TANBead® Nucleic Acid Extraction Kit

OptiPure FFPE DNA Auto Plate

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

CE IVD

61PA46

(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 can automatically isolate and purify total DNA from formalin-fixed paraffin-embedded (FFPE) tissue sections. 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	Minimal requirement of 5 μm or curl input
Elution Volume	70~100 μL
Typical DNA yield	Up to 2 μg
Typical A260 / A280	Up to 1.9

4. Component Supplied with the Kit

Auto Plates	6	Auto Plate with reagent buffers
Proteinase K	1.0 mL x 2	Proteinase K
Elution Buffer	1.5 mL x 1	Nuclease-Free Water
Incubation Buffer	35 mL x 1	Tris buffer, surfactants, pH 8.0
Mineral Oil	35 mL x 1	Nuclease-Free mineral oil
Strip	12	8-channel strip
Protocol	1	Instruction guides for user

5. Auto Plate Content

Well	Buffer	Volume (μL)
1 / 7	-	-
2 / 8	-	-
3 / 9	Washing Buffer 2	800
4 / 10	Washing Buffer 2	800
5 / 11	Magnetic Beads	800
6 / 12	Elution Buffer	100

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 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.

8. Materials required, Not Supplied

1) TANBead® Nucleic Acid Extraction System
   Model: SLA-16 / 32 / E13200 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
7) IPA: Isopropanol for molecular biology

9. Sample Collection, Transportation, and Storage

- **Sample collection and storage**
  FFPE can be stored at 2-25°C for long-term preservation.
- **Specimen transportation**
  Transportation of FFPE specimens should follow specific FFPE tissue transportation-related laws. FFPE should be kept between 2~25°C during transportation.

10. Nucleic Acids Extraction Protocol

1) Put FFPE tissue sections into a 1.5 mL tube.
2) Add **300 μL Mineral oil** into a 1.5 mL tube and mix vigorously by vortexing.
3) Incubate at **80°C** for **5 minutes**.
4) Add **300 μL Incubation Buffer** and **20 μL Proteinase K** into 1.5 mL tube, then mix vigorously by vortexing.
5) Centrifuge at **6000 RPM** for **1 minute**. If any pellet appears in the aqueous phase, pipette it carefully to resuspend it without disturbing the upper layer.
6) Incubate at **56°C** for **1~2.5 hours** (or until the sample has been completely lysed).
7) Incubate at **90°C** for **1 hour**.
8) Centrifuge at **10000 RPM** for **15 seconds**.
9) Collect **colorless lower aqueous phase** as a sample (approximately 200 μL).
10) Mix the sample with **Isopropanol** as a **1:1 ratio (v / v)**.
11) Carefully remove the aluminum foil from Auto Plate.
12) Divide the mixture equally into column **#1 / #7** and **#2 / #8**.
13) Push Auto Plates completely to the bottom of plate rack. Make sure that the chamfer of the plate is at the lower left.
14) Select the program "**LQ-W5-AUTO**". The parameters are given in the following section.
15) Carefully take out Auto Plate when the program is finished.
16) Use micropipette to transfer the purified nucleic acid from column **#6 / #12** to a clean tube.
17) Discard the used Auto Plate and strips into the waste recovery can.

11. Program

- **SLA-16 / 32 series**

Program Name: LQ-W5-AUTO					Model: SLA-16 / 32 series			
Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	5	1	6	On	Medium	800	Off	0
2	1	1	6	On	Medium	800	Off	0
3	2	1	6	On	Medium	800	Off	0
4	3	1	6	On	Medium	800	Off	0
5	4	1	6	On	Medium	800	Off	5
6	6	1	50	On	Medium	150	Off	0
7	5	1	0	Off	Medium	800	Off	0
8	0	0	0	Off	Medium	0	Off	0

- **SLA-E13200 series**

Program Name: LQ-W5-AUTO						Model: SLA-E13200 series			
Step	Well	Temp (°C)	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	5	N / A	0.1	6	On	Medium	800	Off	0
2	1	N / A	1	6	On	Medium	800	Off	0
3	2	N / A	1	6	On	Medium	800	Off	0
4	3	N / A	0.5	6	On	Medium	800	Off	0
5	4	N / A	0.5	6	On	Medium	800	Off	5
6	6	N / A	1	50	On	Medium	150	Off	0
7	5	N / A	0.1	0	Off	Medium	800	Off	0
8	0	N / A	0	0	Off	Medium	0	Off	0

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 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%.

- **Detection limit of FFPE DNA samples: ≥ 5 μm**

- **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 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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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.