Troubleshooting guide

Problem	Causes	Comments and suggestions
Physical damage of the kit	Upside down during transportation may cause beads to stick with sealing film	Spin down the 'Cartridge' by hand before open it.
	Insufficient reagent volume due to evaporation or lifting of the sealing film	If reagent volumes are insufficient, extraction efficiency may decrease. Do not use it and contact customer service immediately.
	Broken 'Cartridge'	Do not use it and contact customer service immediately.
Inappropriate specimen condition	Specimen condition is not favorable due to inappropriate storage condition (ex. coagulation)	Perform vortex and pipetting of specimen. If sample is still coagulated, add a bit of PBS or distilled water and vortex again.
	Specimen condition is abnormal due to inappropriate storage condition (ex. stored in room temperature)	Increase sample volume up to 300 µl, if extraction efficiency is low.
Abnormal extraction	Too much beads left in Elution buffer	If the total nucleic acid density is within the normal range, proceed with the eluted solution. In the case of low total nucleic acid density, transfer the eluted solution to a 1.5 ml tube and centrifuge before use.
	Eluted total nucleic acid should not appear transparent or sticky	Refer to 'Inappropriate specimen condition' part of trouble shooting if specimen condition is abnormal, perform extraction again. If the specimen condition and total nucleic acid density are normal, proceed with the extracted total nucleic acid. In cases where the specimen condition is normal but the total nucleic acid density is too sticky, transfer the eluted solution to 1.5 ml tube and dilute it with distilled water before use.

Warnings and precautions

- Intended for in vitro diagnostics.
- Intended for professional use only.
- Read and follow the Instruction for Use (IFU) before using the product.
- Use extracted nucleic acid as soon as possible, if long-term storage is needed, store it below -70 °C.
- Be cautious of contaminants such as microorganisms after opening the product.
- Be sure to wear personal protective equipment such as gloves and goggles when using this product and wash hands after handling specimens and reagents.
- Avoid contamination with DNase or RNase during product use.
- Store the product at the specified storage temperature and do not use it beyond its expiration date.
- Read and follow the IFU for the nucleic acid extraction device (AllEx® Mini Automated Nucleic Acid Extraction System) used with this product.
- Do not dispose of reagents from this product with bleach or acidic substances, as they contain irritants.
- This product is a single use and should not be reused.

* A notice to the user that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Storage conditions

- Temperature : 15 ˚C to 25 ˚C
- Relative humidity : 20 % to 80 %

Symbol	Used for	Symbol	Used for
LOT	Batch number		Manufacturer
REF	Catalogue number		Do not re-use
	Consult instructions for use		Date of manufacture
	Caution		Expiry date
	Temperature limit		

GeneAll Bldg., 303-7 Dongnam-ro, Songpa-gu, Seoul, 05729, Republic of Korea
E-mail : sales@geneall.com
Tel : 82-2-407-0096 Fax : 82-2-407-0779

Factory
A-1201~A-1204, Hanam Techno Valley U1 Center, 947,
Hanam-daero, Hanam-si, Gyeonggi-do, 12982, Republic of Korea

GENEALL BIOTECHNOLOGY CO., LTD.

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www.geneall.com

Ver. 1.0

GeneAll®

Store between 15 °C and 25 °C
Expiration date: Refer to the product box label

AllEx® Mini
Viral DNA/RNA Kit

Description

The AllEx® Mini Viral DNA/RNA Kit is a specialized nucleic acid extraction reagent designed for use with the AllEx® Mini Automated Nucleic Acid Extraction System (AllEx® Mini). The Kit protocols are optimized to extract viral DNA and RNA using AllEx® Mini Cartridge, which can extract up to 12 sample at once. Each cartridge comes preloaded with essential reagents, enabling dependable and efficient nucleic acid extraction while minimizing user effort.

Intended purpose

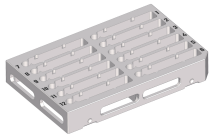
AllEx® Mini Viral DNA/RNA Kit provides fast and easy methods for the purification of total nucleic acids from viral samples such as whole blood, serum, plasma, buffy coat, cultured cell, CSF, BAL, urine, body fluid, buccal swab, saliva using AllEx® Mini Automated Nucleic Acid Extraction System.
The extracted viral DNA/RNA is of excellent quality and suitable for most downstream applications including PCR, qPCR, RT-PCR, or any other downstream application.

Kit contents

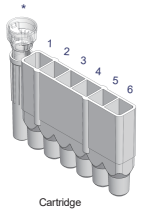
Components	972-048
Number of preparation	48 preps/kit
Reagents pre-filled cartridge	6 pks
Carrier RNA (lyophilized) 370 µg *	1 ea
Nuclease-free water 1 ml *	1 ea

** Reconstitute the lyophilized Carrier RNA by adding 370 µl of Nuclease-free water (provided) before use.*


Cartridge


Cassette

Brief workflow



Cartridge

1. Lysis buffer
2. Washing buffer I
3. Washing buffer II
4. Washing buffer III + bead
   [Note] If particles are not visible in well 4, shake down the cartridge to dislodge particles that may have adhered to the seal material before removing the seal.
5. Elution buffer
6. Washing buffer IV

* Strip

- AllEx® Mini Cartridge is designed for low throughput, allowing flexible processing of up to 12 individual samples.
- The Strip pocket has a Strip that keeps the magnet safe from magnetic beads while making sure samples and reagents mix well.
- Six consecutive wells are aligned horizontally, each containing specific reagents for extraction.
- The first well contains lysis buffer that breaks down cell membranes and releases DNA and RNA.
- To prevent damage, the magnetic beads are placed in the fourth well until the extraction process begins, at which point the AllEx® Mini transfers them to the first well.The second, third, fourth, and sixth well contain washing buffer I, II, III, and IV, which remove unwanted cellular components and residual buffers. Finally, the elution buffer in the fifth well separates DNA and RNA from the magnetic beads, completing the extraction process.

