ANDiS Viral RNA Auto Extraction & Purification Kit

Instructions for Use

For use with

Automated Nucleic Acids Extraction System ANDiS 350

CE

IVD For in vitro diagnostic use

REF Catalog number: 3103010025

64 Tests

15°C to 25°C

Read the instructions

3D Biomedicine Science & Technology Co., Ltd. Block A, Building 2, No.158 Xinjunhuan Rd. Shanghai, 201114, China

EC REP Caretechion GmbH
Niederrheinstr 71, 40474 Duesseldorf, Germany

3D Biomedicine Science & Technology Co., Ltd.
http://www.3dmedcare.com
(+86)400-021-1661
Email : ivd-support@3dmedcare.com

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Intended Use

The ANDiS Viral RNA Auto Extraction & Purification Kit utilize magnetic beads-based technology for automated isolation and purification of RNA from biological samples.

The product is intended to be used by professional users that are trained in molecular biological techniques.

The ANDiS Viral RNA Auto Extraction & Purification Kit is for in vitro diagnostic use.

Principle

The ANDiS Viral RNA Auto Extraction & Purification Kit is intended to be used only in combination with Automated Nucleic Acids Extraction System ANDiS 350. The kit provides reagents for fully automated purification of RNA. Magnetic beads-based technology enables purification of high-quality nucleic acids that are free of nuclease, proteins and other impurities. The purified nucleic acids are ready for the downstream applications such as RT-qPCR. Automated Nucleic Acids Extraction System ANDiS 350 performs all the steps of purification procedure. Up to 32 samples are processed in a single run. The purification procedure comprises the following four (4) steps to ensure the safe and reproducible handling of potential infectious samples.

- Lysis
- Bind
- Wash
- Elute

Material Provided

The ANDiS Viral RNA Auto Extraction & Purification Kit contents are listed in Table 1.

Table 1: Contents of the ANDiS Viral RNA Auto Extraction & Purification Kit

Component	64 Tests Cat.3103010025	Storage Condition
Pre-filled Reagent Plate	4 plate	15°C – 25°C
Proteinase K	1.4 mL	2°C – 8°C
8-strip rod comb	8 strips	15°C – 25°C

Note: Plate is a 96-well deep plate contains the reagents required for purification

Table 2: Components in each 96-well deep plate

	1	2	3	4	5	6	7	8	9	10	11	12
A	700µl Lysis Buffer	900µl Wash Buffer A	900µl Wash Buffer B and 10µl Magnetic Beads	Empty	Empty	100µl Elution Buffer	700µl Lysis Buffer	900µl Wash Buffer A	900µl Wash Buffer B and 10µl Magnetic Beads	Empty	Empty	100µl Elution Buffer
B												
C												
D												
E												
F												
G												
H												

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)
- MicroPlate centrifuge
- Vortex Mixer
- Single- and multi-channel pipettes
- Pipette tips with filters
- 1.5mL microcentrifuge tubes (DNase/RNase free)

Warnings and Precautions

For In Vitro Diagnostic Use.

- 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, "DNAZap™" or "RNaseAWAY™" 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.

Proteinase K

Contains: Proteinase K. Danger! Cause mild skin irritation. May cause allergy or asthma symptoms if inhaled. Dispose of contents/container to an approved waste disposal plant. If experiencing respiratory symptoms: call a POISON CENTER or doctors/physicians.

Washing Buffer A and Wash Buffer B

Contains: Ethanol, guanidine salt.

Warning: may be harmful if swallowed. Cause skin irritation. Cause serious eye irritation. Flammable liquid and vapor. Dispose of contents/container to an approved waste disposal plant. If eye irritation persists, get medical attention/advice. Keep away from heat/spark/open flams/hot surface. No smoking. Store in a well-ventilated place. Keep cool. Wear protective gloves/protective clothing/eye protection/face protection.

Reagent Storage and Handling

- Store the components of ANDiS Viral RNA Auto Extraction & Purification Kit according the storage 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) Handle all specimens in compliance with your local and international regulations that cover the infectious using safe laboratory procedures. (As recommended by WHO Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with epidemic-causing pathogens, https://www.who.int, or Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19, https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html.)

