IVD

Nucleic Acid Extraction Reagent

Instruction for Use

For Professional Use Only

Product Name

Nucleic Acid Extraction Reagent

Catalogue Reference Number

2001FC

Model

MNP-96C

Packing Specifications

Specification: 96 Preps /kit

Product Description

The Nucleic Acid Extraction Reagent is designed for rapid and reliable isolation of total nucleic acid from swab, saliva, and other body fluids. The Nucleic Acid Extraction Reagent provides high-quality RNA or 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 with reagents for 96 isolations was designed for the isolation DNA/RNA from upper respiratory tract specimens (including oral swabs, throat swabs, nasal swabs and nasopharyngeal extracts), lower respiratory tract specimens (including bronchoalveolar lavage fluid and alveolar lavage fluid).

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

Kit Storage and Handling

The Nucleic Acid Extraction Reagent (96 Preps) 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

Typical clinical samples are throat swab and bronchoalveolar lavage.

Throat Swab: Use the plastic rod swab with polypropylene fiber head to wipe the bilateral pharyngeal tonsils and the posterior pharyngeal wall at the same time, immerse the swab head into the tube containing physiological saline, discard the tail, and tighten the tube cover.

Bronchoalveolar Lavage: Collect bronchoalveolar lavage for test. The collected sample should be used for detection as soon as possible. If the sample need to be transferred and cannot be detected immediately, please store it at low temperature.

The sample can be stored for 24 hours at 2°C ~8°C and for a long time below -70°C. It can also be stored in refrigerator at -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
2. Magnetic beads are added to specimens lysate, and total nucleic acids (RNA, DNA) are bound onto the magnetic beads during incubation.
3. Magnetic beads are separated by magnetic separator and unbound material is removed by washing.
4. Nucleic acids (RNA and DNA) are eluted from the magnetic beads. At this stage, the nucleic acids can be used for DNA and RNA analysis.

Kit Contents and Preparation of Working Solution

Table 1 MNP-96C Reagent plate

Name of Component	Preps per Plate	No. of Plate	Storage Condition
MNP Lysis-binding Buffer	96 Preps /plate	1 plate	Store at 10°C~ 30°C (50°F~86°F)
MNP Magnetic Beads	96 Preps /plate	1 plate	
MNP Washing Buffer I	96 Preps /plate	1 plate	
MNP Washing Buffer II	96 Preps /plate	1 plate	
MNP Elution Buffer	96 Preps /plate	1 plate	

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

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

Materials and Equipment to be Supplied by User:

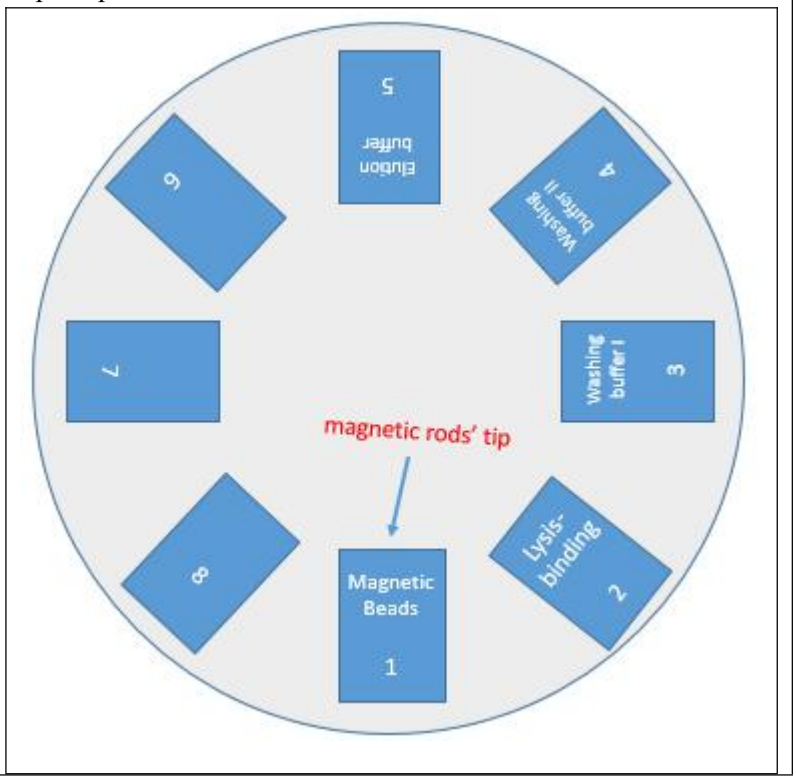
Equipment

- Centrifuge suitable for deep-well plates
- Auto-Pure 96 Nucleic Acid Purification System (Hangzhou Allsheng Instruments Co., Ltd.) or KingFisher™ Flex-96 (Thermo Fisher Scientific)

