

Instructions for Use (Handbook)

MagPurix[®] Plasma cfDNA Extraction Kit

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Manual No.: IFU-MP02-02033
Version: 1.5

**RUO**

ZINEXTS LIFE SCIENCE CORP.
16F., No. 93, Sec. 1, Xintai 5th Rd.,
Xizhi Dist., New Taipei City 221416,
Taiwan (R.O.C.)

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

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Intended Use

The MagPurix® Plasma cfDNA Extraction Kit utilizes unique magnetic ZiBeads® technology for automated isolation and purification of circulating cell-free DNA (cfDNA) from plasma samples.

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

For research use only. Not for use in diagnostic procedures.

Introduction

Product Name	MagPurix® Plasma cfDNA Extraction Kit
Catalogue Number	ZP02033
Product Overview	The MagPurix® Plasma cfDNA Extraction Kit is designed to extract cfDNA from plasma samples using MagPurix® EVO series automated instruments. The kit is applied with unique magnetic ZiBeads® technology, which achieves consistent and high product yield and reproducible results. The purified DNA is suitable for a wide range of diagnostic and research applications, including sequencing, genotyping and qPCR detection.
Applicable Instruments Model	MagPurix® EVO series Instruments
Display Protocol Name on the Instrument	2033 Plasma cfDNA 1ml 2033 Plasma cfDNA 2ml 2033 Plasma cfDNA LV
Applicable Instrument Firmware	Please check and download the latest firmware from www.zinexts.com

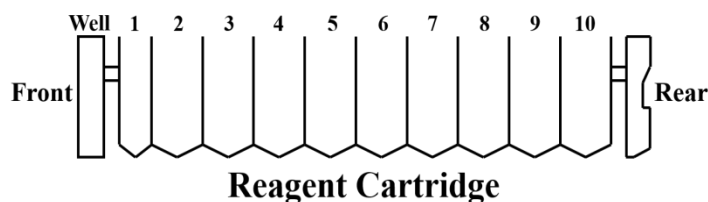
Kit Contents and Storage

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	8 pcs
	2 Reaction Chamber	8 pcs
	3 Tip Holder	8 pcs
	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
	Small Tip	50 pcs
	Lysis Buffer 11 (100 ml)	2 pcs
	Proteinase K, 10 mg/ml (10 ml)	1 pc
	Zmag-S6 Magnetic Bead (1 ml)	2 pc
	Barcode Sticker (EVO only)	50 pcs

Reagent Cartridge Contents

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

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



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. Pipettes and filter tips
3. Phosphate-buffered saline (PBS, may be required for diluting samples)
4. Sample Rack for 7 ml Sample Tubes
5. Heat block or thermomixer with adaptor for 15/50 ml centrifuge tube
6. Optional: Magnet or magnetic stand
7. Optional: 50 ml Centrifuge Tube
8. Optional: Additional Lysis Buffer 11 and Proteinase K for sample volume larger than 2 ml. Please refer to Table A on page 8 for selection guide.

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.

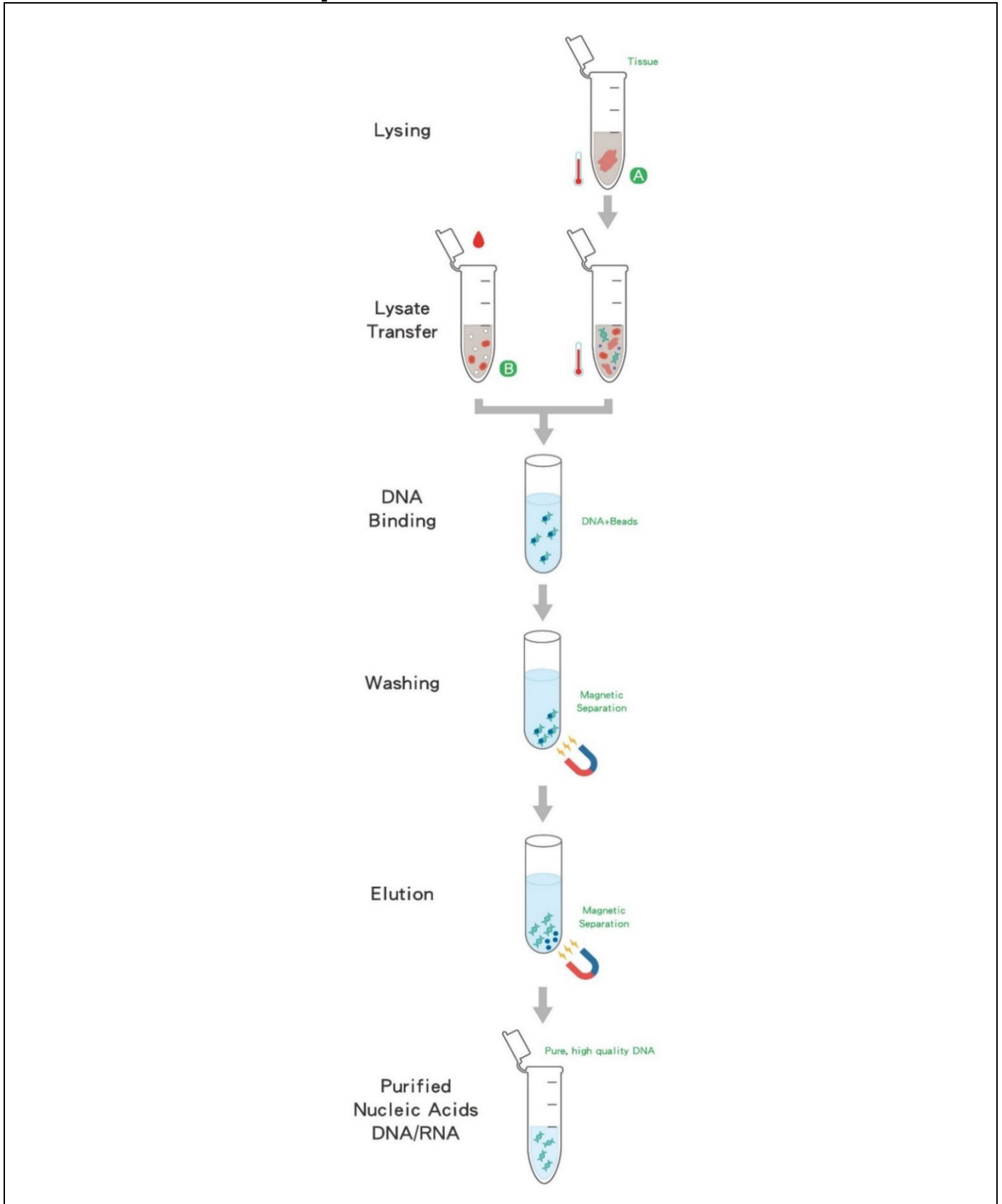
When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at [MSDS \(Material Safety Data Sheets\) – Downloads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



