Instructions for Use (Handbook)

MagPurix® Coronavirus RNA Extraction Kit

Catalog No.: 311B061A, 311B063A
Manual No.: IFU-MP02-311B06
Version: 1.9

Σ 48

IVD

For *in vitro* diagnostic use

EU 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 2
Introduction 2
Kit Contents and Storage 3
Materials Required but not Provided 4
Warnings and Precautions 4
Purification Principle 5
Things to Do Before Starting 6
    Sample Preparation 6
Procedure of MagPurix System 7
Purification Protocol - MagPurix® EVO series 7
Troubleshooting 9
Related Products 10
References 11
Symbols 12
Limited Product Warranty 13
Revision History 13

Intended Use

MagPurix® Coronavirus RNA Extraction Kit provides a complete set of reagents and consumables for the rapid automated purification of viral RNA from serum, plasma, saliva, sputum, clinical swabs, cell-free body fluids and cerebrospinal fluid (CSF), 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® Coronavirus RNA Extraction Kit
Catalogue Number	311B061A, 311B063A
Product Overview	The MagPurix® Coronavirus RNA Extraction Kit is designed to extract viral nucleic acid from serum, plasma, saliva, sputum, clinical swabs, cell-free body fluids and cerebrospinal fluid (CSF). 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	MagPurix® EVO Instruments
Display Protocol Name on The Instrument	Coronavirus RNA
Applicable Instrument Firmware	Check and download the latest firmware from www.zinexts.com
Processing Time	MagPurix® EVO series 39-40 minutes

Kit Contents and Storage

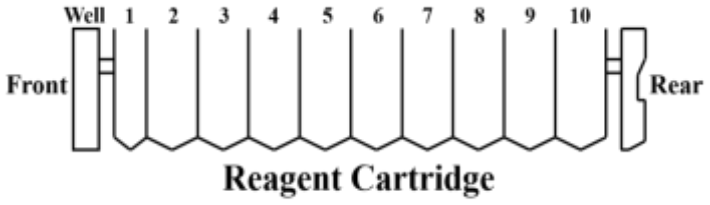
Shipping and Storage	The kit is shipped at room temperature. Upon receipt, store the kit at room temperature. All kit components are stable when stored properly until the expiration date shown on the kit box.
Kit Content	The components supplied in the kit are listed below. Sufficient reagents are supplied to perform 48 purifications.

Contents	Amount
1 Reagent Cartridge	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 (2 ml)	50 pcs
7 Elution Tube (1.5 ml)	50 pcs
Barcode Sticker (EVO only)	50 pcs

Reagent Cartridge Contents

Each Reagent Cartridge has 10 positions with 10 sealed wells. Positions 1–10 contain the reagents required for this protocol.

Reagent	Well No.
Empty	1
Lysis Buffer 7	2
Empty	3
Magnetic Bead Solution	4
Washing Buffer 7	5
Washing Buffer A	6
Washing Buffer B	7
RNase-free water	8
RNase-free water	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. **Optional**: Plastic consumables, RNA Carrier

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.