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 a RNA extraction could not be performed within 48 hours, specimens should be stored at -70°C or lower.
  3） Extracted RNA should be stored at -70°C or lower.

Instructions for Use

RNA extraction is performed using the ANDiS Viral RNA Auto Extraction & Purification Kit on the Automated Nucleic Acids Extraction System ANDiS 350.

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, mix well by flick the tube for 5 times and then spin briefly.
4. Check whether precipitate has formed in 96-well deep plate. If necessary, dissolve by heating to 50°C with gentle agitation, and centrifuge the plate at 2,000 rpm briefly.
5. Unseal the 96-well deep plate carefully.
6. Add 20 µL of Proteinase K and 200 µL of each inactivated clinical sample into wells A1 to H1 and A7 to H7 containing lysis buffer.
   Important Note: if an Internal Control is required for downstream application, mix the required Internal Control with 200µL of clinical sample and 20µLof Proteinase K.
7. Switch on the ANDiS 350 Automated Nucleic Acids Extraction System.
8. Ensure the instrument is in idle mode, and then open the chamber.
9. Load the 96-well deep plate onto the heating stand with A1 in the upper left corner.
10. Fit 8-strip rod combs to the magnetic rod cover holder firmly.
11. Close the chamber.
12. Start Automated Nucleic Acid Extraction System ANDiS 350 by following the procedures described in Instruction for Use supplied with instrument (IFU-I-0004).

Note: prior to start an extraction run, ensure the run parameters used match the extraction parameters summarized in table 3 or table 4 or table 5， Standard parameters in table 3 was recommended for virus RNA extraction, Fast parameters in table 4 was validated for SARS-CoV-2 RNA extraction ,Super fast parameters in table 5 was validated for SARS-CoV-2 RNA extraction.

Table 3: Standard RNA Extraction Parameters

Step	Well	Name	Wait (min)	Mix (min)	Attract (sec)	Volume (μL)	Mix Speed	Temperature °C
1	3	transfer beads	0	1	20	900	3	OFF
2	1	lysis	0	20	20	900	3	OFF
3	2	wash 1	0	2	20	900	3	OFF
4	3	wash 2	0	2	20	900	3	OFF
5	6	elution	2	6	20	100	1	60
6	3	discard beads	0	1	0	900	3	OFF

Table 4: Fast RNA Extraction Parameters

Step	Well	Name	Wait (min)	Mix (min)	Attract (sec)	Volume (μL)	Mix Speed	Temperature °C
1	3	transfer beads	0	1	20	900	3	OFF
2	1	lysis	0	8	20	900	3	OFF
3	2	wash 1	0	2	20	900	3	OFF
4	3	wash 2	0	2	20	900	3	OFF
5	6	elution	2	2	20	100	1	60
6	3	discard beads	0	1	0	900	3	OFF

Table 5: Super fast RNA Extraction Parameters

Step	Well	Name	Wait (min)	Mix (min)	Attract (sec)	Volume (μL)	Mix Speed	Temperature °C
1	3	transfer beads	0	0	10	900	3	OFF
2	1	lysis	0	4	10	900	3	60
3	2	wash 1	0	1	10	900	3	OFF
4	3	wash 2	0	1	10	900	3	OFF
5	6	elution	0	2	10	100	1	80
6	3	discard beads	0	1	0	900	3	OFF

13. Once the program is completed, transfer each of an approximately 100 µL of the extracted RNA from A6 to H6 and from A12 to H12 into a clean 1.5 mL DNase/RNase free tube labeled with sample ID.
14. Store the extracted RNA at -70°C or lower.
15. Discard the used 96-well deep plate and 8-strip rod comb according to the local safety regulation.
16. Clean the automated Nucleic Acid Extraction System ANDiS 350 by following the maintenance instruction in the IFU supplied with instrument
17. Switch off the Automated Nucleic Acid Extraction System ANDiS 350.

Quality Control

- In accordance with ISO-certified Quality Management System in 3D Biomedicine Science & Technology Co., Ltd., each lot of ANDiS RNA Auto Extraction & Purification Kit is tested against predetermined specifications to ensure consistent product quality.
- 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 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.