TANBead® Nucleic Acid Extraction Kit

OptiPure Viral Auto Plate

(For use with the SLA-16 / 32 / E13200 series)

CE IVD

665A46

(For Professional Use Only) V5

1. Intended Purpose

The TANBead® Nucleic Acid Extraction Kit is a nucleic acid purification kit based on magnetic bead technology by using with corresponding TANBead® Nucleic Acid Extractor, which can automatically isolate and purify total RNA from a broad range of viruses, such as hepatitis C virus in human serum and samples suspended in phosphate buffered saline (PBS). The purified RNA can be used with any downstream application employing PCR-based qualitative, semi-quantitative and quantitative assays. The kit is intended for use by technicians, physicians, and biologists with well-trained in molecular biological techniques, the techniques of magnetic bead purification and in vitro diagnostic procedures. Any diagnostic results generated by using the sample preparation procedure in conjunction with any downstream diagnostic assay should be interpreted related to other clinical or laboratory findings. The kit is not limited to any specific disorder, condition, or other additional accompanying diagnostics. It is applicable for all population.

2. The basic principle

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

3. Specification

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

4. Component Supplied with the Kit

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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

5. 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

6. 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.

7. Precautions

1) It can only be used for *in vitro* diagnostic.
2) Avoid using expired reagents.
3) When the temperature is below 20°C, place the Auto Plates 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 to air. The evaporation would lead to pH change, or effect on the extraction effectiveness.
7) Please check the integrity of the Auto Plates 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.

8. Materials required, Not Supplied

1) 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

9. 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.

10. 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) Carefully remove the aluminum foil on the Auto Plates.
2) Pipet **300 µL serum** or **PBS suspension** and **10 µL Proteinase K** into wells of 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 Auto Plates completely to the bottom of the 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-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 well of column **#6 / #12** to a clean tube.
9) Put the used Auto Plate and strips into the waste recycling bin.

11. Program

- **SLA-16 / 32 series**

Program Name: VIRUS-40-5					Model: SLA-16 / 32 series			
Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	5	0	60	On	Medium	800	Off	0
2	1	10	60	On	Low	800	Off	0
3	2	1	60	On	Medium	800	Off	0
4	3	1	60	On	Medium	800	Off	0
5	4	1	60	On	Medium	800	Off	10
6	6	5	60	On	Medium	150	Off	0
7	3	1	0	Off	Medium	800	Off	0
8	0	0	0	Off	Medium	0	Off	0

- **SLA-E13200 series**

Program Name: VIRUS-40-5						Model: SLA-E13200 series			
Step	Well	Temp (°C)	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	5	50	0	60	On	Medium	800	Off	0
2	1	50	10	60	On	Low	800	Off	0
3	2	50	1	60	On	Medium	800	Off	0
4	3	50	1	60	On	Medium	800	Off	0
5	4	50	1	60	On	Medium	800	Off	10
6	6	50	5	60	On	Medium	150	Off	0
7	3	N / A	1	0	Off	Medium	800	Off	0
8	0	N / A	0	0	Off	Medium	0	Off	0

12. 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.

13. 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**
  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 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

14. Explanation of Symbols

	Manufacturer		Consult instructions for use
15°C~35°C	Temperature limit	Σ	Contains sufficient for test
CE	CE mark	IVD	*In vitro* diagnostic medical use
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

EC REP

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15. Post-market surveillance conclusion

After a risk assessment and clinical evaluation assessment, when weighing the benefits of medical device, patients, and the risks associated with the use of the device, the risk is acceptable. The post-market surveillance report shows that no death or serious adverse events occurred.