Glossary of Symbols

Symbol	Meaning	Symbol	Meaning
IVD	*In vitro* diagnostic medical device		Temperature limit
	Manufacturer		Use-by date
	Date of Manufacture		Do not re-use
LOT	Batch code		Consult instructions for use
EC REP	Authorized representative in the European Community / European Union	CE	CE Symbol
	Caution	UDI	Unique device identifier
REF	Catalogue number		Do not use if package is damaged and consult instructions for use

Basic Information

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EC REP
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Version: A/1 **Effective Date:** 2022-06-24

CE IVD

Version: A/1

Viral DNA/RNA Kit
Instructions for Use

Packaging Specifications

50 tests/box; 200 tests/box

Intended Use

It is used for nucleic acids isolation, enrichment and purification. The processed products can be used for clinical diagnosis *in vitro*.

Test Principle

Viral DNA/RNA Kit provides a simple, rapid and efficient method to extract DNA/RNA from whole blood, tissue homogenate, swab, serum, plasma, bronchoalveolar lavage fluid and other cell-free body fluids. The unique buffer system enables the nucleic acid in the lysate to be efficiently and specifically adsorbed onto the silica membrane adsorption column. The obtained nucleic acid has high purity, stable quality, and is free of protein, nuclease and other contaminants and inhibitors. It can be applied to various conventional operations, including PCR, fluorescence quantitative PCR and other experiments.

Components of the Kit

Name	50 tests/box	200 tests/box	Main contents
Lysis Buffer	15 mL/bottle×1	60 mL/bottle×1	Guanidine Hydrochloride, NaCl, SDS, Tris-HCl
Washing Buffer 1	15 mL/bottle×1	60 mL/bottle×1	Guanidine Hydrochloride, NaCl, Tris-HCl, Absolute ethanol
Washing Buffer 2	7.5 mL/bottle×1	30 mL/bottle×1	NaCl, Tris-HCl, Absolute ethanol
RNase-Free Water	10 mL/bottle×1	25 mL/bottle×1	
Adsorption Columns	50/package×1	50/package×4	
Collection Tubes	50/package×1	50/packagee×4	

Materials and Equipment Required but Not Provided

Constant temperature mixer, Centrifuge, Isopropanol/ Ethanol, Proteinase K (Whole blood and tissue homogenate required, but not provided)

Storage Condition and Shelf Life

Manufacturing and expiration dates are printed on the label.
The kit can be stored at 4-37°C up to 18 months.
It is recommended to transport at 4-37°C for no more than 30 days.

Specimen Collection, Handling, and Storage

● Swab, serum, plasma, bronchoalveolar lavage fluid and other cell-free body fluids (proteinase K not required)
● Whole blood, tissue homogenate (proteinase K required, but not provided)

Reagent Preparation

1. Washing Buffer 1 and Washing Buffer 2 are supplied as concentrates. Before using for the first time, add the appropriate amount of isopropanol or 100% ethanol as indicated on the bottle to obtain a working solution. If added， please mark on the label.
2. Mix all the reagents and invert 3-5 times before use.

Procedure

1. Add 200 µL sample (Equilibrate samples to room temperature) and 200 µL Lysis Buffer to 1.5 mL centrifugal tube (supplied by user).

   Note: For wet swab sample, mix it thoroughly and take 200 µL. For dry swab sample, soak it in 400 µL normal saline and mix well, let stand for 5 minutes, centrifugate at 12,000 rpm for 1 minute, and take 200 µL.

   1.1 If sample is whole blood or tissue homogenate sample, need to add 20 µL, 20 mg/ml of the Proteinase K solution to 1.5 mL centrifugal tube (supplied by user).

   1.2 If sample is serum, plasma, bronchoalveolar lavage fluid and other cell-free body fluids, Proteinase K solution is not required.
2. Vortex for 5 seconds, then shake 5 minutes with a constant temperature mixer of 1200 rpm at 80°C.
3. Add 300 µL Isopropanol/ Ethanol to 1.5 mL centrifugal tube, vortex for 5 seconds, briefly centrifuge, transfer solution to Adsorption Columns, centrifuge at 12,000 rpm (~ 13400×g) for 1 minute, and discard the liquid in Collection Tubes, then place the Adsorption Column back into the Collection Tube.
4. Add 500 µL Washing Buffer 1 to Adsorption Column, centrifuge at 12,000 rpm for 1 minute, and discard the liquid in Collection Tubes, then place the Adsorption Column back into the Collection Tube.
5. Add 500 µL Washing Buffer 2 to Adsorption Column, centrifuge at 12,000 rpm for 1 minute, and discard the liquid in Collection Tubes, then place the Adsorption Column back into the Collection Tube.
6. Centrifuge at 12,000 rpm for 2 minutes, place the Adsorption Column to new Collection Tube. Open the cap of Adsorption Column and place it at room temperature for 2 minutes to dry.
7. Add 40-100 µL RNase-Free Water to the middle of Adsorption Column, place it at room temperature for 2 minutes, centrifuge at 12,000 rpm for 1 minute, collect nucleic acid solution. Store nucleic acid solution at -80°C for prolonged preservation.

GHS07

H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

Warnings and Precautions

1. For *in vitro* diagnostic use (IVD) only.
2. This product is intended for professional use only.
3. Check the package before use it. If damaged, it is strictly prohibited to use.
4. DO NOT drink, touch or remove the reagent from the vial.
5 Avoid reuse.
6. If any serious incident that has occurred in relation to the product shall be reported to the manufacturer and the competent authority.
7. If there is crystal precipitation in Lysis Buffer, please dissolve and mix it in a 56°C water bath/oven before use.