



# TANBead® Nucleic Acid Extraction Kit

OptiPure Viral Auto Plate

(for use with the Maelstrom 8)



REF M665A46

(For Professional Use Only)

## 1. Intended Use

TANBead® Nucleic Acid Extraction Kit (REF M665A46) is suitable for isolate nucleic acid from various viruses. Automated nucleic acid extraction can be performed by Maelstrom 8 Autostage. Extracted nucleic acids can be analyzed by downstream application, such as real-time PCR, next-generation sequencing.

## 2. Purpose

TANBead® Nucleic Acid Extraction Kit (REF M665A46) is suitable for extract nucleic acids of various viruses, such as hepatitis C virus, hepatitis B virus and influenza virus. Samples need to be treated with proteinase K prior to automated/semi-automated nucleic acid extraction process by Maelstrom 8. Nucleic acids extracted can be analyzed in downstream application, such as real-time PCR. With high sensitivity, this reagent kit can be applied for clinical diagnostics and research.

## 3. Principle

The silicon dioxide layer coated on the magnetic beads can adsorb negative charged molecules in order to purify nucleic acid from samples.

**Sample Types:** 300 µl serum or PBS suspension

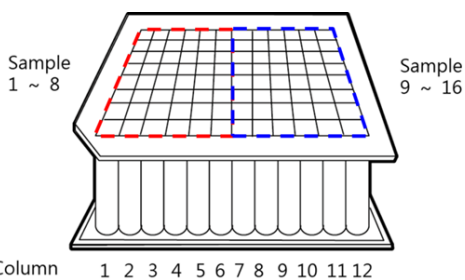
**Suitable Instrument:** Maelstrom 8 Autostage

## 4. Reagent Components

REF M665A46		96 Assays
Auto Plates	6	96 well plate with reagent buffers
Elution Buffer	1.5 ml	Nuclease-Free Water
Proteinase K	1 ml	20 mg/ml Proteinase K, store at 4°C
Spin tips	96	Spin tip
Protocol	1	Instruction guide for user

### Auto Plate Content

Column	Buffer Solution	Volume
1/7	Lysis Buffer	600 µl
2/8	Washing Buffer 1	800 µl
3/9	Washing Buffer 2	800 µl
4/10	Washing Buffer 2	800 µl
5/11	Magnetic Beads	800 µl
6/12	Elution Buffer	80 µl



## 5. Storage and shelf life

- Components under room temperature (15-35 °C) can be stored until the expiration date labeled on the box.
- The proteinase K is transported at room temperature. When received, please store proteinase K at 4°C.

## 6. Precautions

- It can only be used for in vitro diagnostic.
- Avoid using expired reagents.
- When the temperature is below 20°C, place the reagent plate in an oven (preheated 42 - 60°C) 5 to 10 minutes.
- Avoid vigorous shaking, in order to avoid excessive formation of foam.
- Do not exposure opened reagent or plate to air. The evaporation would lead to pH change, or influence the extraction effectiveness.
- Reagents are all colorless and transparent. Colored reagent

indicate contamination, please replace a fresh plate before proceeding.

- Before use, please check the integrity of the reagent plate, and remember to mount the spin tips into the appropriate position.
- Please wear a mask and disposable gloves when handling.
- Remove aluminum foil carefully to avoid splashing.
- Use sterile consumables to avoid nuclease contamination.
- Reagent solution contains guanidine salt, avoid using bleach containing detergent.
- Avoid eyes, skin and clothing contact with reagents. In case of any contact, flush with flowing water.
- If any serious incident that has occurred, please report to manufacturer and the competent authority of the member state in which the user and/or the patient is established.