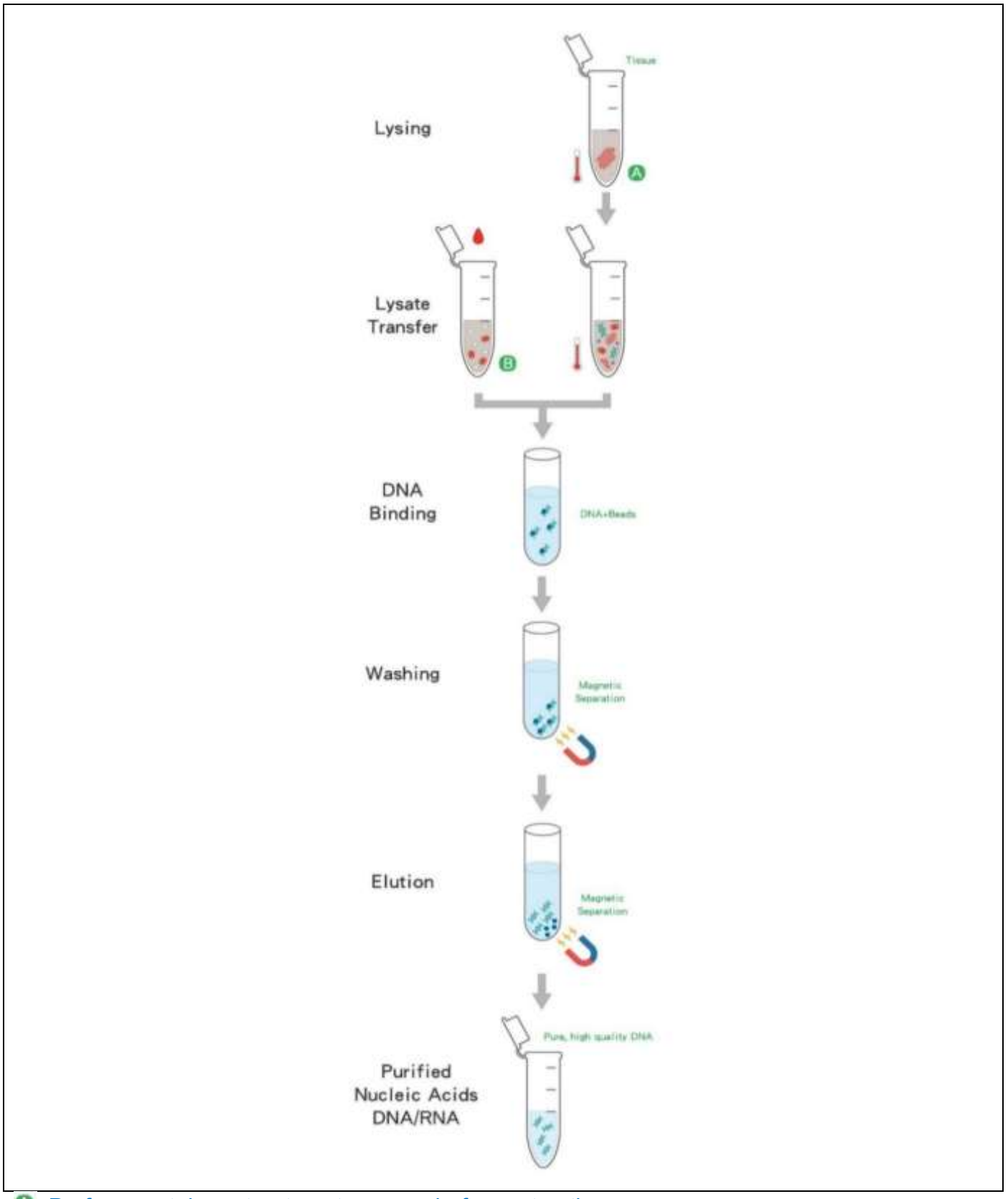
When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at **MSDS (Material Safety Data Sheets) – Downloads – 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 100-200 µl serum, plasma, saliva, sputum, clinical swab samples, cell-free body fluids or cerebrospinal fluid (CSF).

Serum	a. **Optional:** (Add an appropriate volume of RNA Carrier into each Sample Tube.) b. Dispense 100-200 µl sample into each Sample Tube. c. If the sample volume is lower than described, please complete the volume with appropriate amount of 1X PBS.
Plasma	a. **Optional:** (Add an appropriate volume of RNA Carrier into each Sample Tube.) b. Dispense 100-200 µl sample into each Sample Tube. c. If the sample volume is lower than described, please complete the volume with appropriate amount of 1X PBS.
Cerebrospinal fluid (CSF)	a. **Optional:** (Add an appropriate volume of RNA Carrier into each Sample Tube.) b. Dispense 100-200 µl sample into each Sample Tube. c. If the sample volume is lower than described, please complete the volume with appropriate amount of 1X PBS.
Cell-free body fluid(s)	a. **Optional:** (Add an appropriate volume of RNA Carrier into each Sample Tube.) b. Dispense 100-200 µl sample into each Sample Tube. c. If the sample volume is lower than described, please complete the volume with appropriate amount of PBS.
(Compatible) Swab samples	a. Collect 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. Dispense 100-200 µl sample into each Sample Tube.

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 effect on nucleic acid amplification reaction).

Optional: 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 may 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 samples (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 samples after thawing. If precipitation is visible in samples, 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
Serum	100-200 µl	50-200 µl
Plasma		
Cerebrospinal fluid (CSF)		
Cell-free body fluids	100-200 µl	
Swab samples		

