IVD

WizMag™ DNA Clinical II

User Manual

Ver 1.0

REF W7200 | W7201 | W7202 | W7203

For *in vitro* diagnostic use.

wizbiosolutions
THE INNOVATION OF GENOMICS

INTENDED USE

The WizMag™ DNA Clinical II kit is designed for the CLEO™ AP16 and AP48 Nucleic Acid Extractor System. It provides an automated method for purifying total DNA from various biological samples including cultured cells, swabs, body fluids, and other cell-containing liquid media. Purified DNA 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	W7200	W7201	W7202	W7203	Storage
No. of preparation	64	192	32	96	Room Temperature (15-25°C)
Prepacked 96-well plate	4 ea	12 ea	-	-	
Prepacked 6-well tube	-	-	32 ea	96 ea	
Plunger strip	8 ea	24 ea	8 ea	24 ea	
Buffer PKR	1.5 mL	6 mL	1 mL	3 mL	
Proteinase K**	14 mg x 2	42 mg x 2	14 mg	42 mg	
Blank solution A	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). Prolonged exposure to heat sources can significantly deteriorate the performance of the kit.

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

QUALITY CONTROL ANALYSIS

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

QRECONSTITUTION 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°C.

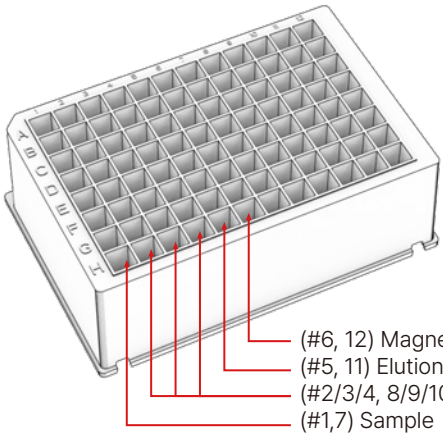
QPRECAUTIONS

- 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.

- 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 (W7200 | W7201)

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



Columns 7 - 12 in the right half of a 96-well plate have the same composition as columns 1 - 6 in the left half.

COMPOSITION OF THE PRE-PACKED 6-WELL STRIP (W7202 | W7203)

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

PROTOCOL

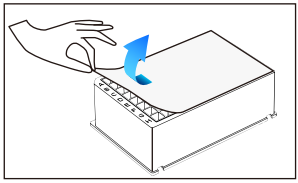
A. Setup of program (For CLEO™ AP16 & AP48 devices, preset program can be used.)
Edit and run the experiment program as follows:

No.	1	2	3	4	5	6	7
Well No.	6	1	2	3	4	5	6
Step	Beads	Lysis	Wash	Wash	Wash	Elute	Discard
Volume (µL)	200	600	750	750	500	80	200
Wait time	-	-	-	-	-	02:00	-
Mix time 1	00:15	10:00	00:10	00:10	01:00	00:15	00:15
Method 1	Medium	Fast	Bottom	Bottom	Fast	Bottom	Medium
Mix time 2	-	-	00:20	00:20	-	00:45	-
Method 2	-	-	Fast	Fast	-	Medium	-
Loop count	-	-	4	3	-	3	-
Collect time	00:15	00:20	00:15	00:15	00:15	01:00	-
Collect speed	Strong	Strong	Strong	Strong	Strong	Strong	Normal
Temperature		65°C				60°C	

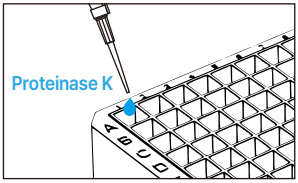
B. Sample Preparation

1. **Liquid samples (plasma, serum, whole blood, body fluids, urine, and virus-containing media)**
   - Use 200 µL of a liquid sample directly.
2. **Swab samples (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 the immersion solution.
   - For swab-transporting media, use 200 µL of the media directly.
3. **Cell-containing samples**
   - Pellet the cells by centrifuging at 13,000 xg for 3 minutes.
   - Resuspend the pellet completely in 200 µL of 1x PBS.
   - Use the 200 µL of the suspension as a sample.

