TANBead® Nucleic Acid Extraction Kit

Fungi DNA Auto Tube

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

CE IVD

61FS46

(For Professional Use Only) V1

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 extract nucleic acids from wide ranges of Fungi samples such as the yeast and filamentous fungi. Fungi specimens are pre-treated with glass beads first them processed through a series of automatic extraction steps and the high-quality nucleic acids 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	Fungi specimen (OD_{600}= 1.0)
Elution Volume	90~130 µL
Typical DNA yield	1 µg
Typical A260 / A280	≥1.7

4. Component Supplied with the Kit

Σ_{96}

Auto Tube	6 trays	Auto Tube with reagent buffers
Lysis Buffer	90 mL x 1	Guanidine salt, Tris buffer, surfactants
Elution Buffer	20 mL x 1	Nuclease-Free Water
Base	2	A rack for 8 Auto Tubes
Strips	24	8-channel strip
Protocol	1	Instruction guide for user

5. Auto Tube Content

Well	Buffer	Volume (µL)
1 / 7	-	-
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	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 tube 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 Tube to air. The evaporation would lead to pH change, or effect on the extraction effectiveness.
7) Please check the integrity of the Auto Tube and remember to insert 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.
13) The reagents are all colorless and transparent. Colored reagents indicate contamination, please replace it with a fresh Tube before proceeding.

8. Materials required, Not Supplied

1) Taneda® Nucleic Acid Extraction System
   Model: SLA-16 / 32 / E13200 series (non-sterile)
2) Disposable gloves
3) Scissors, utility knives
4) Micropipette, disposable tips (10 uL / 200 uL / 1000 uL)
5) 1.5 mL microcentrifuge tube
6) 1~2 mm glass beads

9. Sample Collection, Transportation, and Storage

■ **Sample collection and storage**

1) Fungi samples can be stored at
   a. RT for 12 hours.
   b. 2~8°C up to 7 days.
   c. - 80°C long-term preservation.

■ **Specimen transportation**

Transportation of fungi specimens should follow specific transportation related law and should be kept between 2~25°C during transportation.

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 **45°C**.

1) Preparing the Assembled Auto Tubes by inserting Auto Tubes into the Base completely
2) Harvest sample by centrifugation at 5000 rpm for 5 minutes, then discard the culture medium.
3) Add appropriate amount of **100 µL glass beads (1~2 mm)** and **800 µL Lysis Buffer** the microcentrifuge tube.
4) Grind the sample by bead homogenizer equipment for 5 min.
5) Incubation at **room temperature for 5~10 min** to precipitate beads and lysate.
6) Carefully remove the aluminum foil on the Auto Tubes.
7) Use micropipette to load **800 µL lysate** into column **#1 / #7** of Auto Tube.
8) Push Auto Plates completely to the bottom of the plate rack. Make sure that the chamfer of the plate is at the lower left.
9) Push strips completely to the bottom of strip rack frame.
10) Close the door panel.
11) Select the program "**L-BNA-PK-AUTO**". The parameters are given in following section.
12) Carefully remove the Auto Tubes when the program is finished.
13) Use micropipette to transfer the purified nucleic acids from well **#6 / #12** to a clean tube.
14) Discard used Auto Tube and strips into the waste recycling bin.

11. Program

■ **SLA-16 / 32 series**

Program Name: L-BNA-PK-AUTO					Model: SLA-16 / 32 series			
Step	Well	Mixing (M)	Collect (S)	Rod	Mixing speed (RPM)	Volume (µL)	Pause	Vapor (M)
1	3	1	90	On	Medium	800	Off	0
2	2	1	0	Off	Medium	800	Off	0
3	1	10	0	Off	Low	800	Off	0
4	2	1	90	On	Medium	800	Off	0
5	1	10	90	On	Medium	800	Off	0
6	2	5	90	On	Medium	800	Off	0
7	3	5	90	On	Medium	800	Off	0
8	4	5	90	On	Medium	800	Off	0
9	5	5	90	On	Medium	800	Off	10
10	6	10	120	On	Medium	130	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: L-BNA-PK-AUTO						Model: SLA-E13200 series			
Step	Well	Temp (°C)	Mixing (M)	Collect (S)	Rod	Mixing speed (RPM)	Volume (µL)	Pause	Vapor (M)
1	3	45	1	90	On	Medium	800	Off	0
2	2	45	1	0	Off	Medium	800	Off	0
3	1	45	10	0	Off	Low	800	Off	0
4	2	45	1	90	On	Medium	800	Off	0
5	1	45	10	90	On	Medium	800	Off	0
6	2	45	5	90	On	Medium	800	Off	0
7	3	45	5	90	On	Medium	800	Off	0
8	4	45	5	90	On	Medium	800	Off	0
9	5	45	5	90	On	Medium	800	Off	10
10	6	45	10	120	On	Medium	130	Off	0
11	5	N / A	1	0	Off	Medium	800	Off	0
12	0	N / A	0	0	Off	Medium	0	Off	0

12. 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

13. 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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14. 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.