

WizMag™ Blood DNA

User Manual

Ver 2.0

REF W7010 | W7011 | W7012 | W7013

For in vitro diagnostic use.



INTENDED USE

The WizMag™ Blood DNA kit is designed to be used on the CLEO™ AP16 Nucleic Acid Extractor System for simple and easy purification of total DNA from whole blood or its derivatives. This kit utilizes advanced magnetic-silica technology to purify high-quality DNA and up to 200 µL of mammalian whole blood can be processed per prep in less than 40 minutes. 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 | W7010 | W7011 | W7012 | W7013 | 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 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). 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™ Blood DNA 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 $2-8^{\circ}\text{C}$.

PRECAUTIONS



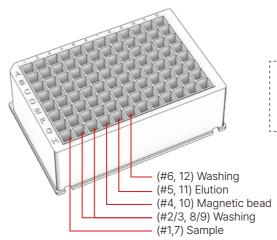
- This product is reserved exclusively for *in vitro* diagnostic purposes.
- · Intended for single use only. Do not reuse.
- Check the expiration date on the box. Do not use it after the expiration date.
- Wear protective clothing, and use disposable gloves, goggles, and a mask.
- Do not eat, drink or 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.
- Regular decontamination of commonly used equipment is recommended, especially micropipettes and work surfaces.

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

- 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 (W7010 | W7011)

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 (W7012 | W7013)



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

PROTOCOL

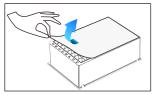
A. Setup of program (For CLEO™ AP16 & AP48 devices, preset program can be used.) Edit and run the experiment program as follows:

| No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---------------|--------|--------|--------|--------|--------|--------|--------|---------|
| Well# | 4 | 1 | 2 | 3 | 4 | 6 | 5 | 4 |
| Step | Beads | Lysis | Wash | Wash | Wash | Wash | Elute | Discard |
| Volume(µL) | 750 | 700 | 750 | 750 | 750 | 750 | 80 | 750 |
| Wait time | - | - | - | - | - | - | 03:00 | - |
| Mix time 1 | 00:20 | 15:00 | 00:15 | 00:10 | 01:00 | 01:00 | 00:15 | 00:15 |
| Mix speed 1 | Medium | Fast | Bottom | Bottom | Bottom | Fast | Bottom | Bottom |
| Mix time 2 | - | - | 00:15 | 00:20 | 00:20 | - | 00:45 | - |
| Mix speed 2 | - | - | Fast | Fast | Fast | - | Fast | - |
| Mix loop | 1 | 1 | 4 | 3 | 2 | 1 | 3 | - |
| Collect time | 00:20 | 00:25 | 00:20 | 00:20 | 00:20 | 00:20 | 01:00 | - |
| Collect speed | Strong | Normal |
| Temperature | | 65°C | | | | | 60°C | |

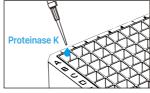
B. Sample Preparation

| Sample type | Preparation |
|-----------------------|--|
| Mammalian whole blood | Use 200 µL of whole blood or buffy coat as sample |
| Nucleated blood | Add 190 - 195 µL of 1x PBS to 5 - 10 µL of nucleated blood to make 200 µL of sample. |

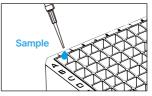
C-1. DNA extraction procedure (W7010, W7011)



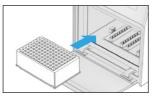
1. Carefully peel off the film of the 96-well Plate not to cross-contaminate.



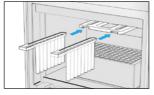
2. Add 20 uL of Proteinase K solution into the each first well (#1,7)



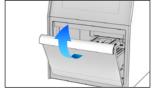
3. Add 200 µL of the sample into the each first well (#1.7)



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.

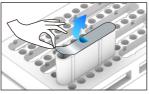


6. Close the front door of the instrument

C-2. DNA extraction procedure (W7012, W7013)



1. Mount the 6-well Strip onto 2. Carefully peel off the film of the Strip Adapter Plate.



the 6-well Strip not to cross-contaminate.



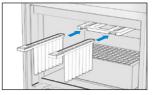
3. Add 20 uL of Proteinase K solution into the each first well (#1)



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 ▶ Blood DNA on the screen.



- 8. Press 'RUN' button on the screen.
- 9. After the alarm finishes, open the door and carefully remove the Plunger.
- 10. Detach the 96-well plate (or the Strip Adapter Plate) from the machine carefully.
- 11. Transfer the 60 80 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.
- 12. 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 cells in the starting sample | Some samples may have a low population of cells, and some whole blood may contain low numbers of white blood cells. When the cell mass is very low, an addition of carrier RNA (5~10 ug/sample) into the sample can be helpful for the recovery of DNA. |
| Low yield | Too much sample volume used | Do not overload the sample. Keep the volume of a sample as a procedure. |
| | Degenerated Proteinase K | Degenerated Proteinase K may cause inefficient lysis. Proteinase K solution should be stored at 2~8°C for maintenance of proper activity. |
| Low purity or the colored residue in eluate | Incomplete removal of hemoglobin | In case of DNA preparation from a certain animal's blood or improperly stored blood, it is hard to remove hemoglobin from their blood. Use a freshly harvested sample or try again with a half volume of whole blood. Make 200 µL with 1x PBS. |
| Degraded DNA | Starting sample is too old or improperly stored | Too old or improperly stored samples have degraded DNA. Use a fresh sample. |
| Inconsistent 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 plates or tubes always should be stored in proper condition. Before removing the film from the plate or the tube, it is recommended to shake off the deposit on the film while holding the plate or the tube tightly. |

SYMBOL GLOSSARY

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

ORDERING INFORMATION

| Product | Cat No. | Package | Note | |
|-----------------------------------|---------|----------|---------------|--|
| | W7010 | 64 Prep | 16 prep/run | |
| WizMaq™ Blood DNA | W7011 | 192 Prep | то ргер/тип | |
| | W7012 | 32 Prep | - Single prep | |
| | W7013 | 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-23-833



Technical Support



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