TANBead® Nucleic Acid Extraction Kit

Tissue RNA Auto Plate

(For use with the Maelstrom 9600 series)

CE IVD

W6K2A46

(For Professional Use Only) V4

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 RNA from animal samples, tumors, cell lines, living specimens, etc. This kit, with manually pipette buffer into the corresponded column, can simplify nucleic acid extraction. With simple treatment of samples, it does not need repetitive centrifugations, reducing time for manual processing, and lowering the risk of cross-contamination. 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	2~5 x 10^5 cells and 30~50 mg tissues
Elution Volume	70~100 µL
Typical RNA yield	≥ 2 µg

4. Component Supplied with the Kit

∇_{96}

Auto Plate	6	Auto Plate with reagent buffers
Lysis buffer	90 mL	Guanidine salt, Tris buffer, surfactants
Elution Buffer	1.5 mL	Nuclease-Free Water
Spin tips	96 tips	Spin tip assembled box
Protocol	1	Instruction guide for user

5. Auto Plate Content and Plate Position

Plate Position	Buffer	Volume (µL)
1	-	-
2	Washing Buffer 1	800
3	Magnetic Beads	800
4	Washing Buffer 2	800
5	Washing Buffer 2	800
6	Elution Buffer	100
7	N / A	N / A
8	Spin tip	-

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.

7. Precautions

1) It can only be used for *in vitro* diagnostic.
2) Avoid using expired reagents.
3) When the temperature is below 20°C, place the reagent plate in an oven (preheated 42~60°C) for 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 to air. The evaporation would lead to pH change, or affect the extraction effectiveness.
7) Please check the integrity of the Auto Plate, 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 9600 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
7) Isopropanol Alcohol (Molecular biology grade)

9. Sample Collection and Pretreatment

1) For cell (2~5 x 10^5 cells)
   a. Cultured cells are centrifuged at **3000 RPM, 4°C for 10 minutes,** and then remove supernatant thoroughly.
   b. Resuspend the pellet with **500 µL Lysis Buffer** and incubation on ice **for 10 minutes.**
2) For tissue (30~50 mg tissues)
   a. Use **800 µL Lysis Buffer** to homogenize tissue sample.
   b. Mix well and stand for **10 minutes** on ice.
   c. Centrifuged at **6000 RPM for 5 minutes**.

10. Nucleic Acids Extraction Protocol

1) Carefully remove the aluminum foil on the Auto Plates.
2) Gently transfer **500 µL Lysate** into wells of **Plate 1** and place **500 µL of IPA** into **Plate 1** as well.
3) Select the program **"6K2"**. The parameters are given in the following section.
4) Follow the guide shown on the screen and place plates carefully. Make sure that the chamfer of the plate faces toward the same direction.
5) Carefully remove the Auto Plates when the program is finished.
6) Use a micropipette to transfer the purified nucleic acids from **plate 6** to a clean tube.
7) Discard used Auto Plates and spin tips into the waste recycling bin.

11. Program

■ **Maelstrom 9600**

Program Name: 6K2								
Plate	1	2	3	4	5	6	7	8
Volume(μL)	800	800	800	800	800	100	-	-
Keep Temp.	40	40	40	-	-	30	-	-
Action	For.	For.	For.	For.	For.	For.	-	-
Name	LB	WB1	MB	WB2	WB2	EB	-	TIP

Step	Plate	Temp. (°C)	Mixing (min)	Mixing (rpm)	Collect (sec)	Vapor (min)	Pause
1	3	45	0.5	3000	30	0	Off
2	2	45	0.5	3000	30	0	Off
3	1	45	10	3000	30	0	Off
4	2	45	2	3000	30	0	Off
5	3	45	2	3000	30	0	Off
6	4	-	2	3000	30	0	Off
7	5	-	2	3000	30	10	Off
8	6	40	10	3000	30	0	Off
9	6	40	0	3000	30	0	Off
10	5	-	0.2	3000	0	0	Off

⚠ **Temperature set as "0" represents room temperature!**

■ **Maelstrom 9610**

Program Name: 6K2								
Plate	1	2	3	4	5	6	7	8
Volume(μL)	800	800	800	800	800	100	-	-
Keep Temp.	40	40	40	-	-	30	-	-
Action	For.	For.	For.	For.	For.	For.	-	-
Name	LB	WB1	MB	WB2	WB2	EB	-	TIP

Step	Plate	Temp. (°C)	Mixing (min)	Mixing (rpm)	Collect (sec)	Vapor (min)	Pause
1	3	45	0.5	3000	30	0	Off
2	2	45	0.5	3000	30	0	Off
3	1	45	10	3000	30	0	Off
4	2	45	2	3000	30	0	Off
5	3	45	2	3000	30	0	Off
6	4	-	2	3000	30	0	Off
7	5	-	2	3000	30	10	Off
8	6	40	10	3000	30	0	Off
9	6	40	0	0	30	0	Off
10	5	-	0.2	3000	0	0	Off

⚠ **Temperature set as "25" represents room temperature!**

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 RNA**

Storage Conditions	RNA 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	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.