TANBead® Nucleic Acid Extraction Kit

Forensic DNA Auto Tube

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

CE IVD

M6TFS46

(For Professional Use Only) V2

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 DNA from a broad range of forensic samples, including human blood stain, dried blood spot, hair follicle, semen, cigarette, chewing gum, and nail. The purified DNA can be used with any downstream application employing PCR-based qualitative, semi-quantitative and quantitative assays. 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	Forensic samples (blood stain, dried blood spot, hair follicle, semen, cigarette, chewing gum, nail)
Elution Volume	90~130 µL

4. Component Supplied with the Kit

96

Auto Tube	8 trays	Auto Tube with reagent buffers
Proteinase K	1.0 mL x 2	Proteinase K
Incubation Buffer	65 mL x 1	Tris buffer, surfactants, pH 8.0
Elution Buffer	1.5 mL x 1	Nuclease-Free Water
Base	2	A rack for 8 Auto Tubes
Spin tips	48 tips x 2 boxes	Spin tip assembled box
Protocol	1	Instruction guide for user

5. Auto Tube Content

Well	Buffer	Volume (µL)
1 / 7	Lysis Buffer	500
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	130

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

7. Precautions

1) It can be used for *in vitro* diagnostic use.
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) Before using, if the incubation buffer precipitates, please preheated over 40°C at least 5 minutes until the precipitates dissolve.
9) Please wear a mask and disposable gloves when handling.
10) Use sterile consumables to avoid nuclease contamination.
11) Reagent solution contains guanidine salt, avoid using bleach containing detergent.
12) Avoid eyes, skin, and clothing contact with reagents. In case of any contact, flush with flowing water.
13) 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) 1M Dithiothreitol (DTT)

9. Sample Collection, Storage and Transportation

■ **Sample collection**

Sample	Collection
Cigarette	Cut out 1/2 of the front filter and divide it into two pieces. Put both pieces (contain filter and outer paper) into a 1.5 mL tube.
Hair	Collect at least five hairs (0.5 - 1 cm with follicle) into 1.5 mL tube.
Blood stain	Collect stains with cotton swab and put the cotton part of swab into a 1.5 mL tube.
Dried blood spot	Collect 1 piece of dried blood spot (Φ = 6mm) into a 1.5 mL tube.
Semen stains	Collect stains with cotton swab and put the cotton part of swab into a 1.5 mL tube.
Chewing gum	Cut chewing gum into at least 10 mg and transfer them to a 1.5 mL tube.
Nail	Collect one nail and put it into a 1.5 mL tube.

■ **Specimen storage**

1) Forensic specimen should be analyzed as fresh as possible, if you need to storage specimen, follow the instruction:
   a. RT for 24 hours.
   b. 2~8°C up to 7 days.
   c. -20°C for long-term preservation.

■ **Specimen transportation**

Transportation of forensic specimen should follow specific forensic sample related regulation and keep specimen at RT during transportation.

10. Nucleic Acids Extraction Protocol

1) Sample pre-treatment

Sample	Treatment
Cigarette	Add **600 µL Incubation Buffer**, **20 µL Proteinase K** into 1.5 mL tube, then mix well.
Hair	Add **300 µL Incubation Buffer**, **20 µL Proteinase K** and **20 µL 1M DTT** into 1.5 mL tube, then mix well.
Blood stain	Add **600 µL Incubation Buffer**, **20 µL Proteinase K** into 1.5 mL tube, then mix well.
Dried blood spot	Add **600 µL Incubation Buffer**, **20 µL Proteinase K** into 1.5 mL tube, then mix well.
Semen stains	Add **600 µL Incubation Buffer**, **20 µL Proteinase K** and **20 µL 1M DTT** into 1.5 mL tube, then mix well.
Chewing gum	Add **300 µL Incubation Buffer**, **20 µL Proteinase K** into 1.5 mL tube, then mix well.
Nail	Add **300 µL Incubation Buffer**, **20 µL Proteinase K** and **20 µL 1M DTT** into 1.5 mL tube, then mix well.

