



Multi-type Sample DNA/RNA Extraction-Purification Kit (magnetic beads method)
Instructions for use

[Product Name] Multi-type Sample DNA/RNA Extraction-Purification Kit (magnetic beads method)

[Specification] 24 reactions/kit,32 reactions/kit,48 reactions/kit, 64 reactions/kit,96 reactions/kit

[Intended Use]

The kit is used for nucleic acid extraction, enrichment, purification. The products processed can be used for clinical in vitro testing.

[Principle of Inspection]

The kit adopts magnetic beads and buffer system with unique isolation function, which is fast, highly sensitive and effective in extracting viral DNA and RNA from specimens. The high efficient virus cleavage component will destroy virus shell and release nucleic acid into buffer system. Special coated magnetic beads in the buffer system has a strong affinity to the target nucleic acid, and when conditions change, magnetic bead release the adsorbed nucleic acids. The washing system can remove impurities such as protein and small molecules in solution, which can achieve the purpose of rapid nucleic acid separation and purification, and simultaneously does not use toxic reagents such as chloroform.

[Main Components]

Component	24 reactions/kit	32 reactions/kit	48 reactions/kit	64 reactions/kit	96 reactions/kit	main components
Lysis Solution AL	14.4mL	19.2mL	28.8mL	38.4mL	57.6mL	salt solution
Lysis Solution B	480uL	640uL	960uL	1280uL	1920uL	Protease K
Washing liquid W1	12mL	16mL	24mL	32mL	48mL	high-concentration salt solution
Washing liquid W2	12mL	16mL	24mL	32mL	48mL	high-concentration salt solution
Eluent EB	2.4mL	3.2mL	4.8mL	6.4mL	9.6mL	Tris buffer, EDTA
Magnetic beads B	7.2mL	9.6mL	14.4mL	19.2mL	28.8mL	hydroxyl silica magnetic beads

Note: Reagents of different batches are not allowed to be cross-used.

[Storage and Stability]

The Lysis Solution B should be stored at 2 ~ 8℃ and other components should be sealed at room temperature. The validity of the kit is 12 months.

Note: Please refer to the product label for production date and expiration date.

[Applicable Instrument]

The kit is suitable for BIOBASE nucleic acid extraction instrument or other nucleic acid extractors based on magnetic bead adsorption principle..

[Specimen Requirements]

Suitable specimen types: oral swab, nasal swab, saliva, serum, plasma, lymph, allantoic fluid, semen, acellular fluid, cell culture supernatant or other liquid specimens.

The collection of specimens shall refer to the common collection methods of medical specimens and be stored in a sterile RNase free centrifuge tube for extraction. Non-liquid specimens containing virus - can be liquefied and applied to this kit In liquid form.

Specimen storage and transport: The processed specimens can be immediately used for testing, or stored at -20±5℃(3 months), long-term storage should be placed below -70℃.Repeated freezing and thawing should be avoided. The specimens shall be transported in sealed curling or foam containers with dry ice.

[TEST PROCEDURE]

1. Remove the pre-packaged 96-well plate from the kit.
2. The magnetic beads were suspended by oscillating the 4 angles of the 96-well plate with a vortex oscillator.
3. Carefully tear off the 96-well plate aluminum foil sealing to avoid the vibration of the well plate and prevent the liquid from splashing out.
4. 20μl Lysis Solution B and 200μl of sample were added to the hole containing Lysis Solution AL.
5. Put the 96-well plate and plastic sleeve into the corresponding position of the instrument and run the program.
6. After the extraction procedure is completed, the liquid in Eluent EB well is the DNA/RNA solution of the specimen, which can be used for analysis experiments or stored at - 20 ℃.

[Limitations of inspection methods]

Specimen test results are related to the quality of specimen collection, processing, and preservation, and any errors will result in inaccurate results. If cross-contamination is not properly controlled during operation, false-positive results may occur.

【Performance Characteristics】















1. Accuracy
The test result for the positive nucleic acid reference extract should be positive, and the test for the negative nucleic acid reference extract should be negative.
2. Precision
The precision within the batch should conform to the coefficient of variation of the Ct value (CV%) ≤5%.
3. Interfering substances
When the triglyceride concentration in the specimen ≤300 mg/dL, the bilirubin concentration ≤10 mg/dL, the hemoglobin concentration ≤200 mg/dL, the total protein ≤10 g/dL and the IgG ≤1 g/dL, the interference deviation of the test results should be within ±10%.

【Cautions】

- 1 When the kit is taken out from a refrigerated environment for use, it is best to let it stand at room temperature for 10 minutes before adding the specimen.
- 2 Because the tested specimen may contain viruses, although it is generally not biologically contaminated after being lysed by the kit, it still needs to be treated as biologically contaminating, and various protective measures must be prepared before operation.
- 3 Use centrifuge tubes, pipettes, tip heads, reagents and gloves that do not contain DNA and RNase, and workers wear masks for operation.
- 4 Magnetic beads B must be thoroughly mixed before use.
- 5 Wear latex gloves and glasses when handling, to avoid skin, eyes and clothing contaminated, and avoid inhalation of the mouth and nose. If it is contaminated with skin or eyes, immediately rinse with plenty of water or saline, and seek medical advice if necessary.

【Index of CE Symbols】

	Use-by date		Consult instructions for use
--	-------------	--	------------------------------

	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	CE mark		Authorized representative in the European Community
	Catalog number		Contains sufficient for <n> tests
	Please don't reuse it		Biological risks
	Upper		Keep dry
	Date of manufacture		Avoid overexposure to the sun


Biobase Biotechnology (Shandong) Co., Ltd.

Address: Biobase Biotechnology Park, Crossing of East Jingshi Road and Mingbu Road, Mingshui
Economic Development Zone, Zhangqiu, Jinan, Shandong, China.


Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Tel: +31644168999 Email: peter@lotusnl.com

Instruction Approval and Revision Date

Approval Date: 2020.08.26

Revision Date: 2021.06.24