



TANBead® Nucleic Acid Extraction Kit

Blood RNA Auto Plate

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



M621A46

(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 human RNA from 50 up to 200 µL fresh whole blood, which 100 µL blood yields 50~300 ng RNA in average. Compared with other commercial kits, samples used in TANBead® Blood RNA extraction kit are less, while the yield of high quantity and quality RNA will be suitable for downstream applications like qPCR, PCR, next generation sequencing (NGS). 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	50~200 µL fresh whole blood
Elution Volume	50~80 µL
Typical RNA yield	50~300 ng per 100 µL Blood

4. Component Supplied with the Kit

Auto Plate	6	Auto Plate with reagent buffers
Lysis Buffer	100 mL x 1	Guanidine salt, surfactants
DNase I	1	Add 300 µL Elution Buffer before use.
Proteinase K	1.0 mL x 3	Proteinase K
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	-	-
2 / 8	Washing Buffer 1	1000
3 / 9	Washing Buffer 2	1200
4 / 10	Magnetic Beads	800
5 / 11	Washing Buffer 2	1200
6 / 12	Elution Buffer	80

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 received, please store proteinase K at 2~8°C.
- The DNase I is transported at room temperature. When received, please store DNase I at -20°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
- Isopropanol for molecular biology
- β-mercaptoethanol for molecular biology

9. Sample Collection, Transportation, and Storage

■ Sample collection and storage

- Whole blood
 - Whole blood specimens must be obtained from sodium citrate or EDTA collection tubes.
- Specimen storage
 - Fresh whole blood specimens can be stored at room temperature for 6 hours.

■ Specimen transportation

Transportation of whole blood specimens should be followed by specific pathogen transportation-related laws. The whole blood sample should be kept between 2~25°C during transportation.

10. Nucleic Acids Extraction Protocol

■ Preparing Samples

- Add **50~200 µL Blood with lysis buffer in ratio of 1:1** into 1.5mL microcentrifuge tube.
- Add **30 µL Proteinase K** and mix by vortexing briefly.
- Incubate at **60°C for 10 minutes**.
- Add **10 µL β-ME** and mix by vortexing briefly.

■ Preparing Auto Plate

- Carefully remove the aluminum foil on the Auto Plate.
- Transfer **total lysate** into column **#1 / #7**.
- Add **Isopropanol (Isopropanol: blood = 4:1)** into column **#1 / #7**.

- Set up spin tips:

Maelstrom 8 series: Handle to mount tips and make sure that there is no gap between the neck of the 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 "621-1" for input specimens at column **#1** or "621-7" for input specimens at column **#7**.

Maelstrom 4800 series: "621".

The parameters are given in following section.

- Carefully remove the Auto Plate when the program is finished.
- Use micropipette to transfer the purified nucleic acid from column **#6 / #12** to a clean tube.
- Discard used Auto Plates and spin tips into the waste recycling bin.

■ DNA Removal in Solution

- 1) Add 2.5 μL of DNase I to RNA solution (RNA solution transferred from column #6 / #12).
- 2) Incubate at room temperature (20~25°C) for 10 minutes.
- 3) After DNase I treatment inactivate the enzyme by incubating at 75°C for 10 minutes.
- 4) Spin at 10,000 x g for an additional minute.

11. Program

■ Maelstrom 8 series

Program Name: 621-1 / 7						
Well	1 / 7	2 / 8	3 / 9	4 / 10	5 / 11	6 / 12
Volume	1200 (μL)	1000 (μL)	1200 (μL)	800 (μL)	1200 (μL)	80 (μL)

Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temp.	Temp. Control
1	4 / 10	Mixing	2500	30	0	0	No
2	4 / 10	Collection	0	30	0	0	No
3	2 / 8	Mixing	2500	30	0	0	No
4	2 / 8	Collection	0	30	0	0	No
5	1 / 7	Mixing	2500	600	0	0	No
6	1 / 7	Collection	0	60	0	0	No
7	2 / 8	Mixing	2500	120	0	0	No
8	2 / 8	Collection	0	60	0	0	No
9	3 / 9	Mixing	2500	60	0	0	No
10	3 / 9	Collection	0	30	0	0	No
11	4 / 10	Mixing	2500	60	0	0	No
12	4 / 10	Collection	0	30	0	0	No
13	5 / 11	Mixing	2500	60	0	0	No
14	5 / 11	Collection	0	30	0	0	No
15	5 / 11	Vapor	0	600	0	0	No
16	6 / 12	Mixing	2500	180	0	0	No
17	6 / 12	Collection	0	60	0	0	No
18	4 / 10	Mixing	2500	30	0	0	No

■ Maelstrom 4800 series

Program Name: 621				Model: Maelstrom 4800 series			
Temp1	Temp2						
Off	Off						
Well	Name	Volume (μL)	Action	Mixing	Collect		
1 / 7	LB	1200	For.	Low	Low		
2 / 8	WB1	1000	For.	Low	Low		
3 / 9	WB2	1200	For.	Low	Low		
4 / 10	MB	800	For.	Low	Low		
5 / 11	WB2	1200	For.	Low	Low		
6 / 12	EB	80	For.	Low	Low		
Step	Well	Temp (°C)	Mixing (M)	Mixing Speed (RPM)	Collect (M)	Vapor (M)	Pause
1	4	-	0.5	2500	0.5	0	Off
2	2	-	0.5	2500	0.5	0	Off
3	1	Off	10	2500	1	0	Off
4	2	-	2	2500	1	0	Off
5	3	-	1	2500	0.5	0	Off
6	4	-	1	2500	0.5	0	Off
7	5	-	1	2500	0.5	10	Off
8	6	Off	3	2500	1	0	Off

9	4	-	0.5	2500	0	0	Off
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12. Result

Total RNA yield was detected using Qubit RNA HS assay kit: 50~300 ng RNA per 100 mL blood. Nucleic acid product purified by TANBead® nucleic acid extraction kit can perform qualitative / quantitative analysis of specific genes by PCR, RT-PCR, Q-PCR or qRT-PCR. Please refer to the molecular diagnostic kit manual.

13. Reagent performance

■ 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	10 times

14. 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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15. 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.