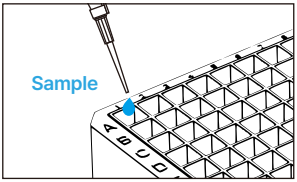
C-1. DNA extraction procedure (W7200, W7201)



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

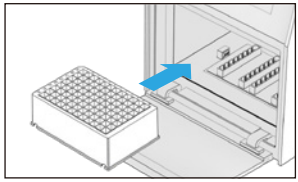


2. Add 20 µL of Proteinase K solution into the each first well (#1,7)

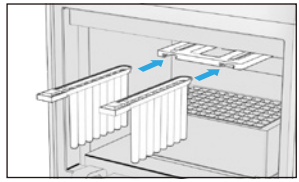


3. Add 200 µL of the sample into the each first well (#1,7)

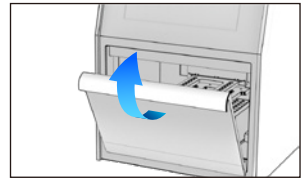
(Optional) If RNA removal is required, add 5 uL of RNase A (100 mg/mL, not provided) into each of the second wells (#2, #8).
▶ Avoid treating with RNase A if a low DNA yield is anticipated.



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

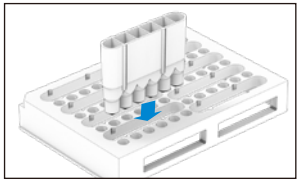


5. Insert a Plunger all the way into the socket above the 96-well Plate.

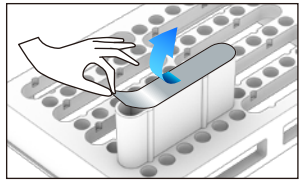


6. Close the front door of the instrument.

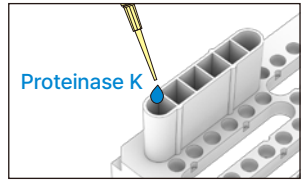
C-2. DNA extraction procedure (W7202, W7203)



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

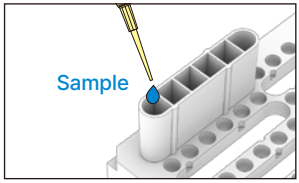


2. Carefully peel off the film of the 6-well Strip not to cross-contaminate.

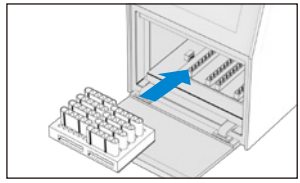


3. Add 20 µL of Proteinase K solution into the each first well (#1)

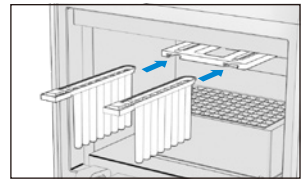
(Optional) If RNA removal is required, add 5 uL of RNase A (100 mg/mL, not provided) into each of the second wells (#2, #8).
▶ Avoid treating with RNase A if a low DNA yield is anticipated.



4. Add 200 µL 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 ▶ DNA ▶ DNA Clinical II** 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 60 - 70 µL 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 or no recovery	Low cells in the starting sample	Some samples may have low population of cells. When the cell mass is very low, an addition of carrier RNA (5-10 µg/sample) into the sample can be helpful for the recovery of DNA.
	Too many cells in the starting sample	The sample amount over the maximum capacity will lead to poor lysis of cells, resulting in significantly low recovery. Reduce the amount of starting sample.
Low purity	Too much sample amount used	Do not overload the sample. Keep the volume and the cell number of sample as procedure.
High A_{260}/A_{280} ratio	RNA contamination	RNA can inhibit some downstream enzymatic reactions, but not PCR itself. If RNA should be removed from the preparation, add RNase A solution into well#2 at DNA recovery procedure. Alternatively, RNase A solution can be applied to the sample directly by 5 µL per sample.
Degraded DNA	Starting sample is too old or improperly stored	Too old or improperly stored samples may have degraded DNA. Use a fresh sample.
Inconsisten recovery of DNA	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		Manufacturer		Use-by date
LOT	Batch code		Do not re-use		Temperature limitation
IVD	in-vitro diagnostic use		Instructions for use		Keep away from sunlight
	Contents sufficient for <n> tests		Caution		Keep dry
	Do not use if package is damaged	UDI	Unique Device Identification		

ORDERING INFORMATION

Product	Cat No.	Package	Note
WizMag™ DNA Clinical II	W7200	64 Prep	16 prep/run
	W7201	192 Prep	
	W7202	32 Prep	Single prep
	W7203	96 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-25-578

Technical Support

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ISO13485:2016, GMP certified
WS-IFU-W7200-01(EU) (V.1.0.4, 19-05-25)