TANBead® Nucleic Acid Extraction Kit

HPV DNA Auto Plate

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

CE IVD

M61HA46

(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 human papillomavirus (HPV) DNA in cervical swab or liquid-based cytology samples. 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 cervical swab or liquid-based cytology samples
Elution Volume	50-80 µL

4. Component Supplied with the Kit

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	400
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	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) 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

9. 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.

10. Nucleic Acids Extraction Protocol

1) Carefully remove the aluminum foil on the Auto Plates.
2) Add **300 µL cervical swab** or **liquid-based cytology samples** and **10 µL Proteinase K** into well **#1 / #7** of Auto Plate.
   Note: For nucleic acids extraction of **mucus samples**, please transfer **300 µL cervical swab** or **liquid-based cytology samples** into the 1.5 mL 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 / #7** of Auto Plate and **10 µL Proteinase K** into well **#1 / #7**.
3) 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.
4) Push Auto Plates completely to the bottom of the plate rack. Make sure that the chamfer of the plate is at the lower left.
5) Select the program.
   Maelstrom 8 series: Press **"61H-1"** for input specimens at column #1 or **"61H-7"** for input specimens at column #7.
   Maelstrom 4800 series: Press **"61H"**.
   The parameters are given in following section.
6) Carefully remove the Auto Plates when the program is finished.
7) Use micropipette to transfer the purified nucleic acids from well **#6 / #12** to a clean tube.
8) Discard used Auto Plates and spin tips into the waste recycling bin.

11. Program

■ **Maelstrom 8 series**

Program Name: 61H-1/ 7						
Well	1/ 7	2/ 8	3/ 9	4/ 10	5/ 11	6/ 12
Volume	800(μL)	800(μL)	800(μL)	800(μL)	800(μL)	100(μL)

Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temp. (°C)	Temp. Control
1	3/ 9	Collection	0	30	0	0	No
2	1/ 7	Mixing	3000	900	0	85	Yes
3	1/ 7	Collection	0	30	0	85	Yes
4	2/ 8	Mixing	3000	12	0	0	No
5	2/ 8	Collection	0	30	0	0	No
6	4/ 10	Mixing	3000	30	0	0	No
7	4/ 10	Collection	0	30	0	0	No
8	5/ 11	Mixing	3000	30	0	0	No
9	5/ 11	Collection	0	30	0	0	No
10	5/ 11	Vapor	0	300	0	0	No
11	6/ 12	Mixing	3000	120	0	40	Yes
12	6/ 12	Collection	0	60	0	40	Yes
13	3/ 9	Mixing	3000	6	0	0	No

■ **Maelstrom 4800 series**

Program Name: 61H				Model: Maelstrom 4800 series			
Temp1	Temp2						
120	Off						
Well	Name	Volume	Action	Mixing	Collect		
1/ 7	LB	800	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	100	For.	Low	Low		
Step	Well	Temp (°C)	Mixing (M)	Mixing Speed (RPM)	Collect (M)	Vapor (M)	Pause
1	3	-	0	3000	0.5	0	Off
2	1	120	15	3000	0.5	0	Off
3	2	-	0.2	3000	0.5	0	Off
4	4	-	0.5	3000	0.5	0	Off
5	5	-	0.5	3000	0.5	5	Off
6	6	Off	2	3000	1	0	Off
7	3	-	0.1	3000	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, 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 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

14. Explanation of Symbols

	Manufacturer		Consult instructions for use
15°C 25°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		Keep away from sunlight
	Date of manufacture		Use-by date

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.