MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit B (ZP02012)

Instructions for Use (Handbook)

Version: 2.0

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IVD

For *in vitro* diagnostic use

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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

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Intended Use

The MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit B provides a complete set of reagents and consumables for the automated purification of viral and bacterial nucleic acids from cell-rich samples, such as inactivated pathogenic microorganism, bacterial pellet/colony from culture, clinical swab samples in liquid transport media, and environment material (water, soil, etc.) with the MagPurix system.

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® Viral/Pathogen Nucleic Acids Extraction Kit B
Catalogue Number	ZP02012
Product Overview	The MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit B is designed to extract viral and bacterial DNA/RNA from cell-rich samples, such as inactivated pathogenic microorganism, bacterial pellet/colony from culture, clinical swab samples in liquid transport media, and environment material (water, soil, etc.) The kit uses unique magnetic ZiBeads® technology and in combination with MagPurix® series automatic instruments, achieved 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, such as sequencing, genotyping, qPCR, ddPCR and NGS assays.
Applicable Instrument Model	All MagPurix® Instrument
Display Protocol Name on The Instrument	2012 VIR./PATHOGEN B 2012 VIR./PATH. RAPID (EVO only)
Applicable Instrument Firmware	Please check and download the latest firmware from www.zinexts.com
Processing Time	MagPurix® 12 series 50-70 minutes MagPurix® 24 series 55-75 minutes MagPurix® EVO series 50-60 minutes (**RAPID**: 32-33 min)

Kit Contents and Storage

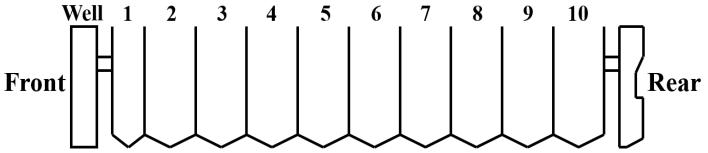
Shipping and Storage	The kit is shipped at room temperature. Upon receipt, store the kit at room temperature. All kit components are stable when stored properly until the expiration date shown on the kit box.	
Kit Content	The components supplied in the kit are listed below. Sufficient reagents are supplied 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 (2 mL)	50 pcs
7 Elution Tube (1.5 mL)	50 pcs
RNA Carrier (1 mg)	1 pc
Barcode sticker (EVO only)	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.
Proteinase K Solution	1
Lysis Buffer 3	2
Binding Buffer 1	3
Magnetic Bead Solution	4
Washing Buffer 2	5
Washing Buffer A	6
Washing Buffer B	7
RNase-free water	8
RNase-free water	9
BL2 Buffer	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 tables display required and special equipment along with the list of consumables.

Item
MagPurix® series instrument
1.5 or 2.0 ml microcentrifuge tubes
Pipettes and filter tips
Phosphate-buffered saline (PBS, may be required for diluting samples)
Optional: Plastic consumables, DNase-free RNase A (to minimize RNA content)

Warnings and Precautions

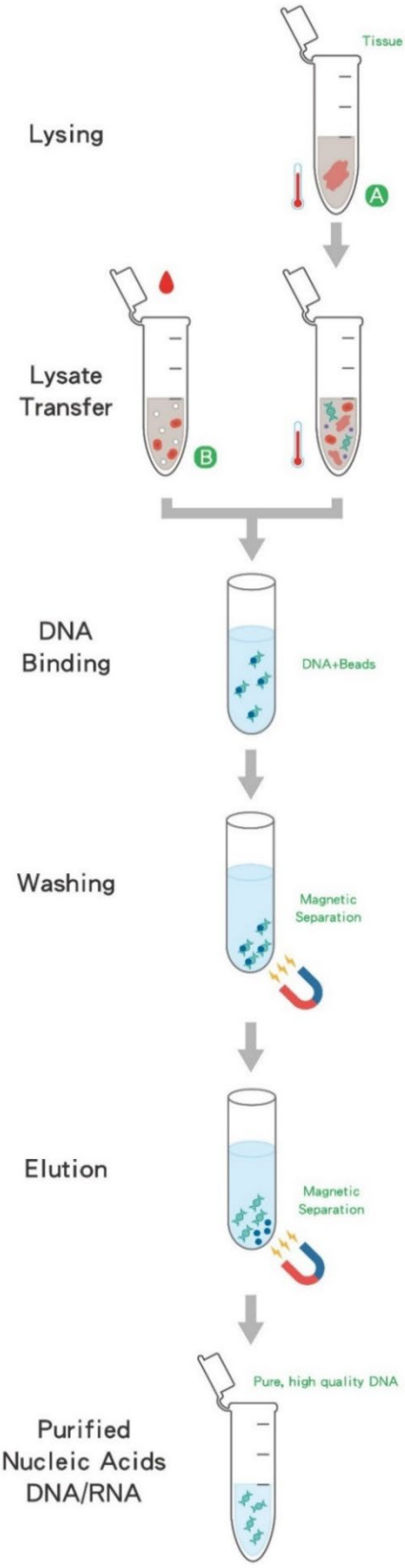
For *in vitro* diagnostic use only. Read all the instructions carefully before using the kit. Use of this product should be limited to trained personnel in the techniques of DNA purification. Strict compliance with the user manual is required for optimal results. Attention should be paid to expiration 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 **http://www.zinexts.com/download.php?lang=en&tb=1&cid=7** where you can find, view, and print the SDSs for each kit and kit component.

