TANBead® Nucleic Acid Extraction Kit

OptiPure cfDNA Auto Plate

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

CE IVD

61CA46

(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 cell-free DNA (cfDNA) from human serum and plasma. The purified cfDNA can be used with any downstream application employing PCR-based qualitative, semi-quantitative, quantitative assays and capillary electrophoresis. 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 plasma / serum
Elution Volume	70 – 100 µL
Typical DNA yield	Up to 100 ng per mL plasma / serum
Typical DNA size	100 – 300 bp

⚠ **DNA yield will vary from 1 – 100 ng according to sample source and storage method. The average DNA yield is 20ng per mL of serum from healthy individuals.**

4. Component Supplied with the Kit

Auto Plate	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
Protocol	1	Instruction guide for user
Strip	12	8-channel strip

5. Auto Plate Content

Well	Buffer	Volume (µL)
1 / 7	Lysis Buffer	800
2 / 8	Washing Buffer 2	1000
3 / 9	Washing Buffer 1	1000
4 / 10	Washing Buffer 2	1000
5 / 11	Magnetic Beads	1000
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 be used for *in vitro* diagnostic.
2) Avoid using expired reagents.
3) When the temperature is below 20°C, place the Auto Plates 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 to air. The evaporation would lead to pH change, or effect on the extraction effectiveness.
7) Please check the integrity of the Auto Plates 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) 20% SDS (Sodium dodecyl sulfate)
8) Streck Cell-Free DNA BCT tubes or other Cell-Free DNA collection tube

9. Sample Collection, Storage and Transportation

■ **Sample collection and storage**

1) Prepare cell-free plasma sample
   a. Blood samples collected in Streck Cell-Free DNA BCT tubes is recommended. It is stable for up to 14 days.
   b. Centrifuge whole blood at **1600 x g** for **10 minutes**.
   c. Transfer the upper plasma layer to a new conical tube.
   d. Centrifuge at **16000 x g** for **10 minutes**.
   e. Carefully transfer the supernatant to a new conical tube for cfDNA isolation.
2) Prepare cell-free serum sample
   a. Blood samples collected in serum separator tube.
   b. Let the blood clot for at least **30 minutes** in room temperature.
   c. Centrifuge whole blood at **1600 x g** for **10 minutes**.
   d. Transfer the upper serum layer to a new conical tube.
   e. Centrifuge at **16000 x g** for **10 minutes**.
   f. Carefully transfer the supernatant to a new conical tube for cfDNA isolation.
3) Specimen storage
   a. After centrifugation, the plasma / serum can be stored at
      i. 2~8°C up to 7 days.
      ii. -20°C for long-term preservation.

■ **Specimen transportation**

Transportation of whole blood, plasma and serum specimens should be followed by specific pathogen transportation-related regulations. The whole blood sample should be kept between 2~25°C during transportation and within 6 hours for separated serum. Plasma / Serum sample can be transported between 2~8°C or by frozen.

10. 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 **25°C.**

1) Add **300 µL plasma / serum** with **30 µL 20% SDS** and **20 µL PK**.
2) Mix well and incubate at **60°C** for **20 minutes**.
3) Carefully remove the aluminum foil on the Auto Plates.
4) Add **total mixture** to **well #1 / #7**.
5) Push Auto Plates completely to the bottom of plate rack. Make sure that the chamfer of the plate is at the lower left.
6) Push strips completely to the bottom of strip rack frame.
7) Close the door panel.
8) Select the program **"CFDNA"**. The parameters are given in following section.
9) Once the program has ended, buzzer shall alarm. Take out Auto Plate carefully.
10) Carefully remove the Auto Plates when the program is finished.
11) Use micropipette to transfer the purified nucleic acids from well

#6 / #12 to a clean tube.

12) Discard used Auto Plates and strips into the waste recycling bin.

11. Program

■ **SLA-16 / 32 series**

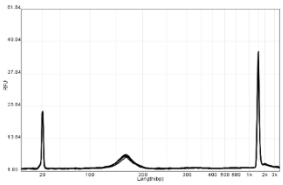
Program Name: CFDNA					Model: SLA-16 / 32 series			
Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (µL)	Pause	Vapor (M)
1	5	1	30	On	Medium	1000	Off	0
2	1	10	30	On	Very Low	1200	Off	0
3	3	10	0	Off	Medium	1000	Off	0
4	5	1	0	Off	Fast	1000	Off	0
5	3	0	60	On	Medium	1000	Off	0
6	2	3	0	Off	Medium	1000	Off	0
7	5	1	0	Off	Fast	1000	Off	0
8	2	0	60	On	Medium	1000	Off	0
9	4	5	30	On	Medium	1000	Off	5
10	6	4	60	On	Medium	100	Off	0
11	5	1	0	Off	Medium	1000	Off	0

■ **SLA-E13200 series**

Program Name: CFDNA						Model: SLA-E13200 series			
Step	Well	Temp (°C)	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (µL)	Pause	Vapor (M)
1	5	45	1	30	On	Medium	1000	Off	0
2	1	45	10	30	On	Very Low	1200	Off	0
3	3	45	10	0	Off	Medium	1000	Off	0
4	5	45	1	0	Off	Fast	1000	Off	0
5	3	45	0	60	On	Medium	1000	Off	0
6	2	45	3	0	Off	Medium	1000	Off	0
7	5	45	1	0	Off	Fast	1000	Off	0
8	2	45	0	60	On	Medium	1000	Off	0
9	4	45	5	30	On	Medium	1000	Off	5
10	6	45	4	60	On	Medium	100	Off	0
11	5	NA	1	0	Off	Medium	1000	Off	0

12. Result

Total DNA yield was quantified using Qubit dsDNA HS assay kit: 1~100 ng per mL serum / plasma. The expected peak bp (100~300 bp fragments) and low amount of gDNA contamination were observed by using Qsep 100 capillary gel electrophoresis system.



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 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	5 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.