TANBead® Nucleic Acid Extraction Kit

Tissue RNA Auto Plate

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

CE IVD

M6K2A46

(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

Well	Buffer	Volume (µL)
1 / 7	-	-
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	100

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 Auto Plates 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 Plates 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
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 Column**#1 / #7** and place **500 µL of IPA** into Column**#1 / #7** as well.
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: "**6K2-1**" or "**6K2-7**" for input specimen at column **#1** or column **#7**, respectively.
   Maelstrom 4800 series:"**6K2**"
6) The parameters are given in the following section.
7) Carefully remove the Auto Plates when the program is finished.
8) Use a micropipette to transfer the purified nucleic acids from well **#6 / #12** to a clean tube.
9) Discard used Auto Plates and spin tips into the waste recycling bin.

11. Program

■ **Maelstrom 8 series**

Program Name: 6K2-1 / 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)	150 (μL)

Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temp.	Temp. Control
1	3 / 9	Mixing	3000	10	0	55	Yes
2	3 / 9	Collection	0	30	0	55	Yes
3	2 / 8	Mixing	3000	30	0	55	Yes
4	2 / 8	Collection	0	30	0	55	Yes
5	1 / 7	Mixing	3000	600	0	55	Yes
6	1 / 7	Collection	0	30	0	55	Yes
7	2 / 8	Mixing	3000	120	0	45	Yes
8	2 / 8	Collection	0	30	0	45	Yes
9	3 / 9	Mixing	3000	120	0	45	Yes
10	3 / 9	Collection	0	30	0	45	Yes
11	4 / 10	Mixing	3000	120	0	45	Yes
12	4 / 10	Collection	0	30	0	45	Yes
13	5 / 11	Mixing	3000	120	0	45	No
14	5 / 11	Collection	0	30	0	45	Yes
15	5 / 11	Vapor	0	600	0	45	Yes
16	6 / 12	Mixing	3000	600	0	45	Yes
17	6 / 12	Collection	0	60	0	45	Yes
18	5 / 11	Mixing	3000	30	0	0	No

■ **Maelstrom 4800 series**

Program Name: 6K2				Model: Maelstrom 4800 series			
Temp 1	**Temp 2**						
45	40						
Well	**Name**	**Volume**	**Action**	**Mixing**	**Collect**		
1 / 7	LB	1200	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	-	0.2	3000	0.5	0	Off
2	2	-	0.5	2500	0.5	0	Off
3	1	55	10	2500	0.5	0	Off
4	2	-	2	2500	0.5	0	Off
5	3	-	1	1500	0.5	0	Off
6	4	-	1	1500	0.5	0	Off
7	5	-	1	1500	0.5	10	Off
8	6	45	5	2500	0.5	0	Off
9	3	-	0.2	3000	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 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**
	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.