Fully automated nucleic acid extraction reagent 「MagDEA Dx MV II」

Precision System Science Co., Ltd

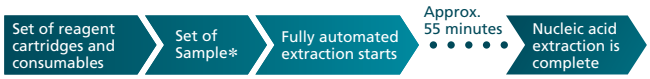
〈Introduction〉

Precision System Science Co., Ltd. has developed the MagDEA Dx series of magnetic particle-based nucleic acid extraction reagents and automated systems.

The newly developed "MagDEA Dx MV II" is a nucleic acid extraction reagent that can extract viral DNA/RNA and cell-free DNA (cfDNA) from a 1 mL sample. This product is suitable for use with the fully automated nucleic acid extraction systems magLEAD 6gC, magLEAD 12gC, and geneLEAD VIII.

〈Product overview〉

This product's nucleic acid extraction method can extract target nucleic acids easily without any complicated process steps. The resulting eluate can be used as shown in the process chart below.



*Pretreatment is required for some sample matrices.

〈Product specifications〉

Sample volume	1 mL	
Elution volume	50 µL, 100 µL, and 200 µL (Selectable)	
Extraction time	Approx. 55 minutes	
Nucleic acid	Viral DNA/RNA	Cell-free (cf) DNA
Sample matrices	Serum, plasma, swabs(throat and nasal), urine, saliva (pretreated)	Serum, plasma, urine, saliva (pretreated)
Protocol	MagDEA Dx MV II	MagDEA Dx MV II cfDNA
Instrument	magLEAD 6gC, magLEAD 12gC, geneLEAD VIII	

〈Extraction performance for viral DNA/RNA〉

Nucleic acid extraction performance evaluation (linearity, reproducibility, and extraction performance by sample type) was performed. The M13KO7 phage (M13) was used as a DNA virus model and the MS2 phage (MS2) as an RNA virus model. Extraction performance was evaluated by real-time PCR with detection protocols for each phage. Nucleic acids were extracted from pooled plasma (EDTA-2K) and pooled serum containing 1× 10^2-1×10^8 copies of M13. Ct values of the target genes were measured by real-time PCR. Dependencies of Ct value variation and linearity were observed (**Fig. 1**).

