TANBead® Nucleic Acid Extraction Kit

HBV Auto Plate

(For use with the Maelstrom 8 series and Maelstrom 4800 series)

CE IVD

M615A46

(For Professional Use Only) V5

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 Extraction kit provides an effective way of viral DNA extraction from serum. This kit allows rapid and efficient purification of DNA from common viruses, especially the hepatitis B virus with low concentrations (less than 100 IU / mL). Serum specimens are processed through a series of automatic extraction steps and finally, the high-quality DNA can be applied directly to the following qualitative 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	300 µL serum or PBS suspension
Elution Volume	50~80 µL

4. Component Supplied with the Kit

96

Auto Plate	6	Auto Plate with reagent buffers
Proteinase K	1.0 mL x 1	Proteinase K
Elution Buffer	1.5 mL x 1	Nuclease-Free Water
Spin tips	96 tips	Spin tip assembled box
Protocol	1	Instruction guide for user

5. Auto Plate Content

Well	Buffer	Volume (µL)
1 / 7	Lysis Buffer	400
2 / 8	Washing Buffer 1	800
3 / 9	Magnetic Beads	800
4 / 10	Washing Buffer 3	800
5 / 11	Washing Buffer 3	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.
2) The proteinase K is transported at room temperature. Upon received, please store proteinase K at 2~8°C.

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) Do not expose the opened reagents or plates to air. The evaporation would lead to pH change or effect on the extraction efficiency.
6) The reagents are all colorless and transparent. Colored reagent indicates contamination, please replace it with a fresh plate before proceeding.
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) Carefully remove aluminum foil to avoid splashing.
10) Use sterile consumables to avoid nuclease contamination.
11) Reagent solution contains guanidine salt, avoid using bleach-containing detergent.
12) Avoid eyes, skin, and clothing contact with reagents. In case of any contact, flush with flowing water.
13) 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**

1) Serum, whole blood
   a. Serum specimens must be obtained from serum collection tubes, whole blood specimens must be obtained from sodium citrate or EDTA collection tubes.
   b. Fresh whole blood specimens can be stored at room temperature for 6 hours.
   c. After centrifugation, the serum sample can be stored at
      i. Room temperature for 24 hours.
      ii. 2~8°C up to 7 days.
      iii. -20°C for long-term preservation.

■ **Specimen transportation**

Transportation of whole blood, serum specimens should be followed by specific pathogen transportation-related laws. The whole blood sample should be kept between 2~25°C during transportation and within 6 hours for separated serum. Serum samples can be transported between 2~8°C or by freezing.

10. Nucleic Acids Extraction Protocol

1) Set up spin tips.
   Maelstrom 8 series: Handle to mount tips and make sure that there is no gap between the necks of spin tips and the spin shaft.
   Maelstrom 4800 series: Go to Tip page and press the mount tips region.
2) Pipet **300 µL serum or PBS suspension** into a 1.5 mL tube. Add **10 µL Proteinase K** and mix well. Then incubate for 10~20 min at 56°C.
3) Carefully remove the aluminum foil from Auto Plate.
4) Gently transfer **310 µL mixture** into column **#1 / #7**.
   Note: The volume ratio of mixture and lysis buffer is about 300 µL: 400 µL. Changing this ratio might affect the performance.
5) Push Auto Plates completely to the bottom of the plate rack. Make sure that the chamfer of the plate is at the lower left.
6) Select the program:
   Maelstrom 8 series: "**615-1**" or "**615-7**" for input specimen at column **#1** or column **#7**, respectively.
   Maelstrom 4800 series: "**615**"
   The parameters are given in the following section.
7) Once the program has ended, take out Auto Plate carefully.
8) Use a micropipette to transfer the purified nucleic acids from column **#6 / #12** to a clean tube.
9) Discard the used Auto Plate and spin tips into the waste recovery can.

11. Program

■ **Maelstrom 8 series**

Program Name: 615-1 / 7						
Well	**1 / 7**	**2 / 8**	**3 / 9**	**4 / 10**	**5 / 11**	**6 / 12**
Volume	800 (μL)	800 (μL)	800 (μL)	800 (μL)	800 (μL)	100 (μL)

Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temp.	Temp. Control
1	3 / 9	Mixing	3000	60	0	55	Yes
2	3 / 9	Collection	0	30	0	55	Yes
3	2 / 8	Mixing	3000	60	0	55	Yes
4	1 / 7	Mixing	3000	1200	0	55	Yes
5	2 / 8	Collection	0	30	0	55	Yes
6	1 / 7	Mixing	3000	600	0	55	Yes
7	1 / 7	Collection	0	30	0	55	Yes
8	2 / 8	Mixing	3000	120	0	45	Yes
9	2 / 8	Collection	0	30	0	45	Yes
10	3 / 9	Mixing	3000	120	0	45	Yes
11	3 / 9	Collection	0	30	0	45	Yes
12	4 / 10	Mixing	3000	120	0	45	Yes
13	4 / 10	Collection	0	30	0	45	Yes
14	5 / 11	Mixing	3000	120	0	45	Yes
15	5 / 11	Collection	0	30	0	45	Yes
16	5 / 11	Vapor	0	600	0	45	Yes
17	6 / 12	Mixing	3000	300	0	45	Yes
18	6 / 12	Collection	0	60	0	45	Yes
19	5 / 11	Mixing	3000	60	0	0	No

■ **Maelstrom 4800 series**

Program Name: 615				Model: Maelstrom 4800 series			
Temp 1	**Temp 2**						
45	40						
Well	**Name**	**Volume**	**Action**	**Mixing**	**Collect**		
1 / 7	LB	800	For.	Low	Low		
2 / 8	WB1	800	For.	Low	Low		
3 / 9	MB	800	For.	Low	Low		
4 / 10	WB3	800	For.	Low	Low		
5 / 11	WB3	800	For.	Low	Low		
6 / 12	EB	100	For.	Low	Low		
Step	**Well**	**Temp (°C)**	**Mixing (M)**	**Mixing Speed (RPM)**	**Collect (M)**	**Vapor (M)**	**Pause**
1	3 / 9	-	0.2	3000	0.5	0	Off
2	2 / 8	-	1	3000	0	0	Off
3	1 / 7	55	20	3000	0	0	Off
4	2 / 8	-	0.2	3000	0.5	0	Off
5	1 / 7	55	10	3000	0.5	0	Off
6	2 / 8	-	2	3000	0.5	0	Off
7	3 / 9	-	2	3000	0.5	0	Off
8	4 / 10	-	2	3000	0.5	0	Off
9	5 / 11	-	2	3000	0.5	10	Off
10	6 / 12	45	5	3000	1	0	Off
11	3 / 9	-	0.2	3000	0	0	Off

12. 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.

13. Reagent performance

■ **Repeatability**

Under repeatability conditions where nucleic acids are extracted with the same reagent kit on the same HBV serum 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 100 IU / mL of HBV serum 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%.

■ **Detection limit of HBV virus: ≥ 100 IU / mL**

■ **Interfering substance**

According to preclinical tests, the performance of extraction kit will not be affected by EDTA, Li-Heparin, Sodium Citrate, D-Glucose, Hemoglobin, lipoprotein and triglyceride in samples.

■ **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**
15°C 35°C	**Temperature limit**	Σ	**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.

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