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FastPure Viral DNA/RNA Mini Kit
Instruction for Use (Version 1.0)

PRODUCT NAME
FastPure Viral DNA/RNA Mini Kit

CATALOG NUMBER & SIZE

CATALOG	SIZE
RC312-01	50 tests/kit
RC312-02	100 tests/kit

INTENDED USE
This product is used for the steps of nucleic acid extraction, enrichment and purification. This kit is applicable for extracting highly pure viral nucleic acid (DNA/RNA) from samples such as human nasopharyngeal swabs, sputum, broncho lavage fluid and alveolar lavage fluid. The obtained nucleic acid can be used in the clinical in vitro testing.

PRINCIPLE
Based on the technology of purification of silica gel column. The nucleic acid could be absorbed on filter membrane by the hydrogen bond and electrostatic interaction, while protein and other impurities cannot be absorbed. The isolation of total nucleic acid with high purity, free of protein and other impurities, and can be used in various downstream experiments such as Reverse Transcription, PCR, RT- PCR, Real-Time PCR, Next Generation Sequencing and Northern Blot.

PRODUCT CONTENTS

Components	50 tests	100 tests	Main Ingredient
Lysis Solution	18 mL	36 mL	Trimethylolaminomethane, Ethylene diamine tetraacetic acid, Guanidine isothiocyanate
Washing Buffer	15 mL	30 mL	Trimethylolaminomethane
Elution Buffer	3 mL	6 mL	Nuclease-free water
Adsorption Columns	50 tubes	100 tubes	Polypropylene, Silica membrane
Collection Tubes (2 mL)	50 tubes	100 tubes	Polypropylene
Collection Tubes (1.5 mL)	50 tubes	2 x 50 tubes	Polypropylene

Note:
1. Additional Materials Required: RNase-free tips, 1.5 mL of RNase-free tubes, centrifuges. vortexer, pipette, absolute ethanol.
2. Do not mix the components from different batches for detection.
3. Before using for the first time, add the appropriate volume of ethanol (96%–100%) as indicated on the bottle to the Lysis Solution and Washing Buffer, shake thoroughly to obtain a working solution.
4. Please wear lab coats, disposable latex gloves, disposable masks and apply Nuclease-free consumables, etc. in the use of this kit, to avoid RNase contamination to the greatest extent.

STORAGE & SHELF LIFE
All components should be stored and transported at room temperature (15 ~ 25°C). The reagents are stable for 12 months when stored at the recommended condition.

SAMPLING & HANDLING
1. The collection, transportation and storage of samples comply with relevant operating specifications.
2. The collected specimen should be used for detection within the same day. Otherwise, please store the specimen as follows:
Store at 2 ~ 8°C for no more than 24 hours;
Store at < -20°C for no more than 10 days;
Store at < -70°C for long-term, avoiding repeated freeze-thaw cycles.

PROTOCOL

PREPARATION
1. Additional Materials Required: RNase-free tips, 1.5 mL of RNase-free tubes, centrifuges, vortexer, pipette, absolute ethanol.
2. Before using for the first time, add the appropriate volume of ethanol (96%–100%) as indicated on the bottle to the Lysis Solution and Washing Buffer, shake thoroughly to obtain a working solution.
3. The Lysis Solution may precipitate when stored at low temperature. Dissolve at room temperature for a while, or preheat at 37°C if necessary to thaw the precipitation and mix thoroughly before use.

PROTOCOL 1
Using Vazyme Virus Sample Stabilizer for specimen collection, please refer to the protocol as follows:

INACTIVATION TREATMENT
Even though Sample Stabilizer can inactivate the virus, but it is still recommended to do a complete heat inactivation of SARS-CoV-2 by incubate the specimen at 56°C for 30 min and balance at room temperature for 10 min avoiding aerosols;

