Instructions for Use (Handbook)

MagPurix® HPV DNA Extraction Kit for Swab Sample

Catalog No.: ZP02007
Manual No.: IFU-MP02-02007
Version: 2.1

Σ 48

CE IVD

For *in vitro* diagnostic use

EC REP

Obelis s.a.
Bd Général Wahis 53
1030 Brussels Belgium
Tel: +(32) 2 732-59-54
Fax: +(32) 2 732-60-03
mail@obelis.net

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

Contents

Intended Use

The MagPurix® HPV DNA Extraction Kit for Swab Samples provides a complete set of reagents and consumables for the automated purification of HPV DNA from cervical swab samples, collected in transport medium, using 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® HPV DNA Extraction Kit
Catalogue Number	ZP02007
Product Overview	The MagPurix® HPV DNA Extraction Kit for Swab Samples is designed to extract HPV DNA from cervical swab samples in transport medium using MagPurix® series automatic instruments. The kit is applied with unique magnetic ZiBeads® technology, which achieves 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® Instruments
Display Protocol Name on The Instrument	2007 HPV DNA 2007 HPV RAPID (EVO only)
Applicable Instrument Firmware	Please check and download the latest firmware from www.zinexts.com
Processing Time	MagPurix® 12 series 45-65 minutes MagPurix® 24 series 50-65 minutes MagPurix® EVO series 40-50 minutes (**RAPID**: 22-26 min)

Kit Contents and Storage

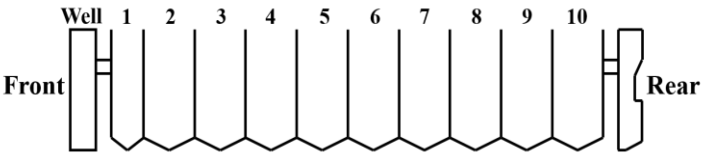
Shipping and Storage	The kit is shipped at room temperature. Upon receipt, store the kit at room temperature. All kit components are stable when stored properly until the expiration date shown on the kit box.	
Kit Content	The components supplied in the kit are listed below. Sufficient reagents are supplied 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
BL4 Buffer (25 ml)	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 2A	2
Binding Buffer 1	3
Magnetic Bead Solution	4
Washing Buffer 1	5
Washing Buffer A	6
Washing Buffer B	7
Elution Buffer 1	8
Elution Buffer 2	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® / 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. **Optional**: Plastic consumables, DNase-free RNase A (to minimize RNA content)

Warnings and Precautions

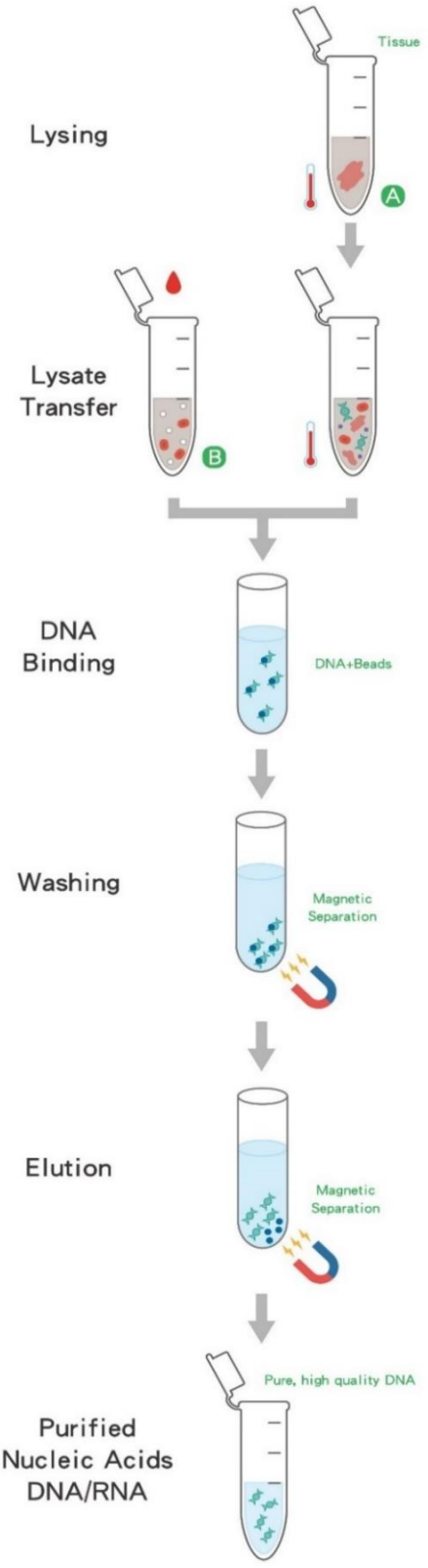
For *in vitro* diagnostic use only. Read all the instructions carefully before using the kit. Use of this product should be limited to trained personnel in the techniques of DNA purification. Strict compliance with the user manual is required for optimal results. Attention should be paid to expiration 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 **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



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 the use of 100-400 µl of cervical cell samples, collected with cervical brush, broom or genital swab and stored in liquid-based media.

