Cat. No.: ZP02003 (for 48 Tests) **Display Name:** 2003 VIRAL

MagPurix® Viral Nucleic Acid Extraction Kit

For the automated purification of nucleic acids using MagPurix® Instruments

For *in vitro* diagnostic use

CE IVD

【Introduction - MagPurix® Purification Technology】

Zinexts Life Science is specialized in developing advanced, efficient and reliable technologies in nucleic acid purification, enabling successful delivery of extraction results from varied sample types.

MagPurix® Extraction Kits are intended to use for the purification of nucleic acid from biological specimen used with MagPurix® instruments as IVD accessory.

Nucleic acids purified by the MagPurix® assortment, are suitable for a variety of subsequent uses, e.g., polymerase chain reaction (PCR) tests for human *in vitro* diagnostics purposes.

MagPurix® Instruments and Extraction Kits are intended for professional use only!

The MagPurix® technology is a state of the art platform that uses magnetic beads to extract nucleic acids from samples. The platform commits a truly walk-away automation in nucleic acid purification from samples to results. The purification process contains steps of lysis, binding, washing and elution as the figure below.

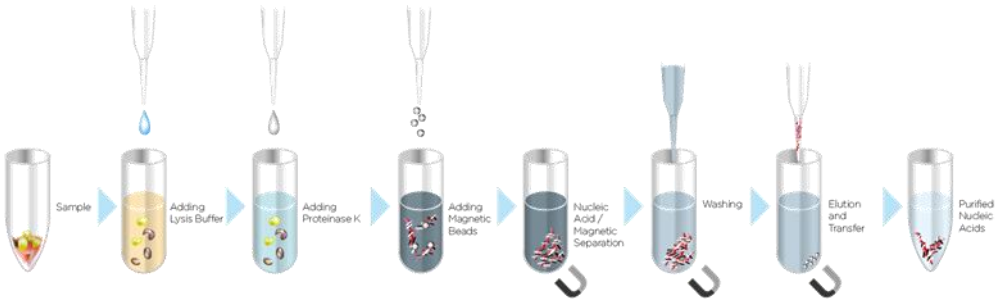


Figure: MagPurix® magnetic bead extraction process

【Product Use Limitations】

MagPurix® Instruments and Extraction Kits are not intended to use as part of a specific *in vitro* diagnostic test. The user is responsible for establishing performance characteristics necessary for downstream diagnostic applications. Appropriate controls must be included in any downstream diagnostic applications using nucleic acids, purified by MagPurix® Instruments and Extraction Kits.

【Intended use】

MagPurix® Viral Nucleic Acid Extraction Kit is intended to use with MagPurix® Instruments for the extraction of Viral DNA or RNA from human biological specimens such as serum, plasma, and other cell-free fluids.

【Process Time】

- for MagPurix® 12 series: 40 - 55 minutes
- for MagPurix® 24 series: 40 - 70 minutes

【Kit and Reagent contents】

Reagent Kit Components		Reagent Cartridge Content		
Parts	Quantity			
Reagent Cartridge	48 pcs (6x8)	well-1	Proteinase K solution	30 µl
Reaction Chamber	48 pcs (6x8)	well-2	Lysis Buffer 4	720 µl
Tip Holder	48 pcs (6x8)	well-3	Binding Buffer 1	1000 µl
Filter tip	50 pcs (50x1)	well-4	Magnetic Bead Solution	800 µl
Piercing Pin	50 pcs (50x1)	well-5	Washing Buffer 2	1000 µl
Sample Tube (2 mL)	50 pcs (50x1)	well-6	Washing Buffer A	1000 µl
Elute Tube (1.5 mL)	50 pcs (50x1)	well-7	Washing Buffer B	1000 µl
RNA Carrier (1 mg)	1 pc	well-8	RNase-free water	1000 µl
Barcode Paper	1 pc	well-9	RNase-free water	1000 µl
Selection guide	1 pc	well-10	Empty	

【Storage Conditions】

- MagPurix® Viral Nucleic Acid Extraction Kit should be stored at room temperature (15 - 25 °C). **Do not** freeze the reagent cartridges. Under this condition, the Kits are stable for 18 months.
- After dissolve the RNA carrier, store it at 4 °C (short-term, up to 1 month) or - 20 °C (long-term). **Do not** freeze–thaw the Frozen RNA carrier more than 3 times.
- Store the purified total nucleic acid at 4 °C (up to 24 hours) or - 20 °C for longer storage. Repeated freeze thawing is not allowed.

