Instructions for Use (Handbook)

MagPurix® cfDNA Extraction Kit LV

Catalog No.: ZP02025
Manual No.: IFU-MP02-02025
Version: 2.2

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CE IVD

For *in vitro* diagnostic use

EC REP

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Read and follow these Instructions for Use prior to using this product. The latest revision of this document can be found at www.zinexts.com

Contents

Intended Use

The MagPurix® cfDNA Extraction Kit LV utilizes unique magnetic ZiBeads® technology for automated isolation and purification of circulating cell-free DNA (cfDNA) from cell-free samples, such as plasma, or from a pool of cell-free body fluids.

The product is intended to be used by professional users, such as technicians and physicians who are trained in molecular biology techniques.

Introduction

Product Name	MagPurix® cfDNA Extraction Kit LV
Catalogue Number	ZP02025
Product Overview	The MagPurix® cfDNA Extraction Kit LV is designed to extract cfDNA from cell-free samples, such as plasma, or from a pool of cell-free body fluids using MagPurix® EVO series automatic instruments. The kit is applied with unique magnetic ZiBeads® technology, which achieves superior product quality, consistent and high product yield and reproducible results. The final product is suitable for a wide range of diagnostic and research applications, including sequencing, genotyping and qPCR detection.
Applicable Instrument Model	MagPurix® EVO Instruments
Display Protocol Name on The Instrument	2025 cfDNA LV
Applicable Instrument Firmware	Check and download the latest firmware from www.zinexts.com
Processing Time	MagPurix® EVO series 45-52 minutes

Kit Contents and Storage

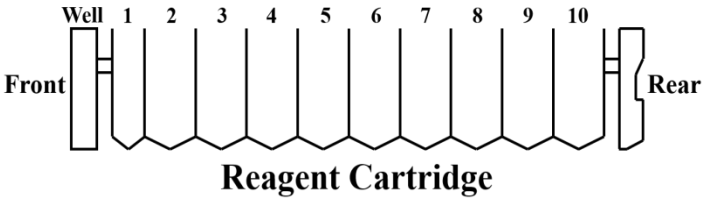
Shipping and Storage	The kit is shipped at room temperature. Upon receipt, store the kit at room temperature. All kit components are stable when stored properly until the expiration date shown on the kit box.	
Kit Content	The components supplied in the kit are listed below. Sufficient reagents are supplied to perform 48 purifications.	
	Contents	Amount
	1 Reagent Cartridge	48 pcs (6x8)
	2 Reaction Chamber	48 pcs (6x8)
	3 Tip Holder	48 pcs (6x8)
	4 Piercing Pin	50 pcs
	5 Filter Tip	50 pcs
	6 Sample Tube (7 ml)	50 pcs (25x2)

7 Elution Tube (1.5 ml)	50 pcs
S Small Tip	50 pcs
LB1 Buffer (300 ml)	1 pc
Magnetic Bead Solution C (6 ml)	1 pc
Barcode Sticker	50 pcs

Reagent Cartridge Contents

Each Reagent Cartridge has 10 positions with 10 sealed well. Positions 1-10 contain wells filled reagents for this protocol

Reagent	Well No.
Empty	1
Empty	2
Empty	3
Empty	4
Washing Buffer 8	5
Washing Buffer 8	6
Washing Buffer A	7
Washing Buffer B	8
Elution Buffer 3	9
Empty	10



Reagent Cartridge

Materials Required But Not Provided

The following general laboratory equipment and consumables are required to perform the extraction. All laboratory equipment should be installed, calibrated, operated, and maintained according to the manufacturer's recommendations. The following table lists the required equipment and consumables.

