

WizMag™ Viral DNA/RNA

User Manual

Ver 2.0

REF W7020 | W7021 | W7022 | W7023

For in vitro diagnostic use



INTENDED USE

The WizMag™ Viral DNA/RNA kit is designed to be used on the CLEO™ AP16 Nucleic Acid Extractor System for simple and easy purification of total viral RNA and DNA from various biological samples including serum, plasma, swab, body fluids, and other virus-infected/contained liquid media. Purified nucleica acid is free of enzyme inhibitors and other contaminants, and highly suited for downstream applications such as PCR-based or enzyme-based reactions.

KIT CONTENTS

Contents	W7020	W7021	W7022	W7023	Storage	
No. of preparation	64	192	32	96		
Pre-packed 96-well Plate	4 ea	12 ea	-	-		
Pre-packed 6-well Strip	-	-	32 ea	96 ea	Room	
Plunger	8 ea	24 ea	8 ea	24 ea	Temperature	
Buffer PKR	1.5 ml	6 ml	1 ml	3 ml	(15-25°C)	
Proteinase K *	14 mg x 2	42 mg x 2	14 mg	42 mg		
Blank solution N	500 μL	500 µL	500 µL	500 µL		

This kit is delivered under ambient conditions. When being used immediately on arrival, all the components can be stored at room temperature (15 - 25 °C). But if the kit is going to be stocked for a long time, Proteinase K should be stored at 2 - 8°C for optimal conservation. Long exposure to heat sources can deteriorate the performance of the kit significantly.

QUALITY CONTROL ANALYSIS

In accordance with Wizbiosolutions Inc. ISO 13485-certified Quality Management System, each lot WizMag™ Viral DNA/RNA kit is tested against predetermined specifications to ensure consistent product quality.

RECONSTITUTION OF PROTEINASE K

Before the first experiment, dissolve completely Proteinase K with Buffer PKR, as indicated on the product label. Do not vortex when dissolving. Store the reconstituted Proteinase K solution at $2-8^{\circ}$ C.

PRECAUTIONS



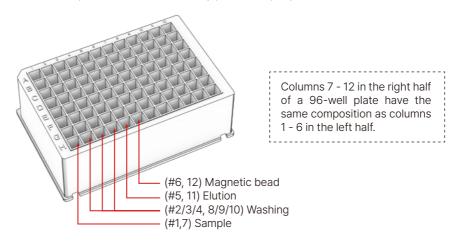
- This product is reserved exclusively for *in vitro* diagnostic purposes.
- Intended for single use only. Do not reuse.
- Check the expiration date on the box. Do not use it after the expiration date.
- Wear protective clothing, and use disposable gloves, goggles, and a mask.
- Do not eat, drink or smoke in areas where samples or test reagents are being used. Once you finish the test wash your hands.
- Specimens must be treated as potentially infectious as well as all reagents and materials that have been exposed to the samples and handled in the same manner as an infectious agent.

^{*} After dissolving, store proteinase K solution at 2 - 8°C for optimal conservations.

- Regular decontamination of commonly used equipment is recommended, especially micropipettes and work surfaces.
- This product contains irritants that are harmful when in contact with skin or eyes, or inhaled or swallowed. Care should be taken when handling this product.
- Some of the reagents in the 96-well Plate contain chaotropic which can form highly reactive compounds when combined with bleach. Do NOT add bleach or acidic solutions directly to the sample-preparation waste.
- Any significant incidents related to the product should be notified to the competent authorities and manufacturers.
- · Do not use it if the package is damaged.

COMPOSITION OF THE PRE-PACKED 96-WELL PLATE (W7020 | W7021)

A total of 16 samples can be simultaneously processed per plate.



COMPOSITION OF THE PRE-PACKED 6-WELL STRIP (W7022 | W7023)



- (#1) Sample
- (#2,3,4) Washing
- (#5) Elution
- (#6) Magnetic bead

PROTOCOL

A. Setup of program (For CLEO™ AP16 and AP48 devices, the preset program can be used.)

- 1. Select 'EDIT' on the main menu.
- 2. Set up the program as show below.

