Instructions for Use

Magtration® Reagent

MagDEA Dx MV II

Version 2.0

Content: January 20th, 2026

48 tests

This product is a nucleic acid extraction reagent intended for use in combination with automated 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.

REF **E1323**

10 ℃ 30 ℃

CE IVD

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Contents

1. Symbols

	CE marking
	In vitro diagnostic medical device
	Authorized Representative in the European Community
	Informations on the Swiss authorised representative
	Batch code/lot number
	Catalog number
	Contents
	Unique Device Identification
	Caution
	Temperature limitation
	Sufficient for
	Do not reuse
	Consult instructions for use
	Manufacturer
	Use by
	Acute toxicity
	Acute aquatic toxicity
	Flammable
	Health hazard

2. Abstract of product

2.1. Intended Use

«MagDEA Dx MV II» is a ready-to-use cartridge containing reagents for the extraction and purification of nucleic acids (NA). This reagent is used in combination with magLEAD and geneLEAD systems (Precision System Science Co., Ltd.).

The NA extraction protocol is based on magnetic beads and is designed for automated preparation of viral DNA/RNA and human cell-free DNA (cfDNA) from the following human clinical samples.

The performance of this product for each extraction protocol viral DNA/RNA and cfDNA has been established through performance evaluation using following sample types:

- Viral DNA/RNA from Human serum, plasma that include EDTA or citric acid, swabs (throat and nasal), urine, and saliva.
- Human cfDNA from the human serum, plasma that include EDTA or citric acid, urine, and saliva.

Caution

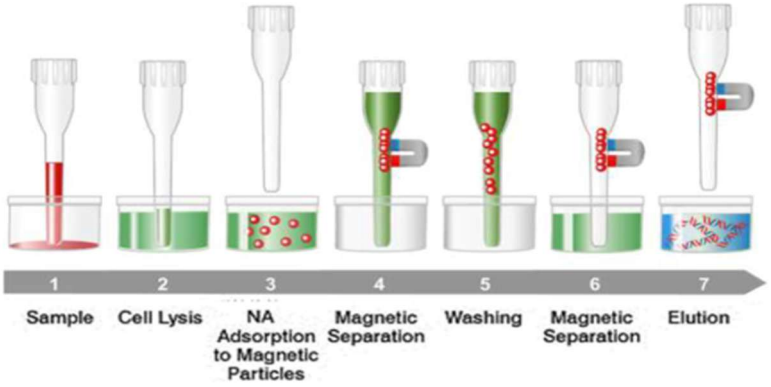
- Regulation (EU) 2017/746 Annex VIII CLASSIFICATION RULES As a result of evaluation according to Rule 1-5, this product is Class “A” because it corresponds to Rule 5 (a).
- This reagent does not provide diagnostics results by itself. To obtain diagnostics results, this product must be used with a NA amplification assay.
- This product is intended for use by professionals such as technicians, physicians and biologists trained in molecular biological techniques.
- The performance of MagDEA Dx MV II kit has been established by performance evaluation using above mentioned sample matrices for extraction of nucleic acid.
  The kit validation is limited to sample matrices above mentioned in Intended use.
  No guarantee is issued with sample is used different from these validated by Precision System Science Co., Ltd (PSS). The user is responsible to validate the performance of the product if used with assays different from those sample.
- Inform your PSS representative and your local competent authority about any serious incidents which may occur when using this product.
- The user is responsible to validate the performance of the product if used with assays different from those validated by PSS as reported in the instructions for use.
- This product must be handled by personnel qualified competent and trained in molecular biology techniques, such as extraction, amplification and detection of nucleic acids, to avoid incorrect results with potentially serious consequences for the patient in subsequent steps of the analysis performed on the extracted nucleic acids.

2.2. Extraction principle（Magtration Technology）

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.

In «MagDEA Dx MV II», 50, 100, or 200 µL of eluate is recovered from 1 mL of sample. The extraction process takes approximately 55 minutes.

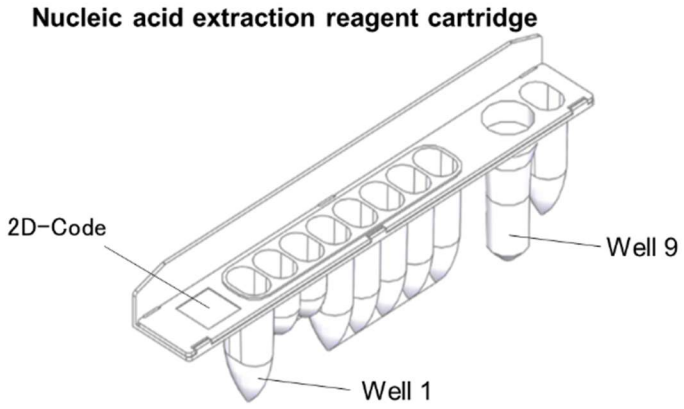
Principles of Magtration Extraction Technology



2.3. Kit contents

The kit contains 48 unitary prefilled Nucleic Acid extraction cartridges

Each Nucleic acid extraction cartridge contains:



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	

2.4. Warnings and precautions specific for the components

The following components of «MagDEA Dx MV II» contain hazardous reagents.

For further information, please, see Safety Data Sheets (SDS).

