

(For Research Use Only) V2

1. Intended Use

The TANBead® Nucleic Acid Extraction Kit (685A46) 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 (685A46) 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

| Elution Volume 50-80 µL | | | | |
|-------------------------|------|-----------------------------|--|--|
| | | rine | | |
| | 2. S | aliva | | |
| | bı | uffer | | |
| Starting Materials | m | edium (VTM) or PBS | | |
| | CC | ollected in virus transport | | |
| | or | opharyngeal swab | | |
| | 1. N | asal, nasopharyngeal or | | |

| 5. Component Supplied with the Kit | | | | | |
|------------------------------------|----|---------------------------------|--|--|--|
| Auto Plate | 6 | Auto Plate with reagent buffers | | | |
| Strip | 12 | 8-channel strip | | | |
| Protocol | 1 | Instruction guide for user | | | |

| 6. Auto F | Plate Content | |
|-----------|------------------|-------------|
| Well | Buffer | Volume (μL) |
| 1/7 | Lysis Buffer | 600 |
| 2/8 | - | - |
| 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

 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.
- 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.
- 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.
- 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 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) Carefully remove the aluminum foil on the Auto Plates.
- 2) Transfer 300 μL samples into well #1 / #7 of Auto Plate. 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.
- Push auto plate completely to the bottom of plate rack. Make sure that the chamfer of the reagent is at the lower left.
- 4) Push strips completely to the bottom of strip rack frame.
- 5) Close the door panel.
- Select the program "685". The parameters are given in following section.
- 7) Carefully remove the auto plate when the program is finished.
- 8) Use micropipette to transfer the purified nucleic acids from well #6 / #12 to a clean tube.
- Discard used auto plate and strips into the waste recycling bin.

13. Program

■ SLA-16/32 series

| Progra | 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 |
| 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%.

■ <u>Detectable viral input:</u> ≥ 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 | []i | Consult instructions for use |
|------|-----------------------|-------------|---|
| 15°C | Temperature limit | Σ | Contains sufficient for test |
| REF | Catalogue number | \triangle | Caution |
| LOT | Batch code | NON | Non-sterile |
| 8 | Do not re-use | 紫 | Protect from heat and radioactive sources |
| ~ | Date of manufacture | 8 | Use-by date |
| RUO | For research use only | | |