FFPE Tissue gDNA Isolation Kit (Beads)

(BW-MGD2212-A32 and A96)

CE

IVD For In VitDiagnostic Use Only

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European Authorized Representative

EC REP

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BEIWO FFPE Tissue gDNA Isolation Kit is designed for genomic DNA purification from formalin-fixed, paraffin-embedded (FFPE) tissue samples. Instead of using xylene, the kit utilizes a proprietary nontoxic deparaffinization reagent for safe and convenient paraffin removal. To overcome the cross linking of nucleic acids caused by formalin fixation, specially formulated buffers and lysing conditions are developed to release DNA from tissue sections. The purified genomic DNA is suitable for downstream applications such as quantitative real-time RT-PCR, sequencing and mutation screening. MGD2212-A32 is compatible with BEIWO BW Express 16, Allsheng Auto-Pure 32A; MGD2212-A96 is compatible with Allsheng Auto-Pure 96, Hamilton, Beckman Biomek, Tecan, Thermo KingFisher.and other similar nucleic acid purification systems.

KIT CONTENTS

① **BW-MGD2212-A32**

Catalog#	Well position	BW-MGD2212-A32-10	BW-MGD2212-A32-11	BW-MGD2212-A32-12
Preps	-	1 x 32	10 x 32	20 x 32
FFPE A	-	4 mL	40 mL	80 mL
Buffer TL	-	20 mL	180 mL	360 mL
Buffer FBL	**Column 1/7**	400 µL	400 µL	400 µL
Buffer MKB	**Column 2/8**	600 µL	600 µL	600 µL
DNA Wash Buffer	**Column 3/9**	600 µL	600 µL	600 µL
DNA Wash Buffer / Beads	**Column 4/10**	610 µL	610 µL	610 µL

Buffer MEB	**Column 6/12**	100 µL	100 µL	100 µL
Proteinase K	-	0.8 mL	7.5 mL	14 mL
8-strip Tip Comb	-	4	40	80

Note： FFPE A, Buffer TL, and Proteinase K are bottled reagents. Magnetic Beads were dispensed in DNA Wash buffer.

② BW-MGD2212-A96

Catalog#	Plate position	BW-MGD2212-A96-10	BW-MGD2212-A96-11	BW-MGD2212-A96-12
Preps	-	1 x 96	4 x 96	10 x 96
FFPE A	-	12 mL	46 mL	115 mL
Buffer TL	-	55 mL	210 mL	530 mL
Buffer FBL	4	400 µL	400 µL	400 µL
Buffer MKB	5	600 µL	600 µL	600 µL
DNA Wash Buffer	6	600 µL	600 µL	600 µL
DNA Wash Buffer / Beads	7	610 µL	610 µL	610 µL
Buffer MEB	8	100 µL	100 µL	100 µL
Proteinase K	-	2.2 mL	8.8 mL	22 mL
96-Well Tip Comb	-	1	4	10

Note： FFPE A, Buffer TL, and Proteinase K are bottled reagents. Magnetic Beads were dispensed in DNA Wash buffer.

STORAGE

FFPE Tissue gDNA Isolation Kit should be stored dry and at room temperature (15–25°C). They can be stored for at least 12 months without showing any significant reduction in performance, capacity, or quality of separation.

EXPECTED USAGE

For nucleic acid extraction, enrichment, purification and other steps. The processed product is used for clinical in vitro detection.

BEFORE STARTING

- ☑ Operate in an environment with the appropriate biosafety laboratory level (e.g BSL-2 or higher level) and wear appropriate personal protective equipment (e.g. gowns, gloves, goggles) when working with clinical specimens.
- ☑ Ultraviolet disinfection of the Nucleic Acid Purification Instrument prior to use is recommended.

☑ Buffer may form precipitates upon storage, dissolve precipitates at 37ºC before use.

☑ **Set the temperature of water baths or dry baths at 55℃ and 98℃ in advance.**

SAFETY INFORMATION

☑ When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate material safety data sheets.

☑ The product should be used in strict accordance with the instructions. If it is not used in accordance with the regulations, it may cause pollution to the environment.

☑ Products are disposable, do not reuse, and the used product should be placed in the designated position in time.

☑ Exceeding the expiration date of this product, the performance of the product may be reduced, so it should be used within the expiration date.

