TANBead® Nucleic Acid Extraction Kit

Stool Cell DNA Auto Plate

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

CE IVD

M6SCA46

(For Professional Use Only) V5

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 high-quality microbial and host DNA from stool of human and other species. Moreover, additional step in pretreatment can be performed to enrich the desired extraction products of microbiome. The isolated DNA is ready for downstream applications such as PCR, Real-time PCR and microbiome profiling. 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 mg stool
Elution Volume	50~80 µL
Typical DNA yield	≥2 µg

4. Component Supplied with the Kit

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Auto Plate	6	Auto Plate with reagent buffers
Proteinase K	1.0 mL x 2	Proteinase K
Elution Buffer	1.5 mL	Nuclease-Free Water
Incubation Buffer -B845	120 mL	Phosphate buffer for omnivore use
Incubation Buffer -B871	120 mL	Phosphate buffer for herbivore use
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	600
2 / 8	Washing Buffer 1	800
3 / 9	Washing Buffer 2	800
4 / 10	Washing Buffer 2	800
5 / 11	Magnetic Beads	800
6 / 12	Elution Buffer	80

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 receipt, please store proteinase K at 2~8°C.

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 / 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 Collection, Transportation, and Storage

■ **Sample collection and storage**

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

■ **Specimen transportation**

Transportation of stool specimen should be followed by specific infectious biological materials transportation-related law.

10. Nucleic Acids Extraction Protocol

1) Carefully remove the aluminum foil on the Auto Plates.
2) Add **500 µL incubation buffer-B845 / B871** and **20 µL Proteinase K** into 1.5 mL tube.
   Note: Incubation buffer-B845: For Omnivore Use; Incubation buffer-B871: For Herbivore Use.
3) Add about 50 mg stool into 1.5 mL tube and mix well.
4) Incubate at **60°C for 10 minutes** on heater.
5) **For Bacterial gDNA:** Centrifuged at **10,000 x *g* for 1 minute**.
   For Human gDNA: Skip this step and continue to the next step.
6) 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.
7) Transfer the supernatant into column **#1 / #7** of Auto Plate.
   Note: If samples are difficult to transferred, please use a cut off pipette tip and pipette gently.
8) Push Auto Plates completely to the bottom of the plate rack. Make sure that the chamfer of the plate is at the lower left.
9) Select the program:
   Maelstrom 8 series: **"6SC-1"** or **"6SC-7"** for input specimen at column **#1** or column **#7**, respectively.
   Maelstrom 4800 series: **"6SC"**
   The parameters are given in following section.
10) When the program ends, take out the assembled auto plate carefully.
11) Use micropipette to transfer the purified nucleic acids from column **#6 / #12** to a clean tube.
12) Discard the used Auto Plates and spin tips into the waste recycling bin.

11. Program

■ **Maelstrom 8 series**

Program Name: 6SC-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)	100 (μL)

Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temp.	Temp. Control
1	5 / 11	Collection	0	30	0	60	Yes
2	1 / 7	Mixing	3000	600	0	60	Yes
3	1 / 7	Collection	0	30	0	60	Yes
4	2 / 8	Mixing	3000	60	0	45	Yes
5	2 / 8	Collection	0	30	0	45	Yes
6	3 / 9	Mixing	3000	60	0	45	Yes
7	3 / 9	Collection	0	30	0	45	Yes
8	4 / 10	Mixing	3000	60	0	45	Yes
9	4 / 10	Collection	0	30	0	45	Yes
10	4 / 10	Vapor	0	600	0	45	Yes
11	6 / 12	Mixing	3000	300	0	45	Yes
12	6 / 12	Collection	0	30	0	45	Yes
13	5 / 11	Mixing	3000	60	0	0	Yes

■ **Maelstrom 4800 series**

Program Name: 6SC				Model: Maelstrom 4800 series			
Temp 1	**Temp 2**						
40	40						
Well	**Name**	**Volume**	**Action**	**Mixing**	**Collect**		
1 / 7	LB	900	Rev. U / D	Low	Low		
2 / 8	WB1	800	For.	Low	Low		
3 / 9	WB2	800	For.	Low	Low		
4 / 10	WB2	800	For.	Low	Low		
5 / 11	MB	800	For.	Low	Low		
6 / 12	EB	150	For.	Low	Low		
Step	**Well**	**Temp (°C)**	**Mixing (M)**	**Mixing Speed (RPM)**	**Collect (M)**	**Vapor (M)**	**Pause**
1	5	-	0.5	2500	0.5	0	Off
2	1	55	12	2500	0.5	0	Off
3	2	-	2	2500	0.5	0	Off
4	3	-	1	1500	0.5	0	Off
5	4	-	1	1500	0.5	10	Off
6	6	Off	5	2500	1.5	0	Off
7	3	-	0.5	2500	0	0	Off

12. Result

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

■ **Qualitative Analysis**

A specific gene fragments can be amplified from nucleic acids products isolated from TANBead® nucleic acid extraction kit by PCR (Polymerase Chain Reaction) or RT-PCR (Reverse Transcription-PCR). This kit can work with different molecular biology reagents and apply for verity of molecular diagnosis.

■ **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	10 times

14. 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

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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.