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.

Before Starting

Preparation of sample materials

The purification procedure is optimized for extracting viral and bacterial DNA/RNA from 100-200 µl of cell-rich samples, such as inactivated pathogenic microorganism, bacterial pellet/colony from culture, clinical swab samples in liquid transport media, and environment material (water, soil, etc.)

Inactivation of pathogenic microorganism	Method 1 - liquid samples (e.g. liquid transport media) a. Collect the samples in liquid transport media. b. Incubate for 10 minutes at 95°C. c. Centrifuge briefly to collect all the sample at the bottom of the tube. d. Allow the samples to cool down or chill on ice. e. Transfer 200-400 µl into each Sample Tube. Method 2 - Non-liquid samples (e.g. dry swab) a. Place the samples in 440 µl PBS containing a common fungicide. b. Incubate for 30 minutes at room temperature. c. Incubate for 10 minutes at 95°C. f. Allow the samples to cool down or chill on ice. g. Transfer 400 µl suspension into each Sample Tube.
Viscous samples	a. Collect viscous samples (e.g., BAL, sputum or other mucus specimen). b. Prepare a fresh DTT stock solution for liquefaction*. (e.g., 5X DTT stock is about 0.75 %) c. Add DTT solution in the sample (final concentration: 0.15%). d. Incubate the sample (e.g., with shaking at 850 rpm for 30 minutes at 37°C) until it can be pipette easily. e. Transfer 200 µl into each Sample Tube. * The liquefaction could be done by using other solutions, such as NALC (N-Acetyl-L-Cysteine)-NaOH or other agents, which could digest mucous material.
Gram-positive bacterial species.	a. Follow the regular homogenization* procedures in the laboratory. * Especially for samples that contain particles (e.g., stool)
Bacterial colony	a. Take 1-3 bacterial colony from culture plate with an inoculation loop and suspend in 220 µl PBS by stirring vigorously. b. Transfer 200 µl suspension into each Sample Tube.
Bacterial suspension cultures	a. Transfer 200 µl bacterial culture into each Sample Tube.
Swab samples	a. Collect the swab samples (e.g., eye, nasal, pharyngeal, or other swabs) in liquid transport media or 1 ml PBS containing a common fungicide. b. Incubate for 30 minutes at room temperature. c. Transfer 200 µl into each Sample Tube.
Large volume liquid samples	a. Centrifuge* the sample at 10,000-16,000 x *g* for 5-10 minutes to concentrate bacterial cells into a pellet. b. Discard the supernatant and resuspend the pellet in 220 µl PBS. c. Transfer 200 µl concentrated sample into each Sample Tube. * Especially for samples that have low or unknown bacterial loads. (e.g., water collected from pool/rive/stream/tower, soil, urine.)

Note:

RNA Carrier has two roles in the purification process. First, it enhances the binding of viral nucleic acids to the silica surface of magnetic particles, especially when there are few target molecules in the sample. Second, in rare cases that chaotropic salts and detergents in the lysis buffer could not denature RNase, RNA carrier can help protecting RNA from degradation. If RNA carrier is not added to the reaction, recovery of DNA or RNA may be reduced.

Using fresh sample (stored at 2-8°C for up to 6 hours) for extraction is recommended. Viral and bacterial nucleic acids 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 equilibration 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.

*For large volume liquid samples with low or unknown bacterial content, e.g., water, soil, urine, or other, follow the recommended concentration procedure.

The suggested starting material and elution volume ranged for each nucleic acid extraction.