Procedure of MagPurix System



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

Purification Protocol - MagPurix® EVO series

1	Turn on the Instrument	a. b.	Turn on the power switch and wait for the screen to turn on. Login the instrument and enter the Home Page.
2	Load new Consumable(s) and Cartridge(s)	a. b. c.	Open the door and remove the Sample Rack from the instrument. Open the Tip-Holder Lid. 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 39-40 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 (48) ST	311A011A
MagPurix® Blood DNA Extraction Kit 200 (48) DP	311A013A
MagPurix® Blood DNA Extraction Kit 200 (48) N.E.O.	311A014A
MagPurix® Blood DNA Extraction Kit 1200 (48) ST	311A021A
MagPurix® Blood DNA Extraction Kit 1200 (48) DP	311A023A
MagPurix® Blood DNA Extraction Kit 1200 (48) N.E.O.	311A024A
MagPurix® Viral Nucleic Acid Extraction Kit (48) ST	311B011A
MagPurix® Viral Nucleic Acid Extraction Kit (48) DP	311B013A
MagPurix® Viral Nucleic Acid Extraction Kit (48) N.E.O.	311B014A
MagPurix® Tissue DNA Extraction Kit (48) ST	311D011A
MagPurix® Tissue DNA Extraction Kit (48) DP	311D013A
MagPurix® Tissue DNA Extraction Kit (48) N.E.O.	311D014A
MagPurix® Cultured Cell DNA Extraction Kit (48) ST	311E011A
MagPurix® Cultured Cell DNA Extraction Kit (48) DP	311E013A
MagPurix® Bacterial DNA Extraction Kit (48) ST	311C011A
MagPurix® Bacterial DNA Extraction Kit (48) DP	311C013A
MagPurix® Bacterial DNA Extraction Kit (48) N.E.O.	311C014A
MagPurix® HPV DNA Extraction Kit for Swab Samples (48)	311F011A
MagPurix® HPV DNA Extraction Kit for Swab Samples (48) DP	311F013A
MagPurix® HPV DNA Extraction Kit for Swab Samples (48) N.E.O.	311F014A
MagPurix® TB DNA Extraction Kit (48) ST	311G011A
MagPurix® TB DNA Extraction Kit (48) DP	311G013A
MagPurix® TB DNA Extraction Kit (48) N.E.O.	311G014A
MagPurix® FFPE DNA Extraction Kit (48) ST	311H011A
MagPurix® FFPE DNA Extraction Kit (48) DP	311H013A
MagPurix® FFPE DNA Extraction Kit (48) N.E.O.	311H014A
MagPurix® Forensic DNA Extraction Kit (48) ST	311I011A
MagPurix® Forensic DNA Extraction Kit (48) DP	311I013A
MagPurix® Forensic DNA Extraction Kit (48) N.E.O.	311I014A
MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit A (48) ST	311B031A
MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit A (48) DP	311B033A
MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit A (48) N.E.O.	311B034A
MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit B (48) ST	311B041A
MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit B (48) DP	311B043A
MagPurix® Viral/Pathogen Nucleic Acids Extraction Kit B (48) N.E.O.	311B044A
MagPurix® Viral RNA Extraction Kit (48) ST	311B051A
MagPurix® Viral RNA Extraction Kit (48) DP	311B053A
MagPurix® Viral RNA Extraction Kit (48) N.E.O.	311B054A
MagPurix® Plant DNA Extraction Kit (48) ST	311J011A
MagPurix® Plant DNA Extraction Kit (48) DP	311J013A
MagPurix® Plant DNA Extraction Kit (48) N.E.O.	311J014A
MagPurix® Total RNA Extraction Kit (48) ST	311K011A
MagPurix® Total RNA Extraction Kit (48) DP	311K013A
MagPurix® Total RNA Extraction Kit (48) N.E.O.	311K014A

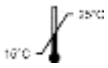
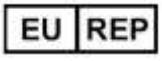
MagPurix® Viral Nucleic Acid Extraction Kit LV (48) ST	311B021A
MagPurix® Viral Nucleic Acid Extraction Kit LV (48) DP	311B023A
MagPurix® Viral Nucleic Acid Extraction Kit LV (48) N.E.O.	311B024A
MagPurix® CFC DNA Extraction Kit (48) ST	311L011A
MagPurix® CFC DNA Extraction Kit (48) DP	311L013A
MagPurix® CFC DNA Extraction Kit (48) N.E.O.	311L014A
MagPurix® Coronavirus RNA Extraction Kit (48) ST	311B061A
MagPurix® Coronavirus RNA Extraction Kit (48) DP	311B063A
MagPurix® Urine cfDNA Extraction Kit (48) ST	311L041A
MagPurix® Urine cfDNA Extraction Kit (48) DP	311L043A
MagPurix® Plasma cfDNA Extraction Kit (48) ST	311L051A
MagPurix® Plasma cfDNA Extraction Kit (48) DP	311L053A

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 mark
	For In Vitro Diagnostic Use
	Catalogue number
	Lot/Batch number
	Sufficient for [n] samples
	Instructions for Use
	Expiry date
	Storage temperature (15°C – 25°C)
	For single use only
	Manufacturer
	European Authorized Representative
	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
1.9	26 Jun. 2026	1. Update symbol for European Authorized Representative 2. Update the Display Protocol Name