MagaBio Bacterium DNA Purification Kit III

Instructions for Use

Effective Date: 2021-11-30

For professional use only.

For in vitro diagnostic use only.

IVD 2℃ 25℃ CE

REF BSC96T1S / BSC96S1S
BSC96T1E / BSC96S1E

INTENDED USE

MagaBio Bacterium DNA Purification Kit III is used for extraction and purification of bacterium DNA. The purified bacterium DNA is suitable for clinical in vitro testing or use in amplification-based in vitro diagnostic assays. Diagnostic results obtained using the nucleic acid purified with the kit must be interpreted in conjunction with other clinical or laboratory data.

The kit is intended to be used by professional users, such as technicians or physicians who are trained in molecular biological techniques.

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For in vitro diagnostic use only.

PRINCIPLE OF THE PROCEDURE

The DNA in the bacterial sample is released under the action of Lysis Buffer and PK. In the presence of Binding Buffer, the released DNA is specifically bound to the magnetic beads. The DNA-bound magnetic bead particles are captured by the magnetic material, and the contaminants are removed through the washing process of 2~3 times. Finally, the DNA is eluted and collected from the magnetic beads under the action of Elution Buffer.

KIT COMPONENTS

Catalog	BSC96T1S	BSC96S1S	BSC96T1E	BSC96S1E
Kit size (Tests/Kit)	16	32	16	32
Proteinase K (PK)	320μL	640μL	320μL	640μL
RNase A	64μL	128μL	64μL	128μL
Lysozyme	128mg	256mg	128mg	256mg
TET Buffer	6.4mL	12.8mL	6.4mL	12.8mL

Lysis Buffer	6.4mL	12.8mL	6.4mL	12.8mL
Binding Buffer	16 test strips prefilled with reagents for 1 test per strip	32 test strips prefilled with reagents for 1 test per strip	Two 96 well plates prefilled with reagents for 8 tests per plate	Two 96 well plates prefilled with reagents for 16 tests per plate
WB1 Buffer				
Wash Buffer				
Elution Buffer				
MagaBio Reagent				
Instructions for Use	1 Piece	1 Piece	1 Piece	1 Piece

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

1. Nucleic Acid Purification System from Bioer, GenePure Pro (NPA-32P)
2. Vortex mixer, centrifuge, centrifuge tubes and micropipettes, micropipette tips;
3. Disposable gloves, etc.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use (IVD). Do not use expired products.
- For professional use only. The kit is intended to be used by professional users, such as technicians and physicians that are trained in molecular biological techniques.
- Do not use the kits with any obvious damage or leakage.
- Store the kit in the required environment. Prolonged exposure to humidity or heat will affect product performance. Screw the lid tightly after use.
- Avoid microbial and nuclease (DNase) contamination of reagents. It's highly recommended to use sterile DNase-free disposable tubes and pipette tips.
- Read the Instructions for Use carefully before operation. The appropriate operations from specimen collection, storage and transportation, and laboratory test should be strictly manipulated in line with relevant regulations of biosafety and molecular laboratory management.
- Follow standard precautions. All specimens and/or positive controls should be considered potentially infectious and handled accordingly.
- Use personal protective equipment such as (but not limited to) gloves, eye protection, and lab coats when handling kit reagents, while performing

this assay and handling materials including samples, reagents, pipettes, and other equipment and reagents.

- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- Wash hands thoroughly after performing the test.
- Dispose of used / unused kit reagents and specimens according to local, state, and federal regulations.
- Consult the manufacturer for additional warnings, precautions, procedures or information.

STORAGE AND TRANSPORTATION

The kit should be stored at 2°C ~25°C for the duration of the shelf life.
Do not use beyond the expiration date printed on the box.
The kit can be transported at room temperature.
The kit can be stored for up to 12 months if all components are kept on the conditions above.

SPECIMEN COLLECTION AND PREPARATION

1. Specimen: Gram positive bacteria (G+ bacteria) and Gram negative bacteria (G- bacteria).
2. Specimen collection: Specimens of all types are collected by conventional methods.
3. Specimen storage: It is highly recommended to process the specimen as soon as possible after collection. If delayed processing is expected, the specimens should be stored by conventional methods or at -70°C or lower. Specimens should not be frozen and thawed frequently.
4. Specimen transportation: Specimen should be transported with 0°C curling bottle or foam box sealed with ice.
5. Specimen pre-treatment:

1) Pipet 100μL～3mL of bacterial solution, into a 1.5mL centrifuge tube, centrifuge at 13,000×g for 1 minute, discard the supernatant, and absorb the supernatant as much as possible.
2) Add 200μL of TET Buffer (with Lysozyme added), shake to disperse and resuspend the bacteria sufficiently. When dealing with Staphylococcus bacteria, it is best to add 1μL Lysostaphin (20mg/mL).

