

Intended Use

TANBead® Nucleic Acid Extraction Kit (REF M61CA46) is suitable for isolating cell free DNA (cfDNA). Automated nucleic acid extraction can be performed by Maelstrom 8 Autostage. Extracted nucleic acids can be analyzed by downstream application, such as real-time PCR, next-generation sequencing.

2. Purpose

TANBead® Nucleic Acid Extraction Kit (REF M61CA46) is suitable for extract cell free DNA from plasma or serum of various species. Samples need to be treated with proteinase K during automated/semi-automated nucleic acid extraction process by Maelstrom 8. The isolated cfDNA can be directly used for real time-PCR and DNA library preparation suitable for next generation sequencing. With high sensitivity, this reagent kit can be applied for clinical diagnostics and research.

3. Principle

The silicon dioxide layer coated on the magnetic beads can adsorb negative charged molecules in order to purify nucleic acid from samples.

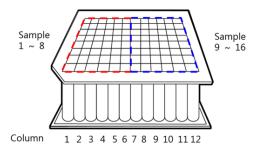
Sample Types: 1200 μl plasma/serum/body fluid **Suitable Instrument:** Maelstrom 8 Autostage

4. Reagent Components

REF M61CA46		∑ 96 Assays
Auto Plate	6	96 well plate with reagent buffers
Elution Buffer	1.5 ml	Nuclease-Free Water
Proteinase K	1 ml ×2	20 mg/ml Proteinase K, store at 4°C
Spin tips	96	Spin tip
Protocol	1	Instruction guide for user

Auto Plate Content

Column	Buffer Solution	Volume
1/7	Lysis Buffer	1000 μΙ
2/8	Lysis Buffer	1000 μΙ
3/9	Washing Buffer 1	500 μΙ
4/10	Magnetic Beads	500 μΙ
5/11	Washing Buffer 2	500 μΙ
6/12	Elution Buffer	50 μΙ



5. 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. When received, please store proteinase K at 4°C.
- 6. Precautions
- 1) Avoid using expired reagents
- 2) When the temperature is below 20°C, place the reagent plate in an oven (preheated 42 60°C) 5 to 10 minutes.
- Avoid vigorous shaking, in order to avoid excessive formation of foam.
- Do not exposure opened reagents or plates to air. The evaporation would lead to pH change, or influence the extraction effectiveness.
- 5) Reagents are all colorless and transparent. Colored reagent indicate contamination, please replace a fresh plate before

proceeding.

- Before use, please check the integrity of the reagent plate, and remember to mount the spin tips into the appropriate position.
- 7) Please wear a mask and disposable gloves when handling.
- 8) Remove aluminum foil carefully to avoid splashing.
- 9) Use sterile consumables to avoid nuclease contamination.
- 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 that has occurred, please report to manufacturer and the competent authority of the member state in which the user and/or the patient is established.

7. Provided Materials

 TANBead® Nucleic Acid Extraction Kit a.Auto Plate b.Proteinase K c. Elution Buffer d.Spin tips

8. Required but not provided

- TANBead® Nucleic Acid Extraction System Model: Maelstrom 8 Autostage(non-sterile)
- 2) Disposable gloves
- 3) Scissors, utility knives
- 4) Micropipette, disposable tips (10μl / 200 μl / 1000 μl)
- 5) 1.5 ml microcentrifuge tube

9. Sample collection, transport, storage and pre-treatment

- Sample collection and storage
 - 1) Plasma/Serum/Body fluid, whole blood
 - I. Blood should be sampled in Blood Collection Tube for cell-free DNA Preservation.
 - II. Fresh whole blood specimen can be stored at RT for 6 hrs.
 - III. After centrifugation, the plasma/serum/body fluid sample can be stored at
 - RT for 24 hours
 - \bullet 2-8°C up to 7 days
 - -20°C long-term preservation
- Specimen transportation

Transportation of whole blood, serum specimen should follow specific pathogen transportation related law. Whole blood sample should be kept between 2-25°Cduring transportation and separate plasma/serum within 6 hrs. Plasma/Serum sample can be transport between 2-8°C or by frozen.

10. Nucleic acid extraction protocol

- 1) Centrifuge sample for 5 min at >16000 g.
- 2) Carefully remove the aluminum foil on the Auto Plate.
- 3) Pipet 600 μl sample and then 10 μl Proteinase K into column #1/ #7 and column #2/ #8 of Auto Plate.

Note: The volume ratio of mixture and lysis buffer is about 600 μl / 1000 μl . If it is changed, it might be affected the performance.

- 4) Place Auto Plate to the plate holder of Autostage. Make sure that the missing corner of base faces toward the lower left.
- 5) Mount spin tips on Maelstrom 8.
- 6) Edit/ Select the program "61C-1/7". The parameters are given in following section.
- 7) Use micropipette to transfer the purified nucleic acid from column #6/ #12 to a clean tube.

 Discard used Auto Plate and spin tips into the waste recovery can.

11. Program

Program Name:61C-1/7					
well 1/7	well 2/8	well 3/9	well 4/10	well 5/11	well 6/12
900 (µl)	(الم) 900	500 (µl)	500 (µl)	500 (µl)	100 (μl)

Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temperature	Temperature_ Control
1	4/10	Mixing	1500	30	0	55	YES
2	4/10	Collection	0	30	0	55	YES
3	1/7	Mixing	1500	480	0	55	YES
4	1/7	Collection	0	60	0	55	YES
5	2/8	Mixing	1500	480	0	55	YES
6	2/8	Collection	0	60	0	55	YES
7	3/9	Mixing	1500	120	0	45	YES
8	3/9	Collection	0	30	0	45	YES
9	4/10	Mixing	1500	120	0	45	YES
10	4/10	Collection	0	30	0	45	YES
11	5/11	Mixing	1500	120	0	45	YES
12	5/11	Collection	0	30	0	45	YES
13	5/11	Vapor	0	600	0	45	YES
14	6/12	Mixing	1500	300	0	45	YES
15	6/12	Collection	0	90	0	45	YES
16	5/11	Mixing	1500	30	0	0	NO

12. Result

• Qubit ® dsDNA HS Assay Kit analysis

Sample: 1200 µl fresh plasma form healthy individual

Concentration: 0.1 – 0.2 ng/µl
• Capillary electrophoresis analysis
Fragment size: 100 – 200 bp
Target peak population: ≥95%

13. Reagent performance

Repeatability

Under repeatability conditions where nucleic acids are extracted with the same reagent kit on 40 μ l 100 bp DNA ladder 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 30 μ l 100 bp DNA ladder 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/RNA

Storage Conditions	DNA/RNA 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



Lot: As indicated on pack label Shelf life: As indicated on pack label

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