

Instructions for Use

Magtration® Reagent MagDEA® Dx SV



Version 2.1

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This reagent is designed for automation system. Please surely read and understand this document and operation manual of the system prior to usage. geneLEAD and magLEAD series are applied as automated systems.

This new revision of the Instruction for Use (IFU) contains the following changes:

- Update for the precautions in association with regarding reagents.

Composition, use and performance of the product are unchanged.



E1300



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1. Symbols



In vitro diagnostic medical device



Authorized Representative in the European Community



Caution



Batch code/lot number



Catalog number



Contents



Unique Device Identification



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. Introduction

MagDEA® Dx SV is the nucleic acid extraction reagent for the fully automated extraction – diagnostics system. (geneLEAD and magLEAD series are applied as automated systems.) The system is based on the Magtration® Technology and it is possible to use up to 200 µL samples and 400 µL samples. Extracted nucleic acid can be used for real time PCR or RT-PCR analysis, and it is possible to use this specific reagent kit by a simple procedure. PSS automated extraction system is based on the Magtration® Technology and magnetic particles, and there are no need for centrifugation or spin column steps. The use of MagDEA® Dx SV significantly reduce the risk of contamination from outside. Another advantage is that this procedure extracts high quality nucleic acid in less time compare with a manual process.

2.2. Intended use

- Viral NA extraction from human serum, plasma that include EDTA or citric acid, nasal swab, throat swab, urine cerebrospinal fluid (CSF), sputum and stool.
- DNA extraction from human whole blood that include EDTA or citric acid.

MagDEA® Dx SV cannot provide diagnostic data by itself however, the use of the integrated system or another commercial available nucleic acid amplification assay, can fulfill the need of a fully usable diagnostic tool. Sample containing heparin affects result of PCR.

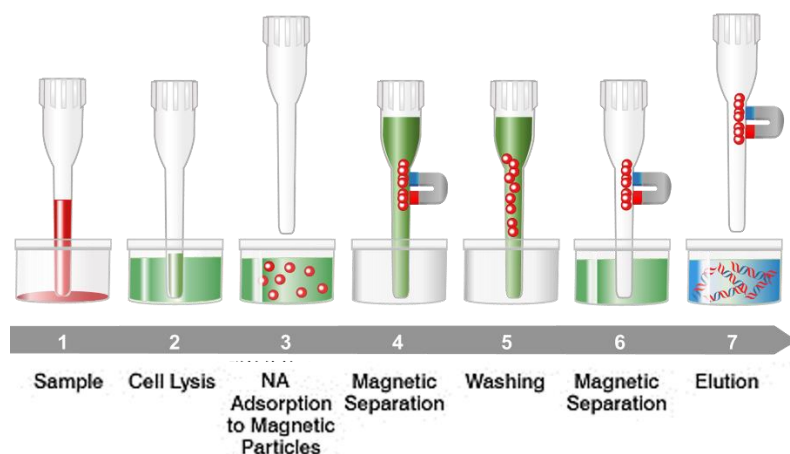


Caution

- 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).
- The performance of MagDEA Dx SV 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. 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.

2.3. Extraction principle (Magtration® Technology)

The Magtration® Technology is based on magnetic particles located inside of a tip, to segregate the particles from the liquid. (1) Sample is prepared. (2) Protein in sample is lysed using Proteinase K and lysis solution. (3) Nucleic acid is absorbed to magnetic particles with hydrophilic surface using chaotropic ion and alcohol. (4) Magnetic particles is recovered from reaction buffer by Magtration® Technology. (5) Magnetic particles is washed using wash buffer containing alcohol. (6) Magnetic particles is recovered from wash buffer by Magtration® Technology. (7) Nucleic acid is eluted using hot water as elution buffer, and eluate is recovered to collection tube.

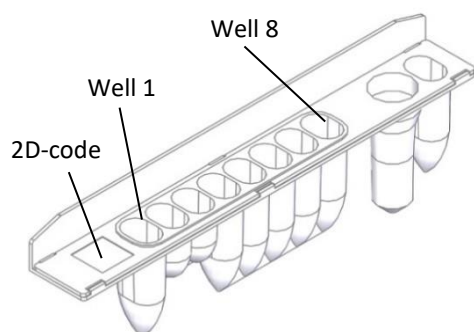


2.4. Kit contents

The kit contains 48 unitary prefilled Nucleic Acid extraction cartridges

Each Nucleic acid extraction cartridge contains:

Nucleic acid extraction reagent



| Well No. | Reagent name | Quantity |
|----------|--------------------|----------|
| 1 | Lysis solution | 400 µL |
| 2 | PK solution | 80 µL |
| 3 | Carrier solution | 80 µL |
| 4 | Magnetic particles | 200 µL |
| 5 | Binding buffer | 1000 µL |
| 6 | Wash buffer 1 | 1200 µL |
| 7 | Wash buffer 2 | 700 µL |
| 8 | Distilled water | 1200 µL |

2.5. Warnings and precautions specific for the components

The following components of the MagDEA Dx SV contain hazardous reagents.

