DNA&RNA Extraction Kit Instruction Manual

【Product Name】 DNA&RNA Extraction Kit

【Specification】 BRG-03 (magnetic bead method):96T

【Intended Use】The kit is intended for nucleic acid extraction, enrichment, purification, and other steps. The kit can quickly extract DNA/RNA of pathogens such as viruses, protozoa, bacteria, fungi and helminth from various liquid samples such as serum, plasma, urine, throat swabs, genital tract swabs, stool samples, liquefied washed sputum, blood (in the case of blood, centrifugation is necessary). The extracted nucleic acid is stable, and it can be used in various routine molecular diagnostic tests. The processed product is used for clinical in vitro detection.

【Principle of Detection】 This kit extract, enrich and purify DNA and RNA in specimens using magnetic bead technology. The nucleic acids in the specimen are combined with the magnetic particles in the buffered condition, and then gathered, transferred, dispersed in the presence of external magnetic fields, in order for the extraction and separation of the nucleic acids.

Kit Contents	
Pre-filled 96 Deep-well Plate 1 (Lysis Buffer)	1
Pre-filled 96 Deep-well Plate 2 (Washing Buffer A)	1
Pre-filled 96 Deep-well Plate 3 (Washing Buffer B)	1
Pre-filled 96 Deep-well Plate 4 (Eluent)	1
Mixing Sleeves	1
Instruction Manual	1

【Storage and validity】 The kit should be stored at room temperature (0-30℃) and are stable for 12 months.

【Instrument】TANBead Maelstrom 9600.

【Sample】

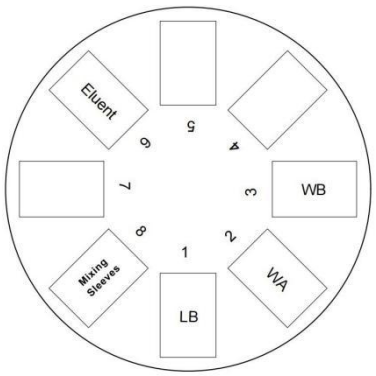
1. Sample type: serum, plasma, urine, human nasopharyngeal swabs, genital tract swabs, stool samples, liquefied washed sputum, blood (In the case of blood, centrifugation is necessary).

2. Sample storage: Do not exceed 24 hours at a temperature of 2~8 °C; In case of long-term storage, it must be stored in a refrigerator below -70 °C. Avoid defrosting and freezing too often. Specimens must be sealed in a foam box with ice packs for transport.

【Protocol】

A. Add 300μl sample to the columns of Pre-filled 96 Deep-well Plate 1(Lysis Buffer).

B. Put the Mixing Sleeves and the plates in the instrument according to the picture beside, align A1 well of the 96 deep-well plate with A1 mark on the plate position of the instrument.If the plate positions 1 and 6 do not have a heating plate in the TANBead Maelstrom 9600, that the lysis and elution plates should be placed on the positions with heating plates.



C. Set up a new program named **"Bioreal-GlobalX"** according to the table below and run the program.

Program Name: Bioreal-GlobalX								
Plate	1	2	3	4	5	6	7	8
Volume(μl)	650	650	650			100		
Keep Temp.	70	-	-			70		
Action	For.	For.	For.			For.		
Name	Lysis Buffer	Wash Buffer A	Wash Buffer B			Elution Buffer		Mixing Sleeves

Step	Plate	Temp.	Mixing(min)	Mixing(rpm)	Collect(sec)	Vapor(min)	Pause
1	1	70	8	2000	60	0	OFF
2	2	0	1	2000	60	0	OFF
3	3	0	1	2000	60	1	OFF
4	6	70	2	2000	90	0	OFF
5	2	0	0.1	2000	0	0	OFF

Note: The extraction protocol allows the automated procedure to be performed in a maximum of 30 minutes.

D. When the program is finished, extract the extraction product from the Pre-filled 96 Deep-well Plate 4 (Eluent) to 1.5ml DNase&RNase-free tubes(not included in the kit) for amplification experiment like real-time PCR. The used 96 deep-well plates and Mixing Sleeves shall be disposed of as medical waste.

E. There may be residual magnetic beads in the pre-filled 96 deep well plate 4 (eluent) due to differences between instruments. It is necessary to extract the product from the pre-filled 96 deep well plate 4 (eluent) into nuclease-free tubes and centrifuge for 3 minutes at 12,000 rpm. Alternatively, the magnetic absorption time of the instrument can be appropriately extended.

F. After the experiment, wipe the inside of the instrument with 75% alcohol and a soft cloth, close the door of the instrument and open the ultraviolet ray for disinfection for more than 30 minutes.

【Limitations】

1. The extraction kit is intended for clinical diagnostic samples, forensic materials and scientific research samples. The concentration and purity of its extraction product are affected by instruments and operators.

2. The extraction kit possesses a special elution buffer, which will affect the absorbance value for the UV-visible spectrophotometer. Therefore, it is not recommended to directly measuring to the concentration and purity of extraction product by UV-visible spectrophotometer.

3. It is recommended to use qPCR, membrane hybridization, and ordinary amplification to obtain satisfactory results.

【Performance】

1. The extraction kit can high-efficiency extract nucleic acids from Swab lotion, serum, plasma, sputum, virus preservation solution samples, especially low-abundance samples.

2. The coefficient of variation (CV) of intra-assay and inter-assay for the extraction kit is less than 3%.

3. The extraction kit can extract 1~96 samples simultaneously via Nucleic Acid Extraction System, and the experiment results show good repeatability.

4. Simultaneous extraction of pathogen DNA and RNA, simple and convenient, no organic solvents.

【Notes】 Please read the following notes before using the kit.

1. This kit is prefabricated Proteinase K in the reagent component (found in the Pre-filled 96 Deep-well Plate 1). When using the kit, testers do not need to manually add Proteinase K, and the reagent can be stored and transported at room temperature(0~30℃).

It can shorten the experimental time, reduce the workload of testers, improve the detection efficiency. According to real-time stability verification and the experiment data above, it can still ensure the excellent performance of the reagent during the effective period.

2. The extraction kit is also used for viral DNA/RNA isolation; therefore, all of experiment supplies, such as pipettes, tubes, tips, must be autoclaved. Operator should wear gloves and masks.

3. In the manual method experiment, there may be liquid in the tube cap after vortex shaking, and instant centrifugation is needed before opening the cap to prevent cross-contamination.

4. Before using the kit, please read the manual and strictly follow the protocol. Clinical samples should be processein biosafety cabinet.

5. Do not use components and reagents from different batches.

6. For the extraction of pathogens in blood samples, it is necessary to obtain serum and plasma by centrifugation for experiments. It is not allowed to directly add whole blood for experiments. There are cases of incomplete washing.

7. In the manual extraction of Magnetic Beads, depending on the sample, there will be a "clumping" phenomenon in the Magnetic Beads, which can be dispersed by vortexing.

【Manufacturing Info】

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【Graphical Symbols】

IVD In vitro diagnosis Medical devices
Manufacturer
CE CE Mark
Consult Instruction for Use
EC REP Authorized representative in the European Community
Indicates the date after which the medical device is not to be used.
LOT Batch code
Temperature limit
Date of manufacture