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Chapter 2.3

Instructions for Use

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SHANGHAI ZJ BIO-TECH CO., LTD

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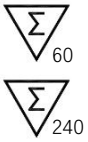
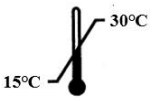
Viral RNA Isolation Kit (Preloaded for Auto-Extraction)

Instructions for Use

REF ME-0044

ME-0045





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Intended Use

Viral RNA Isolation Kit (Preloaded for Auto-Extraction) utilizes magnetic particle technology for isolation and purification of pathogen's nucleic acids from biological specimens.

This kit can be used in combination with automated nucleic acid extraction systems. The product is intended to be used by professional users, such as technicians and physicians who are trained in molecular biological techniques.

Viral RNA Isolation Kit (Preloaded for Auto-Extraction) is intended for *in vitro* diagnostic use.

Procedure Overview

With the effect of lysis buffer, the nucleic acids of pathogen were released and combined to Magnetic Cap. Then the Magnetic Cap with nucleic acids was transferred into washing buffer, proteins and other impurities were washed away. After that, Magnetic Cap was transferred into elution buffer, nucleic acids were eluted and transferred into centrifuge tube. It takes about 20 minutes to extract 36 samples at a time using this kit.

Note that this procedure recovers total nucleic acids, so if cells are present in the sample, cellular RNA/DNA will be recovered along with the viral RNA/DNA.

Materials Provided

(Kit Components)

Component	Amount		Property
	ME-0044 (60 preps)	ME-0045 (240 preps)	
Preloaded Plate （MVR01）†	5 pieces	20 pieces	It contains Lysis buffer, Washing buffer, Elution buffer and RNA Binding Beads.
Magnetic Cap	5 strips	20 strips	Polypropylene
Proteinase K	1.3 mL×1	1.3 mL×4	Protein
Carrier RNA §	1 tube	1 tube×4	Protein
Carrier RNA Buffer	600 µL×1	600 µL×4	Tris buffer

Do not make Preloaded Plate frozen.

Lyophilized Carrier RNA can be stored at room temperature(15°C–30°C) until the expiration date on the kit box. Add 500 µL of Carrier RNA Buffer to each vial of lyophilized Carrier RNA and mix well before use. Once Carrier RNA Buffer has been added into Carrier RNA, this Carrier RNA solution should be divided into conveniently sized aliquots which can be stored at 2℃～8℃ for 6 months or -20℃ for 2 years. The maximum number of freezing and thawing is 2.

Materials Required but not Provided

(Equipment and Reagents to Be Supplied by User)

1. Automated Nucleic Acid Extraction Instrument

After the samples and reagents added, place the Preloaded Plate in the Automatic Nucleic Acid Extraction Instrument, choose the correct extraction procedure (RNA Isolation 2), and the instrument will automatically complete the extraction of nucleic acids from different types of samples such as plasma, serum, swabs (nasopharyngeal and oropharyngeal swab) and Sputum. The product should be used only with the Automated Nucleic Acid Extraction Instrument shown as follows from Liferiver.

Figure 1. Automated Nucleic Acid Extraction Instrument (Liferiver, Cat. No. ZJYY-D-10019E), used with nucleic acid extraction reagents.

2. Centrifuge(with rotor for 2 ml tubes)

3. Silicone Cover (Liferiver, Cat. No. OHC0143)

4. Pipettes (adjustable)

5. Sterile pipette tips (pipette tips with aerosol barriers are recommended to help prevent cross-contamination)

6. 1.5 mL DNase/RNase-free tubes

7. Vortex mixer

8. Normal Saline

Warnings and Precautions

1. Before working with RNA extraction, it is always a good idea to clean and disinfect the workbench before starting the experiment.

2. Wear laboratory gloves, which can protect you from the reagents and can protect the RNA from nucleases that are present on skin, for this procedure.

3.Use RNase-free filter pipette tips and tubes to handle the kit reagents, and avoid putting used tips into the reagent con6tainers.

4. Biological cabinet (negative pressure) or anti-contamination cover should be used during

experimental operation in order to prevent environmental contamination.

