



TANBead® Nucleic Acid Extraction Kit

OptiPure FFPE DNA Auto Plate

(For use with the Maelstrom 8 series and Maelstrom 4800 series)



M61PA46

(For Professional Use Only) V6

1. Intended Purpose

The TANBead® Nucleic Acid Extraction Kit is a nucleic acid purification kit based on magnetic bead technology by using with corresponding TANBead® Nucleic Acid Extractor, which can automatically isolate and purify total DNA from formalin-fixed paraffin-embedded (FFPE) tissue sections. The purified DNA can be used with any downstream application employing PCR-based qualitative, semi-quantitative and quantitative assays. The kit is intended for use by technicians, physicians, and biologists with well-trained in molecular biological techniques, the techniques of magnetic bead purification and in vitro diagnostic procedures. Any diagnostic results generated by using the sample preparation procedure in conjunction with any downstream diagnostic assay should be interpreted related to other clinical or laboratory findings. The kit is not limited to any specific disorder, condition, or other additional accompanying diagnostics. It is applicable for all population.

2. The basic principle

The silicon dioxide layer coated on the magnetic beads can adsorb the negatively charged molecules to purify nucleic acids from samples.

3. Specification

Starting Materials	Minimal requirement of 5 µm or curl input
Elution Volume	70~100 µL
Typical DNA yield	≥ 2 µg
Typical A260 / A280	1.7~1.9

4. Component Supplied with the Kit

Auto Plates	6	Auto Plate with reagent buffers
Proteinase K	1.0 mL x 2	Proteinase K
Elution Buffer	1.5 mL x 1	Nuclease-Free Water
Incubation Buffer	35 mL	Tris buffer, surfactants, pH 8.0
Mineral Oil	35 mL	Nuclease-Free mineral oil
Spin tips	96	Spin tip assembled box
Protocol	1	Instruction guides for user

5. Auto Plate Content

Well	Buffer	Volume (µL)
1 / 7	-	-
2 / 8	-	-
3 / 9	Washing Buffer 2	800
4 / 10	Washing Buffer 2	800
5 / 11	Magnetic Beads	800
6 / 12	Elution Buffer	100

6. Kit Storage and Shelf Life

- Components under room temperature (15~35°C) can be stored until the expiration date labeled on the box.
- The proteinase K is transported at room temperature. Upon receipt, please store proteinase K at 2~8°C.

7. Precautions

- It can only be used for *in vitro* diagnostic.
- Avoid using expired reagents.
- When the temperature is below 20°C, place the Auto Plates / Auto Tubes in an oven (preheated 42~60°C) 5 to 10 minutes.
- Avoid vigorous shaking, in order to avoid excessive formation of foam.
- Carefully remove aluminum foil to avoid splashing.
- Do not expose the opened reagents or Auto Plates / Auto Tubes to air. The evaporation would lead to pH change, or effect on the extraction effectiveness.
- Please check the integrity of the Auto Plates / Auto Tubes and remember to mount the spin tips into the appropriate position of the suitable instrument before operating them.
- Please wear a mask and disposable gloves when handling.

- Use sterile consumables to avoid nuclease contamination.
- Reagent solution contains guanidine salt, avoid using bleach containing detergent.
- Avoid eyes, skin, and clothing contact with reagents. In case of any contact, flush with flowing water.
- If any serious incident occurs, please report to the manufacturer and the competent authority of the member state in which the user and/or the patient is established.

8. Materials required, Not Supplied

- TANBead® Nucleic Acid Extraction System
Model: Maelstrom 8 series, Maelstrom 4800 series (non-sterile)
- Disposable gloves
- Scissors, utility knives
- Micropipette, disposable tips (10 µL / 200 µL / 1000 µL)
- 1.5 mL microcentrifuge tube
- 15 mL / 50 mL conical tube
- IPA: Isopropanol for molecular biology

9. Sample Collection, Transportation, and Storage

■ Sample collection and storage

FFPE can be stored at 2-25°C for long-term preservation.

■ Specimen transportation

Transportation of FFPE specimens should follow specific FFPE tissue transportation-related laws. FFPE should be kept between 2~25°C during transportation.