EXTRACTION
1. Aliquot 200 µl of absolute ethanol to a new 1.5 mL of RNase-free tube, (additional consumable).
2. Add 500 µl of the above sample stabilizer to the tube containing absolute ethanol, then mix thoroughly by inverting the tube.
3. Place the Adsorption Column in a 2 mL of Collection Tube and transfer the mixture to the Adsorption Column, cover the tube cap then centrifuge at 12,000 × g for 1 min.
4. Discard the filtrate and reuse the Collection Tube. Add 600 µl of Washing Buffer (**Make sure absolute ethanol has been added**) to the Adsorption Column, and centrifuged at 12,000 × g for 30 sec, discard the filtrate.
5. Repeat **Step 4** once.
6. Place the Adsorption Column in the 2 mL Collection Tube (reused), centrifuge empty Adsorption Column at 12,000 × g for 2 min.
7. Transfer the Adsorption Column to a new 1.5 mL Collection Tube (provided in the kit), add 50 µl of Elution Buffer. Incubate at room temperature for 1 min, centrifuge at 12,000 × g for 1 min.
8. Discard the Adsorption Column, the eluted DNA/RNA can be used directly in downstream experiments or stored at -20°C for short-term storage, or stored at -70°C for long-term storage.

PROTOCOL 2
Using specimen collection products from other companies, please refer the protocol as follows:

INACTIVATION TREATMENT
Further inactivation treatment should be taken as required before extraction. For heat inactivation of SARS-CoV-2, it is recommended to incubate at 56°C for 30 min, and balance at room temperature for 10 min avoiding aerosols.

EXTRACTION
1. Aliquot 500 µl of Lysis Solution to a new 1.5 mL of RNase-free tube (additional consumable).
(For multiple samples, it is recommended to dispense into each tube.)
2. Add 200 µl of sample to the tube containing Lysis Solution (**Make sure absolute ethanol has been added**), then mix thoroughly by vortex.
(If the sample is less than 200 µl, make up to 200 µl with sterile saline solutions).
3. Place the Adsorption Column in a 2 mL of Collection Tube and transfer the mixture to the Adsorption Column, centrifuge at 12,000 × g for 1 min.
4. Discard the filtrate and reuse the Collection Tube. Add 600 µl of Washing Buffer (**Make sure absolute ethanol has been added**) to the Adsorption Column, and centrifuged at 12,000 × g for 30 sec, discard the filtrate.
5. Repeat **Step 4** once.
6. Place the Adsorption Column in the 2 mL Collection Tube (reused), centrifuge empty Adsorption Column at 12,000 × g for 2 min.

7. Transfer the Adsorption Column to a new 1.5 mL Collection Tube (provided in the kit), add 50 μl of Elution Buffer. Incubate at room temperature for 1 min, centrifuge at 12,000 × g for 1 min.
8. Discard the Adsorption Column, the eluted DNA/RNA can be used directly in downstream experiments or stored at -20°C for short-term storage, or stored at -70°C for long-term storage.

ANNEXE

For the situation without Sample Stabilizer, the swab should be immersed in the saline solution. Then please refer to **PROTOCOL 2** for the extraction operation.

But, SARS-CoV-2 is infectious! It is recommended to place the swab in the Preservation solution which contains the inactivation reagent for Virus.

PRECAUTIONS

1. Inspectors should be Professionally trained. Please read the instructions of the kit carefully before the experiment, and strictly follow the operation steps.
2. Pay attention to protection when handling reagents and samples, and disinfect thoroughly after handling.
3. All samples must be treated as potential sources of infection.
4. Avoid repeated freezing and thawing of samples, otherwise the extracted viral nucleic acids will be degraded and the amount of extraction will decrease.
5. This reagent is for in vitro diagnostic use only.

CONTACT

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DATE OF APPROVAL AND MODIFICATIONOF INSTRUCTION

April 4th, 2020

DATE OF MANUFACTURE AND EXPIRATION

See packaging

Symbols

EC REP	Authorized Representative
IVD	For in vitro diagnostic use only
15 °C – 25 °C	Store between 15~25°C

Σ	Tests per kit
REF	Catalog #
LOT	Lot Number

	Manufacturer
	Expire Date
	Consult instructions for use

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IVD CE

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