5. This experiment needs to be carried out by skilled operator.

6. Regularly clean and disinfect workbench and pipettes with 10% hypochlorous or 75% ethanol, and use UV lamp or ozone to disinfect them for half an hour to one hour.

7. The reagents should be mixed at room temperature before using.

8. Don't mix up reagents of different lots. The kit shall be used within shelf-life period.

9. Improper transportation and storage of clinical samples may lead to poor extraction efficiency or even failure.

10. If reagents spill on skin, rinse with water immediately please.

11. All containers, reagent bottles, package and the remaining samples should be disposed of as medical waste.

12. If serious adverse events occur during use, please contact the manufacturer or the relevant competent authority, which is one of the Member State where the user is based.

Reagent Storage and Handling

1. Do not make Preloaded Plate(†)frozen.

2. Lyophilized Carrier RNA (§) can be stored at room temperature(15℃–30℃) until the expiration date on the kit box. Add 500 μL of Carrier RNA Buffer to each vial of lyophilized Carrier RNA and mix well before use. Once Carrier RNA Buffer has been added into Carrier RNA, this Carrier RNA solution should be divided into conveniently sized aliquots which can be stored at 2℃～8℃ for 6 months or -20℃ for 2 years. The maximum number of freezing and thawing is 2.

3. Store at room temperature(15℃–30℃). The shelf life of the kit is 2 years. Both date of manufacture and the expiry date are indicated on the packaging.

Applicable Specimen Storage and Handling

1. Applicable Specimen

The applicable specimens of the kit are as follows: plasma, serum, sputum, nasopharyngeal and oropharyngeal swab.

2. Plasma

Collect 4 mL whole blood into commercially available anticoagulant-treated tubes (Non-heparin anticoagulation). Cells are removed from plasma by centrifugation at 1000 g for 20 minutes at room temperature or by deposition at 4 ℃ for half an hour to one hour. The resulting supernatant is designated plasma. Transfer the liquid component (plasma) into a clean sterilization tube.

3. Serum

Collect 4 mL whole blood into commercially available non-anticoagulant tubes. After blood clot, cells are removed from serum by centrifugation at 1000 g for 20 minutes at room temperature or by deposition at 4 ℃ for half an hour to one hour. The resulting supernatant is designated serum. Transfer the liquid component (serum) into a clean sterilization tube.

Note: After blood collection, the separation must be accomplished in 6 hours. Recollect the blood sample if hemolysis was found. If white turbidity can be seen in plasma or serum samples, centrifugate at 15000 g for 5 minutes at 4 ℃ and transfer the plasma or serum using pipette.

4. Swab specimen

(1) If there is cell preservation solution in the sample collection tube, mix the tube by pulse-vortexing. The mixture solution is used for subsequent extraction.

(2) If there is no preservation solution in the sample collection tube, add 1 mL of normal saline to the tube, mix the tube by pulse-vortexing. The mixture solution is used for subsequent extraction.

5. Sputum specimen

Use a sterile sputum collector to collect 1-5mL of sputum from the patient and then seal it for examination. Add an equal volume of sputum treatment solution, screw tube cap tightly, mix well for a few seconds, and incubate at room temperature for 30 minutes to fully liquefy the sample. Gently flick the collector to let sputum sample concentrate at tube bottom for subsequent nucleic acid extraction.

Specimen storage and transportation: Samples can be transported using ice box or foam box with dry ice. Samples can be stored at 2℃～8℃ for less than 3 days. With the long-term preservation, store them under -70℃ and avoid repeating freezing and thawing.

Procedure

1. Reagent preparation

(1) Proteinase K: Always mix well before use and store it at room temperature.

(2) Carrier RNA: Before first use of Carrier RNA, add 500 μL Carrier RNA Buffer to each vial of lyophilized Carrier RNA and mix well. Divide this Carrier RNA solution into conveniently sized aliquots, and store them at 2 ℃～8 ℃ for 6 months or at -20°C for 2 years. The maximum number of freezing and thawing is 2.