☑ This kit can only be used for in vitro experiments, and not for clinical, therapeutic and in vivo experiments in animals. If it is not used in accordance with the regulations, the company will not be responsible for the consequences arising therefrom.

PROCEDURE（BW-MGD2212-A32）

1. Take **3-5 paraffin sections** (thickness 5-10 μM, surface area 1×1 cm^2, up to 15 mg), remove excess paraffin as much as possible. Put them into a 1.5-2 mL centrifuge tube, add **100 μL FFPE A**, **500 μL Buffer TL** and **20 μL Proteinase K**, mix well by vortexing for 30 seconds.
2. Incubate at **55ºC** for **30-60 minutes,** then **80ºC** for another **40 minutes.** Vortex several times during incubation. Cool down the sample to room temperature. **Note:** Tubes may burst during incubation. Wear a suitable lab coat, disposable gloves, and protective goggles. Use long tweezers and heat proof safe lock tubes to avoid liquid splash during incubation.
3. Spin the sample at **12,000 rpm** for **5 minutes** at room temperature. Transfer the **clear phase** (middle layer) into a clear tube, avoid the impurities.
4. **Optional:** If RNA free gDNA is desired, add **10 μL RNase A** (20 mg/mL, Self-provided) and incubate at **room temperature** (15-25ºC) for **2 minutes**.
5. Take out a pre-loaded 96-well plate and gently shake it (if necessary), let the reagent or magnetic beads assemble at the bottom of the plate. **NOTE:** If there is any precipitation in **Column 1/7**, incubate the plate at 37ºC to dissolve the precipitation before use.
6. In a biosafety cabinet, carefully remove the sealing foil of the 96-well plate. Aspirate **400 uL Pre-treated Sample** into the deep wells in **Column 1/7**.
7. Put the plate in a BEIWO BW Express 16 or an Allsheng Auto-Pure 32A Nucleic Acid Purification System.
8. Install **two 8-strip Tip Combs** for each plate.

9. Run the program described in **Table 1**.

10. After the program is completed, take out the 96-well plate and aspirate the **gDNA solutions** from **Column 6/12** into new sterile tubes. The gDNA solutions are ready to be used or can be stored at -20℃.

Table 1. Recommended program for Auto-Pure 32A Nucleic Acid Purification System

Step	Well	Name	Mix time (min)	Magnet (sec)	Wait time (min)	Vol. (μL)	Mix speed (1-10)	Temp. (℃)	Mix pos (0-100%)	Mix amp (1-100%)	Magnet pos (0-100%)	Magnet speed (1-10)
1	4	Beads	1	30	0	600	10	OFF	0	80	0	1
2	1	Bind	3	60	0	800	10	OFF	0	80	0	1
3	2	Wash1	1	30	0	600	10	OFF	0	80	0	1
4	3	Wash2	1	30	0	600	10	OFF	0	80	0	1
5	4	Wash3	1	30	1	600	10	OFF	0	80	0	1
6	6	Elute	5	30	0	100	10	80	0	80	0	1
7	4	Drop	0.2	0	0	600	5	OFF	0	80	0	1

Note: Set 'Preheating' , 'Cool Fan Disabled', 'Cooling synchronization', and 'Drying Fan Disabled'

PROCEDURE（BW-MGD2212-A96）

1. Take **3-5 paraffin sections** (thickness 5-10 μM, surface area 1×1 cm^2, up to 15 mg), remove excess paraffin as much as possible. Put them into a 1.5-2 mL centrifuge tube, add **100 μL FFPE A**, **500 μL Buffer TL** and **20 μL Proteinase K**, mix well by vortexing for 30 seconds.

2. Incubate at **55°C** for **30-60 minutes,** then **80°C** for another **40 minutes.** Vortex several times during incubation. Cool down the sample to room temperature. **Note:** Tubes may burst during incubation. Wear a suitable lab coat, disposable gloves, and protective goggles. Use long tweezers and heat proof safe lock tubes to avoid liquid splash during incubation.

3. Spin the sample at **12,000 rpm** for **5 minutes** at room temperature. Transfer the **clear phase** (middle layer) into a new centrifuge tube, avoid the impurities.

4. **Optional:** If RNA free gDNA is desired, add **10 μL RNase A** (20 mg/mL, Self-provided) and incubate at **room temperature** (15-25°C) for **2 minutes**.

