



TANBead® Nucleic Acid Extraction Kit

OptiPure cfDNA Auto Tube
(for use with the Maelstrom 8)



REF M61CS46
(For Professional Use Only)

1. Intended Use

TANBead® Nucleic Acid Extraction Kit (REF M61CS46) 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 M61CS46) 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

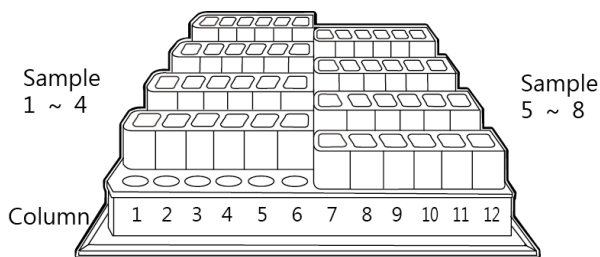
Suitable Instrument: Maelstrom 8 Autostage

4. Reagent Components

REF M61CS46	96 Assays	
Auto Tubes	96	6 well tube with reagent buffers
Elution Buffer	1.5 ml	Nuclease-Free Water
Spin tips	96	Spin tips
Base	2	A rack for 8 Auto Tubes
Proteinase K	1 ml x2	20 mg/ml Proteinase K, store at 4°C
Protocol	1	Instruction guide for user

Auto Tube Content

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



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 tubes in an oven (preheated 42 - 60°C) 5 to 10 minutes.**
- 3) **Avoid vigorous shaking, in order to avoid excessive formation of foam.**
- 4) **Do not exposure opened reagents or tubes to air. The evaporation would lead to pH change, or influence the extraction effectiveness.**
- 5) **Reagents are all colorless and transparent. Colored reagents indicate contamination, please replace a fresh tube before proceeding.**

- 6) **Before use, please check the integrity of the reagent tubes, 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.**
- 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 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

- 1) TANBead® Nucleic Acid Extraction Kit
 - a. Auto Tubes
 - b. Base
 - c. Proteinase K
 - d. Elution Buffer
 - e. Spin tips

8. Required but not provided

- 1) TANBead® Nucleic Acid Extraction System
- 2) Model: Maelstrom 8 Autostage(non-sterile)
- 3) Disposable gloves
- 4) Scissors, utility knives
- 5) Micropipette, disposable tips (10µl / 200 µl / 1000 µl)
- 6) 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
 - 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°C during 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) Prepare the Assembled Auto Tubes by inserting Auto Tubes into the Base completely.
- 3) Remove the aluminum foil from Auto Tube carefully.
- 4) Pipet **600 µl sample** and then **10 µl Proteinase K** into column **#1/ #7** and column **#2/ #8** of Auto Tube.

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.

- 5) Place Assembled Auto Tube to the plate holder of Autostage. Make sure that the missing corner of base faces toward the lower left.
- 6) Mount spin tips on Maelstrom 8.
- 7) Edit/ Select the program **"61C-1/7"**. The parameters are given

in following section.

- 8) Use micropipette to transfer the purified nucleic acid from column #6/ #12 to a clean tube.
- 9) Discard used Auto Tube 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)	900 (μl)	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 μl 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 μl 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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