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

Procedure

Table 2 Automatic extraction protocol

Step	Action
1.Prepare Plate	a. Mix the MNP Magnetic Beads plate up and down to avoid magnetic beads stick to the aluminum film during transportation. b. Centrifuge at 500 rpm for 1 minute to spin down the reagents. Note: If there is no centrifuge available, gently tap the plate to force the reagents to the bottom of the deep well plate. c. Remove the aluminum foil seal from the 96 deep-well plate for next step.
2.Prepare Sample	d. Mix the samples thoroughly, and then add 300 µL sample to MNP Lyisis-binding Buffer plate. e. Note: If samples were deeply frozen, it need to be prewarmed to 15°C to 25°C before use.
3.Set up the processing plates	Processing plates f. Ensure that the instrument is set up for processing. g. Set up the plates in the instrument as follows: 

	h. Mount magnetic rods' tip in the MNP Magnetic Beads plate and select the program on the instrument. i. 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**).
4.Elute the DNA/RNA	When prompted by the instrument (30~35 minutes after the initial start): j. Remove the 96 deep-well plate from the instrument, and then take the DNA/RNA from MNP Elution Buffer for use or store at -20°C to -80°C.

Table 3 Automatic extraction with pre-loaded program or setting up the program following below parameters

Steps	Plate Position	Plate	Action	Mix Time (min)	Magnet Time (sec)	Wait time (min)	Mix Speed	Temp. (℃)
1st	1	MNP Magnetic Beads plate	Transfer beads	1	60	0	high	RT
2nd	2	MNP Lysis-binding Buffer plate	Lysis and binding	15	60	0	high	RT
3rd	3	MNP Washing Buffer I plate	Washing I	1	60	0	high	RT
4th	4	MNP Washing Buffer II plate	Washing II	1	60	0	high	RT
5th	5	MNP Elution Buffer plate	Elution	5	60	0	high	RT
6th	4	MNP Washing Buffer II plate	Discard beads	1	0	0	high	RT

Note: RT is the abbreviation for "Room Temperature".

Limitations of the Procedure

This product is only suitable for upper respiratory tract specimens (including oral swabs, throat swabs, nasal swabs and nasopharyngeal extracts) and lower respiratory tract specimens (including bronchoalveolar lavage fluid and alveolar lavage fluid); performance for other types of samples or samples in other preservation buffers cannot be guaranteed.

Performance Characteristics

1. Yields of viral RNA isolated from biological samples are normally less than 1 μg and therefore difficult to determine photometrically. Keep in mind that this kit extracts total nucleic acid from sample, including DNA and RNA, thus quantitative RT-PCR is recommended for determination of viral RNA yield.

2. Repeat the extraction 10 times for the reference sample, and then the purified RNA or DNA can be determined using quantitative RT-PCR detection kit. Variation coefficient (CV) of Ct values should be less than 10%.

Warnings and Precautions

1. Before use, carefully check whether the reagent components are complete.

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 extracting magnetic beads when aspirating DNA / RNA for subsequent operations.

7. This kit contain guanidine salts (e.g., guanidine thiocyanate and guanidine hydrochloride) that may produce hazardous gases when combined with bleach (sodium hypochlorite) and/or strong acids.

8. After the completion of experiment, it shall use 10% hypochlorous acid, 75% alcohol or ultraviolet radiator for disinfection.

9. The operators should have operational experience and have received professional training.

10. This kit is only used for in vitro diagnosis.

References

1. Brestovac B, Wong ME, Costantino PS, etal. A rapid DNA extraction method suitable for human papillomavirus detection. J Medical Virol. 2014, 86(4): 653-7.
2. Berensmeier S. Magnetic particles for the separation and purification of nucleic acids. Appl Microbiol Biotechnol. 2006, 73(3): 495-504.
3. Katevatis C, Fan A, Klapperich CM. Low concentration DNA extraction and recovery using a silica solid phase. PloS One. 2017, 12(5): e0176848.
4. He H, Li R, Chen Y, etal. Integrated DNA and RNA extraction using magnetic beads from viral pathogens causing acute respiratory infections. Sci Rep. 2017, 7: 45199.

All names, logos and other trademarks listed below are the property of their respective owners:
1. Auto-Pure 96 Nucleic Acid Purification System
2. KingFisher™ Flex-96

Explanation of Symbols

Symbol	Description
	Catalog number
	Contains sufficient for <n> tests
	Batch code
	Date of manufacture
	Use-by-date
	Manufacturer
	In vitro diagnostic
	Consult instructions for use
	Temperature limit

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: **www.fosunpharmausa.com/covid19/pcr/**