- A** Perform certain pretreatment process before extraction.
- B** Transfer sample to extraction directly.

Things to Do Before Starting

Sample Preparation

The purification procedure is optimized for two scales of samples: 1-2 ml and 2-15 ml plasma.

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|--------------------------|--|
| Sample volume:
1-2 ml | <ol style="list-style-type: none"> a. Transfer 1 or 2 ml sample to the 7 ml Sample Tube. If the sample is less than 1 or 2 ml, add PBS to make final sample volume 1 or 2 ml. b. Add 100 or 200 µl Proteinase K to the sample. The volume ratio of sample to Proteinase K is 10:1. c. Add 2 or 4 ml Lysis Buffer 11 to the sample. The volume ratio of sample to Lysis Buffer 11 is 1:2. Mix well by inverting or vortex. d. Add 40 µl Zmag-S6 Magnetic Bead to the mixture. e. Mix the solution by vigorously inverting 10 times and vortex for 15 seconds. f. Incubate at 56°C for 30 minutes with shaking (1000 rpm) on a thermomixer. (If there is no thermomixer, vortex the solution for 10 seconds every 5 minutes.) g. Put the tube on the 7 ml Sample Tube Rack h. Select “2033 Plasma cfDNA 1ml” or “2033 Plasma cfDNA 2ml” protocol for extraction. |
|--------------------------|--|

For sample volume larger than 2 ml, additional Lysis Buffer 11 and Proteinase K are required.

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|---------------------------|--|
| Sample volume:
2-15 ml | <ol style="list-style-type: none"> a. Transfer sample to a 50 ml Centrifuge Tube. b. Add Proteinase K to the sample. The volume ratio of sample to Proteinase K is 10:1. c. Add Lysis Buffer 11 to the sample. The volume ratio of sample to Lysis Buffer 11 is 1:2. Mix well by inverting or vortex. d. Add 40 µl Zmag-S6 Magnetic Bead to the mixture. e. Mix the solution by vigorously inverting 10 times and vortex for 15 seconds. f. Incubate at 56°C for 30 minutes with shaking (1000 rpm) on a thermomixer. (If there is no thermomixer, vortex the solution for 10 seconds every 5 minutes.) g. Place the tube on a magnetic stand for at least 1 minute to hold the magnetic beads to the wall of the tube (until the solution is clear from beads). h. While the tube is still on the magnetic stand, carefully discard the supernatant without disturbing the beads on the tube wall. Leave about 1 ml lysate with beads. i. Resuspend the beads with the left lysate by pipetting and transfer the mixture (containing all the magnetic beads) into a 7 ml Sample Tube. i. Place the tube on the 7 ml Sample Tube Rack and select “2033 Plasma cfDNA LV” protocol for extraction. |
|---------------------------|--|

Note:

This kit is designed to work with fresh or frozen blood samples collected in tubes that contain common anti-coagulants like EDTA, heparin and citrate. (EDTA is recommended to be used as an anticoagulation agent, while heparin has inhibitory effects on nucleic acid amplification reaction).

Use of cfDNA collection tubes is recommended for minimizing the gDNA contamination.