GHS Hazard and Precautions statements of components:

Lysis Solution

Contains Hexadecyl trimethylammonium chloride and Guanidinium chloride

Danger 

H302: Harmful if swallowed.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264: Wash the hands thoroughly after handling.
P270: Do not eat, drink, or smoke when using this product.
P271: Use only outdoors or in a well-ventilated area.
P273: Avoid release to the environment.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312: IF SWALLOWED: Call a POISON CENTER or a doctor if you feel unwell.
P302+P352: IF ON SKIN: Wash with plenty of water.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312: Call a POISON CENTER or a doctor if you feel unwell.
P321: Specific treatment.
P330: Rinse mouth.

P332+P313:	If skin irritation occurs: Get medical advice/attention.
P337+P313:	If eye irritation persists get medical advice/attention.
P362:	Take off contaminated clothing.
P391:	Collect spillage.
P403+P233:	Store in a well-ventilated place. Keep container tightly closed.
P405:	Store locked up.
P501:	Dispose of contents/container according to national regulation.

Binding Buffer Wash Buffer 1, and Wash Buffer 2

Contains 2-propanol.

Danger

H225:	Highly flammable liquid and vapour.
H319:	Causes serious eye irritation.
H335:	May cause respiratory irritation.
H361:	Suspected of damaging fertility or the unborn child.
H370:	Causes damage to organs.
H372:	Causes damage to organs through prolonged or repeated exposure.
H373:	May cause damage to organs through prolonged or repeated exposure.
P201:	Obtain special instructions before use.
P202:	Do not handle until all safety precautions have been read and understood.
P210:	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233:	Keep container tightly closed.
P240:	Ground/bond container and receiving equipment.
P241:	Use explosion-proof electrical/ventilating/lighting equipment.
P242:	Use only non-sparking tools.
P243:	Take precautionary measures against static discharge.
P260:	Do not breathe dust/fumes/gas/mist/vapours/spray.
P261:	Avoid breathing dust/fume/ gas/mist/vapours/spray.
P264:	Wash the hands thoroughly after handling.
P270:	Do not eat, drink, or smoke when using this product.
P271:	Use only outdoors or in a well-ventilated area.
P280:	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353:	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340:	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P311:	If exposed or concerned: Call a POISON CENTER or a doctor.
P308+P313:	If exposed: Call a POISON CENTER or a doctor.
P312:	Call a POISON CENTER or a doctor if you feel unwell.
P314:	Get medical advice/attention if you feel unwell.
P321:	Specific treatment.

P337+P313: If eye irritation persists: Get medical advice/ attention.
P370+P378: In case of fire: use carbon dioxide, foam, dry chemical, and water fog to extinguish.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up.
P501: Dispose of contents/container according to national regulation.

2.5. Materials Required but not provided

The following equipment and reagent are not provided:

- Disposable gloves in nitrile or similar material.
- Micropipettes and sterile tips.
- Vortex mixer depends on assay.
- Bench microcentrifuge depends on assay.
- NA amplification reagent and instrument (if necessary).
- Environment for operating nucleic acid amplification methods such as PCR.

To run samples on the magLEAD systems, the user must use the following materials:

Product name	Product code
magLEAD Consumable Kit	F4430
(as Extra Tube) 2.0mL Cryopreservation Tube W/Cap (200 pcs) or Micro tube 1.5mL (200 pcs)	 F4450 or F4460
(if necessary) Screw Cap (200 pcs)	F4470

To run samples on the geneLEAD systems, the user must use the following materials:

Product name	Product code
geneLEAD VIII Consumable Set	F8900
(as Extra Tube) 2.0mL Cryopreservation Tube W/Cap (200 pcs) or Micro tube 1.5mL (200 pcs)	 F4450 or F4460
(if necessary) Screw Cap (200 pcs)	F4470
(if necessary) geneLEAD VIII PCR Reagent Cassette Set	F8820

2.6. Other Product required

«MagDEA Dx MV II» is used in association with one of the following PSS systems:

Product name	Product code
magLEAD 6gC	A1060
magLEAD 12gC	A1120
magLEAD 12gC LiNK	A1130, A1132, A1133
magLEAD 4gC	A1140
geneLEAD VIII	A2710

Note: magLEAD 6gC and magLEAD 12gC requires a dedicated IC-card with these systems.

3. 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 Safety Data Sheet (SDS) 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 SDS, and dispose of the materials according to local regulations.
- Do not dispose of reagent cartridge near fire or explosives, as it contains flammable materials.

4. Operation procedure

Prior to use, please read carefully the operation procedure about automation system in the operation manual. Consumable kit sold separately is necessary.

1. Power on the instrument.
2. Select functions from Graphic user interface (GUI).
3. Prepare extraction reagent cartridge, consumables, and sample according to GUI guidance. Prior to use, if the reagent sticks inside the wall of the cartridge well, vibrate briefly for the drops to fall down without creating any bubbles.
4. Start the nucleic acid extraction process according to the GUI guidance.
5. After process completion, clean up the instrument according to GUI guidance.

5. 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.

6. Revision history

Revision	Date	Content
1.0	June 4th, 2021	1st revision for Research Use Only kit
2.0	January 20th, 2026	1st revision for IVD kit

Produced by / sold by

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