In liquid-based preservation solution e.g., Hologic Thinprep PreservCyt®, BD Surepath™	a. Transfer 100-400 µl sample (amount recommended in **Table A)** to a 1.5 ml microcentrifuge tube. b. Centrifuge the tube at 1,000 x *g* for 5 minutes. c. Discard the supernatant. d. Resuspend the pellet with 220 µl BL4 Buffer. e. Incubate the mixture at room temperature for 5 minutes. f. Vortex for 5 seconds. g. Transfer 200 µl supernatant into each Sample Tube.
In other STM preservation solution e.g., QIAGEN DNA PAP, Hybribio cell preservation solution	a. Add the same amount of BL4 Buffer directly to the preservation solution (BL4:STM = 1:1). b. Incubate the mixture at room temperature for 5-10 minutes. c. Vortex for 5 seconds. d. Transfer 100-400 µl supernatant into each Sample Tube.

Note:

Cervical cell samples are collected with a cervical brush/broom or genital swab in a liquid-based medium* (e.g., ThinPrep system, SurePath system, etc.) or other liquid Specimen Transport Medium (STM) preservation solution (e.g., QIAGEN DNA PAP Cervical sampler, Roche Cobas® PCR Cell Collection Media, Hybribio cell preservation solution, etc.). *The liquid-based media are formulated for cellular preservation and used in liquid-based cytology (LBC) samples for cytological and molecular diagnosis.

For non-liquid media, it is recommended to add BL4 Buffer for retention.

Samples should be sent to 4-30°C for extraction immediately after collection. Storage conditions depend on the preservation solution.

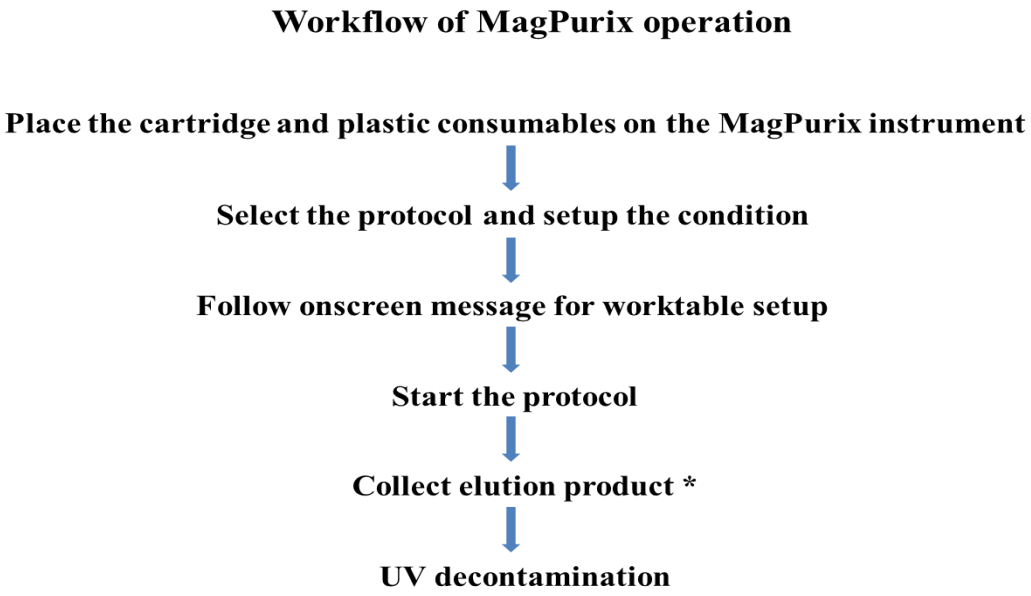
For "signal amplification" detection, the target DNA will not be amplified. A sufficient number of samples must be collected.

The sticky mucus is common in cervical specimens, adding BL4 Buffer during processing will help sample liquefaction and nucleic acid extraction.

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

Sample type	Starting material per sample	Elution Volume
Cervical swab	100-400 µl	50-300 µl (EVO 50-200 µl)
Transfer medium		

Procedure of MagPurix System



* Output the bench record (option)

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 Filter 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 45-65 minutes, 24 series 50-65 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. e. 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. If the instrument will not be used in an extended period of 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.
		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 40-50 minutes) (**RAPID**: 22-26 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 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 (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 tip 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
	Sufficient for [n] samples
	Expiry date
	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
2.1	13. Apr. 2023	1. Correct typo and format 2. Related products: add ZP02032 and ZP02033