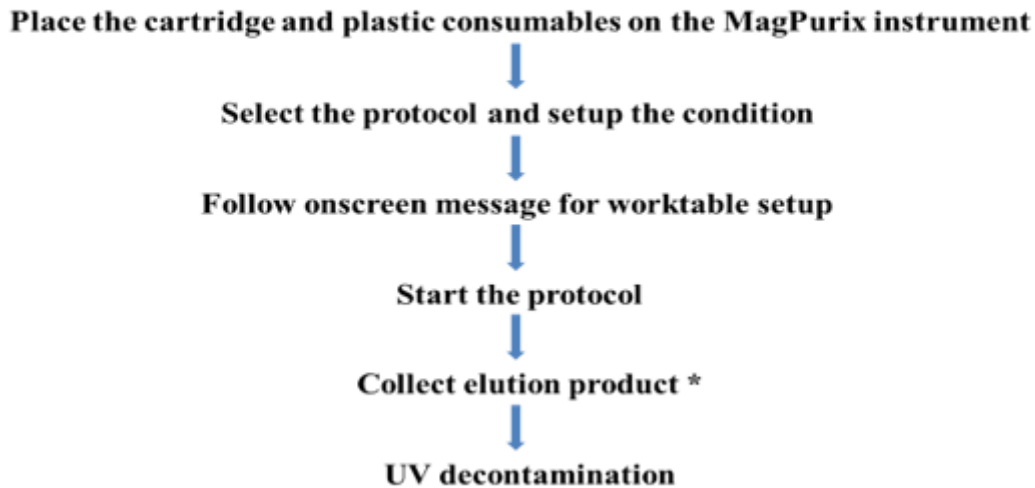
Using fresh whole blood sample (within 1 week, stored at 4-8°C) for extraction is recommended. Total nucleic acid yield and quality will decrease with time or after multiple thawing. For longer storage time, whole blood should be frozen at -20°C or lower and avoid freeze-thaw cycles.

Sample volume (mL)	For 1 sample		For 48 samples	
	Lysis Buffer 11 (ml)	Proteinase K (ml)	Lysis Buffer 11 (ml)	Proteinase K (ml)
1	2	0.1	96	4.8
2	4	0.2	192	9.6
3	6	0.3	288	14.4
4	8	0.4	384	19.2
5	10	0.5	480	24.0
6	12	0.6	576	28.8
7	14	0.7	672	33.6
8	16	0.8	768	38.4
9	18	0.9	864	43.2
10	20	1.0	960	48.0
11	22	1.1	1056	52.8
12	24	1.2	1152	57.6
13	26	1.3	1248	62.4
14	28	1.4	1344	67.2
15	30	1.5	1440	72.0

Sample type	Starting material per sample	Elution Volume
Plasma	1-15 ml	50-200 µl

Procedure of MagPurix System

Workflow of MagPurix operation





* Download the run record (MagPurix EVO & MagPurix N.E.O. series)

Purification Protocol - MagPurix® EVO series

1	Turn on the Instrument	<ul style="list-style-type: none"> a. Turn on the power switch and wait for the screen to turn on. a. Login the instrument and enter the Home Page.
2	Load new Consumable(s) and Cartridge(s)	<ul style="list-style-type: none"> 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. a. Place 7 Elution Tubes into the 7 ml Sample Rack.
3	Load the Samples	<ul style="list-style-type: none"> a. Transfer 7 ml Sample Tubes with mixture into the 7 ml Sample Rack. b. Put the Sample Rack back into the instrument and close the door.
4	Program Set up	<ul style="list-style-type: none"> a. Select the appropriate protocol program on the instrument (2033 Plasma cfDNA 1ml for 1 ml samples, 2033 Plasma cfDNA 2ml for 2 ml samples, 2033 Plasma cfDNA LV for samples more than 2 ml). 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.

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- f. Scan Reagent Cartridge Barcode. Press **NEXT**.
***If the cartridge is expired, the next step cannot be performed.**
- a. 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 **40-45 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.
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- 6** Collect the Elution Tubes
- a. Open the instrument door.
- b. Collect the Elution Tubes containing the purified nucleic acids and place on ice or in temperature lower than 8°C immediately.
- c. The purified nucleic acids are ready for immediate use. Store the purified cfDNA at -20°C or lower temperature. However, freeze-thaw cycles should be avoided, and samples should be accurately quantified once thawed prior to starting 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.
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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 reagents of kit 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 times after arrival. If either Reagent or Buffer precipitates 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 eluent 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.






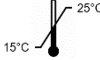


Related Products

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® 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

Symbol	Explanation
	For research use only
	Catalogue number
	Lot/Batch number
	Sufficient for [n] samples
	Expiry date
	Storage temperature (15°C – 25°C)
	Manufacturer
	Caution

Limited Product Warranty

Zinexts Life Science Corp. 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 Corp. 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 the liability of Zinexts Life Science Corp. to only 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
1.5	26. Sept. 2024	<ol style="list-style-type: none">1. Correct typos and format2. Update recommended sample types.3. Revise related products