For all purification procedures:
1. MagPurix® EVO series instrument
2. 1.5 or 2.0 ml microcentrifuge tubes
3. Pipettes and filter tips
4. Phosphate-buffered saline (PBS, may be required for diluting samples)
5. Sample Rack for 7 ml Sample Tubes
6. **Optional**: Plastic consumables, DNase-free RNase A (to minimize RNA content), Proteinase K (20 mg/ml), Sodium dodecyl sulfate (SDS) solution (20%, w/v)
7. **Optional**: Streck Cell-Free DNA BCT tube

Warnings and Precautions

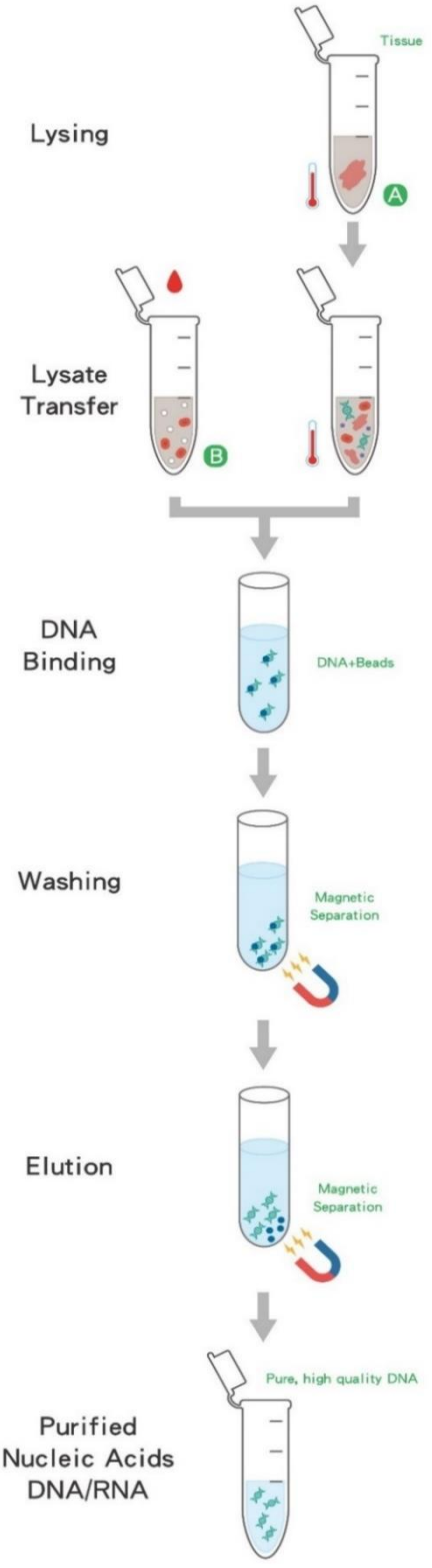
For *in vitro* diagnostic use only. Read all the instructions carefully before using the kit. Use of this product should be limited to trained personnel in the techniques of DNA purification. Strict compliance with the user manual is required for optimal results. Attention should be paid to expiration dates printed on the box and labels of all components. Do not use a kit after its expiration date.

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at **MSDS (Material Safety Data Sheets) – Downloads – www.zinexts.com**.

Please report any serious incident occurred in relation to the device to your local representative/ agent or the manufacturer, and to the competent authority of your country/state.

CAUTION: DO NOT add bleach or acidic solutions directly to the sample preparation waste.

Purification Principle



Ⓐ Perform certain pretreatment process before extraction.

Ⓑ Transfer sample to extraction directly.

Things to Do Before Starting

Sample Preparation

The purification procedure is optimized for the use of 2-5 ml of plasma* samples.

Plasma*

Lysis/binding section:

a. Aliquot 2-5 ml samples to an appropriately sized tube.
b. Add 1.25 ml LB1 Buffer for every 1 ml of sample.
c. Add 25 µl Magnetic Beads Solution C for every 1 ml of sample.
d. Vortex or shake the tube vigorously for 10 minutes at room temperature.
e. Place the tube on the magnetic stand for 5 minutes or until the solution is clear.
f. While keeping the tube on the magnetic stand, remove supernatant. Be careful not to remove magnetic particles.
g. Keep the tube on the magnetic stand for 1 minute, and then remove residual supernatant.
h. Leave 1 ml lysate (with magnetic beads) and transfer into each 7 ml Sample Tube.