(3) Preloaded Plate: Centrifugation for seconds or throwing off before use to confirm the solution of E was in the bottom of the plate.

2. Isolation Procedure

2.1 Procedure for full plate (12 samples)

(1) Take out one piece of preloaded plate and tear the aluminum foil cover carefully.

(2) Add 300 μL of sample, 20 μL of Proteinase K and 6 μL of Carrier RNA into each well A1–A12 of the preloaded plate.

Note: Internal Control (IC) can be added in this step but the use of it should follow the instruction of detection kit for use of Internal Control. If necessary, Carrier RNA, Proteinase K and IC can be mixed before adding.

(3) Put the preloaded plate on the transport platform carefully, and insert the magnetic cap.

(4) According to the user manual of Automated Nucleic Acid Extraction Instrument, choose "RNA Isolation 2" program, then press "START" to run.

(5) After the program has been finished, discard the magnetic cap, take out the preloaded plate and transfer the liquid in well E1–E12 into 1.5 mL DNase/RNase-free tubes. It can be used immediately or stored at -20°C or -80°C for preservation.

2.2 Procedure for Less than 12 samples

(1) Take out one piece of preloaded plate and tear the aluminum foil carefully.

(2) Add 6 μL of Carrier RNA、20 μL of Proteinase K and 300 μL of sample into the corresponding well A of the preloaded plate. For example, if there are totally 5 samples, add 6 μL of Carrier RNA、20 μL of Proteinase K and 300 μL of sample into the well A1–A5 of the preloaded plate separately.

(3) Put the preloaded plate on the transport platform carefully, and insert the magnetic cap.

(4) According to the user manual of Automated Nucleic Acid Extraction Instrument, choose "RNA Isolation 2" program, then press "START" to run the test.

(5) After the program has been finished, discard the magnetic cap, take out the preloaded plate and transfer the liquid in the corresponding well E into 1.5 mL DNase/RNase-free tubes. It can be used immediately or stored at -20°C or -80°C for preservation. For example, samples are added into well A1–A5, then collect the solution in well E1–E5.

(6) Cover the preloaded plate timely with the Silicone Cover (not provided, Cat. No. OHC0143). For the second use, open the silicone cover and operate according to step (2)-(5).

Note: Do not use the same preloaded plate for more than 2 times, and the interval between 2 runs must shorter than 24 hours.

Quality Control

According to Liferiver's ISO certified quality management system, each batch of kits is tested according to predetermined specifications to ensure consistent product quality.

Analytical Performance Characteristics

The high-quality viral RNA isolated using the Viral RNA Isolation Kit (Preloaded for Auto-extraction) performs well in a wide range of downstream applications, including viral

genotyping, viral epidemiology and infectious disease research. The Viral RNA Isolation Kit (Preloaded for Auto-extraction) has been successfully used to recover RNA from viruses, including SARS-CoV-2 virus. Performance of the Viral RNA Isolation Kit (Preloaded for Auto-extraction) is comparable to that achieved with the QIAamp Viral RNA Mini Kit. RNA isolation is proven from commonly used saliva collection and stabilization methods and no cross-contamination was detected. The sensitivity of the Viral RNA Isolation Kit (Preloaded for Auto-extraction) for the Extraction of plasma and serum, swab specimens and sputum specimens are no worse than that of QIAamp® Viral RNA Mini Kit. The CV of Ct value was less than 5%, and the extraction efficiency was more than 85%.

Limitations

This kit is only suitable for the matching Automatic Nucleic Acid Extraction Instrument. If an incorrect instrument or manual extraction is used, the experimental results may be affected.

Contact Information

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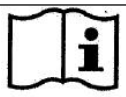
Symbols

Symbol	Symbol definition
	Contains reagents sufficient for <n> tests
	Not to be used twice
	In vitro diagnostic medical device
	Not sterilized

	Temperature limitation
	Conformite Europeenne
	Lot number
	Catalog number
	Do not use if the package is broken
	Consult instructions for use
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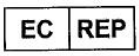	EU Authorized Representative