TANBead® Nucleic Acid Extraction Kit

OptiPure Viral Auto Plate

(For use with the SLA-16/32/E132 series)

RUO

665A46

(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 (665A46) is suitable for extracting nucleic acids of various viruses, such as the hepatitis C virus, hepatitis B virus, and influenza 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 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

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

5. Component Supplied with the Kit

Σ96

Auto Plate	6	Auto Plate with reagent buffers
Proteinase K	1.0 mL x 1	Proteinase K
Elution Buffer	1.5 mL x 1	Nuclease-Free Water
Strips	12	8-channel strip
Protocol	1	Instruction guide for user

6. Auto Plate Content

Well	Buffer	Volume (µL)
1 / 7	Lysis Buffer	600
2 / 8	Washing Buffer 1	800
3 / 9	Washing Buffer 2	800
4 / 10	Washing Buffer 2	800
5 / 11	Magnetic Beads	800
6 / 12	Elution Buffer	80

7. Kit 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. 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 in an oven (preheated 42 - 60°C) from 5 to 10 minutes.
4) Avoid vigorous shaking, to prevent excessive formation of foam.
5) Do not expose the opened reagent or Auto Plates to air. The evaporation would lead to pH change or effect on the extraction effectiveness.
6) The reagents are all colorless and transparent. Colored reagents indicate contamination, please replace it with a fresh plate before proceeding.
7) Please check the integrity of the Auto Plates and remember to mount the spin tips into the appropriate position of the suitable instrument before operating them.
8) Please wear a mask and disposable gloves when handling.
9) Carefully remove aluminum foil to avoid splashing.
10) Use sterile consumables to avoid nuclease contamination.
11) Reagent solution contains guanidine salt, avoid using bleach containing detergent.
12) Avoid eyes, skin, and clothing contact with reagents. In case of any contact, flush with flowing water.
13) 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: SLA-16/ 32 and SLA-E132 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.
   b. Fresh whole blood specimens can be stored at room temperature for 6 hours.
   c. 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 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

1) Carefully remove the aluminum foil from Auto Plate.
2) Pipet **300 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 300 µL: 600 µL. If it is changed, it might be affected the performance.

3) Push regent plate completely to the bottom of plate rack. Make sure that the missing corner of Auto Plate faces toward the door panel.
4) Push strips completely to the bottom of strip rack frame.
5) Close the door panel.
6) Select the program "**VIRUS-40-5**". The parameters are given in following section.
7) 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 recovery can.

12. Program

■ **SLA-16/32 series, SLA-E13200 series**

Program Name: VIRUS-40-5					Model: SLA-16/32, SLA-E132 series			
Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (µL)	Pause	Vapor (M)
1	5	50	0	60	Medium	800	OFF	0
2	1	50	10	60	Low	800	OFF	0
3	2	50	1	60	Medium	800	OFF	0
4	3	50	1	60	Medium	800	OFF	0
5	4	50	1	60	Medium	800	OFF	10
6	6	50	5	60	Medium	150	OFF	0
7	3	N/A	1	0	Medium	800	OFF	0
8	0	N/A	0	0	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 HCV 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 HCV 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 HCV virus: ≥100 IU/mL**
- **Interfering substance**
  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 RNA**

Storage Conditions	RNA stability
-80°C	Over 90 days
-20°C	28 days
4°C	14 days
25°C	2 days
Freeze-thaw	10 times

15. Explanation of Symbols

	Manufacturer		**Consult instructions for use**
15°C 35°C	**Temperature limit**		**Contains sufficient for test**
REF	**Catalogue number**		**Caution**
LOT	**Batch code**	NON STERILE	**Non-sterile**
	Do not re-use		**Keep away from sunlight**
	Date of manufacture		**Use-by date**
RUO	**For research use only**		

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