroughly mixed.
2. Frozen samples should be thawed and mixed before use.
3. The detected sample shall be deemed as having infectious substances, and operation and treatment shall both conform to the requirements of relevant laws and regulations.
4. Sample treatment in the biosafety cabinet, wear work clothes and disposable gloves during the test process and use the dump tubular pipettor. The pipettes used in the experiment should be directly put into the waste tank containing the disinfectant, and discarded after being sterilized together with other waste.
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 amount of magnetic beads may remain during elution. Avoid sucking magnetic beads when sucking DNA for subsequent operations.
7. After the completion of experiment, it shall use 10% hypochlorous acid, 75% alcohol or ultraviolet radiator for disinfection.
8. The operators should have operational experience and have received professional training.
9. This kit is only used for *in vitro* diagnosis.
10. This kit is only for single use.

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Auto-Pure 96 Nucleic Acid Purification System

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/>