# TANBead® Nucleic Acid Extraction Kit

STIs DNA Auto Plate

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

CE IVD

**M6STA46**

(For Professional Use Only) V1

## 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 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

Σ 96

| | | |
|---|---|---|
| Auto Plate | 6 | Auto Plate with reagent buffers |
| Proteinase K | 1.0 mL x 1 | 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 | Lysis Buffer | 600 |
| 2 / 8 | Magnetic Beads | 800 |
| 3 / 9 | Washing Buffer 1 | 800 |
| 4 / 10 | Washing Buffer 2 | 800 |
| 5 / 11 | Washing Buffer 2 | 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 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 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) 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 inspecific 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) Set up spin tips.
2) **Maelstrom 4800 series**: Go to Tip page and press the mount tips region.
3) Carefully remove the aluminum foil on the Auto Plate.
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 Plates completely to the bottom of the plate rack. Make sure that the chamfer of the 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.

## 11. 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 Speed (RPM) | Collect (M) | Vapor (M) | Pause |
| 1 | 2/ 8 | - | 0.5 | 2500 | 0.5 | 0 | Off |

| Step | Well | Temp (°C) | Mixing (M) | Mixing Speed (RPM) | Collect (M) | Vapor (M) | Pause |
|---|---|---|---|---|---|---|---|
| 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 |

## 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.

### 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 |

## 13. Explanation of Symbols

| | | | |
|---|---|---|---|
| | **Manufacturer** | | **Consult instructions for use** |
| 15°C 35°C | **Temperature limit** | Σ | **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** | | **Protect from heat and radioactive sources** |
| | **Date of manufacture** | | **Use-by date** |

EC REP

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## 14. 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.