For further information, please, see Material Safety Data Sheets.

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. |

2.6. Process time

Operation time depends on protocol.

| Protocol | 200 µL protocol | 400 µL Whole Blood Protocol | 400 µL Other matrix Protocol |
|--------------|-----------------|-----------------------------|------------------------------|
| Process time | Approx. 25 min. | Approx. 40 min. | Approx. 30 min. |

2.7. Storage condition

Please keep the extraction reagent kit at 10-30 °C. Do not freeze and keep the reagent away from high temperature including humidity or vibration. To prevent the reagent kit from exposure under direct sunlight, please keep the reagents in external boxes for storage after usage.

Always store the kit cartridges with the sealing on the upper side and not under tilting conditions.

3. How to use this product

3.1. Safety instructions



Please confirm following items prior to use.

- This extraction reagent kit is dedicated for automation system only. Therefore, please read carefully the instrument operation manual prior to use.
- In case of instrument error messages, please refer to the instrument operation manual.

Notes for safety usage

- Reagent inside of prepack cartridge include toxic or flammable material, please refer to hazard and precautionary statements of Material safety data sheet (MSDS) and pay attention to the safety handling paragraph.
- Follow the laboratory safety guidance and pay attention to infection risks.
- Do not drink or smoke close to the test area.
- Wear protective gloves, coat and eye protection gear when using the kit.
- Dispose the gloves and clean your hands carefully after use.

Notes for dispose

- When disposing reagent or consumables, handle them as infection risk. Refer to MSDS and follow your regional regulation for disposables.
- The reagents include iso-propyl alcohol so keep away from fire or explosive items when disposing.

Notes for reagent performance

- Do not use when the cartridge or aluminum seal is damaged or leaks.
- Do not use expired reagent kit.
- Do not re-use extraction cartridge or tip rack.
- Do not damage or dirt 2D code.
- Prior to use, if the reagent stick on the wall inside the cartridge well, vibrate/flick briefly for the drops to fall down without creating any bubbles.
- The elution consists of distilled water however the final elution volume may vary due to remaining's on the magnetic particles, tip surface or due to evaporation.
- Do not leave the reagent for too long time on the instrument before start.
- It is recommended to use controls for PCR, such as internal control or positive control, to get reliable diagnostic results.

3.2. 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, tip set included in consumable kit sold separately and sample by GUI guidance. Prior to use, if the reagent stick inside the wall of the cartridge well, vibrate briefly for the drops to fall down without creating any bubbles.

Consumption of one sample are as follows. Prepare the reagent and the consumables according to GUI of instrument.

| | |
|---|------|
| Nucleic acid extraction cartridge MagDEA® Dx SV | 1 pc |
| Tip set | 1 pc |
| Collection tube | 1 pc |
| Sample tube | 1 pc |

4. Select protocol with help of GUI of instrument or PC.
5. Make sure to set MagDEA® Dx SV, Sample tube or Sonication tube, (if needed Sonication cap), collection tube for elution, Tip rack and PCR cartridges properly based on the GUI guidance.
6. Close the front cover of the instrument.
7. Push Start button to start the nucleic acid extraction process.
8. After process completion, open front cover by GUI guidance.

4. Reagent performance

The performance tests were validated using geneLEAD XII plus of PSS. PCR result of the extract is depended on the PCR condition and the amplification system.

4.1. Linearity test of extracts from various sample matrices, spiked with M13 DNA bacteriophage

M13 DNA bacteriophage, using 10 µL and 7 different concentrations, were added to 200 µL of following human body fluid samples; Serum, plasma (EDTA-2Na), plasma (ACD), swab (throat), swab (nasal), cerebrospinal fluid (CSF) and urine. Those samples were prepared to final numbers of 1×10^2 , 3, 4, 5, 6 7 and 8 copies/extraction (5 replicates). DNA was extracted using MagDEA® Dx SV on geneLEAD XII plus, and the extracts were PCR amplified using ABI 7500 Dx fast (M13 specific TaqMan probe). 100 copies/extraction were detected in all tests. Slopes, coefficient of determination (R^2), PCR efficiency and y-intercept were calculated using the Ct values obtained from samples between $1 \times 10^{2-8}$ copies/extraction (Table 1). No differences were observed between the sample species. PCR amplification curve and Linearity plot graph using serum is shown in Figure 1.

