TANBead® Nucleic Acid Extraction Kit

STIs DNA Auto Tube

(for use with the Maelstrom 4800 series)

RUO

M6STS46

(For Research Use Only) V2

1. Intended Use

TANBead® Nucleic Acid Extraction Kit (M6STS46) is suitable for isolating pathogens' DNA from genital tract or urine samples. Automated nucleic acids extraction can be performed by using a magnetic bead-based technology of TANBead® Nucleic Acid Extractor. The purified nucleic acids demonstrate improved downstream performance in clinical applications such as pathogen identification, antibiotic selection, precise medicine, etc.

2. Purpose

TANBead® Nucleic Acid Extraction Kit (M6STS46) is suitable for extracting pathogens DNA especially for Sexually Transmitted infectious from various types of human genital tract samples, including endocervical swab, vaginal swab, urine, etc. Sample needs to be pre-treated with proteinase K before automated nucleic acids extraction process by Maelstrom 4800 series. The isolated DNA can be directly used for real-time PCR. With highly quantity and purity, this reagent kit can be applied for clinical diagnostics and research.

3. Principle

The silicon dioxide layer coated on the magnetic beads can adsorb the negatively charged molecules to purify nucleic acids from samples.

Sample Types: 300 µL of liquid specimens

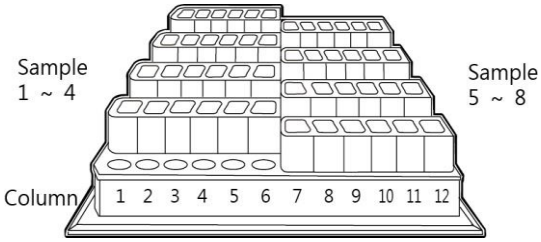
Suitable Instrument: Maelstrom 4800 series

4. Kit Components

M6STS46		**96 Assays**
Auto Tubes	96	Auto tubes with reagent buffers
Proteinase K	1 mL	Proteinase K, Store at 4°C
Elution Buffer	1.5 mL	Nuclease-Free Water
Spin tips	96 tips	Spin Tips Assembled Box
Base	2	A rack for 8 Auto Tubes
Protocol	1	Instruction guide for user

Auto Tube Content

Column	Buffer Solution	Volume
1/ 7	Lysis Buffer	600 µL
2/ 8	Magnetic Beads	800 µL
3/ 9	Washing Buffer 1	800 µL
4/ 10	Washing Buffer 2	800 µL
5/ 11	Washing Buffer 2	800 µL
6/ 12	Elution Buffer	80 µL



5. 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. When this kit is received, please store proteinase K at 4°C.

6. Precautions

1) It can only be used for research.
2) Avoid using expired reagents.
3) When the temperature is below 20°C, place the reagent tubes in an oven (preheated 42 - 60°C) 5 to 10 minutes.
4) Avoid vigorous shaking, to prevent excessive formation of foam.
5) Do not expose the opened reagents or tubes to air. The evaporation would lead to pH change or effect on the extraction effectiveness.
6) The reagents are all colorless and transparent. Colored reagents indicate contamination, please replace it with a fresh plate before proceeding.
7) Please check the integrity of the reagent 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) Carefully remove aluminum foil to avoid splashing.
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.
14) The procedures should not be changed.

7. Materials and devices required but not provided

1) TANBead® Nucleic Acid Extraction System
   Model: 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

8. Sample collection, transportation, storage, and pretreatment

■ 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 urine, genital tract specimens should follow by specific pathogen transportation-related laws. The urine sample should be kept between 2 - 25°C during transportation and within 6 hours for further experiments. Genital tract samples can be transported between 2 - 8°C.

9. Nucleic acids extraction protocol

1) Prepare the Assembled Auto Tubes by inserting Auto Tubes into the Base completely
2) Set up spin tips.
   Maelstrom 4800 series: Go to Tip page and press the mount tipsregion.
3) Carefully remove the aluminum foil on the Auto Tubes.
4) Add **300 µL liquid suspension** and **10 µL Proteinase K** **into column #1/ #7 of Auto Plate.**
   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.
5) Push Auto Tubes completely to the bottom of the plate rack. Make sure that the chamfer of the reagent plate is at the lower left.

6) Select the program
Maelstrom 4800 series: "**6ST**" is recommended.
The parameters are given in the following section.
7) Carefully remove the Auto Plate when the program is finished.
8) Use micropipette to transfer the purified nucleic acids from column **#6/ #12** to a clean tube.
9) Discard used Auto Plates and spin tips into the waste recycling bin

10. Program

■ Maelstrom 4800 series

Program Name: 6ST					Model: Maelstrom 4800 series		
Temp1	Temp2						
40	40						
Well	Name	Volume	Action	Mixing	Collect		
1/ 7	LB	900	Rev. U/D	Low	Low		
2/ 8	MB	800	For.	Low	Low		
3/ 9	WB1	800	For.	Low	Low		
4/ 10	WB2	800	For.	Low	Low		
5/ 11	WB2	800	For.	Low	Low		
6/ 12	EB	150	For.	Low	Low		
Step	Well	Temp (°C)	Mixing (M)	Mixing (RPM)	Collect (M)	Vapor (M)	Pause
1	2/ 8		0.5	2500	0.5	0	Off
2	1/ 7	55	12	1500	0.5	0	Off
3	3/ 9		2	2500	0.5	0	Off
4	4/ 10		1	1500	0.5	0	Off
5	5/ 11		1	1500	0.5	10	Off
6	6/ 12	OFF	5	2500	1.5	0	Off
7	3/ 9		0.5	2500	0	0	Off

11. Result

■ Qualitative Analysis

Specific gene fragments can be amplified from nucleic acid products isolated from the TANBead® nucleic acid extraction kit by PCR (Polymerase Chain Reaction) or RT-PCR (Reverse - transcription PCR). This kit can be combined with different molecular biology reagents and applied for molecular diagnosis. Results: Please refer to PCR or RT-PCR molecular diagnostic kit manual.

■ Quantitative analysis

Nucleic acid products purified by TANBead® nucleic acid extraction kit can be performed a quantitative analysis of specific genes by qPCR (Quantitative real-time Polymerase Chain Reaction) or qRT-PCR (Quantitative Reverse Transcription PCR). It also can be used for detecting viral load or bacterial load and other molecular detection analyses.

Results: Please refer to the qPCR or qRT-PCR molecular diagnostic kit manual.

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 DNA/RNA

Storage Conditions	DNA/RNA stability
-80°C	Over 90 days
-20°C	28 days
4°C	14 days
25°C	2 days
Freeze - thaw	10 times

13. Explanation of Symbols

	Manufacturer		**Consult instructions for use**
15°C 35°C	**Temperature limit**	Σ	**Contains sufficient for test**
RUO	**Research use only**		**Caution**
REF	**Catalogue number**	NON STERILE	**Non-sterile**
LOT	**Batch code**		**Protect from heat and radioactive sources**
	Do not re-use		**Use-by date**
	Date of manufacture		

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