

(For Research Use Only) V1

1. Intended Use

This product is designed for isolating nucleic acid from various samples, which can be performed by using TANBead® Nucleic Acid Extractor and is intended for research use only.

2. Purpose

TANBead® Nucleic Acid Extraction Kit (615S46) provides 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 the hepatitis B virus. Serum / Plasma 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.

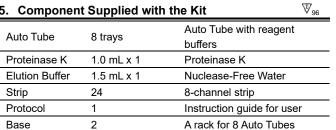
3. The basic principle

The silicon dioxide layer coated on the magnetic beads can adsorb the negatively charged molecules to purify nucleic acids from samples.

4. Specification

Starting Materials	300 µL serum or PBS suspension
Elution Volume	50~80 μL

5. Component Supplied with the Kit



6. Auto Tube Content

Well	Buffer	Volume (μL)
1/7	Lysis Buffer	400
2/8	Washing Buffer 1	800
3/9	Magnetic Beads	800
4 / 10	Washing Buffer 3	800
5 / 11	Washing Buffer 3	800
6 / 12	Elution Buffer	80

7. Kit 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. Upon received, please store proteinase K at 2~8°C.

8. Precautions

- 1) For research use only.
- 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.

9. Materials required, Not Supplied

- 1) TANBead® Nucleic Acid Extraction System Model: Maelstrom 8 series, Maelstrom 4800 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

10. Sample Collection, Transportation, and Storage

Sample collection and storage

- 1) Serum, whole blood
 - a. Serum specimens must be obtained from serum collection tubes, whole blood specimens must be obtained from sodium citrate or EDTA collection tubes.
- 2) Specimen storage
 - a. Fresh whole blood specimens can be stored at room temperature for 6 hours.
 - b. After centrifugation, the serum sample can be stored at
 - i. Room temperature for 24 hours
 - ii. 2~8°C up to 7 days
 - iii. -20°C for long-term preservation

Specimen transportation

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

11. 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 50°C.

- 1) Pipet 300 µL serum / plasma or PBS suspension into a 1.5 mL tube. Add 10 µL Proteinase K and mixing. Then incubate for 10~20 min at 56°C.
- 2) C Preparing the Assembled Auto Tubes by inserting Auto Tubes into the Base completely.
- 3) Carefully remove the aluminum foil on the Auto Tubes.
- Add 310 µL mixture into well #1 / 7 (well filled with lysis buffer).
- 5) Push Assembled Auto Tubes completely to the bottom of the plate rack. Make sure that the chamfer of the plate is at the lower left.
- Push strips completely to the bottom of plate rack.
- 7) Select the program" VIRUS-W4-AUTO".
- Once the program has ended, buzzer shall alarm. Take out the Auto Plates carefully.
- Use micropipette to transfer the purified nucleic acids from well #6 / #12 to a clean tube.
- 10) Discard used Auto Tubes and strips into the waste recycling bin.

12. Program

■ SLA-16 / 3200 series

Progra	Program Name: VIRUS-W4-AUTO				Model: SLA-16 / 32 series			
Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	3	1	60	On	Medium	800	Off	0
2	2	1	0	Off	Medium	800	Off	0
3	1	20	0	Off	Low	900	Off	0
4	2	0	60	On	Medium	800	Off	0
5	1	10	60	On	Medium	900	Off	0
6	2	2	60	On	Medium	800	Off	0
7	3	2	60	On	Medium	800	Off	0
8	4	2	60	On	Medium	800	Off	0
9	5	2	60	On	Medium	800	Off	10
10	6	5	120	On	Medium	150	Off	0
11	5	1	0	Off	Medium	800	Off	0
12	0	0	0	Off	Medium	0	Off	0

■ SLA-E13200 series

Program Name: L-BNA-PK-AUTO					Model: SLA-E13200 series				
Step	Well	Temp (°C)	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	3	45	1	60	On	Medium	800	Off	0
2	2	45	1	0	Off	Medium	800	Off	0
3	1	45	20	0	Off	Low	900	Off	0
4	2	45	0	60	On	Medium	800	Off	0
5	1	45	10	60	On	Medium	900	Off	0
6	2	45	2	60	On	Medium	800	Off	0
7	3	45	2	60	On	Medium	800	Off	0
8	4	45	2	60	On	Medium	800	Off	0
9	5	45	2	60	On	Medium	800	Off	10
10	6	45	5	120	On	Medium	150	Off	0
11	5	N/A	1	0	Off	Medium	800	Off	0
12	0	N/A	0	0	Off	Medium	0	Off	0

13. Result

Nucleic acid product purified by TANBead® nucleic acid extraction kit can perform qualitative / quantitative analysis of specific genes by PCR, RT-PCR, Q-PCR or qRT-PCR.

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%.

■ 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

14. Explanation of Symbols

***	Manufacturer	[]i	Consult instructions for use
15℃	Temperature limit	Σ	Contains sufficient for test
REF	Catalogue number	\triangle	Caution
LOT	Batch code	NON	Non-sterile
\otimes	Do not re-use	漆	Keep away from sunlight
~~	Date of manufacture	8	Use-by date
RUO	For research use only		