TANBead® Nucleic Acid Extraction Kit

Tissue Total DNA Auto Plate

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

CE IVD

M6T2A46

(For Professional Use Only) V7

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 tissue. The purified DNA can be used with any downstream application which is qualitative or semi-quantitative assay. 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	50~100 mg tissue
Elution Volume	90~130 µL
Typical DNA yield	≥2 µg
Typical A260 / A280	≥1.7

4. Component Supplied with the Kit

Auto Plate	6	Auto Plate with reagent buffers
Proteinase K	1.0 mL x 1	Proteinase K
Incubation Buffer	25 mL x 1	Tris buffer, surfactants, pH 8.0
Elution Buffer	1.5 mL x 1	Nuclease-Free Water
Spin tips	96 tips	Spin tip assembled box
Protocol	1	Instruction guide for user

5. Auto Plate Content

Well	Buffer	Volume (µL)
1 / 7	Lysis Buffer	700
2 / 8	Washing Buffer 1	800
3 / 9	Magnetic Beads	800
4 / 10	Washing Buffer 2	800
5 / 11	Washing Buffer 2	800
6 / 12	Elution Buffer	130

6. Kit Storage and Shelf Life

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

7. Precautions

1) It can be used for *in vitro* diagnostic use.
2) Avoid using expired reagents.
3) When the temperature is below 20°C, place the Auto plates / Auto Tubes in an oven (preheated 42~60°C) 5 to 10 minutes.
4) Avoid vigorous shaking, in order to avoid excessive formation of foam.
5) Carefully remove aluminum foil to avoid splashing.
6) 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.
7) 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.
8) Please wear a mask and disposable gloves when handling.
9) Use sterile consumables to avoid nuclease contamination.
10) Reagent solution contains guanidine salt, avoid using bleach containing detergent.
11) Avoid eyes, skin, and clothing contact with reagents. In case of any contact, flush with flowing water.
12) 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

1) TANBead® Nucleic Acid Extraction System
   Model: Maelstrom 8 series, Maelstrom 4800 series (non-sterile)
2) Disposable gloves
3) Scissors, utility knives
4) Micropipette, disposable tips (10 µL / 200 µL / 1000 µL)
5) 1.5 mL microcentrifuge tube
6) 15 mL / 50 mL conical tube

9. Sample Pre-treatment, Storage and Transportation

■ **Sample pre-treatment**

1) Place 50~100 mg minced tissue into 1.5 mL tube then add **200 µL incubation buffer** and **10 µL Proteinase K** then mix well.
2) After incubated at **56°C for 1~2 hours** on heater, centrifuged with **10000 RPM for 5 minutes**.
   Note: Vortex the sample for 10 seconds every 15 minutes to improve extraction efficiency.

■ **Specimen storage**

1) Animal tissue can be stored at
   a. RT for 24 hours.
   b. 2~8°C up to 7 days
   c. -20°C for long-term preservation

■ **Specimen transportation**

Transportation of animal tissue specimen should follow specific infectious biological materials transportation related law.

10. Nucleic Acids Extraction Protocol

1) Carefully remove the aluminum foil on the Auto Plates.
2) Use micropipette to load **200 µL supernatant** into **well #1 / #7**.
3) 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.
4) Push Auto Plates completely to the bottom of the plate rack. Make sure that the chamfer of the plate is at the lower left.
5) Select the program.
   Maelstrom 8 series: Press **"6T2-1"** for input specimens at column #1 or **"6T2-7"** for input specimens at column #7.
   Maelstrom 4800 series: Press **"6T2"**.
   The parameters are given in following section.
6) Carefully remove the Auto Plates when the program is finished.
7) Use micropipette to transfer the purified nucleic acids from **well #6 / #12** to a clean tube.
8) Discard used Auto Plates and spin tips into the waste recycling bin.

11. Program

■ **Maelstrom 8 series**

Program Name: 6T2-1 / 7						
Well	1 / 7	2 / 8	3 / 9	4 / 10	5 / 11	6 / 12
Volume	900 (μL)	800 (μL)	800 (μL)	800 (μL)	800 (μL)	130 (μL)

Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temp.	Temp. Control
1	3 / 9	Mixing	3000	60	0	55	Yes
2	3 / 9	Collection	0	30	0	55	Yes
3	2 / 8	Mixing	3000	60	0	55	Yes
4	1 / 7	Mixing	3000	600	0	55	Yes
5	2 / 8	Collection	0	30	0	55	Yes
6	1 / 7	Mixing	3000	600	0	55	Yes
7	1 / 7	Collection	0	30	0	55	Yes
8	2 / 8	Mixing	3000	300	0	45	Yes
9	2 / 8	Collection	0	30	0	45	Yes
10	3 / 9	Mixing	3000	300	0	45	Yes
11	3 / 9	Collection	0	30	0	45	Yes
12	4 / 10	Mixing	3000	300	0	45	Yes
13	4 / 10	Collection	0	30	0	45	No
14	5 / 11	Mixing	3000	300	0	45	Yes
15	5 / 11	Collection	0	30	0	45	Yes
16	5 / 11	Vapor	0	300	0	45	Yes
17	6 / 12	Mixing	2700	600	0	45	Yes
18	6 / 12	Collection	0	60	0	45	Yes
19	5 / 11	Mixing	3000	30	0	0	No

■ **Maelstrom 4800 series**

Program Name: 6T2				Model: Maelstrom 4800 series			
Temp1	Temp2						
40	40						
Well	Name	Volume (μL)	Action	Mixing	Collect		
1 / 7	LB	900	For.	Low	Low		
2 / 8	WB1	800	For.	Low	Low		
3 / 9	MB	800	For.	Low	Low		
4 / 10	WB2	800	For.	Low	Low		
5 / 11	WB2	800	For.	Low	Low		
6 / 12	EB	130	For.	Low	Low		
Step	Well	Temp (°C)	Mixing (M)	Mixing Speed (RPM)	Collect (M)	Vapor (M)	Pause
1	3 / 9	-	0.5	2500	0.5	0	Off
2	2 / 8	-	0.5	2500	0	0	Off
3	1 / 7	55	10	2500	0	0	Off
4	2 / 8	-	0	0	0.5	0	Off
5	1 / 7	55	10	2500	1	0	Off
6	2 / 8	-	5	2500	1	0	Off
7	3 / 9	-	5	2500	1	0	Off
8	4 / 10	-	5	2500	1	0	Off
9	5 / 11	-	5	2500	1	5	Off
10	6 / 12	OFF	5	1500	1	0	Off
11	3 / 9	-	0.2	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 acids 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 acids extraction concentration is less than 5%.

■ **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	5 times

13. Explanation of Symbols

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

EC REP

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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.