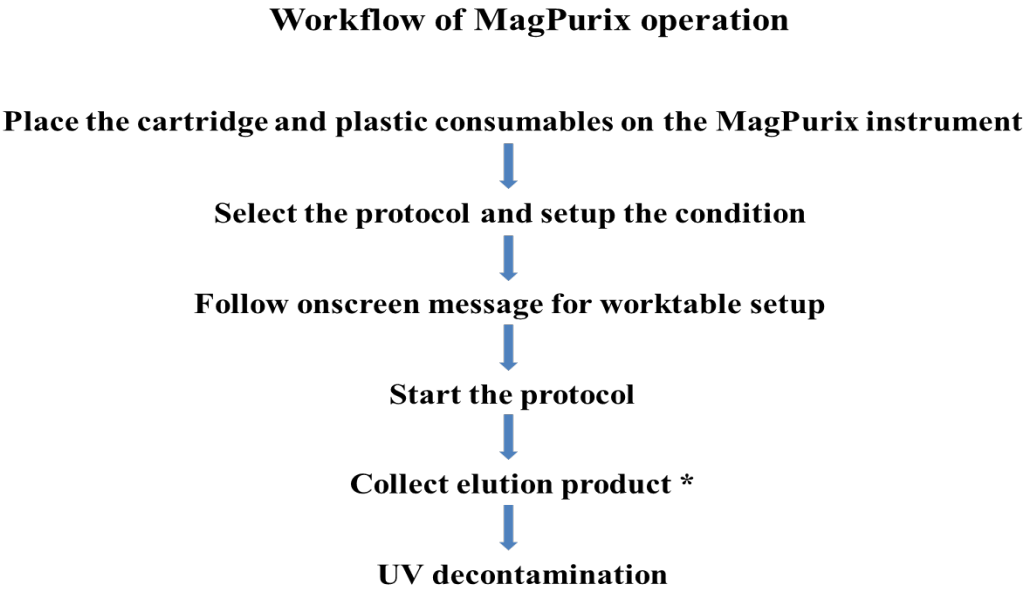
Sample type	Starting material per sample	Elution Volume
Bacteria Pellet	100-200 µl NOTE: The use range is limited to up to 1×10^9 cells/ml (OD_{600} = 3.0) bacteria.	50-300 µl (EVO 50-200 µl)
Bacterial Colony	1-3 bacterial colony	
Bacterial Suspension Cultures	100-200 µl	
Swab Samples	100-200 µl	
Environment Material	100-200 µl *large volume liquid sample pretreatment	
Pretreated Urine	100-200 µl *large volume liquid sample pretreatment	

Preparation of RNA Carrier

RNA Carrier

a. Gently spin the RNA Carrier tube before opening it.
b. Add 1 ml RNase-free water to lyophilized RNA Carrier (supplied) and mix by vortex.
c. Store RNA Carrier at 4°C (short-term, up to 1 month) or -20°C (long-term, aliquots before freezing). Avoid freeze-thaw more than 3 times.
d. Before extraction, add 5 µl RNA carrier (for 100 µl sample), 10 µl (for 200 µl sample) or 20 µl (for 400 µl sample) RNA carrier into each Sample Tube.

Procedure of MagPurix System



* Output the bench record (option)

Note: Perform all steps at room temperature (20-25°C) unless otherwise notified.

Purification Protocol - MagPurix® series

1	Turn on the Instrument	a. Turn on the power switch and wait for the screen to turn on.
2	Load new Consumable(s) and Cartridge(s)	a. Open the door and remove the Sample Rack from the instrument. b. Load 1 Reagent Cartridge, and all plastic disposables (2 Reaction Chamber, 3 Tip Holder, 4 Piercing Pins, 5 Filtered Tips and other components presented in the kit intended to use). c. 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. Scan the protocol barcodes to select the purification protocol, sample volume and elution volume.
5	Start Extraction	a. Follow the instructions displayed on the screen to double check the operating steps being completed before program running. b. Press "**ENTER**" 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 12 series 50-70 minutes, 24 series 55-75 minutes), instrument alarms briefly.
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. If you are not using the instrument immediately, place the Sample Rack back to the workplace, close the instrument door and press "Start" button for 2 seconds to enter sleep mode. Moreover, if the instrument will not be used in a long time, please turn off the power switch.

Purification Protocol - MagPurix® EVO series

1	Turn on the Instrument	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)	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 Filtered 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 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. a. 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. 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 50-60 minutes) (**RAPID**: 32-33 minutes), instrument alarms briefly and the screen indicates "**PROGRAM FINISH**". d. If you do not re-run the experiment, press the function button "HOME" **HOME**" to exist 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 a long 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 (http://www.zinexts.com/index.php?lang=en) 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 in the effective use 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.
Clogged 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 Filtered 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 NA 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	ZP02007
MagPurix® TB DNA Extraction Kit	ZP02008
MagPurix® FFPE DNA Extraction Kit	ZP02009
MagPurix® Forensic DNA Extraction Kit	ZP02010
MagPurix® Viral Pathogen DNA Extraction Kit A	ZP02011
MagPurix® Viral Pathogen DNA Extraction Kit B	ZP02012
MagPurix® Viral RNA Extraction Kit	ZP02013
MagPurix® Plant DNA Extraction Kit	ZP02014
MagPurix® Total RNA Extraction Kit	ZP02015
MagPurix® Viral NA 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

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
	Instructions for Use
	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
2.0	11. Aug. 2022	List of IVD symbols added