Table 1. The linearity test analysis showing obtained Ct values from seven different human sample matrixes.

| | Serum | Plasma (EDTA) | Plasma (ACD) | Swab (Throat) | Swab (nasal) | CSF | Urine |
|--|--------|---------------|--------------|---------------|--------------|--------|--------|
| Slope | -3.447 | -3.406 | -3.415 | -3.369 | -3.391 | -3.361 | -3.397 |
| coefficient of determination (R^2) | 0.995 | 0.997 | 0.998 | 0.999 | 0.999 | 0.996 | 0.998 |
| PCR efficiency (%) | 95.027 | 96.594 | 96.253 | 98.061 | 97.215 | 98.405 | 96.954 |
| y-intercept | 41.863 | 41.556 | 41.782 | 41.097 | 41.463 | 40.883 | 41.052 |

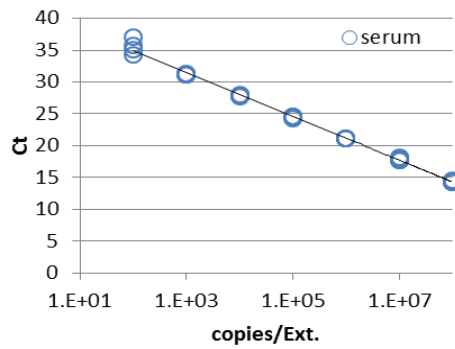


Figure 1. Linearity plot graph showing copy numbers and Ct values from M13 bacteriophage included serum as typical data.

4.2. Genomic DNA from human whole blood

Genomic DNA was extracted from human EDTA-2Na (specimen A) or ACD (specimen B) whole blood samples using MagDEA® Dx SV for total 6 days (6 replicates by each run). The white blood cell (WBC) numbers of specimen A and B were 6.4 and 9.2 k/ μ L respectively. The concentrations and purities of the extracts were measured using ND-1000 spectrometer (NanoDrop) (Figure 2). After 6 runs, there were no significant variations between the two specimens.

Table 2. The $A_{260/280}$, and $A_{260/230}$ of genomic DNA from whole blood sample.

| | $A_{260/230}$ | $A_{260/280}$ |
|------------|-----------------|-----------------|
| Specimen A | 1.70 ± 0.11 | 1.88 ± 0.06 |
| Specimen B | 1.85 ± 0.17 | 1.89 ± 0.05 |

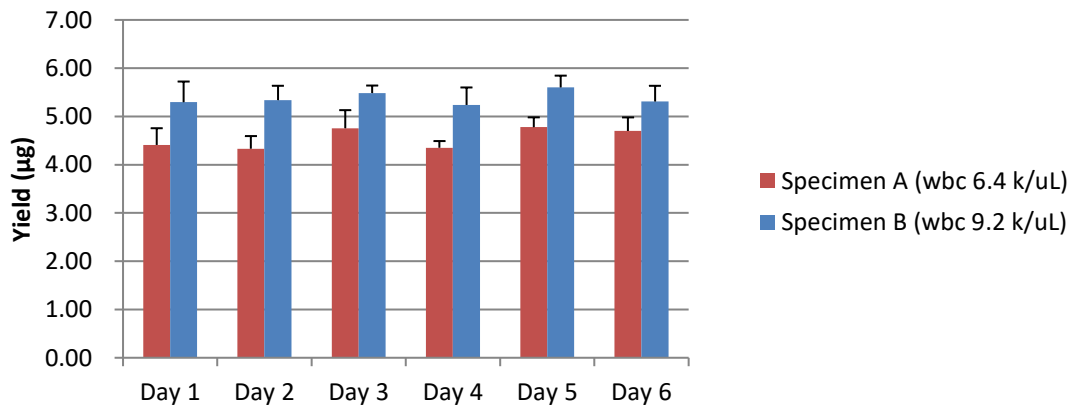


Figure 2. The yield of genomic DNA from whole blood sample.

5. Trouble shooting

In case of finding a general error, please follow the procedure below. Please follow the instrument operation manual in case of an instrument error.

(1) Low extraction yield, not pure enough

| Root cause | Countermeasure |
|------------------------------|--|
| Sample status | Verify that the sample storage condition is appropriate or not. Use fresh sample or sample stored under appropriate condition. Extraction amount can vary from chilled or frozen sample. |
| Reagent status | Verify that the extraction reagent cartridge storage condition is appropriate. In case of kit storage in refrigerator, please place the reagent in room temperature prior to use. Do not freeze the reagent, and prevent storage places with vibration. |
| Solid items remaining | Some specific sample extracts with solid items remaining inside may cause tip stacking, and mixing process may not function properly. The sample should contain a clear solution for smooth handling by 1000uL pipet. Do not use solid sample for extraction. |
| Contamination | Clean all instrument parts well after use, including all surfaces by using 0.1 % sodium hypochlorite, and then clean by 70 % ethanol. |
| Trouble of automation system | Refer the error code of automation system, and accordance with the countermeasure. |

(2) RNA is solved

| Root cause | Countermeasure |
|-------------------------------|--|
| Too much sample amount | In case of adding too high sample concentration, RNase cannot be inactivated. Reduce sample concentration. |
| Elution storage too long time | Do not keep eluted sample for too long time in RT after extraction. Tighten cap of elution tube as soon as possible, and keep samples at -80 °C condition. |
| External RNase contamination | Clean all instrument parts well after use, including all surfaces by using 0.1 % sodium hypochlorite, and then clean by 70 % ethanol. After use, clean all parts on the instrument surface carefully by using RNase removal agent. |

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These explanations are based on the status of 2023/4.
Please be noted information such as specification can be changed without information.

Produced by / sold by



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