TANBead® Nucleic Acid Extraction Kit

Gram Bacteria DNA Auto Tube

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

CE IVD

61GS46

(For Professional Use Only) V4

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 DNA from Gram-positive, Gram-negative bacteria or either positive or negative bacteria such as *Mycobacterium tuberculosis*. The nucleic acid products can be analyzed directly, such as PCR, restriction digestion, PFGE (pulsed-field gel electrophoresis), etc. This kit, with TANBead® Nucleic Acid Extractor, simplifies nucleic acids extraction. With simple treatment of samples, it does not need repetitive centrifugations, reducing time for manual processing, and lowering the risk of cross-contamination. 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	Bacteria suspension
Elution Volume	91~130 µL
Typical DNA yield	2~5 µg
Typical A260 / A280	1.7~1.9

4. Component Supplied with the Kit

Σ_{96}

Auto Tube	8 trays	Auto Tube with reagent buffers
Incubation Buffer	25 mL x 1	Tris buffer, surfactants, pH 8.0
Elution Buffer	1.5 mL x 2	Nuclease-Free Water
Lysozyme	40 mg	Please add 1 mL Elution Buffer before using and store at -20°C
Proteinase K	1.0 mL x 1	Proteinase K
Strip	24	8-channel strip
Base	2	A rack for 8 Auto Tubes
Protocol	1	Instruction guide for user

5. Auto Tubes Content

Well	Buffer	Volume (µL)
1 / 7	Lysis Buffer	500
2 / 8	Washing Buffer 1	800
3 / 9	Magnetic Beads	800
4 / 10	Washing Buffer 2	800
5 / 11	Washing Buffer 2	800
6 / 12	Elution Buffer	130

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 receiving, please store proteinase K at 2~8°C.
3) The Lysozyme was transported at room temperature. When received, please store at -20°C.
4) Repeating freezing and thawing may cause the activity decay of Lysozyme.

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) for 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 affect the extraction effectiveness.
7) Please check the integrity of the Auto Plates / Auto Tubes 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) Bacteria can be stored at
   a. RT for 12 hours.
   b. 2~8°C up to 7 days.
   c. -80°C long-term preservation.
2) Sputum, BAL samples
   a. Samples can be collected and obtained in specific collection tubes for preservation.
   b. Follow the collection guidance of specimens you collected for routinely storage.

■ **Specimen transportation**

Transportation of bacteria specimen should follow specific bacteria transportation-related law and should be kept between 2~25°C during transportation.

10. Sample Pre-treatments

1) Sputum samples
   a. NaOH 1:1 mix with sputum samples for 15 minutes.
   b. Place 500 µL of the mixture into 1.5 mL vial and vortex for 30 seconds.
   c. Centrifuge the mixture at 13000 RPM for 5 minutes.
   d. Discard supernatant and the formed pellet is ready for **12.2** process.
2) BAL
   a. Vortex 30 seconds first.
   b. Place 500 µL of BAL into 1.5 mL vial and vortex for 30 seconds.
   c. Centrifuge the mixture at 13000 RPM for 5 minutes.
   d. Discard supernatant and repeat steps b to d for three times and the formed pellet is ready for **12.2** process.
3) Solid culture
   a. Place 500 µL of PBS into 1.5 mL vial and take seeding loop to take two colonies.
   b. Resuspend with vortex for 30 seconds.
   c. Centrifuge the mixture at 13000 RPM for 5 minutes.
   d. Discard supernatant and repeat steps b to d for three times and the formed pellet is ready for **12.2** process.

4) Liquid sample
   a. Follow the **12** Steps for processing.

11. Nucleic Acids Extraction Protocol

Before operating, turn on the warm-up system of TANBead® Nucleic Acid Extractor, if it is equipped with a temperature controller, please setting at **45°C**.

1) Centrifuge the bacterial culture at **6000 RPM** for **2 minutes**.
2) After removing the supernatant thoroughly, add **200 µL Incubation Buffer**, **10 µL Lysozyme,** and **10 µL Proteinase K**.
3) After mixing well, incubate at **56°C** for **20~30 minutes**.
4) Preparing the Assembled Auto Tubes by inserting Auto Tubes into the Base completely.
5) Carefully remove the aluminum foil on the Auto Tubes.
6) Transfer the lysate into well **#1 / #7** of Auto Tube (Well filled with lysis buffer).
7) Push Assembled Auto Tubes completely to the bottom of the plate rack. Make sure that the chamfer of the plate is at the lower left.
8) Push strips completely to the bottom of strip rack frame.
9) Close the door panel.
10) Select the program "**VIRUS-W4-AUTO**". The parameters are given in the following section.
11) Carefully remove the Auto Tubes when the program is finished.
12) Use a micropipette to transfer the purified nucleic acids from well **#6 / #12** to a clean tube.
13) Discard used Auto Tubes and strips into the waste recycling bin.

12. Program

■ **SLA-16 / 32 series**

Program Name: VIRUS-W4-AUTO					Model: SLA-16 / 32 series			
Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (µL)	Pause	Vapor (M)
1	3	1	60	On	Medium	800	Off	0
2	2	1	0	Off	Medium	800	Off	0
3	1	20	0	Off	Low	900	Off	0
4	2	0	60	On	Medium	800	Off	0
5	1	10	60	On	Medium	900	Off	0
6	2	2	60	On	Medium	800	Off	0
7	3	2	60	On	Medium	800	Off	0
8	4	2	60	On	Medium	800	Off	0
9	5	2	60	On	Medium	800	Off	10
10	6	5	120	On	Medium	150	Off	0
11	5	1	0	Off	Medium	800	Off	0
12	0	0	0	Off	Medium	0	Off	0

■ **SLA-E13200 series**

Program Name: VIRUS-W4-AUTO						Model: SLA-E13200 series			
Step	Well	Temp (°C)	Mixing (M)	Collect (S)	Rod	Mixing speed	Volume (µL)	Pause	Vapor (M)
1	3	45	1	60	On	Medium	800	Off	0
2	2	45	1	0	Off	Medium	800	Off	0
3	1	45	20	0	Off	Low	900	Off	0
4	2	45	0	60	On	Medium	800	Off	0
5	1	45	10	60	On	Medium	900	Off	0
6	2	45	2	60	On	Medium	800	Off	0
7	3	45	2	60	On	Medium	800	Off	0
8	4	45	2	60	On	Medium	800	Off	0
9	5	45	2	60	On	Medium	800	Off	10
10	6	45	5	120	On	Medium	150	Off	0
11	5	N / A	1	0	Off	Medium	800	Off	0
12	0	N / A	0	0	Off	Medium	0	Off	0

13. Reagent performance

■ **Repeatability**

Under repeatability conditions where nucleic acids are extracted with the same reagent kit on the same source samples 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 the same source 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%.

■ **The stability of extracted DNA**

Storage Conditions	DNA 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**
	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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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.