TANBead® Nucleic Acid Extraction Kit

Virapid Virus Auto Plate

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

CE IVD

685A46

(For Professional Use Only) V2

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 nucleic acid from a broad range of viruses in sample, such as nasal swab, oropharyngeal swab collected in virus transport medium, saliva, and urine. The purified nucleic acid 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	1. Nasal, nasopharyngeal or oropharyngeal swab collected in virus transport medium (VTM) or PBS buffer 2. Saliva 3. Urine
Elution Volume	50~80 µL

4. Component Supplied with the Kit

Auto Plate	6	Auto Plate with reagent buffers
Strip	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	-	-
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.

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 / 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.

8. Materials required, Not Supplied

1) TANBead® Nucleic Acid Extraction System
   Model: Maelstrom 8 series, Maelstrom 4800 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**
  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.

10. 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.

11. 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.
3) Push Auto Plate 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 "**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.
9) Discard used Auto Plate and strips into the waste recycling bin.

12. 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
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	N / A	0	6	On	Medium	800	Off	0
2	1	N / A	5	6	On	Medium	900	Off	0
3	3	N / A	0.1	6	On	Medium	800	Off	0
4	4	N / A	0.1	6	On	Medium	800	Off	3
5	6	N / A	0.5	6	On	Medium	150	Off	0
6	3	N / A	0.1	0	Off	Medium	800	Off	0
7	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 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	10 times

15. Explanation of Symbols

	Manufacturer		Consult instructions for use
	Temperature limit		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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16. 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.