Table 1 – The recommended tube size with its corresponding LB1 Buffer and Magnetic Beads Solution C volume according to sample volume

Sample volume	LB1 Buffer	Magnetic Beads Solution C	Recommended tube(s) size
x (x = ml of sample)	1.25x	0.025x	n/a
2 ml	2.5 ml	50 µl	15 ml
5 ml	6.25 ml	125 µl	50 ml

Optional: Proteinase K Treatment

If samples were collected using a **Streck Cell-Free DNA BCT tube:**

a. Aliquot 2-5 ml samples to an appropriately sized tube.
b. Add 15 µl Proteinase K (20 mg/ml) for every 1 ml of plasma.
c. Add 50 µl 20% SDS solution for every 1 ml of plasma.
d. Mix by inverting gently for 5 times.
e. Incubate at 60°C for 20 minutes.
f. After incubation, place the tube on ice for 5 minutes to cool the tube to room temperature.
g. Once the tube has cooled, proceed to the Lysis/binding section.

Note:

Plasma must be prepared from fresh or frozen blood samples collected in tubes that contain common anti-coagulants like EDTA and citrate. (Heparin has inhibitory effects on nucleic acid amplification reaction).

If samples were collected using a **Streck Cell-Free DNA BCT tube**, Proteinase K treatment is required to ensure optimal yields. If blood was not collected with **Streck Cell-Free DNA BCT tube,** proceed to the Lysis/Binding step.

Using Magnetic Beads Solution C:
Mix beads well prior to adding. There should be no visible sedimentation at the bottom of the solution after mixing. Beads will settle quickly, so be sure to mix the Magnetic Bead Solution C after adding to each sample. Insufficient mixing may result in inconsistent yields.

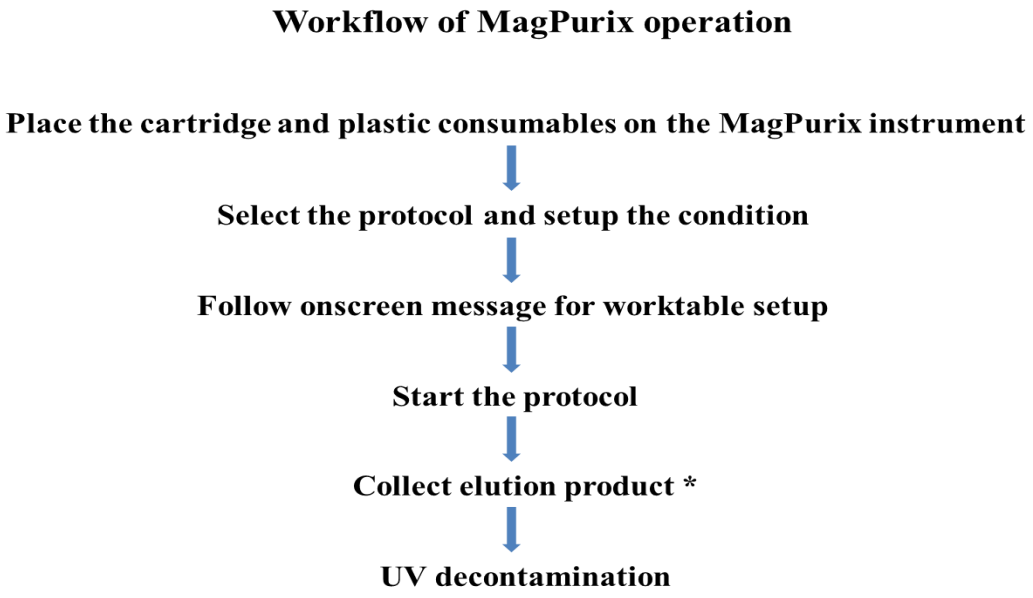
Method of Vortex/shaking:
To obtain high yields, ensure that plasma/buffer solution is mixed vigorously in the tube. A vortex mixer with a tube-holder can allow walk-away mixing, which will make the mixing easier.