【Starting Material】

Sample Type	Target Nucleic Acid	Sample Volume (Amount of starting material)	Elution Volume
Serum	Total Viral Nucleic Acids (DNA + RNA)	100 – 560 µl	50 - 200 µl
Plasma			
CSF			
Pretreated Urine			
Cell-free Body Fluids			
Controls/Internal Control	Add controls / internal control in the extraction procedure if the downstream analysis needed		

- MagPurix® Viral Nucleic Acid Extraction Kit is designed for extraction of viral nucleic acids (e.g., those of HIV, HCV, HBV, CMV and EBV) from plasma or serum, or from a pool of such cell-free body fluids.

- After extraction, store the nucleic acid at 4 °C (up to 24 hours) or - 20 °C for longer storage. Repeated freeze–thawing is not allowed.

- Using appropriate controls for downstream analysis:

Type	Description	Location
Positive Control	Using sample which positive for target	Place in sample tube
Negative Control	Using sample which negative for target or water(NTC)	Place in sample tube
Internal Control (IC)	Using a defined quantity control	Place in sample tube or the round well of the reaction chamber

【Sample Preparation】

- The purification procedure is optimized for use with 100 - 400 µl serum, plasma, CSF, or pretreated urine samples. (Blood samples treated with EDTA or citrate as an anticoagulant can be used for plasma preparation).

- Samples can be either fresh or frozen, provided that they have not been refrozen after thawing.

- After collection and centrifugation, plasma, serum, or CSF can be stored at 2 - 8 °C for up to 6 hours. For longer storage, we recommend freezing aliquots at - 20 °C or - 80 °C. Thaw samples at room temperature (15 - 25 °C), and process the samples immediately when they have equilibrated to room temperature. **Do not** refreeze the aliquots after thawing. Repeated freeze–thawing leads to denaturation and precipitation of proteins, resulting in reduced viral titers and therefore reduced yields of viral nucleic acids. If cryoprecipitates are visible in the samples, centrifuge at 6800 x g for 3 minutes, transfer the supernatants to fresh tubes without disturbing the pellets, and start the purification procedure immediately.

【RNA Carrier】

- **For RNA virus, adding the RNA carrier to the sample before extraction is recommended!!!**

- Add 1.0 ml RNase-free water to the RNA carrier tube (provided with the kit) and mix by vortexing. Store it at 4 °C (short-term, up to 1 month) or - 20 °C (long-term). **Do not** freeze–thaw the Frozen RNA carrier more than three times.

- Add 5 µl RNA carrier (for 100 µl sample), 10 µl (for 200 µl sample) or 20 µl (for 400 µl sample) into the sample tube before add sample.

【Protocol of Extraction】

1. Turn the power switch on and wait until the LCM screen displays “MagPurix® System Stand-By”.

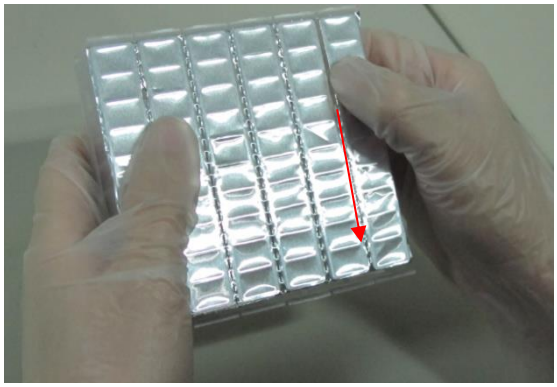
2. Press the “Start” button (The system will process a self-testing, and then go to steady mode).
   Note: The system will block main functions before the self-testing process is completed.

