TANBead® Nucleic Acid Extraction Kit

STIs DNA Auto Plate

(For use with the Maelstrom 9600 series)

CE IVD

W6STA46

(For Professional Use Only) V1

1. Intended Use

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 is suitable for extracting pathogens DNA especially for Sexually Transmitted infectious, such as *Chlamydia trachomatis* in human urine. 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	300 µL of liquid specimens
Elution Volume	50-80 µL

4. Component Supplied with the Kit

Σ96

Auto Plate	6	96 well plate with reagent buffer
Elution Buffer	1.5 mL	Nuclease-Free Water
Proteinase K	1 mL	Proteinase K
Spin tips	96 tips	Spin Tips Assembled Box
Protocol	1	Instruction guide for user

5. Auto Plate Content and Plate Position

Plate Position	Buffer	Volume (µL)
1	Lysis Buffer	600
2	Magnetic Beads	800
3	Washing Buffer 1	800
4	Washing Buffer 2	800
5	Washing Buffer 2	800
6	Elution Buffer	80
7	N/A	N/A
8	Spin Tip	-

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 only be used for *in vitro* diagnostic.
2) Avoid using expired reagents.
3) When the temperature is below 20°C, place the reagent plate 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/ 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 Plate/ Auto Tube, 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 9600 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) Urine sample
   a. Urine sample should be obtained from specific collection tube for preservation.
   b. Follow the collection guidance of specimens for routinely pre-treatment or storage.
2) Genital Tract sample
   a. Genital samples should be collected and obtained in specific collection tubes for preservation.
   b. Follow the collection guidance of specimens you collected for routinely storage

■ **Specimen transportation**

Transportation of whole blood, serum specimens should be followed by specific pathogen transportation-related laws. The whole blood sample should be kept between 2-25°C during transportation and within 6 hours for separated serum. Serum samples can be transported between 2-8°C or by freezing.

10. Nucleic Acids Extraction Protocol

1) Carefully remove the aluminum foil from Auto Plate.
2) Add 300 µL liquid suspension and 10 µL Proteinase K into wells of plate 1.
   Note: The volume ratio of sample and lysis buffer is about 300 µL: 600 µL. Changing this ratio might affect the performance of this kit.
3) Select the program “6ST” The steps and parameters are given in the following section.
4) Follow the guide shown on the screen and place plates carefully. Make sure that the chamfer of the reagent plate faces toward the same direction.
5) Carefully remove Auto Plate when the program finished.
6) Use micropipette to transfer the purified nucleic acid from wells of plate 6 to a clean tube.
7) Discard the used Auto Plates and spin tips into the waste recycling bin.

11. Program

■ **Maelstrom 9600**

Program Name: 6ST								
Plate	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Volume(µL)	900	800	800	800	800	100	-	-
Keep Temp.	45	0	40	-	-	50	-	-
Action	For.	For.	For.	For.	For.	For.	-	-
Name	LB	MB	WB1	WB2	WB2	EB	-	TIP

Step	Plate	Temp. (°C)	Mixing (min)	Mixing (rpm)	Collect (sec)	Vapor (min)	Pause
1	2	0	0	3000	30	0	OFF
2	1	60	10	3000	30	0	OFF
3	3	50	1	3000	30	0	OFF
4	4	-	1	3000	30	0	OFF

5	5	-	1	3000	30	10	OFF
6	6	65	5	3000	60	0	OFF
7	3	0	0.1	3000	0	0	OFF

⚠ **Temperature set as "0" represents room temperature!**

■ **Maelstrom 9610**

Program Name: 6ST								
Plate	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Volume(μL)	900	800	800	800	800	100	-	-
Keep Temp.	45	25	40	-	-	50	-	-
Action	For.	For.	For.	For.	For.	For.	-	-
Name	LB	MB	WB1	WB2	WB2	EB	-	TIP

Step	**Plate**	**Temp. (°C)**	**Mixing (min)**	**Mixing (rpm)**	**Collect (sec)**	**Vapor (min)**	**Pause**
1	2	25	0	0	30	0	OFF
2	1	60	10	3000	30	0	OFF
3	3	50	1	3000	30	0	OFF
4	4	-	1	3000	30	0	OFF
5	5	-	1	3000	30	10	OFF
6	6	65	5	3000	60	0	OFF
7	3	25	0.1	3000	0	0	OFF

⚠ **Temperature set as "25" represents room temperature!**

12. Result

Nucleic acid product purified by TANBead® nucleic acid extraction kit can perform qualitative/ quantitative analysis of specific genes by PCR, Q-PCR. Please refer to the molecular diagnostic kit manual.

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	10 times

14. Explanation of Symbols

	Manufacturer		**Consult instructions for use**
	Temperature limitation		**Contains sufficient for <N> test**
	Use by date	IVD	**For in vitro diagnostic use**
REF	**Catalog number**		**Caution**
LOT	**Batch code**		**Non-sterile**
	Do not use if package is damaged		**Keep away from sunlight**
	Keep dry		**Do not re-use**

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.