ANDiS Viral RNA Auto Extraction & Purification Kit

Catalog # 3103010024 / 3103010025 / 3103010026

16 Tests / 64 Tests / 128 Tests

Instructions for Use

For use with

ANDiS 350 Automated Nucleic Acids Extraction System

CE

IVD For in vitro diagnostic use

REF Catalog number: 3103010024 / 3103010025 / 3103010026

16 Tests / 64 Tests / 128 Tests

15°C to 25°C

Read the instructions

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Intended Use

The ANDiS Viral RNA Auto Extraction & Purification Kit is designed for rapid extraction and purification of nucleic acids from clinical specimens using magnetic bead-based technology. Purified nucleic acids can be directly used for the downstream application such as RT-qPCR. This kit is optimized for automated nucleic acid extraction and purification with the ANDiS 350 Automated Nucleic Acids Extraction System.

Principle

This kit uses a unique system of magnetic beads and buffers to isolate and purify high quality nucleic acids from serum, plasma, swab, urine and other types of clinical specimens. The magnetic beads with a silica-like surface have a strong affinity to nucleic acids under certain conditions. When conditions change, nucleic acids are released from magnetic beads, thereby achieving rapid isolation and purification of nucleic acids.

Components

The ANDiS Viral RNA Auto Extraction & Purification Kit (Cat. 3103010024 /3103010025 /3103010026) contains components listed in Table 1.

Table 1: Components of the ANDiS Viral RNA Auto Extraction & Purification Kit (3103010025)

Component	16 Tests	64 Tests	128 Tests	Storage Condition
Reagent Pre-filled Plate	1 plate	4 plate	8 plate	15°C – 25°C
Proteinase K	400µL	1.4 mL	2.8 mL	2°C – 8°C
8-Strip Rod Comb	2 strips	8 strips	16 strips	15°C – 25°C

Materials and Instruments Required but Not Provided with the Kit

The following materials are not provided in the kit but are required to perform the nucleic acid extraction and purification. Please ensure all these materials/instruments are ready for use before starting the procedure.

- ANDiS 350 Automated Nucleic Acids Extraction System (Cat. 3105020003)
- Microcentrifuge, capable of 16,000 x g (Eppendorf, Part No. 5415D; or equivalent)
- Vortex Mixer
- Single- and multi-channel pipettes
- Pipette tips with filters

1.5 mL microcentrifuge tubes (DNase/RNase free)

Warnings and Precautions

- Follow necessary precautions when handling specimens. All specimens and positive controls should be considered potentially infectious and handled accordingly.

- Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- Handle all specimens as if infectious using safe laboratory procedures.
- Specimen processing should be performed in accordance with national biological safety regulations.
- Perform all manipulations of live virus samples within a Class II (or higher) biological safety cabinet (BSC).
- If infection with an epidemic-causing pathogen is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions.
- Use of this product is limited to personnel specifically instructed and trained in the techniques of molecular in vitro diagnostic procedures.
- Use of this product is limited to qualified clinical laboratories where laboratory personnel have been trained on authorized instruments.
- Results need to be interpreted in conjunction with clinical signs, symptoms and travel/contact history of the patient.
- Use separate and segregated work areas for (1) specimen preparation, (2) reaction set-up and (3) amplification/detection activities. Workflow in the laboratory should proceed in a unidirectional manner.
- Always wear a clean lab coat and powder-free disposable gloves (not previously worn). Change gloves between samples, before entering another area or whenever contamination is suspected.
- Dedicate supplies and equipment to the separate work areas and do not move them from one area to another.
- Always check the expiration date prior to use. Do not use expired reagents.
- Change aerosol barrier pipette tips between all manual liquid transfers.
- During preparation of samples, compliance with good laboratory techniques is essential to minimize the risk of cross-contamination between samples, and the inadvertent introduction of nucleases into samples during and after the extraction procedure. Proper aseptic technique should always be used when working with nucleic acids.
- Maintain separate, dedicated equipment (e.g., pipettes, microcentrifuges) and supplies (e.g., microcentrifuge tubes, pipette tips) for assay setup and handling of extracted nucleic acids.
- Keep reagent and reaction tubes capped or covered as much as possible
- Work surfaces, pipettes, and centrifuges should be cleaned and decontaminated with cleaning product such as 10% bleach, “DNAZapTM” or “RNaseAWAYTM ” to minimize risk of nucleic acid contamination. Residual bleach should be removed using 70% ethanol.
- Purified RNA should be maintained on cold block or on ice during preparation and use to ensure stability.
- Dispose of unused kit reagents and human specimens according to local, state, and federal regulations.

Reagent Storage and Handling

- Store the ANDiS Viral RNA Auto Extraction & Purification Kit at the conditions specified in Table 1.
- Always check the expiration date prior to use. Do not use expired reagents.

Specimen Collection, Handling and Storage

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results.

Training in specimen collection is highly recommended due to the importance of specimen quality.