2) Incubate at **56°C**, **900 rpm** for **at least 1 hour**.
3) Preparing the Assembled Auto Tubes by inserting Auto Tubes into the Base completely.
4) Carefully remove the aluminum foil on the Auto Tubes.
5) Use micropipette to load **all lysate** into **well #1 / #7**.
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) Push Assembled Auto Tubes completely to the bottom of the plate rack. Make sure that the chamfer of the plate is at the lower left.
8) Select the program.
   Maelstrom 8 series: Press **"6TF-1"** for input specimens at

column #1 or "**6TF-7**" for input specimens at column #7.
Maelstrom 4800 series: Press "**6TF**".
The parameters are given in following section.

9) Carefully remove the Auto Tubes when the program is finished.
10) Use micropipette to transfer the purified nucleic acids from **well #6 / #12** to a clean tube.
11) Discard used Auto Tubes and spin tips into the waste recycling bin.

11. Program

■ **Maelstrom 8 series**

Program Name: 6TF-1 / 7						
Well	1 / 7	2 / 8	3 / 9	4 / 10	5 / 11	6 / 12
Volume	1100 (μL)	800 (μL)	800 (μL)	800 (μL)	800 (μL)	130 (μL)

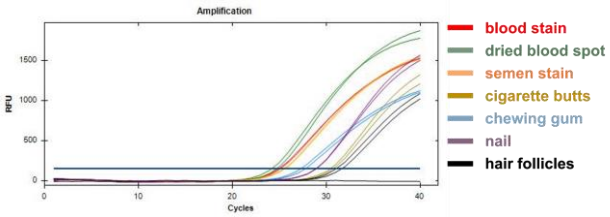
Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temp.	Temp. Control
1	3 / 9	Mixing	3000	30	0	0	NO
2	3 / 9	Collection	0	30	0	0	NO
3	2 / 8	Mixing	3000	30	0	0	NO
4	1 / 7	Mixing	3000	420	0	70	YES
5	2 / 8	Collection	0	30	0	0	NO
6	1 / 7	Mixing	3000	480	0	0	NO
7	1 / 7	Collection	0	180	0	0	NO
8	2 / 8	Mixing	3000	120	0	0	NO
9	2 / 8	Collection	0	60	0	0	NO
10	3 / 9	Mixing	3000	60	0	0	NO
11	3 / 9	Collection	0	30	0	0	NO
12	4 / 10	Mixing	3000	60	0	0	NO
13	4 / 10	Collection	0	180	0	0	NO
14	5 / 11	Mixing	3000	60	0	0	NO
15	5 / 11	Collection	0	180	0	0	NO
16	5 / 11	Vapor	0	480	0	0	NO
17	6 / 12	Mixing	3000	300	0	0	NO
18	6 / 12	Collection	0	480	0	0	NO
19	3 / 9	Mixing	3000	10	0	0	NO

■ **Maelstrom 4800 series**

Program Name: 6TF				Model: Maelstrom 4800 series			
Temp1	Temp2						
40	40						
Well	Name	Volume (μL)	Action	Mixing	Collect		
1 / 7	LB	1100	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 / 9	-	0.5	3000	0.5	0	Off
2	2 / 8	-	0.5	3000	0	0	Off
3	1 / 7	70	7	3000	0	0	Off
4	2 / 8	-	0	500	0.5	0	Off
5	1 / 7	OFF	8	3000	3	0	Off
6	2 / 8	-	2	3000	1	0	Off
7	3 / 9	-	1	3000	0.5	0	Off
8	4 / 10	-	1	3000	3	0	Off
9	5 / 11	-	1	3000	3	8	Off
10	6 / 12	OFF	5	3000	8	0	Off
11	3 / 9	-	0.2	3000	0	0	Off

12. Result

7 different samples (blood stain, dried blood spot, semen stain, chewing gum, nail, hair and cigarette butts) were purified by TANBead® nucleic acid extraction kit. Human *GAPDH* expression were detected by qPCR.



13. 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 DNA**

Storage Conditions	DNA stability
-80°C	Over 90 days
-20°C	28 days
4°C	14 days
25°C	2 days
Freeze-thaw	5 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

mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany

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.