Precision System Science Co., Ltd.

Instructions for Use

Magtration® Reagent

MagDEA® Dx MV II

(For research use only)

Version 1.0

Content: May 2021

48 tests

This product is a nucleic acid extraction reagent intended for use in combination with automated nucleic acid extraction systems (geneLEAD and magLEAD series). Ensure to thoroughly read and understand this manual and the instruction manual of the nucleic acid extraction system before use.

10 ℃ – 30 ℃

REF E1323

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Contents

1. Symbols

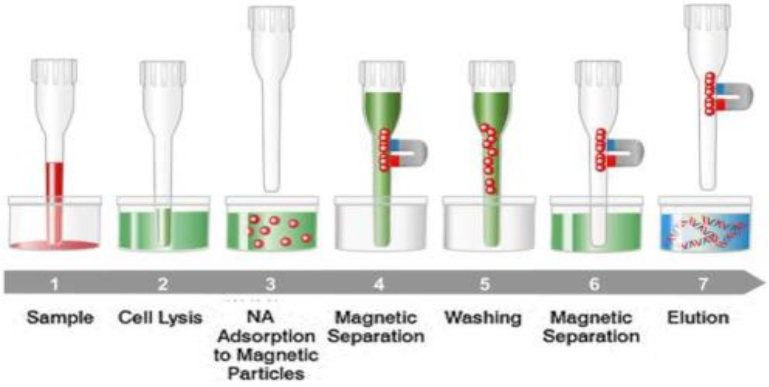
	Caution
	Batch code/lot number
	Catalog number
	Temperature range
	Sufficient for
	Do not reuse
	Consult instructions for use
	Manufacturer
	Expiry date
	Health hazard
	Water hazard
	Flammable
	Health hazard

2. Introduction

The MagDEA® Dx MV II nucleic acid extraction reagent has been developed for use with automated nucleic acid extraction systems based on the Magtration® Technology. This product is capable of extracting nucleic acid from 1 mL sample volumes. The extracted nucleic acid (eluate) can be used in downstream applications, including real-time PCR and RT-PCR.

Magtration® Technology is a proprietary automated separation technique developed by Precision Systems Science Co., Ltd. that uses magnetic particles. By capturing magnetic particles inside the tip, they are separated from liquid components. Nucleic acid extraction systems equipped with Magtration® Technology allow extracting nucleic acids more easily and reliably than manual extraction methods.

Principles of Magtration® Extraction Technology



3. Product overview

Reagent cartridge	MagDEA® Dx MV II	
Sample volume	1 mL	
Elution volume	50 µL, 100 µL, and 200 µL (selectable*1)	
Extraction time	Approx. 55 minutes	
Nucleic acids purified	Viral DNA/RNA	Cell-free (cf) DNA
Sample matrices	Human serum, plasma that include EDTA or citric acid, swabs (throat and nasal), urine, saliva (pretreated*2)	Human serum, plasma that include EDTA or citric acid, urine, saliva (pretreated*2)
Protocol	MagDEA Dx MV II	MagDEA Dx MV II cfDNA

*1 The eluent is sterile distilled water. The amount of recovered fluid may vary depending on the residue and evaporation of the eluate on the surface of magnetic particles and tips.

*2 Please refer to the technical notes for more information on the pretreatment methods.

NOTE) MagDEA® Dx MV II does not provide any data. To obtain results, the instrument must be used in conjunction with a downstream application, e.g., a nucleic acid amplification system.

NOTE) The combination of reagent cartridges, sample volumes, target nucleic acid, and protocols must be followed. If a different combination is used, the extraction performance may be affected. It may also result in instrument failure.

NOTE) Samples containing heparin will affect the downstream PCR process.

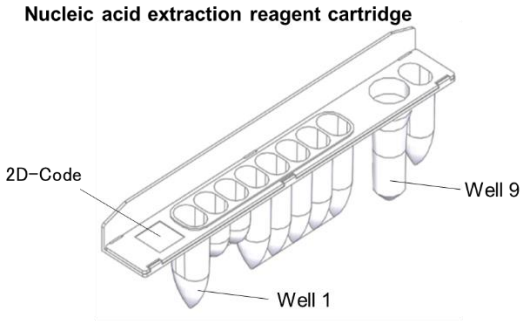
Instrument/protocol

Instrument	Protocol	Product code
MagLEAD 6gC	MagDEA Dx MV II	I8206 (IC Card for 6gC)
	MagDEA Dx MV II cfDNA	I8306 (IC Card for 6gC)
MagLEAD 12gC	MagDEA Dx MV II	I8212 (IC Card for 12gC)
	MagDEA Dx MV II cfDNA	I8312 (IC Card for 12gC)
geneLEAD VIII	MagDEA Dx MV II	Please contact PSS.
	MagDEA Dx MV II cfDNA	Please contact PSS.

NOTE) The nucleic acid extraction cannot be performed if the combination of instrument and protocol differs from that listed above.

