



TANBead® Nucleic Acid Extraction Kit

Tissue RNA Auto Plate

(For use with the SLA-16 / 32 / E13200 series)

CE IVD
6K2A46

(For Professional Use Only) V3

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

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
Strip	12	8-channel strip
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

- Components under room temperature (15~35°C) can be stored until the expiration date labeled on the box.

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 in an oven (preheated 42~60°C) for 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 to air. The evaporation would lead to pH change, or affect the extraction effectiveness.
- Please check the integrity of the Auto Plates and remember to insert the strips 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: SLA-16 / 32 / E13200 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
- Isopropanol Alcohol (Molecular biology grade)

9. Sample Collection and Pretreatment

- For cell (2~5 x 10⁵ cells)
 - Cultured cells are centrifuged at **3000 RPM, 4°C for 10 minutes**, and then remove supernatant thoroughly.
 - Resuspend the pellet with **500 µL Lysis Buffer** and incubation on ice **for 10 minutes**.
- For tissue (30~50 mg tissues)
 - Use **800 µL Lysis Buffer** to homogenize tissue sample.
 - Mix well and stand for **10 minutes** on ice.
 - Centrifuged at **6000 RPM for 5 minutes**.

10. Nucleic Acids Extraction Protocol

Before operating, turn on the warm-up system of TANBead® Nucleic Acid Extractor, if it is equipped with a temperature controller, please setting at **45°C**.

- Carefully remove the aluminum foil on the Auto Plates.
- Gently transfer **450 µL Lysate** into wells of Column#1 / #7 and place **450 µL of IPA** into Column#1 / #7 as well.
- Push Auto Plates completely to the bottom of plate rack. Make sure that the chamfer of the plate is at the lower left.
- Push strips completely to the bottom of strip rack frame.
- Close the door panel.
- Select the program "**B10-W4-AUTO**". The parameters are given in the following section.
- Carefully remove the Auto Plates when the program is finished.
- Use a micropipette to transfer the purified nucleic acids from Column#6 / #12 to a clean tube.
- Discard used Auto Plates and strips into the waste recycling bin.

11. Program

■ SLA-16 / 32 series

Program Name: B10-W4-AUTO					Model: SLA-16 / 32 series			
Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	3	1	60	On	Medium	800	Off	0
2	2	1	60	On	Medium	800	Off	0
3	1	10	60	On	Medium	800	Off	0
4	2	2	60	On	Medium	800	Off	0
5	3	2	60	On	Medium	800	Off	0
6	4	2	60	On	Medium	800	Off	0
7	5	2	60	On	Medium	800	Off	10
8	6	10	120	On	Medium	150	Off	0
9	5	1	0	Off	Medium	800	Off	0
10	0	0	0	Off	Medium	0	Off	0

■ SLA-E13200 series

Program Name: B10-W4-AUTO					Model: SLA-E13200 series				
Step	Well	Temp (°C)	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	3	45	1	60	On	Medium	800	Off	0
2	2	45	1	60	On	Medium	800	Off	0
3	1	45	10	60	On	Medium	800	Off	0
4	2	45	2	60	On	Medium	800	Off	0
5	3	45	2	60	On	Medium	800	Off	0
6	4	45	2	60	On	Medium	800	Off	0
7	5	45	2	60	On	Medium	800	Off	10
8	6	45	10	120	On	Medium	150	Off	0
9	5	N / A	1	0	Off	Medium	800	Off	0
10	0	N / A	0	0	Off	Medium	0	Off	0

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 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

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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.