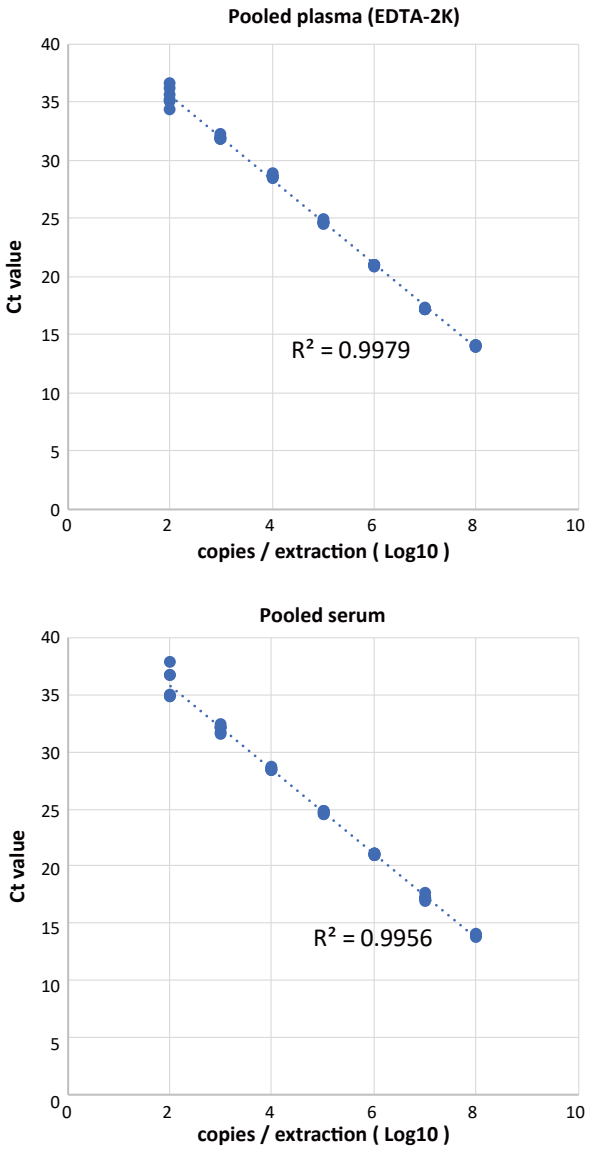


Fig. 1 : Linearity test results

〈Nucleic acid extraction performance〉

Nucleic acid extractions from pooled plasma (EDTA-2K) and pooled serum containing M13 equivalent to 100 copies (the lower limit of detection) were performed multiple times (N=24), and the target genes in the resulting eluates were detected by real-time PCR. Equivalent Ct-values were observed in all samples containing M13 (**Table 1**).

Positive sample Ct value (100 copies)		Negative sample Ct value (0 copy)	
Pooled plasma (EDTA-2K)	Pooled serum	Pooled plasma (EDTA-2K)	Pooled serum
34.2	33.7	undetermined	undetermined
33.7	34.1	undetermined	undetermined
33.9	34.3	undetermined	undetermined
33.7	33.6	undetermined	undetermined
33.8	33.1	undetermined	undetermined
34.0	34.5	undetermined	undetermined
34.0	33.9	undetermined	undetermined
34.1	34.2	undetermined	undetermined
33.6	33.5	undetermined	undetermined
33.8	34.0	undetermined	undetermined
33.7	34.8	undetermined	undetermined
33.3	33.4	undetermined	undetermined
34.2	33.8	undetermined	undetermined
33.8	34.7	undetermined	undetermined
33.3	34.3	undetermined	undetermined
33.6	33.7	undetermined	undetermined
33.4	33.9	undetermined	undetermined
34.1	34.2	undetermined	undetermined
35.0	34.2	undetermined	undetermined
34.1	33.9	undetermined	undetermined
34.5	34.2	undetermined	undetermined
33.8	34.2	undetermined	undetermined
33.8	34.2	undetermined	undetermined
33.9	34.1	undetermined	undetermined

Table 1 : Reproducibility test results

Three samples each of throat swab, nasal swab, urine, and saliva were prepared. The nucleic acid extraction performance was evaluated by adding M13 (equivalent to 2×10^3 copies) to the sample and MS2 (equivalent to 1×10^4 copies) to the reagent cartridge. To achieve sample homogenization and virus inactivation, each sample was pretreated as described in the following procedures.

Pretreatment of throat/nasal swabs and urine (for inactivation)	Saliva pretreatment (for homogenization and inactivation)
① Dispense 750 µL of sample volume.	① Sample: Sputazyme = 1:3
② Add 250 µL of Prep Buffer A.	② Incubate at room temperature for 15 minutes
③ After mixing, incubate at room temperature for 5 minutes	③ Centrifuge at 16,000×g for 2 minutes
	④ Separate 750 µL of supernatant.
	⑤ Add 250 µL of Prep Buffer A
	⑥ After mixing, incubate at room temperature for 5 minutes

Ct values of M13 and MS2 were measured for all samples(**Fig. 2**).

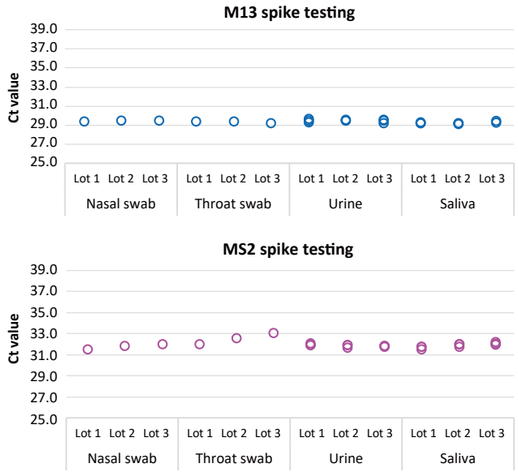


Fig. 2 : M13, MS2 spiking test results by sample species.