Kit contents

Constituent	Quantity
MagDEA® Dx MV II (Reagent cartridge)	48 pcs



Well No.	Reagent name	Quantity	H-code / P-code
1	Binding buffer	48 x 1250 µL	H225,H302,H315,H319,H335 H361,H370,H372,H373,H400 H410 P201,P202,P210,P233,P240 P241,P242,P243,P260,P261 P264,P270,P271,P273,P280 P312,P314,P321,P330,P391 P450,P501,P301+P312 P302+P352,P332+P313 P303+P361+P353,P304+P340 P305+P351+P338,P308+P331 P308+P313,P337+P313 P370+P378,P403+P223 P403+P235
2	PK solution	48 x 300 µL	
3	Carrier solution	48 x 200 µL	
4	Magnetic particles	48 x 200 µL	
5	Binding buffer	48 x 1250 µL	
6	Wash buffer 1	48 x 1200 µL	
7	Wash buffer 2	48 x 700 µL	
8	Distilled water	48 x 1200 µL	
9	Lysis solution	48 x 1200 µL	

4. Operational notes

⚠ **Caution: Ensure to check the following precautions before use.**

Precautions for storage

- This product should be stored at 10°C to 30°C.
- Do not freeze. Avoid high temperature, high humidity, and vibrating environments.
- Keep the reagent box closed so that the reagent cartridge is not directly exposed to light.
- Do not store the reagent cartridge in an overturned position and keep the reagent cartridges with the aluminum seal facing up.
- Do not store the reagent cartridge near fire or explosives, as it contains flammable materials.

Precautions for use

- Reagents in the reagent cartridge contain toxic or flammable materials. Please refer to the Material Safety Data Sheet (MSDS) and handle it with care.
- Do not reuse the used reagent cartridges and consumables.
- Do not use reagent cartridges or consumables that are past the expiry date.
- Do not damage or deface the 2D code.
- Follow the laboratory safety procedures and always consider the risk of infections. Wear appropriate protective equipment when handling samples, reagent cartridges, consumables, etc.
- If the extraction operation is started with extraction reagents (especially solutions containing magnetic particles) adhering to the inside of the prepack seal, the extraction reagents may not be sufficiently aspirated during the reaction process, and the designed extraction performance may not be achieved. Furthermore, if downstream is PCR, it is highly advised to use internal control or positive control according to the instruction manual of PCR reagent in order to obtain the accurate detection result of PCR.

Precautions for disposal

- Reagent cartridges and consumables should be disposed of as infectious material. Refer to the MSDS, and dispose of the materials according to local regulations.
- Do not dispose of reagent cartridge near fire or explosives, as it contains flammable materials.

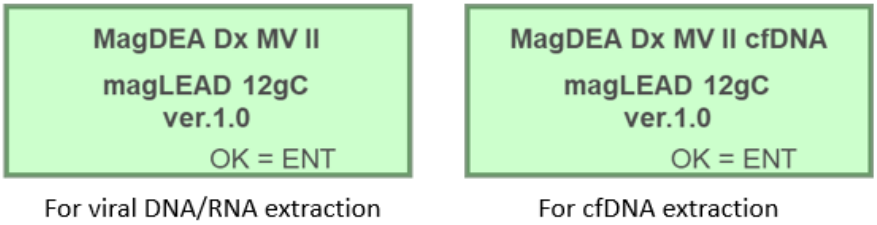
5. Extraction procedure

5.1. Extraction procedure of using magLEAD 6gC, magLEAD 12gC.

Read the instructions manual of the nucleic acid extraction instrument and I.C. card carefully before starting the procedure.

1. Insert the I.C. card and close the door to switch on the instrument.
2. When the home-menu screen is displayed, press the "START" button. Verify that the name of the correct protocol is displayed and press the "(E.N.T.)" button.

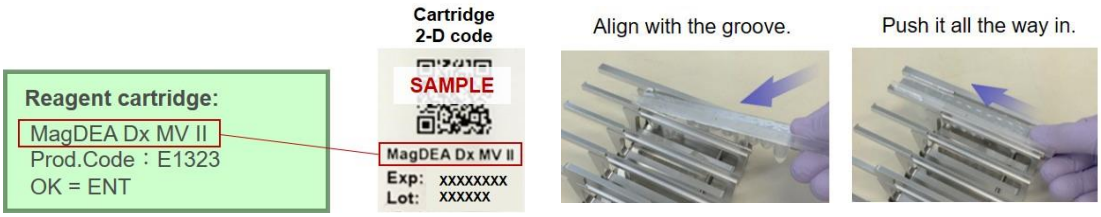
<Displayed message on magLEAD 12gC>



For viral DNA/RNA extraction　　For cfDNA extraction

3. To enter the batch information, press the "E.N.T." button to enter the batch information according to the on-screen display. (a bar code reader and software are required to enter the batch information.) If it is no need to enter the batch information, press the "START" button.

4. The reagent cartridge information will be displayed. Ensure that the reagent name shown on the display and the reagent name on the 2D code of the reagent cartridge are the same, then place it in the cartridge rack and press the "E.N.T." button.