10. Nucleic Acids Extraction Protocol

- Put FFPE tissue sections into a 1.5 mL tube.
- Add **300 µL Mineral oil** into a 1.5 mL tube and mix vigorously by vortexing.
- Incubate at **80°C** for **5 minutes**.
- Add **300 µL Incubation Buffer** and **20 µL Proteinase K** into 1.5 mL tube, then mix vigorously by vortexing.
- Centrifuge at **6000 RPM** for **1 minute**. If any pellet appears in the aqueous phase, pipette it carefully to resuspend it without disturbing the upper layer.
- Incubate at **56°C** for **1~2.5 hours** (or until the sample has been completely lysed).
- Incubate at **90°C** for **1 hour**.
- Centrifuge at **10000 RPM** for **15 seconds**.
- Collect **colorless lower aqueous phase** as a sample (approximately 200 µL).
- Mix the sample with **Isopropanol** as a **1:1 ratio (v / v)**.
- Carefully remove the aluminum foil on the Auto Plate.
- Divide the mixture equally into column **#1 / #7** and **#2 / #8**.
- Set up spin tips.
Maelstrom 8 series: Handle to mount tips and make sure that there is no gap between the necks of spin tips and the spin shaft.
Maelstrom 4800 series: Go to Tip page and press the mount tips region.
- Push Auto Plates completely to the bottom of the plate rack. Make sure that the chamfer of the plate is at the lower left.
- Select the program
Maelstrom 8 series: Press "**61P-1**" for input specimens at column **#1** or "**61P-7**" for input specimens at column **#7**.
Maelstrom 4800 series: Press "**61P**".
The parameters are given in following section.
- Carefully remove the Auto Plate when the program is finished.
- Use micropipette to transfer the purified nucleic acids from column **#6 / #12** to a clean tube.
- Discard used Auto Plates and spin tips into the waste recycling bin.

11. Program

■ Maelstrom 8 series

Program Name: 61P-1 / 7						
Well	1 / 7	2 / 8	3 / 9	4 / 10	5 / 11	6 / 12
Volume	800(μL)	800(μL)	800(μL)	800(μL)	800(μL)	100(μL)

Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temp.	Temp. Control
1	5 / 11	Mixing	3000	5	0	0	No
2	5 / 11	Collection	0	5	0	0	No
3	1 / 7	Mixing	3000	60	0	0	No
4	1 / 7	Collection	0	60	0	0	No
5	2 / 8	Mixing	3000	60	0	0	No
6	2 / 8	Collection	0	5	0	0	No
7	3 / 9	Mixing	3000	30	0	0	No
8	3 / 9	Collection	0	5	0	0	No
9	4 / 10	Mixing	3000	30	0	0	No
10	4 / 10	Collection	0	5	0	0	No
11	4 / 10	Vapor	0	300	0	0	No
12	6 / 12	Mixing	3000	30	0	0	No
13	6 / 12	Collection	0	10	0	0	No
14	5 / 12	Mixing	3000	5	0	0	No

■ Maelstrom 4800 series

Program Name: 61P				Model: Maelstrom 4800 series			
Temp 1	Temp 2						
Off	Off						
Well	Name	Volume (μL)	Action	Mixing	Collect		
1 / 7	LB	800	For.	Low	Low		
2 / 8	LB	800	For.	Low	Low		
3 / 9	WB1	800	For.	Low	Low		
4 / 10	WB2	800	For.	Low	Low		
5 / 11	MB	800	For.	Low	Low		
6 / 12	EB	100	For.	Low	Low		
Step	Well	Temp (°C)	Mixing (M)	Speed (RPM)	Collect (M)	Vapor (M)	Pause
1	5	-	0.1	3000	0.1	0	Off
2	1	Off	1	2500	0.1	0	Off
3	2	-	1	2500	0.1	0	Off
4	3	-	0.5	2500	0.1	0	Off
5	4	-	0.5	2500	0.1	5	Off
6	6	Off	1	2500	0.8	0	Off
7	3	-	0.1	2500	0	0	Off

12. Reagent performance

■ Repeatability

Under repeatability conditions where nucleic acids are extracted with the same reagent kit on the same source samples by the same operator. The coefficient of variation of nucleic acid extraction concentration is less than 5%.

■ Reproducibility















A five-day reproducibility test was carried out with the same source samples for 5 consecutive days with the same reagent kit by different operators. The coefficient of variation of nucleic acid extraction concentration is less than 5%.

■ Detection limit of FFPE DNA samples: ≥ 5 μm

■ The stability of extracted DNA

Storage Conditions	DNA stability
-80°C	Over 90 days
-20°C	28 days
4°C	14 days
25°C	2 days
Freeze-thaw	10 times

13. Explanation of Symbols

	Manufacturer		Consult instructions for use
	Temperature limit		Contains sufficient for test
	CE mark		In vitro diagnostic medical use
	Catalogue number		Caution
	Batch code		Non-sterile
	Do not re-use		Keep away from sunlight
	Date of manufacture		Use-by date

EC REP

mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany

14. Post-market surveillance conclusion

After a risk assessment and clinical evaluation assessment, when weighing the benefits of medical device, patients, and the risks associated with the use of the device, the risk is acceptable. The post-market surveillance report shows that no death or serious adverse events occurred.