Using fresh sample (stored at 2-8°C for up to 6 hours) for extraction is recommended. Total nucleic acid yield and quality will decrease with time or after multiple freeze-thaw cycles. For longer storage time, samples should be frozen at -20°C or lower and avoid freeze-thaw cycles. Thaw samples at room temperature (15-25°C) and process the sample immediately after the temperature reaches to room temperature. **Do not** refreeze sample after thawing. If precipitation is visible in sample, centrifuge at 6,800 x *g* for 3 minutes and transfer supernatant to a new tube without disturbing the precipitate, and immediately start the purification procedure.

Table A – The suggested starting material and elution volume range for each nucleic acid extraction

Sample type	Starting material per sample	Elution Volume
Plasma	2000-5000 µl	50-200 µl

Procedure of MagPurix System



* Output the bench record (option)

Purification Protocol - MagPurix® EVO series

1	Turn on the Instrument	a.	Turn on the power switch and wait for the screen to turn on.
		b.	Login the instrument and enter the Home Page.
2	Load new Consumable(s) and Cartridge(s)	a.	Open the door and remove the Sample Rack from the instrument.
		b.	Open the Tip-Holder Lid.
		c.	Load 1 Reagent Cartridge and all plastic disposables (2 Reaction Chamber, 3 Tip Holder, 4 Piercing Pins, 5 Filter Tips and other components presented in the kit intended to use).
		d.	Close the Tip-Holder Lid.
		e.	Paste the Barcode Stickers on Elution Tubes.
		f.	Place 6 Sample Tubes and 7 Elution Tubes into the Sample Rack.
3	Load the Samples	a.	Transfer appropriate volume of sample into each Sample Tube on the Sample Rack.
		b.	Put the Sample Rack back into the instrument and close the door.
4	Program Set up	a.	Select the appropriate protocol program on the instrument. Press **NEXT**.
		b.	Select the appropriate Sample Volume and Elution Volume and press **NEXT**.
		c.	Press the number button to select the right Sample Numbers.
		d.	Scan/Edit each primary Sample ID directly. After finished, press **NEXT**.
		e.	Scan/Edit each Elution Tube ID directly. After finished, press **NEXT**.
		f.	Scan Reagent Cartridge Barcode. Press **NEXT**. *If the cartridge is expired, the next step cannot be performed.
		g.	Follow the instructions on the screen to double-check the operating steps being completed before running the program. Press **NEXT**.
5	Start Extraction	a.	Check "**PROGRAM CONFIRMATION**" on the screen.
		b.	Press "**START**" to start the experiment. Instrument will run the protocol program automatically until the whole process is completed.
		c.	At the end of the run (approximately 45-52 minutes), instrument alarms briefly and the screen indicates "**PROGRAM FINISH**".
		d.	If you want to perform the same protocol, press "**RERUN**" to perform the same experiment. If you do not need to re-run the experiment, press the function button "**HOME**" to exit the experiment mode.
6	Collect the Elution Tubes	a.	Open the instrument door.
		b.	Collect the Elution Tubes containing the purified nucleic acids.
		c.	The purified nucleic acids are ready for immediate use. Store the purified nucleic acids at 4°C (short-term, less than 10 days) or aliquot and store at -70°C (long-term) before performing downstream analysis.
		d.	Discard the used cartridges and all plastic consumables into biohazard waste. *Do not reuse the cartridges.
		e.	If you are not using the instrument immediately, please put the Sample Rack back into the instrument, close the instrument door, and press the "**POWER**" function button to enter sleep mode. If the instrument will not be used in an extended period of time, please turn off the power switch.