※ Reagent solution may stick to the inside of the reagent cartridge aluminum seal. In such cases, shake it off gently to prevent bubbling before use.

※ Slide the reagent cartridge from the front side of the rack into the groove. Push it in until it stops at the back.

5. The set positions of the samples and consumables in the rack are displayed. Follow the instructions and press the "E.N.T." button.

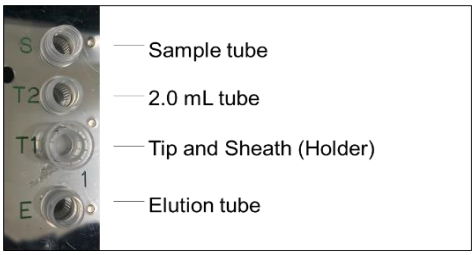
Hole E : 1.5 mL tube
Hole T1 : Tip & Holder

OK = ENT, Prev. = ESC

→

Hole T2 : 2.0 mL tube
Hole S : Sample

OK = ENT, Prev. = ESC



※ The Sample tube (Micro tube 1.5 mL), Tip and Sheath, and Elution tube (Micro tube 1.5 mL) are not included in this product. Please purchase the magLEAD Consumable Kit (product code: F4430).

※ 2.0 mL tube is not included in this product. Please purchase the 2.0 mL Cryopreservation Tube W/Cap (200pcs) (product code: F4450).

⚠ **Caution: Be sure to remove the tube cap, as it may cause instrument failure.**

6. The elution volume selection screen will be displayed. Press one of the buttons (1 to 3) to select the elution volume.

Select elution vol.
1. 50 µL 2. 100 µL
3. 200 µL
Next = 1 - 3 Prev. = ESC

7. The sample volume and elution volume are displayed. Confirm that the sample volume is 1000 µL and that the elution volume is the one you selected, and then press the E.N.T. button. If you want to change the elution volume, press the "E.S.C." button to return to the previous screen.

Sample : 1000 µL
Elution : 50 µL

OK = ENT, Prev. = ESC

8. The operation start screen are displayed. Close the door and press the "START" button to start the extraction operation (it will take approx. 55 minutes to complete the procedure).

Ready to Start.
Press START key !

Next = START, Prev. = ESC

9. When the operation is completed, an acoustic signal sounds, and the end time is displayed.

```
COMPLETED !
            HH : MM

Press ENT key
```

10. The following screen is displayed. Open the door and remove rack, eluent, reagent cartridge, and consumables.

⚠ **Caution: Do not leave the product unattended after an operation. Be careful not to spill any liquid when removing the product.**

```
Open the door.
Remove elution tube,
reagent and plastic
OK = ENT
```

11. To perform the U.V. irradiation, close the door, press the "E.N.T." button, and then follow the on-screen instruction to enter the data and perform the U.V. irradiation. If there is no need for a U.V. irradiation, press the "START" button.

```
UV decontamination ?

 Yes = ENT
 Skip = START
```

12. The following screen will be displayed when all processes are completed.

```
All process finished !


Press ENT Key
```

13. Return to the home screen and turn off the instrument.

⚠ **Caution: If you want to remove the IC card, turn off the power of the instrument.**

5.2. Extraction procedure for use with the geneLEAD VIII instrument

For the extraction procedure by geneLEAD VIII, check the instructions for use of the geneLEAD VIII instrument.

6. Troubleshooting

Low extraction yield, not pure enough

Root Cause	Countermeasure
Sample status	Ensure that there is no problem with the sample storage condition. Use fresh or correctly stored specimens whenever possible. When using refrigerated or frozen samples, equilibrate samples to room temperature before placing them in an instrument. When using samples that have been refrigerated or frozen, the yield may decrease depending on the storage period.
Tip clogging during extraction	The use of samples containing solids or highly viscous specimens may result in tip clogging during the extraction, leading to inadequate agitation at each step. To ensure easy pipetting, suspend the sample thoroughly before placing it on the instrument. Do not use coagulated blood specimens.
Contamination	Clean all instrument parts well after use, including all surfaces, with 0.1 % sodium hypochlorite or 70 % ethanol.
Instrument errors	Refer to the error code of the instrument, and follow the recommended countermeasures.

RNA is degraded.

Root Cause	Countermeasure
Too much sample	If the sample concentration is too high, the RNase cannot be inactivated. Dilute the sample to reduce the concentration.
Eluate stored for too long	Do not keep eluates for an extended time at room temperature after extraction. Close the elution tube cap tightly and immediately after extraction. Store the eluates at -80°C.
External RNase contamination	After use, clean all parts on the instrument surface carefully by using an RNase removal agent.

7. Related products

Product name	Product code
magLEAD 6gC	A1060
magLEAD 12gC	A1120
geneLEAD VIII	A2710
magLEAD Consumable Kit	F4430
geneLEAD VIII Consumable Set	F8900
2.0mL Cryopreservation Tube W/Cap (200pcs)	F4450

Produced by / sold by

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