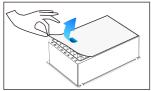
No.	1	2	3	4	5	6	7
Well #	6	1	2	3	4	5	6
Step	Beads	Lysis	Wash	Wash	Wash	Elute	Discard
Volume (µL)	200	600	500	500	500	80	200
Wait time	-	-	-	-	-	02:00	-
Mix time 1	00:10	08:00	00:10	00:10	00:30	03:00	00:10
Method 1	Medium	Fast	Bottom	Bottom	Fast	Bottom	Medium
Mix time 2	-	-	00:10	00:10	-	-	-
Method 2	-	-	Fast	Fast	-	-	-
Loop count	-	-	3	2	-	-	-
Collect time	00:12	00:15	00:12	00:12	00:12	00:15	-
Collect speed	Strong	Strong	Strong	Strong	Strong	Strong	Normal
Temperature		40°C				Off	

3. Save the program for later use.

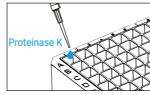
B. Sample Preparation

- 1. Liquid samples: Plasma, serum, whole blood, body fluids, urine, and virus-containing liquid media
 - Use 200 µL of sample directly.
- 2. Swab sample: buccal, nasopharyngeal, cervical, rectal, fecal
 - Place the swab head in 400 μL of saline or 1X PBS, and vortex vigorously for 30 seconds.
 - Use 200 μL of immersion solution.
- 3. Cell-containing samples
 - Centrifuge the cells at 13,000 xg for 3 minutes. Then, resuspend the pellet completely in 200 uL of 1X PBS.
 - Use 200 µL of the suspension as a sample.

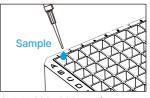
C-1. DNA extraction procedure (W7020, W7021)



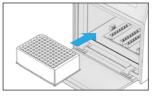
1. Carefully peel off the film of the 96-well Plate not to cross-contaminate.



2. Add 20 µL of Proteinase K solution into each first well (#1,7)



3. Add 200 -300 µL of the sample into the each first well (#1,7)



4. Mount the 96-well Plate on the CLEO™ AP16 carefully.



5. Insert a Plunger all the way into the socket above the 96-well Plate.



6. Close the front door of the instrument.

C-2. DNA extraction procedure (W7022, W7023)



1. Mount the 6-well Strip onto the Strip Adapter Plate.



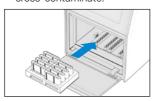
2. Carefully peel off the film of the 6-well Strip not to cross-contaminate.



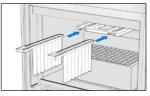
3. Add 20µL of Proteinase K solution into the each first well (#1).



4. Add 200 - 300 μ L of the sample into the each first well (#1).



5. Mount the 6-well Strip Adapter Plate on the CLEO™ AP16 carefully.



6. Insert a Plunger all the way into the socket above the Plate

- 7. Close the front door of the instrument.
- 8. Select MENU ▶ RNA ▶ Viral on the screen.



- 9. Press 'RUN' button on the screen.
- 10. After the alarm finishes, open the door and carefully remove the Plunger.
- 11. Detach the 96-well plate (or the Strip Adapter Plate) from the machine carefully.
- 12. Transfer the 50 70 μ L eluate of each fifth well (#5, 11) into a new 1.5 mL centrifuge tube. **NOTE**: The volume of eluate can be decreased slightly during the process.
- 13. Dispose of 96-well Plates (or 6-well Strip) and Plunger used in the test according to local or national waste disposal methods.

TROUBLE SHOOTING GUIDE

Problem	Possible causes	Recommendations		
Low yield	Low viral titer in the sample	Use more sample. Concentrate the larger sample to 300 µL using micro-concentrator.		
	Poor quality of starting material	Use a freshly harvested sample or well-conserved sample if possible. Repeated freezing and thawing of sample should be avoided.		
Inconsisten recovery of DNA/RNA	Contamination between reagent wells	The reagent in the well may evaporate and form a deposit on the film during storage, which may cause contamination between wells when the film is removed. Prepacked plate or tube always should be stored at proper condition. Before removing the film of the plate or the tube, it is recommended to shake off the deposit on the film with holding the plate or the tube tightly.		

SYMBOL GLOSSARY

REF	Catalogue number	4	Manufacturer	Σ	Use-by date
LOT	Batch code	2	Do not re-use	1	Temperature limitation
IVD	in-vitro diagnostic use	i	Instructions for use	*	Keep away from sunlight
Σ	Contents sufficient for <n> tests</n>	\triangle	Caution	**	Keep dry
®	Do not use if package is damaged	UDI	Unique Device Identification		

ORDERING INFORMATION

Product	Cat No.	Package	Note	
	W7020	64 Prep	16 prep/run	
 WizMag™ Viral DNA/RNA	W7021	192 Prep	то ргер/тип	
,	W7022	32 Prep	Cingle prop	
	W7023	96 Prep	Single prep	
CLEO™ AP16 Nucleic acid Extractor	CL2016	1 system	1-16 sample	
CLEO™ AP48 Nucleic acid Extractor	CL2048	1 system	1-48 sample	

MFDS License No.: IVD-23-836



Technical Support



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