- Collecting Specimens
    1） Refer to the WHO Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with epidemic-causing pathogens (https://www.who.int).
    2） Follow specimen collection devices manufacturer instructions for proper collection methods.
    3） Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron, and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended. Place swabs immediately into sterile tubes containing 3 mL of viral transport media.
    4） Other applicable specimens: sputum, nasal discharge, bronchial lavage fluid, alveolar lavage fluid, whole blood or serum, urine, and etc.
- Transporting Specimens
    1） Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential epidemic-causing pathogen specimens.
    2） Store specimens at 2-8°C and ship overnight to testing facility on ice pack. If a specimen is frozen at -70°C or lower, ship overnight to testing facility on dry ice.
- Storing Specimens
    1） Specimens can be stored at 2-8°C for up to 48 hours after collection.
    2） If an RNA extraction could not be performed within 48 hours, specimens should be stored at -70°C or lower.
    3） Extracted nucleic acids should be stored at -70°C or lower.

Instructions for Use

RNA extraction is performed using the ANDiS Viral RNA Auto Extraction & Purification Kit (Cat. 3103010024/3103010025/3103010026) in the ANDiS 350 Automated Nucleic Acids Extraction System (Cat. 3105020003).

ANDiS Viral RNA Auto Extraction & Purification Kit contains the following components:

- one (1) / Four (4) / Eight (8) 96-well deep plates containing lysis buffer, magnetic beads, wash buffer and elution buffer

- One (1) tube of Proteinase K (400μL /1.4 mL/2.8 mL)
- Two (2) / Eight (8) / sixteen (16) pieces of 8-Strip Rod Comb

1. Equilibrate inactivated clinical specimens tube to room temperature.
2. Vortex the specimens for 10 seconds and spin briefly.
3. Equilibrate Proteinase K to room temperature and spin briefly.
4. Mix the Internal Control and Proteinase K following the recipe given in Table 2.

Table 2: Recipe for IC Mix

Reagent Label	Volume per Test (μL)	Volume per N Tests (μL)
Internal Control	1	1 x (N+1)
Proteinase K	20	20 x (N+1)
Total Volume	21	21 x (N+1)

Note: For the RNA extraction for other purpose, this step can be skipped.

5. Label a 1.5 mL DNase/RNase free tube as "IC Mix"
6. Mix thoroughly by vortexing for 5 seconds, spin briefly to collect contents to bottom of the tube.
7. Invert the 96-well deep plate 5 times and centrifuge the plate at 2,000 rpm briefly.
8. Unseal the 96-well deep plate carefully.
9. Add 20 μL of IC Mix and 200μL of each inactivated clinical sample into wells A1 to H1 and A7 to H7 containing lysis buffer.
10. Switch on the ANDiS 350 Automated Nucleic Acids Extraction System.
11. Ensure the instrument is in idle mode, and then open the chamber.
12. Load the 96-well deep plate onto the heating stand with A1 in the upper left corner.
13. Fit 8-strip rod comb to the magnetic rod cover holder firmly.
14. Close the chamber.
15. In the touch screen user interface, choose "Program Management", select "create new program", enter a new program and press "Enter" to create a new program with the parameters specified in Table 3.

Table 3: RNA Extraction Parameters

Step	Well Position	Action	Mixing Time (min)	Bead Collection time (Sec)	Holding time (Min)	Volume (μL)	Mixing Speed (1 to 3)	Temperature
1	3	Transfer beads	1	20	0	900	3	15℃ to 25 ℃
2	1	Lysis	20	20	0	900	3	
3	2	Wash 1	2	20	0	900	3	

4	3	Wash 2	2	20	0	900	3	
5	6	Elution	6	20	2	100	1	60°C
6	3	Discard Beads	1	0	0	900	3	15°C to 25°C

- If an extraction program already exists, press the program icon to review the parameters. Ensure that the parameters match with those provided in Table 3
- Start the program.
- Once the program is completed, transfer approximately 100μL of the extracted RNA to a clean 1.5 mL DNase/RNase free tube labeled with sample ID.
- Store the extracted RNA at -70°C or lower.
- Discard the used 96-well deep plate properly.

Quality Control

- Quality Control requirements must be performed in conformance with local, state and federal regulations or accreditation requirements and the user's laboratory's standard quality control procedures.
- Quality control procedures are intended to monitor reagent and assay performance.
- Good laboratory practice (cGLP) recommends including a positive extraction control in each nucleic acid isolation batch.

Limitations

- All user, analysts, and any person reporting diagnostic results should be trained to perform this procedure by a competent instructor. They should demonstrate their ability to perform the test and interpret the results prior to performing the test independently.
- 3DMed will limit the distribution of this kit to only those users who have successfully completed a training course provided by 3DMed instructors or designees.
- Performance of the ANDiS Viral RNA Auto Extraction & Purification Kit may be affected by the source of specimens, transportation of specimens, storage conditions, specimen types, and other factors that have not been evaluated.

Disposal

Dispose of hazardous or biologically contaminated materials according to the practice of your institution.