5. Carefully remove the sealing foil of a 96-well plate named **Buffer FBL**, aspirate **400 μL pre-treated sample** into the well, then put the plate on **position 4** of the Auto-Pure 96 instrument put them on the **corresponding positions** according to the following **Table 2**. **NOTE:** If there is any precipitation in **Buffer FBL**, incubate at 37°C to dissolve the precipitation before use.

6. Carefully remove the sealing foil of a 96-well plate named **Buffer MKB**, put it on **position 5** of the Auto-Pure 96 instrument.

7. Carefully remove the sealing foil of a 96-well plate named **DNA Wash Buffer**, put a **96-Well Tip Comb** into the plate, and put them on **position 6** of the Auto-Pure 96 instrument together.
8. Carefully remove the sealing foil of a 96-well plate named **DNA Wash Buffer / Beads**, put it on **position 7** of the Auto-Pure 96 instrument.
9. Carefully remove the sealing foil of a 96-well plate named **Buffer MEB**, put it on **position 8** of the Auto-Pure 96 instrument.
10. Run the program described in **Table 3**.
11. After the program is completed, take out the **Buffer MEB** plate on **position 8**, aspirate the **gDNA solutions** into new sterile tubes.

Table 2. 96-well plates setting in the Auto-Pure 96 Nucleic Acid Purification System

Plate position	Catalog#	Sample / Reagent	Vol. (μL)	Note
4	Buffer FBL	Buffer FBL	400	Pre-loaded
		Pre-treated Sample	400	Added by user.
5	Buffer MKB	Buffer MKB	600	Pre-loaded
6	DNA Wash Buffer	DNA Wash Buffer	600	Pre-loaded
		96-Well Tip Comb	-	Put in DNA Wash Buffer plate
7	DNA Wash Buffer / Beads	DNA Wash Buffer	600	Pre-loaded
		Beads	10	Pre-loaded
8	Buffer MEB	Buffer MEB	100	Pre-loaded

Table 3. Recommended program for the Auto-Pure 96 Nucleic Acid Purification System

Step	Name	Plate	Mix Time (min)	Mix Amp (%)	Wait Time (min)	Vol. (μL)	Mix Speed (1-10)	Temp. (°C)	Seg-ments (0-5)	1st Seg. time (s)	2nd Seg. time (s)	3rd Seg. time (s)	4th Seg. time (s)	5th Seg. time (s)	Cycle times (1-10)	Mag. speed (1-10)	Lip-lvl (0-30s)	Anti-Splash (0-30s)
1	Load	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	Beads	7	0.5	80	0	600	8	OFF	1	5	-	-	-	-	2	1	0	0
3	Bind1	4	1	30	0	800	10	OFF	0	-	-	-	-	-	1	-	0	0
4	Bind2	4	2	80	0	800	1	OFF	5	20	20	15	15	1	1	1	0	0
5	Wash1	5	1	30	0	600	8	OFF	1	1	-	-	-	-	4	1	0	0
6	Wash2	6	1	30	0	600	8	OFF	1	1	-	-	-	-	3	1	0	0
7	Wash3	7	1	30	0	600	8	OFF	1	1	-	-	-	-	5	1	0	0
8	Elute1	8	1	80	0	100	10	70	0	-	-	-	-	-	1	-	0	0
9	Elute2	8	4	80	0	100	3	70	2	15	15	-	-	-	5	1	10	0
10	Unload	6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Note: Set 'Heating synchronization', 'Cool Fan Disabled', 'Cooling synchronization', and 'Drying Fan Disabled'

Appendix

Index of Symbols

IVD	In vitro diagnostic medical device
LOT	Lot number
	Manufacturer
	Attention, see instruction for use
EC REP	Authorized representative in the European Community
	Date of manufacture
	Use until year & month (Expiration date)
CE	CE mark

LIMITED USE AND WARRANTY

This product is warranted to perform as described in its labeling and in BEIWO's literature when used in accordance with instructions. No other warranties of any kind, express or implied, including, without limitation, implied warranties of merchantability or fitness for a particular purpose, are provided by BEIWO. BEIWO's sole obligation and purchaser's exclusive remedy for breach of this warranty shall be, at the option of BEIWO, to replace the products, BEIWO shall have no liability for any direct, indirect, consequential, or incidental damage arising out of the use, the results of use, or the inability to use it product. For technical support or learn more product information, please contact us at 400-115-2855 or visit our website at www.beiwobiomedical.com

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