



## AmoyDx<sup>®</sup> Blood/Bone Marrow DNA Kit (Spin Column)

For purification of DNA from whole blood/ bone marrow

Instructions for Use

**REF** 8.02.0077 36 tests/kit



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This importer information is only applicable  
for EU market

Version: V01

## Intended Use

The AmoyDx® Blood/Bone Marrow DNA Kit is specially designed for isolation and purification of DNA from whole blood/ bone marrow. The purified DNA is suitable for downstream applications such as reverse transcription, RT-PCR, and real-time quantitative RT-PCR (qRT-PCR).

## Intended User

The AmoyDx® Blood/Bone Marrow DNA Kit is intended to be used by laboratory professionals only.

## Principle

The AmoyDx® Blood/Bone Marrow DNA Kit provides silica-based membrane and special lysis buffer system for blood/bone marrow DNA extraction effectively. Whole blood/ bone marrow sample are lysed with Buffer BDL and Proteinase K solution to release DNA. Then the lysate is mixed with ethanol to provide appropriate binding conditions for DNA, then the mixture is applied to a DNA spin column, where the DNA binds to the membrane and impurities are removed with wash buffer. The DNA is eluted in Buffer BDE.

## Kit Contents

This kit contains sufficient reagents to perform 36 tests (Table 1).

Table 1 Kit Contents

Tube No.	Component	Symbol	Quantity
—	DNA Spin Columns	DNA Spin Columns DNA 吸附柱	36 pcs ×1
—	Collection Tubes (2 mL)	Collection Tubes (2 mL) 2 mL 收集管	72 pcs ×1
—	Centrifugal Tubes (1.5 mL)	Centrifugal Tubes (1.5 mL) 1.5 mL 离心管	72 pcs ×1
1	Buffer BDL	Buffer BDL 裂解液 BDL	27 mL ×1
2	Proteinase K Solution	Proteinase K Solution 蛋白酶 K 溶液	1.4 mL ×1
3	Buffer DW1	Buffer DW1 洗涤液 DW1	13 mL ×1
4	Buffer DW2	Buffer DW2 洗涤液 DW2	6 mL ×1
5	Buffer BDE	Buffer BDE 洗脱液 BDE	10 mL ×1

### Note:

- 1) **Buffer BDL** and **Buffer DW1** contain guanidine salt, not compatible with disinfectants containing bleach or acidic solutions.
- 2) For the first time use, add 17 mL ethanol (96~100%) into **Buffer DW1** and mix thoroughly; add 24 mL ethanol (96~100%) into **Buffer DW2** and mix thoroughly. Tick the check box on the bottle label.

## Storage and Stability

The shelf life of the kit is 12 months. The kit should be transported and stored dry at room temperature (10~30°C).

## Additional Reagents and Equipment Required but Not Supplied

- 1) Ethanol (96~100%).
- 2) Water bath or heated orbital incubator (56°C adjustable).
- 3) Microcentrifuge (13,000×g adjustable).
- 4) Vortexer.
- 5) Palm centrifuge.
- 6) Sterile, DNase-free pipet tips

## Precautions and Handling Requirements

For *in vitro* diagnostic use.

### Precautions

- Please read the instruction carefully and become familiar with all components of the kit prior to use, and strictly follow the instruction during operation.
- DO NOT use the kit or any kit component after their expiry date.
- DO NOT use any other reagents from different lots in the tests.
- DO NOT use any other reagent in the other test kits.

### Safety Information

- **Buffer BDL and Buffer DWI** contain guanidine salt, which can form highly reactive compounds when combined with bleach. **Do not add bleach or acidic solutions directly to the sample-preparation waste.** If the liquid containing this buffer is spilt, clean with suitable laboratory detergent and water.



#### Signal Word

#### Hazard Statements:

H302+H332:

H315:

H319:

#### Precautionary Statements

P261:

P264:

P301+P312:

P302+P352:

P304+P340+P312:

P305+P351+P388:

#### Warning

Harmful if swallowed or harmful if inhaled.

Causes skin irritation.

Causes serious eye irritation.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wash skin thoroughly after handling.

IF SWALLOWED: Call a POISON CENTER or doctor/physician IF you feel unwell.

IF ON SKIN: Wash with plenty of soap and water.

IF INHALED: Remove victim to fresh air and Keep at rest in a position comfortable for breathing.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

- Handle all specimens and components of the kit as potentially infectious material using safe laboratory procedures.
- Only trained professionals can use this kit. Please wear suitable lab coat and disposable gloves while handling the reagents.
- If a spill contains potentially infectious reagents, clean the affected area first with laboratory detergent and water, then with 1% (v/v) sodium hypochlorite or a suitable laboratory disinfectant.
- Avoid skin, eyes and mucous membranes contact with the chemicals. In case of contact, flush with water immediately.
- DO NOT pipet by mouth.

### Decontamination and Disposal

- Gloves should be worn and changed frequently when handling samples and reagents to prevent contamination.
- Using separate, dedicated pipettes and filtered pipette tips when handling samples and reagents to prevent cross-contamination.
- All disposable materials are for one time use. DO NOT reuse.
- The unused reagents, used kit, and waste must be disposed of properly.

### Cleaning

- After the experiment, wipe down the work area, spray down the pipettes and equipment with 75% ethanol or 10% hypochlorous acid solution.

### Specimen Collection, Transport and Storage

Whole blood (with anticoagulants such as citrate, or EDTA)/bone marrow sample. Be sure to:

- 1) Do not use heparin as anticoagulant, since heparin will inhibit PCR amplification and restriction enzyme digestion.
- 2) Blood samples should be treated as infectious materials. Take caution in handling the samples.

