



TANBead® Nucleic Acid Extraction Kit

HBV Auto Plate

(for use with the Maelstrom 8)



REF M615A46

(For Professional Use Only)

1. Intended Use

TANBead® Nucleic Acid Extraction Kit (REF M615A46) is suitable for isolating nucleic acid from serum specimen. It's a pre-processing system, and the purified nucleic acid is suitable for any molecular biology procedure, including but not limited to PCR (Polymerase Chain Reaction) amplification, restriction digestion, cloning, and sequencing.

2. Purpose

TANBead® Nucleic Acid Extraction Kit (REF M615A46) provide an effective way of viral DNA extraction from serum. In addition to extracting DNA samples from general common viruses, the kits are effectively improved for the DNA extraction of hepatitis B virus. Serum specimens are processed through a series of automatic extraction steps and finally the high-quality DNA can be applied directly to the following qualitative and quantitative assays. These kits can detect viral DNA from less than 100 IU / ml B virus specimens. They are with excellent gradients, sensitivity and reproducibility.

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: 300 µl serum or PBS suspension

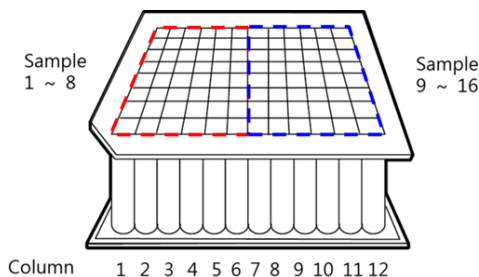
Suitable Instrument: Maelstrom 8 Autostage

4. Reagent Components

REF M615A46		96 Assays
Auto Plates	6	96 well plate with reagent buffers
Elution Buffer	20 ml	Nuclease-Free Water
Proteinase K	1 ml	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	400 µl
2/8	Washing Buffer 1	800 µl
3/9	Magnetic Beads	800 µl
4/10	Washing Buffer 3	800 µl
5/11	Washing Buffer 3	800 µl
6/12	Elution Buffer	80 µl



5. Storage and shelf life

- Components under room temperature (15-35 °C) can be stored until the expiration date labeled on the box.
- The proteinase K is transported at room temperature. When received, please store proteinase K at 4°C.

6. Precautions

- It can only be used for in vitro diagnostic.
- Avoid using expired reagents.
- 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.

- 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.
- Please wear a mask and disposable gloves when handling.
- Remove aluminum foil carefully to avoid splashing.
- Use sterile consumables to avoid nuclease contamination.
- Reagent solution contains guanidine salt, avoid using bleach containing detergent.
- Avoid eyes, skin and clothing contact with reagents. In case of any contact, flush with flowing water.
- 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
 - Auto Plates
 - Proteinase K
 - Elution Buffer
 - Spin tips

8. Required but not provided

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

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

■ Sample collection and storage

- Serum, whole blood
 - Serum specimens must be obtained from serum collection tubes, whole blood specimens must be obtained from sodium citrate or EDTA collection tubes.
 - Fresh whole blood specimen can be stored at RT for 6 hrs.
 - After centrifugation, the serum 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 serum within 6 hrs. Serum sample can be transport between 2-8°C or by frozen.

10. Nucleic acid extraction protocol

- Pipet **300 µl serum or PBS suspension** into a 1.5 ml tube.
- Add **10 µl Proteinase K** and mixing.
- Carefully remove the aluminum foil from Auto Plate.
- Carefully transfer **310 µl mixture** into column **#1/ #7**.
Note: The volume ratio of mixture and lysis buffer is about 300 µl: 400 µl. If it is changed, it might be affected the performance.
- Place Auto Plate completely to the autostage of plate. Make sure that the missing corner of base faces toward the lower left.
- Mount spin tips on Maelstrom 8.
- Edit/ Select the program "**615-1/7**". The parameters are given in following section.

- 8) Once the program has ended, take out Auto Plate carefully.
- 9) Use micropipette to transfer the purified nucleic acid from column #6/ #12 to a clean tube.
- 10) Discard the used Auto Plate and spin tips into the waste recovery can.

11. Program

Program Name:615-1/7					
well 1/7	well 2/8	well 3/9	well 4/10	well 5/11	well 6/12
800 (μl)	800 (μl)	800 (μl)	800 (μl)	800 (μl)	100 (μl)

Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temperature	Temperature Control
1	3/9	Mixing	3000	60	0	55	YES
2	3/9	Collection	0	30	0	55	YES
3	2/8	Mixing	3000	60	0	55	YES
4	1/7	Mixing	3000	1200	0	55	YES
5	2/8	Collection	0	30	0	55	YES
6	1/7	Mixing	3000	600	0	55	YES
7	1/7	Collection	0	30	0	55	YES
8	2/8	Mixing	3000	120	0	45	YES
9	2/8	Collection	0	30	0	45	YES
10	3/9	Mixing	3000	120	0	45	YES
11	3/9	Collection	0	30	0	45	YES
12	4/10	Mixing	3000	120	0	45	YES
13	4/10	Collection	0	30	0	45	YES
14	5/11	Mixing	3000	120	0	45	YES
15	5/11	Collection	0	30	0	45	YES
16	5/11	Vapor	0	600	0	45	YES
17	6/12	Mixing	3000	300	0	45	YES
18	6/12	Collection	0	60	0	45	YES
19	5/11	Mixing	3000	60	0	0	NO

12. Result

• Qualitative Analysis

A specific gene fragments can be amplified from nucleic acid products isolated from TANBead® nucleic acid extraction kit by PCR (Polymerase Chain Reaction) or RT-PCR (Reverse Transcription-PCR). This kit can work with different molecular biology reagents, and apply for verity of molecular diagnosis.

Result: Please refer to PCR or RT-PCR molecular diagnostic kit manual

• Quantitative analysis

Nucleic acid product purified by TANBead® nucleic acid extraction kit can perform quantitative analysis of specific genes by Q-PCR (Quantitative real time Polymerase Chain Reaction) or qRT-PCR (Quantitative Reverse Transcription PCR). Can be used for detecting viral load or Bacterial load and other molecular detection analysis.

Results: Please refer to the Q-PCR or qRT-PCR 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 50 IU / ml of HBV serum 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 HBV virus ≥ 50 IU/ml

• Interfering substance

According to preclinical tests, the performance of extraction kit will not be affected by EDTA, Li-Heparin, Sodium Citrate, D-Glucose, Hemoglobin, lipoprotein and triglyceride in samples.

• 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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