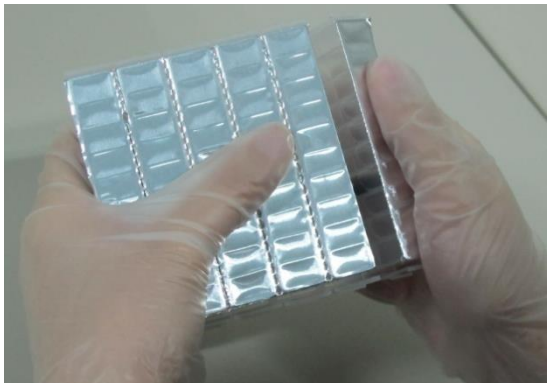
3. Open the reagent drawer and remove the sample rack out of the instrument.

4. Load Reagent Cartridges and all plastic disposables (Polygon Reaction Chamber®, Tip Holder, Piercing Pin, Filter Tip), as numbered.

Insert the reagent cartridges:

Note:
How to pull apart reagent cartridges
Slash/open the dotted line with the nail and snap it with a little bit of force.





Insert Polygon Reaction Chambers®:

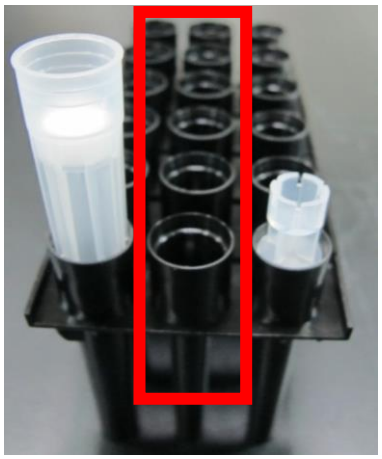
Insert Tip Holder:

Insert Piercing Pins:

Insert Filter Tips:

Note:

A. **The positions of piercing pin and filter tip are as following**, the middle position should be "**EMPTY**'', as long you have no other instructions from the manufacturer side.



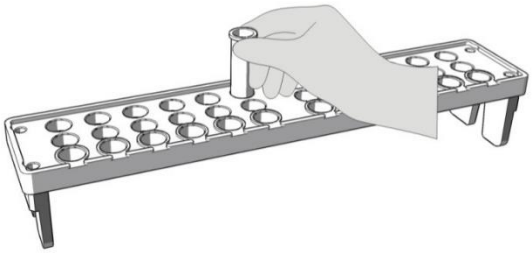
B. **Load one Reagent Cartridge and one set of plastic disposable per sample**

Important:

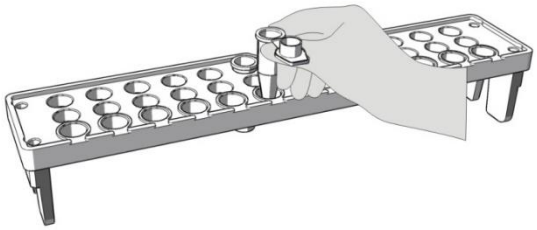
- Set Cartridges in order of the numbers from left to right.
- Make sure that you insert the Cartridges tightly into the Cartridge Tray.
- You can load 1 - 12 Cartridges on the tray depending on the number of samples that you desire to process.

5. Load Sample Tube and Elute Tube into Sample Rack.

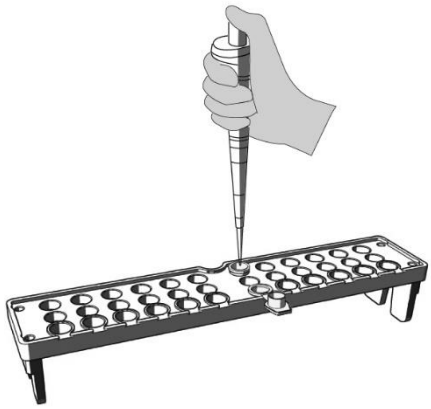
Insert Sample Tube:



Insert Elute Tube:



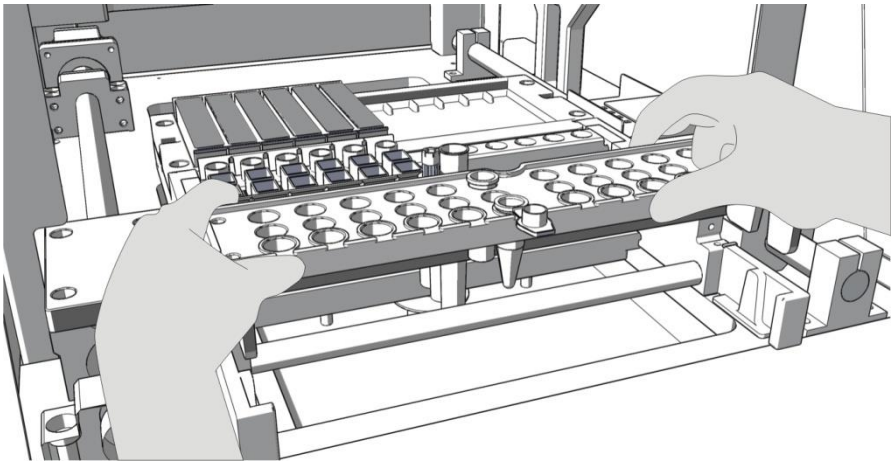
6. Load the sample(s) to Sample Tube(s).



Note:

- Pretreatments are essential for some sample types before loading to Sample Tube.
- Make sure the caps of Elute Tube are open as the figure shown above.

7. Place the Sample Rack on the instrument platform.



Note:

- Use two hands to handle the Sample Tray.
- Make sure to place the Sample Tray correctly into the instrument.

8. Close the Reagent drawer.

9. Scan the barcodes to select the purification protocol, sample and elute volume.

Note:

- The related barcode sheet is part of the standard content in the reagent boxes.
- Protocol name, sample and elution volume will be shown on LCM screen after protocol barcode is scanned.

10. Follow the instructions on the LCM screen to double-check the operating steps being completed before program running.

11. Press “Enter” to confirm. Instrument will start to run the protocol program automatically until whole processes are completed.

Note:
It takes from 40 to 70 minutes to complete the extraction according to reagent types.

12. At the end of the run, the instrument alarms briefly and the LCM screen indicates "Protocol Completed".

13. Open the instrument door.

14. Remove the elute tubes containing the purified nucleic acid.

Note:
Store the purified nucleic acids at 4 °C for short-term storage or store at - 70 °C for long-term storage.

15. Discard the used cartridges, all plastic consumables into biohazard waste. **Do not** reuse the cartridges.

16. If you are not using the instrument, place the Sample Rack back to the workplace, close the instrument door and press "Start" button for 2 seconds to get into "sleeping mode". Moreover, for longer time not using the instrument turn the power switch off.

【Safety Information】

When working with chemicals or samples, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate material safety data sheets (MSDSs). You can find, download, view, and print them from our website www.zinexts.com.

【Quality Control】

In accordance with Zinexts Life Science's ISO-certified Quality Management System, each lot of MagPurix® Viral Nucleic Acid Extraction Kits are tested against predetermined specifications to ensure consistent product quality.

【Warranty】

Zinexts Life Science is committed to providing 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 questions or concerns, contact our Technical Support Representatives.

Zinexts Life Science guarantees the performance of all products according to specifications stated on our product literature. The purchaser / user must determine the suitability of the product for its 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 in accordance with instructions.

【Satisfaction Guarantee】

For any product that fails to perform satisfactorily due to any reason other than unintended use, Zinexts Life Science will replace it free of charge, simply call your distributor to get a replacement!

【Technical Support】

For technical assistance and further information, please visit our website www.zinexts.com, contact our Technical Support or your local distributor.

【Manufacturer Information】

Manufacturer: Zinexts Life Science Corp.
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Product of Origin: TAIWAN (R.O.C.)

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EC REP

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