TANBead® Nucleic Acid Extraction Kit

Virapid Virus Auto Tube

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

RUO

685S46

(For Research Use Only) V2

1. Intended Use

The TANBead® Nucleic Acid Extraction Kit (685S46) is the viral nucleic acids isolation kit that is developed for the extraction from swab, saliva and urine samples using magnetic beads. The kits and specific Auto Plate or Auto Tube are designed for use with the TANBead® Nucleic Acid Extraction Systems. The extracted nucleic acids could be applied to qualitative and quantitative molecular analyses, such as real-time PCR or RT-PCR.

2. Purpose

The TANBead® Nucleic Acid Extraction Kit (685S46) is designed to perform the rapid viral nucleic acids extraction. By using with TANBead® Nucleic Acid Extraction Systems, the one-step-to-extraction can be performed automatically. The swab, saliva and urine specimens are processed through a series of automatic extraction steps and the high-quality nucleic acids can be applied directly to the further applications. The nucleic acids extraction performance of the corona virus samples is examined.

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	1. Nasal, nasopharyngeal or oropharyngeal swab collected in virus transport medium (VTM) or PBS buffer 2. Saliva 3. Urine
Elution Volume	50-80 µL

5. Component Supplied with the Kit

96

Auto Tube	8 trays	Auto Tube with reagent buffers
Base	2	A rack for 8 Auto Tubes
Strip	24	8-channel strip
Protocol	1	Instruction guide for user

6. Auto Plate Content

Well	Buffer	Volume (µL)
1	Lysis Buffer	600
2	-	-
3	Washing Buffer 2	800
4	Washing Buffer 2	800
5	Magnetic Beads	800
6	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.

8. Precautions

1) It can only be used 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 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) 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: SLA-16/32 and SLA-E13200 (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**

  The collection of samples should follow the guidance of collecting container provided by the supplier. And the storage of collected sample should follow the guidance or regulation of local authority.

- **Specimen transportation**

  Transportation of samples should be followed by specific clinical samples transportation-related laws.

11. Sample Preparation Protocols

- **Swab**

  Vortex the collection tube for 10 seconds and spin down the medium before opening the cap to avoid aerosol contamination.

- **Saliva**

  Centrifuge the sample at 10,000 g for 3 minutes, harvest the supernatant for the testing.

- **Urine**

  Vortex the collection tube for 10 seconds and spin down before the testing.

12. Nucleic Acids Extraction Protocol

1) Preparing the Assembled Auto Tubes by inserting Auto Tubes into the Base completely.
2) Carefully remove the aluminum foil on the Auto Tubes.
3) Transfer **300 µL samples** into well **#1 / #7** of Auto Tube.
   Note: The volume ratio of sample and lysis buffer is about 300 µL: 600 µL. Changing this ratio might affect the performance of this kit. If the samples are not enough for extraction, the shortage can be replaced by PBS buffer.
4) Push Assembled Auto Tubes completely to the bottom of the plate rack. Make sure that the chamfer of the reagent plate is at the lower left.
5) Push strips completely to the bottom of strip rack frame.
6) Close the door panel.
7) Select the program **"685"** The parameters are given in following section.
8) Carefully remove the Assembled Auto Tubes when the program is finished.
9) Use micropipette to transfer the purified nucleic acids from well **#6 / #12** to a clean tube.
10) Discard used Auto Tubes and spin tips into the waste recycling bin.

13. Program

- **SLA-16/32 series**

Program Name: 685					Model: SLA-16/ 32 series			
Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (µL)	Pause	Vapor (M)
1	5	0	6	ON	Medium	800	OFF	0
2	1	5	6	ON	Medium	900	OFF	0
3	3	1	6	ON	Medium	800	OFF	0
4	4	1	6	ON	Medium	800	OFF	3

Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
5	6	1	6	ON	Medium	150	OFF	0
6	3	1	0	OFF	Medium	800	OFF	0
7	0	0	0	OFF	Medium	0	OFF	0

- **SLA-E13200 series**

Program Name: 685						Model: SLA-E13200 series			
Step	Well	Temp (°C)	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (μL)	Pause	Vapor (M)
1	5	NA	0	6	ON	Medium	800	OFF	0
2	1	NA	5	6	ON	Medium	900	OFF	0
3	3	NA	0.1	6	ON	Medium	800	OFF	0
4	4	NA	0.1	6	ON	Medium	800	OFF	3
5	6	NA	0.5	6	ON	Medium	150	OFF	0
6	3	NA	0.1	0	OFF	Medium	800	OFF	0
7	0	NA	0	0	OFF	Medium	0	OFF	0

14. 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.

15. Reagent performance

- **Repeatability**
  Under repeatability conditions where nucleic acids are extracted with the same reagent kit on the same sample 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 1000 copies/test of Coronavirus 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%.
- **Detectable viral input:** ≧ 500 copies/extraction.
- **Interfering substance**
  According to preclinical tests, the performance of the 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

16. Explanation of Symbols

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