〈Extraction performance for cfDNA〉

The extraction performance for cfDNA was evaluated to determine reproducibility and extraction performance by sample type.
Five runs of cfDNA extraction were performed from pooled plasma (EDTA-2K) and pooled serum from healthy donors, and copy-number quantification was performed by detecting EGFR gene (Wild type and L858R mutation) using droplet digital PCR (ddPCR)(**Table 2**).

Sample	Run	Qubit dsDNA HS Assay (ng)	Wild type copies	L858R copies	Type
Pooled plasma (EDTA-2K)	Run 1	9.7	84.7	0	Wild type
	Run 2	7.5	66.7	0	Wild type
	Run 3	7.6	70.7	0	Wild type
	Run 4	8.1	71.7	0	Wild type
	Run 5	7.3	63.7	0	Wild type
Pooled serum	Run 1	8.0	36.3	0	Wild type
	Run 2	7.9	37.3	0	Wild type
	Run 3	6.9	29.0	0	Wild type
	Run 4	6.4	39.3	0	Wild type
	Run 5	6.9	48.0	0	Wild type

Table 2 : Reproducibility test results

Twelve samples of healthy human plasma (EDTA-2K) were prepared, and cfDNA extraction performance was compared with other methods (spin column, and magnetic particles provided by other companies). cfDNA yield, cfDNA peak, and EGFR wild-type copy-number were determined by TapeStation and ddPCR, respectively (**Fig. 3, 4, 5**).

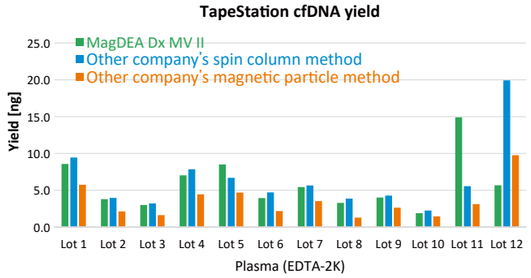


Fig. 3 : cfDNA yield

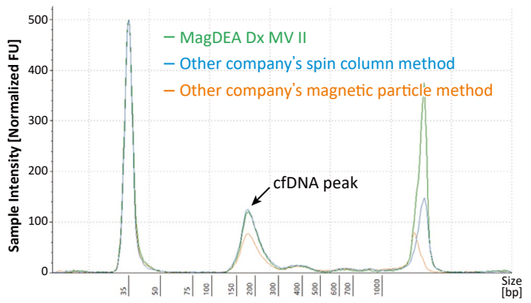


Fig. 4 : ccfDNA peak (Lot.1)

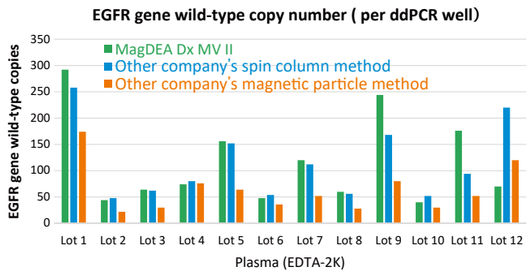


Fig. 5 : EGFR wild-type copy number

Twelve samples of healthy human serum were prepared, and cfDNA extraction performance was compared with the spin column method of other companies. cfDNA yield, cfDNA peak, EGFR wild-type copy-number were determined by TapeStation and ddPCR, respectively (**Fig. 6, 7, 8**).

