# TANBead® Nucleic Acid Extraction Kit

HPV DNA Auto Tube

(For use with the SLA-16 / 32 / E13200 series)

RUO

**61HS46**

(For Research Use Only) V1

## 1. Intended Use

This product is designed for isolating nucleic acid from various samples, which can be performed by using TANBead® Nucleic Acid Extractor and is intended for research use only.

## 2. Purpose

The TANBead® Nucleic Acid Extraction Kit (61HS46) is designed to perform the HPV nucleic acids extraction. By using with TANBead® Nucleic Acid Extraction Systems, the one-step-to-extraction can be performed automatically. The cervical swab or liquid based cytology samples are processed through a series of automatic extraction steps and the high-quality nucleic acids can be applied directly to the further applications. The nucleic acids extraction performance of the HPV samples is examined.

## 3. The basic principle

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

## 4. Specification

| | |
|---|---|
| Starting Materials | 300 µL cervical swab or liquid based cytology samples |
| Elution Volume | 50~80 µL |

## 5. Component Supplied with the Kit

96

| | | |
|---|---|---|
| Auto Tube | 8 trays | Auto Tube with reagent buffers |
| Base | 2 | A rack for 8 Auto Tubes |
| Proteinase K | 1.0 mL x 1 | Proteinase K |
| Elution Buffer | 1.5 mL x 1 | Nuclease-Free Water |
| Strip | 24 | 8-channel strip |
| Protocol | 1 | Instruction guide for user |

## 6. Auto Tube Content

| Well | Buffer | Volume (µL) |
|---|---|---|
| 1 | Lysis Buffer | 400 |
| 2 | Washing Buffer 1 | 800 |
| 3 | Magnetic Beads | 800 |
| 4 | Washing Buffer 2 | 800 |
| 5 | Washing Buffer 2 | 800 |
| 6 | Elution Buffer | 80 |

## 7. 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.

## 8. Precautions

1) For research use only.
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 insert the strips 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.

## 9. Materials required, Not Supplied

1) TANBead® Nucleic Acid Extraction System
   Model: SLA-16 / 32 / E13200 series (non-sterile)
2) DTT (dithiothreitol)
3) Disposable gloves
4) Scissors, utility knives
5) Micropipette, disposable tips (10 µL / 200 µL / 1000 µL)
6) 1.5 mL microcentrifuge tube
7) 15 mL / 50 mL conical tube

## 10. Sample Collection, Transportation, and Storage

- **Sample collection and storage**
  The collection of samples should follow the guidance of collecting container provided by the supplier. And the storage of collected sample should follow the guidance or regulation of local authority.
- **Specimen transportation**
  The transportation of cervical swab or liquid based cytology samples should be followed by specific pathogen transportation-related regulations.

## 11. Nucleic Acids Extraction Protocol

Before operating, turn on the warm-up system of TANBead® Nucleic Acid Extractor, if it is equipped with temperature controller, please setting at **70°C**.

1) Preparing the Assembled Auto Tubes by inserting Auto Tubes into the Base completely.
2) Carefully remove the aluminum foil on the Auto Tubes.
3) Add **300 µL cervical swab** or **liquid based cytology samples** and **10 µL Proteinase K** into well **#1** of Auto Tube.
   **Note:** For nucleic acids extraction of **mucus samples**, please transfer **300 µL cervical swab** or **liquid based cytology samples** into the 1.5mL microcentrifuge tube, add **20 µL 1M DTT (dithiothreitol)** and vortex for 10 sec. Briefly spin down the samples and **incubate for 10 - 20 mins at 37°C**. Then transfer **320 µL samples** into well **#1** of Auto Tube and **10 µL Proteinase K** into well **#1**.
4) 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.
5) Push strips completely to the bottom of strip rack frame.
6) Close the door panel.
7) Select the program "**61H**". The parameters are given in following section.
8) Carefully remove the Auto Tubes when the program is finished.
9) Use micropipette to transfer the purified nucleic acids from well **#6** to a clean tube.
10) Discard used Auto Tubes and strips into the waste recycling bin.

## 12. Program

- **SLA-16 / 32 series**

| Program Name: 61H | | | | | Model: SLA-16 / 32 series | | | |
|---|---|---|---|---|---|---|---|---|
| Step | Well | Mixing (M) | Collect (S) | Rod | Mixing speed | Volume (μL) | Pause | Vapor (M) |
| 1 | 3 | 0 | 30 | ON | Medium | 800 | OFF | 0 |
| 2 | 1 | 20 | 30 | ON | Medium | 800 | OFF | 0 |
| 3 | 2 | 1 | 30 | ON | Medium | 800 | OFF | 0 |
| 4 | 4 | 1 | 30 | ON | Medium | 800 | OFF | 0 |
| 5 | 5 | 1 | 30 | ON | Medium | 800 | OFF | 5 |
| 6 | 6 | 2 | 60 | ON | Medium | 100 | OFF | 0 |
| 7 | 3 | 1 | 0 | OFF | Medium | 800 | OFF | 0 |
| 8 | 0 | 0 | 0 | OFF | Medium | 0 | OFF | 0 |

- **SLA-E13200 series**

| Program Name: 61H | | | | | | Model: SLA-E13200 series | | | |
|---|---|---|---|---|---|---|---|---|---|
| Step | Well | Temp (°C) | Mixing (M) | Collect (S) | Rod | Mixing speed | Volume (μL) | Pause | Vapor (M) |
| 1 | 3 | 70 | 0 | 30 | ON | Medium | 800 | OFF | 0 |
| 2 | 1 | 70 | 20 | 30 | ON | Medium | 800 | OFF | 0 |
| 3 | 2 | 70 | 1 | 30 | ON | Medium | 800 | OFF | 0 |
| 4 | 4 | 70 | 1 | 30 | ON | Medium | 800 | OFF | 0 |
| 5 | 5 | 70 | 1 | 30 | ON | Medium | 800 | OFF | 5 |
| 6 | 6 | 70 | 2 | 60 | ON | Medium | 100 | OFF | 0 |
| 7 | 3 | 70 | 0.1 | 0 | OFF | Medium | 800 | OFF | 0 |
| 8 | 0 | NA | 0 | 0 | OFF | Medium | 0 | OFF | 0 |

## 13. 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.

## 14. 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 acid 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 acid 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 |

## 15. Explanation of Symbols

| | | | |
|---|---|---|---|
| | Manufacturer | | Consult instructions for use |
| 15°C 35°C | Temperature limit | Σ | Contains sufficient for test |
| 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 |
| RUO | For research use only | | |

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