## 7. Provided Materials

- TANBead® Nucleic Acid Extraction Kit
  - Auto Plates
  - Proteinase K
  - Elution Buffer
  - Spin tips

## 8. Required but not provided

- TANBead® Nucleic Acid Extraction System Model: Maelstrom 8 Autostage(non-sterile)
- Disposable gloves
- Scissors, utility knives
- Micropipette, disposable tips (10µl / 200 µl / 1000 µl)
- 1.5 ml microcentrifuge tube

## 9. Sample collection, transport, storage and pre-treatment

### ■ Sample collection and storage

- Serum, whole blood

I. Serum specimens must be obtained from serum collection tubes, whole blood specimens must be obtained from sodium citrate or EDTA collection tubes.

II. Fresh whole blood specimen can be stored at RT for 6 hrs.

III. After centrifugation, the serum sample can be stored at

- RT for 24 hours
- 2-8°C up to 7 days
- 20°C long-term preservation

### ■ Specimen transportation

Transportation of whole blood, serum specimen should follow specific pathogen transportation related law. Whole blood sample should be kept between 2-25°C during transportation and separate serum within 6 hrs. Serum sample can be transport between 2-8°C or by frozen.

## 10. Nucleic acid extraction protocol

- Carefully remove the aluminum foil on the Auto Plate.
- Add **300 µl serum** or **PBS suspension** and **10 µl Proteinase K** into column **#1/ #7** of Auto Plate.

**Note:** The volume ratio of mixture and lysis buffer is about 300 µl : 600 µl. If it is changed, it might affect the performance.

- Mount spin tips on Maelstrom 8.
- Place Auto Plate to the plate holder of Autostage. Make sure that the missing corner of base faces toward the lower left.
- Select a program "665-1/7" The parameters are given in following section.
- When the program ends, take out the Auto Plate carefully.
- Use micropipette to transfer the purified nucleic acid from column **#6/ #12** to a clean tube.

- 8) Discard used Auto Plate and spin tips into the waste recovery can.

## 11. Program

Program Name:665-1/7					
well 1/7	well 2/8	well 3/9	well 4/10	well 5/11	well 6/12
900 (μl)	800 (μl)	800 (μl)	800 (μl)	800 (μl)	100 (μl)

Step	Well	Action	RPM	Time (Second)	CW/CCW (Second)	Temperature	Temperature Control
1	5/11	Collection	0	30	0	60	YES
2	1/7	Mixing	3000	480	0	60	YES
3	1/7	Collection	0	30	0	60	YES
4	2/8	Mixing	3000	60	0	45	YES
5	2/8	Collection	0	30	0	45	YES
6	3/9	Mixing	3000	60	0	45	YES
7	3/9	Collection	0	30	0	45	YES
8	4/10	Mixing	3000	60	0	45	YES
9	4/10	Collection	0	30	0	45	YES
10	4/10	Vapor	0	300	0	45	YES
11	6/12	Mixing	3000	300	0	45	YES
12	6/12	Collection	0	30	0	45	YES
13	5/11	Mixing	3000	60	0	0	NO

## 12. Result

### • Qualitative Analysis

A specific gene fragments can be amplified from nucleic acid products isolated from TANBead® nucleic acid extraction kit by PCR (Polymerase Chain Reaction) or RT-PCR (Reverse Transcription-PCR). This kit can work with different molecular biology reagents, and apply for verity of molecular diagnosis.

Result: Please refer to PCR or RT-PCR molecular diagnostic kit manual

### • Quantitative analysis

Nucleic acid product purified by TANBead® nucleic acid extraction kit can perform quantitative analysis of specific genes by Q-PCR (Quantitative real time Polymerase Chain Reaction) or qRT-PCR (Quantitative Reverse Transcription PCR). Can be used for detecting viral load or bacterial load and other molecular detection analysis.

Results: Please refer to the Q-PCR or qRT-PCR molecular diagnostic kit manual.

## 13. Reagent performance

### • Repeatability

Under repeatability conditions where nucleic acids are extracted with the same reagent kit on the same HCV 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 HCV 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 HCV virus:  $\geq 100$  IU/ml

### • Interfering substance

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

### • The stability of extracted DNA/RNA

Storage Conditions	DNA/RNA 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



Lot: As indicated on pack label

Shelf life: As indicated on pack label

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