Troubleshooting

***This table is helpful for solving common problem. If you need other technical support, please contact Zinexts team (sales@zinexts.com) or your distributor.**

Problem	Possible Cause	Comments and suggestions
Poor DNA quality or yield	Deterioration or contamination of reagents.	Please ensure that the kit reagents are still within the effective shelf-life period before use. Discard any kit reagent that shows discoloration or evidence of microbial contamination.
	Kit stored under non-optimal conditions.	Store kit at 15-25°C at all time after arrival. If either reagent or buffer precipitate upon shipping in cold weather or during long-term storage, dissolve precipitates by gently warming and stirring the solution. Please do not freeze the Reagent Cartridges.
	Insufficient sample input.	DNA yield depends on the sample type and the number of nucleated cells in the sample. Please proportionally adjust the total input amount of sample to increase the DNA yield.
	Too much of elution buffer was used.	The elution volume can be reduced proportionally.
	The eluate of final product(s) is not enough.	Please collect issue information and provide it to your Support Representative/Technical Support as soon as possible.
Clogging issue	Too much sample material was used.	Decrease the input amount of sample material or dilute your sample.
No results in downstream analysis	No signal/The PCR was inhibited.	Using appropriate controls for analysis. Check the positive control, negative control, water (NTC) and internal control to clarify the possible causes.
Instrument malfunction/abnormal sound	Abnormal consumables: 1. Deformed Filter Tips 2. Deformed Reaction Chamber 3. Deformed Tip Holder	Please replace the batch with normal consumables.
	Abnormal action of instrument: 1. Inaccurate correction value 2. Spare parts or components damaged	Please collect issue information (videos and pictures) and provide it to your Support Representative/Technical Support as soon as possible to calibrate or replace any other damaged or worn parts.

Related Products

Product Name	Cat. no.
MagPurix® Blood DNA Extraction Kit 200	ZP02001
MagPurix® Blood DNA Extraction Kit 1200	ZP02002
MagPurix® Viral Nucleic Acid Extraction Kit	ZP02003
MagPurix® Tissue DNA Extraction Kit	ZP02004
MagPurix® Cultured Cell DNA Extraction Kit	ZP02005
MagPurix® Bacterial DNA Extraction Kit	ZP02006
MagPurix® HPV DNA Extraction Kit for Swab Samples	ZP02007
MagPurix® TB DNA Extraction Kit	ZP02008
MagPurix® FFPE DNA Extraction Kit	ZP02009
MagPurix® Forensic DNA Extraction Kit	ZP02010
MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit A	ZP02011
MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit B	ZP02012
MagPurix® Viral RNA Extraction Kit	ZP02013
MagPurix® Plant DNA Extraction Kit	ZP02014
MagPurix® Total RNA Extraction Kit	ZP02015
MagPurix® Viral Nucleic Acid Extraction Kit LV	ZP02016
MagPurix® CFC DNA Extraction Kit	ZP02017
MagPurix® cfDNA Extraction Kit Plus	ZP02024
MagPurix® cfDNA Extraction Kit LV	ZP02025
MagPurix® Coronavirus RNA Extraction Kit	ZP02027
MagPurix® Urine cfDNA Extraction Kit	ZP02032
MagPurix® Plasma cfDNA Extraction Kit	ZP02033

References

- Tan SC *et al.* J Biomed Biotechnol. (2009)

Symbols

The following symbols are used on labels and in Instructions for Use (IFU), in compliance with EN ISO 15223-1 standard.

Symbol	Explanation
CE	CE mark
IVD	For In Vitro Diagnostic Use
REF	Catalogue number
LOT	Lot/Batch number
Σ	Sufficient for [n] samples
	Expiry date
15°C 25°C	Storage temperature (15°C - 25°C)
	Manufacturer
EC REP	European Authorized Representative
	Caution

Limited Product Warranty

Zinexts Life Science is committed to provide customers with high-quality products and services. Our goal is to ensure that every customer is 100% satisfied with our products and services. If you have any question or concerns, contact our Technical Support Representatives.

Zinexts Life Science guarantees the performance of all products according to the specifications stated in our product literature. The purchasers/users must determine the suitability of the product for their particular use. We reserve the right to change, alter, or modify any product to enhance its performance and design.

This warranty limits Zinexts Life Science Corporation's liability only to the cost of the product. No warranty is granted for products beyond their listed expiration date. No warranty is applicable unless all product components are stored and used in accordance with instructions.

Revision History

Version	Date	Description
2.2	14. Apr. 2023	1. Add "Optional: Streck Cell-Free DNA BCT tube" in section "Materials Required But Not Provided" 2. Correct typo and format