Protocol

The kit includes two protocols, allowing selection based on the specific extraction purpose.

Protocol	Uses and purpose
P1 Protocol (11 min 26 s)	• Rapid, efficient and PCR-compatible nucleic acid extraction
P2 Protocol (20 min 00 s)	• High-quality nucleic acid extraction for NGS-grade applications

A. Whole blood, serum, plasma, buffy coat, cultured cell

1. Dispense 7 µl of Carrier RNA solution to 1st well.
2. Dispense up to 200 µl of liquid sample to 1st well.
3. *(Optional)* If hemolysis occurs in the blood sample, dilution with a 1:1 ratio using 1 X PBS is recommended.

B. CSF, BAL, urine, body fluid

1. Transfer 1.5 ml of sample to a 1.5 ml microcentrifuge tube and centrifuge at 13,000 rpm for 3 min at room temperature.
2. Discard the supernatant. If the amount of cell is not enough, repeat step 1.
3. Add 300 µl of Buffer CL (not provided) and mix thoroughly by vortexing.
4. Incubate at 90 °C for 15 min. Spin down briefly to remove any drops from inside of the lid.
5. Incubate at room temperature for 2 min.
6. *(Optional)* Add 20 µl of Proteinase K solution (not provided) and mix by vortexing briefly. Incubate at 60 °C for 10 min and spin down briefly to remove any drops from inside of the lid.
7. Transfer up to 200 µl of liquid sample to 1st well.
8. Dispense 7 µl of Carrier RNA solution to 1st well.

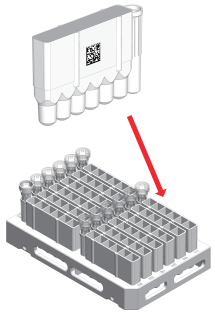
C. Buccal swab

1. Place the swab sample in a 2 ml microcentrifuge tube. Clip off the handle with sterile sharp blade or wire cutter.
2. Add 300 µl of Buffer CL (not provided).
3. Mix thoroughly by vortexing for 1 min and incubate for 10 min at room temperature.
4. Centrifuge at 13,000 rpm for 1 min at room temperature.
5. Carefully remove the supernatant without disturbing the cell pellet.
6. Add 200 µl of 1 X PBS and mix to resuspend pellet.
7. Dispense 7 µl of Carrier RNA solution to 1st well.

D. Saliva

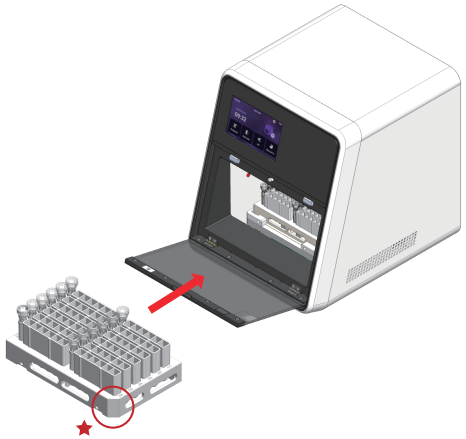
1. Add 1 ml of 1 X PBS to the 1 ml of the saliva sample.
2. Centrifuge at 13,000 rpm for 1 min at room temperature.
3. Carefully remove the supernatant without disturbing the cell pellet.
4. Add 200 µl of 1X PBS and mix to resuspend pellet.
5. (Optional) dispense 15 µl of Proteinase K solution (not provided) to 1st well.
6. Transfer 200 µl of sample to 1st well.

Preparation of Cartridge



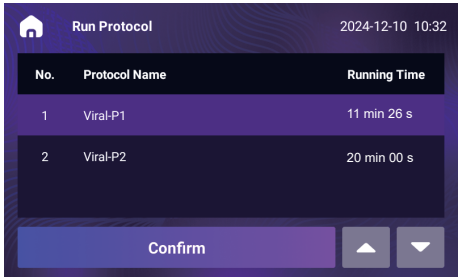
1. Insert up to 12 Cartridges in the desired quantity, starting with position number 1 indicated on the Cassette.
3. Remove the sealing film.
4. Follow the protocol for starting sample type.

System run



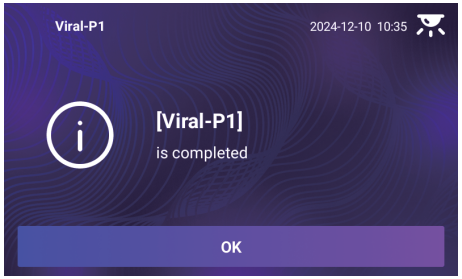
1. Load the Cassette with the inserted Cartridges into the AllEx® Mini, ensuring the diagonally cut edge faces the system door.

2. Tap the play icon to scan the barcode on the Cartridge.



3. The built-in Barcode reader reads the Cartridge barcode, selects protocol and displays the protocol lists. Select the protocol from the list based on uses and purposes.
4. Tap 'Confirm' to start extraction.

End of run



1. Once extraction is complete, tap 'OK' to return to the main menu.
2. Open door and check whether the Strip is correctly placed in the Strip pocket.
3. Remove the Cassette from AllEx® Mini.
4. Regular UV sterilization eliminates bacteria and virus, minimizing internal pollution within the system.
   Before/after the extraction, close the door and proceed with UV sterilization as a decontamination activity.
   The sterilization will continue for 10 min.