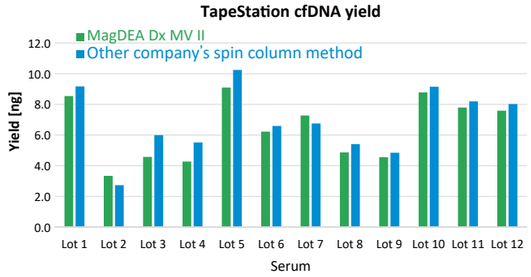


Fig. 6 : cfDNA yield

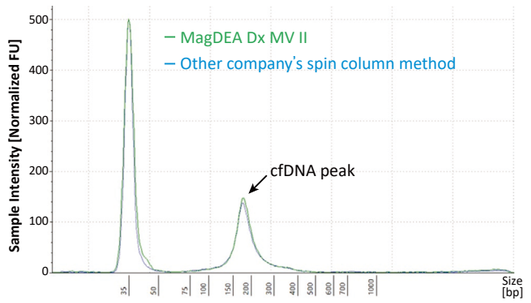


Fig. 7 : cfDNA peak (Lot.1)

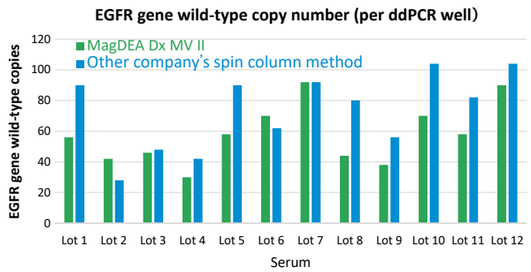


Fig. 8 : EGFR wild-type copy number

cfDNA was extracted from pretreated human urine and human saliva. The results of cfDNA extraction from urine were similar to those of other spin column methods. cfDNA peaks were measured using saliva samples (**Fig. 9**).

Pretreatment method for urine	Pretreatment method for saliva
① Centrifuge at 16,000×g for 10 minutes	① Sample: Sputazyme = 1:3
② Separate 1000 µL of supernatant	② Incubate at room temperature for 15 minutes.
	③ Centrifuge at 16,000×g for 2 minutes
	④ Separate 1000 µL of supernatant

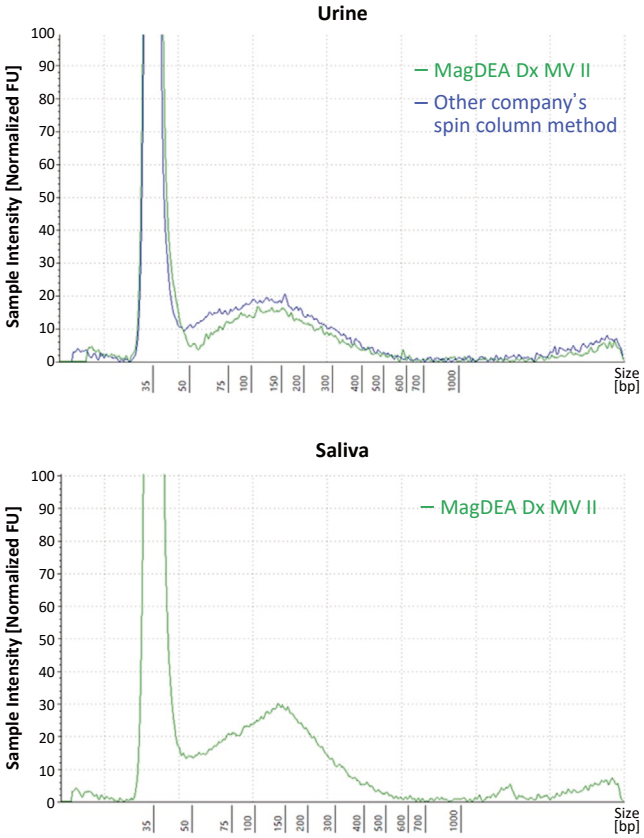


Fig. 9 : Results of cfDNA extraction from urine and saliva

〈Product information〉

Product name	Product code
MagDEA Dx MV II	E1323
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
Prep Buffer A (reagent for inactivation)	E1400

〈Protocol〉

Instrument name	Protocol name	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

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