## Assay Procedure

### Note:

- For the first time use, please add 17 mL ethanol (96~100%) into **Buffer DW1**, add 24 mL ethanol (96~100%) into **Buffer DW2**, and mark it clearly.
  - Before the DNA extraction, please check the reagents without leakage. Shake the reagents gently to mix the solutions. If the reagents contain precipitates, dissolved by heating at 50°C.
- 1) Briefly pipet 200  $\mu$ L whole blood/bone marrow sample into a clean 1.5 mL centrifugal tube.
  - 2) Add 30  $\mu$ L **Proteinase K Solution** and 600  $\mu$ L **Buffer BDL**, mix by vortexing for 10 seconds.
  - 3) Briefly centrifuge for 5 seconds. Incubate at 56°C for 20 min.
  - 4) Add 200  $\mu$ L **Ethanol** (96~100%), mix by vortexing for 10 seconds. Briefly centrifuge for 5 seconds.
  - 5) Transfer 600  $\mu$ L lysate into the DNA Spin Column (in a 2 mL collection tube) without wetting the rim, close the lid, and centrifuge at 13,000 $\times$ g for 30 seconds. Discard the flow-through in collection tube.
  - 6) Transfer the rest of the lysate into the DNA Spin Column, and centrifuge at 13,000 $\times$ g for 30 seconds. Discard the collection tube with flow-through.
  - 7) Place the DNA Spin Column in a clean 2 mL collection centrifugal tube.
  - 8) Add 700  $\mu$ L **Buffer DW1** into DNA Spin Column, centrifuge at 13,000 $\times$ g for 30 seconds. Discard the flow-through in collection tube.
  - 9) Add 700  $\mu$ L **Buffer DW2** into DNA Spin Column, centrifuge at 13,000 $\times$ g for 30 seconds. Discard the flow-through in collection tube.
  - 10) Add 700  $\mu$ L **Ethanol** (96~100%) into DNA Spin Column, centrifuge at 13,000 $\times$ g for 30 seconds. Discard the flow-through in collection tube.
  - 11) Centrifuge at 13,000 $\times$ g for 3 min. Discard the collection tube with flow-through.
  - 12) Place the DNA Spin Column in a clean 1.5 mL centrifugal tube. Open the tube and incubate at 56°C for 3 min.
  - 13) Apply 50~200  $\mu$ L **Buffer BDE** to the center of the membrane. Do not touch the membrane. Incubate at 56°C for 2 min. Centrifuge at 13,000 $\times$ g for 1 min.

### Note:

- *Buffer BDE is only for elution and storage of DNA, NOT for other use.*
  - *When the elution volume is more than 50  $\mu$ L, two times elution makes for higher DNA yield. (eg. If elution volume is 100  $\mu$ L, firstly apply 50  $\mu$ L Buffer DTE to the center of membrane, incubate at 56°C for 2 min and centrifuge at 13,000 $\times$ g for 1 min. Then apply another Buffer DTE to the center of membrane, incubate at 56°C for 2 min and centrifuge at 13,000 $\times$ g for 1 min.)*
- 14) The eluted DNA is immediately ready for use immediately. If the DNA is not used within 6 hours, it should be stored at -20°C.

## Performance Characteristics

The extraction efficacy of the kit was established by testing of six clinical whole blood or bone marrow samples.

- Extracted DNA: Mean A260  $\geq$  0.1, and Mean A260/A280 ratio  $\geq$  1.6.

## Limitations

- 1) The quality of extracted DNA is subject to the influence of such factors as sample source, sampling process, collection site, storage conditions.
- 2) Sample quality has a high impact on quality and amount of the purified DNA.

## General Notes

If any serious incident has occurred during the use of this device or as a result of its use, please report it to the manufacturer and to your national authority.

## References

- 1) Chevillard S. A method for sequential extraction of RNA and DNA from the same sample, specially designed for a limited supply of biological material. *Biotechniques*. 1993 Jul;15(1):22-4.

**Symbols**

<div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">EC</div> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">REP</div> <div style="margin-left: 10px;">Authorized representative in the European Community/European Union</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="margin-left: 10px;">Manufacturer</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">LOT</div> <div style="margin-left: 10px;">Batch Code</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="margin-left: 10px;">Contains Sufficient for &lt;n&gt; Tests</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="margin-left: 10px;">Consult Instructions For Use</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="margin-left: 10px;">This Way Up</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">COMP</div> <div style="margin-left: 10px;">Kit Components</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">ADD</div> <div style="margin-left: 10px;">Adding</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="margin-left: 10px;">Importer</div> </div>	<div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">IVD</div> <div style="margin-left: 10px;">In Vitro Diagnostic Medical Device</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">REF</div> <div style="margin-left: 10px;">Catalogue Number</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="margin-left: 10px;">Use-by Date</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="margin-left: 10px;">Temperature Limit</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="margin-left: 10px;">Keep Dry</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="margin-left: 10px;">Fragile, Handle With Care</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">Done? <input type="checkbox"/></div> <div style="margin-left: 10px;">Tick the box after adding ethanol to the vial</div> </div> <div style="display: flex; align-items: center; margin-bottom: 5px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">EtOH</div> <div style="margin-left: 10px;">Ethanol</div> </div>
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## Revision History

Revision	Effective Date	Revision History
B1.0	2022-05-26	First edition
V01	2022-11-04	<ol style="list-style-type: none"><li>1. Add the symbol and information of importer;</li><li>2. Add revision history;</li><li>3. Move “effective date” from first page to last page;</li><li>4. Implementation of new coding rules.</li></ol>