TANBead® Nucleic Acid Extraction Kit Viral Auto Plate (For use with the SLA-16 / 32 / E13200 series)

(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 (635A46) is suitable for isolating a variety of viral nucleic acids such as Enterovirus, Japanese encephalitis virus, Dengue virus, Avian Influenza virus, and Epstein-Barr virus. Serum specimens are processed through a series of automatic extraction steps and finally the high-quality nucleic acids can be applied directly to the following qualitative and quantitative assays. With high sensitivity, this reagent kit can be applied for clinical diagnostics and research.

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

5. Component Supplied with the Kit					
Elution Volume	70~100 μL				
Starting Materials	200 μL serum or PBS suspension				

Component Supplied with the Kit

5. Component Capping with the late					
Auto Plate	6	Auto Plate with reagent buffers			
Proteinase K	1.0 mL	Proteinase K			
Elution Buffer	1.5 mL	Nuclease-Free Water			
Strip	12	8-channel strip			
Protocol	1	Instruction guide for user			

6. Auto Plate Content

Well	Buffer	Volume (μL)
1/7	Lysis Buffer	700
2/8	Washing Buffer 1	800
3/9	Magnetic Beads	800
4 / 10	Washing Buffer 2	800
5 / 11	Washing Buffer 2	800
6 / 12	Elution Buffer	100

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 was transported at room temperature. When received, please store at 4°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

- 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

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 45°C.

- 1) Carefully remove the aluminum foil on the Auto Plates.
- 2) Pipet 200 µL serum or PBS suspension and 10 µL Proteinase K into column #1 / #7 of Auto Plate.

Note: The volume ratio of mixture and lysis buffer is about 200 µL: 700 µL. If it is changed, it might be affected the performance.

- 3) Push Auto Plates completely to the bottom of plate rack. Make sure that the chamfer of the plate is at the lower left.
- 4) Push strips completely to the bottom of strip rack frame.
- 5) Close the door panel.
- 6) Select the program "VIRUS-W4-AUTO". The parameters are given in following section.
- Once the program has ended, buzzer shall alarm. Take out Auto Plate carefully.
- 8) Use micropipette to transfer the purified nucleic acid from column #6 / #12 to a clean tube.
- 9) Put the used Auto Plate and strips into the waste recycling bin.

12. Program

■ SLA-16 / 32 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: 635					Model: SLA-E13200 series				
Step	Well	Temp (°C)	Mixin g (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. Please refer to the molecular diagnostic kit manual.

14. Reagent performance

■ Repeatability

Under repeatability conditions where nucleic acids are extracted with the same reagent kit on the same EBV serum concentration 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 100 IU / mL of EBV 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 EBV virus: ≥100 IU / mL

■ Interfering substance

The performance of this extraction kit will not be affected by EDTA, Li-Heparin, Sodium Citrate, D-Glucose, Hemoglobin, lipoprotein, and triglyceride in samples.

■ The stability of extracted RNA

Storage Conditions	RNA stability
-80°C	Over 90 days
-20°C	28 days
4°C	14 days
25°C	2 days
Freeze-thaw	5 times

15. Explanation of Symbols

	Manufacturer	Ţ <u>i</u>	Consult instructions for use
15°℃	Temperature limit	Σ	Contains sufficient for test
REF	Catalogue number	\triangle	Caution
LOT	Batch code	NON	Non-sterile
(2)	Do not re-use	紫	Keep away from sunlight
~J	Date of manufacture	\square	Use-by date
RUO	For research use only		