Optional operation: If RNA needs to be removed, add 2μL RNase A.
Note: Please dissolve all Lysozyme in TET Buffer before using it for the first time and store it at 2-8°C for later use, or prepare lysozyme (20 mg/mL) as needed.

3) Incubate at 37°C for 30～60 minutes (**Note: For G- bacteria, such as E. coli, the incubation time can be shortened to 10～15 minutes. For ordinary G+ bacteria, it is recommended to incubate at 37°C for 30～60 minutes. For G+ bacteria that are particularly difficult to lyse, such as Actinomyces, it is recommended to incubate at 37°C for 60 minutes)**.
4) Add 200μL Lysis Buffer and 20μL PK, shake vigorously for 15～20 seconds.
5) Incubate at 70°C for 10 minutes, then remove the centrifuge tube from the 70°C bath.
6. The recommended specimen volume is up to 2×10^9 bacteria, according to the concentration of bacterial solution to determine the optimum volume.

PROCEDURE –AUTOMATION EXTRACTION - BIOER NPA-32P NUCLEIC ACID PURIFICATION INSTRUMENT

1. Prepare reagents
1.1 Shake the strip(s)/plate(s) upside down for three times, then take out the strip(s)/plate(s) from the plastic bag;
1.2 Centrifuge the strip(s)/plate(s) for a few seconds (or swing by hand a few times) to avoid reagent adhering to the wall of the tubes;
1.3 Tear off the aluminum foil film of strip(s)/plate(s) and identify the direction of the strip(s)/plate (MagaBio Reagent in the well of column 6 or column 12).

⚠ *CAUTION: 96 deep-well plate or the 8-strip tips or individual tube should fit for Bioer NPA-32P*

2. Add specimens:
Transfer all the liquid in the centrifuge tube (from step 6 of specimen preparation procedure) to columns 1 and 7 of the 96-well plate, please avoid cross-contamination.

3. Install Pre-loaded reagents strips or plates :

3.1 Install the 8-strip tips onto the instruments;

3.2 Place the strip(s) / plate(s) into the instruments.

⚠ *CAUTION: Identify the direction of the strip(s) / plate; make sure the MagaBio Reagent in the column 6 or column 12.*

4. Set extraction program:

4.1 Set the extraction program as below:

Step	**Well**	**Name**	**Waiting Time** (min: ss)	**Mixing Tine** (min: ss)	**Magnet Time** (min: ss)	**Adorption**	**Speed**	**Volume** (μL)
1	6	Beads	00 : 00	00 : 15	00 : 30	Strong	S	200
2	1	Binding	00 : 00	08 : 00	00 : 45	Strong	F	700
3	2	Wash 1	00 : 00	01 : 00	00 : 30	Strong	F	600
4	3	Wash 2	00 : 00	01 : 00	00 : 30	Strong	F	600
5	4	Wash 3	00 : 00	01 : 00	00 : 30	Strong	F	600
6	5	Elution	02 : 00	10 : 00	00 : 45	Normal	F	80
7	6	Discard	00 : 00	00 : 30	00 : 00	Normal	S	200

4.2 Set temperature as below:

Elution temperature: 60°C; Elution starts heating at Step 6.

5. Remove the liquid in column 5 or column 11 into a nuclease-free tube with a pipette.

⚠ *CAUTION: It is highly recommended that the extracted nucleic acid should be used as soon as possible. Store the extraction product at -20℃ or lower if it cannot be used immediately.*

PERFORMANCE

The DNA of Gram positive bacteria (**G+** bacteria) and Gram negative bacteria (**G-** bacteria) can be extracted.

LIMITATIONS OF THE PROCEDURE

1. The Kit is only to be used by laboratory personnel trained in PCR techniques.
2. The quality and / or the yield of purified of the DNA is affected by factors including source of sample, sample collection process, collection site and storage conditions, etc.
3. Occasionally a few magnetic beads may appear in the elution buffer. If so, avoid these when transferring the extracted product to the fresh nuclease free tubes.
4. If the extraction is being carried out by a manual procedure, clumping of the magnetic beads can occur using certain sample types which can be dispersed by vortexing.
5. The presence of DNase in the laboratory environment may cause the degradation of the DNA during or after the purification process. All equipment, consumables and the workbench should be treated before starting to ensure all surfaces are DNase free.

REFERENCES

1. Centers for Disease Control and Prevention. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition.
2. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Fourth Edition.

SYMBOL DESCRIPTION

	CE mark		Authorized representative
	Manufacturer		Catalogue number
	Batch code		Consult instructions for use
	In vitro diagnostic medical device		Temperature limitation
	Caution		Use by date

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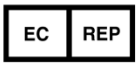

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