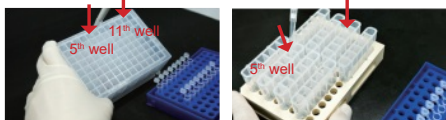


End of run



Once extraction is completed, take Plate/Tube Rack out of the system and collect genomic DNA from 5th/11th wells depending on where samples were dispensed. Transfer eluent into 1.5 ml or PCR tube.

Amount of eluted buffer will be around 80 µl and it is ready to use.

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. |
| | Sealing film is detached and reagent is spilled to other wells due to improper storage temperature | Spin down by hand and measure reagent volume with eyes. If reagent volumes are insufficient, extraction efficiency may decrease. Do not use it and contact customer service immediately. |
| | Broken 'Cartridge' | Broken 'Cartridge' may lead to unfavorable result. 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 not favorable 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 unfavorable, perform extraction again. If the specimen condition and total nucleic acid density are favorable, proceed with the extracted total nucleic acid. In cases where the specimen condition is favorable but the total nucleic acid density is unfavorable, transfer the eluted solution to 1.5 ml tube and centrifuge before use. If the result remains unfavorable, dilute it with distilled water before use. |
| | | |

Warnings and precautions

- Should be used for in vitro diagnostics.
- Intended for professional use only.
- Read and follow the manual before using the product.
- Use extracted nucleic acid as soon as possible, if not, keep it at -70°C for long-term storage.
- 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.
- Be mindful of contamination with DNase or RNase during product use.
- Store the product at the specified storage temperature and do not use it past its expiration date.
- Read and follow the IFU for the nucleic acid extraction device (GENTI™ Advanced Automated Nucleic Acid Extraction Equipment) 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.

* Any serious incident involving the device is reported to the relevant competent authority in the country where the manufacturer, user and patient are located.

Storage conditions

- Temperature : Room temperature (15~25°C)
- Humidity : 20~80%

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



MT PromedConsulting GmbH
Ernst-Heckel-Straße 7, 66386 St.
Ingbert, Germany
Tel : +49 (0) 6894 581020
Fax : +49 (0) 6894 581021

Factory

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

GENEALL BIOTECHNOLOGY CO., LTD.

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| Symbol | Used for | Symbol | Used for |
|--------|------------------------------|--------|---|
| | Batch number | | Manufacturer |
| | Catalogue number | | In-vitro diagnostic medical device |
| | Consult instructions for use | | Do not re-use |
| | Caution | | Date of manufacture |
| | Temperature limit | | CE-Mark |
| | Expiry date | | Authorized representative in the European union |

2024.06

www.geneall.com

Ver. 1.6

Store at room temperature (15~25°C)
Expiration date : 18 months after manufacture



GeneAll®

GENTI™ Advanced
Viral DNA/RNA Extraction Kit (Tube Type/Plate Type)

Description

The GENTI™ Advanced Viral DNA/RNA Extraction Kit provides efficient viral DNA and RNA extraction, in conjunction with magnetic bead-based GENTI™ Advanced Automatic Extraction Equipment.

Available extraction protocols for viral DNA and RNA cater to both medium throughput (1 to 16 samples) with Tube Type Cartridge and high throughput (up to 32 samples) with the Plate Type Cartridge.

Intended use

GENTI™ Advanced Viral DNA/RNA Extraction Kit is formulated to extract viral DNA and RNA from a wide range of samples including cell-free fluid, cell culture medium, plasma, serum, swab, stool, tissue, body fluid, whole blood, urine, and virus-infected liquid sample using GENTI™ Advanced Automated Nucleic Acid Extraction Equipment.

The extracted nucleic acid is suitable for various downstream applications such as PCR, RT-PCR, qPCR, qRT-PCR, and other molecular diagnostic tests.

Kit contents

| Components | Quantity | |
|------------------------------------|----------|----------|
| | 902-048A | 902-096A |
| Number of preparation | 48 T | 96 T |
| Type | Tube * | Plate |
| Reagent pre-filled cartridge | 6 pks | 6 pks |
| Magnetic rod cover (6 pcs/pk) | 4 pks | 2 pks |
| Carrier RNA (lyophilized) 370 µg * | 1 ea | 2 ea |
| Nuclease-free water 1 ml | 1 ea | 2 ea |

* The Tube Rack, which is an essential accessory for using the Tube Types, is provided with GENTI™ Advanced Automatic Extraction Equipment.

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

• Reagent pre-filled cartridge (Plate Type)



• Reagent pre-filled cartridge (Tube Type)



• Disposable magnetic rod cover



• Heating blocks



- Conical shape of the Plate/Tube Type Cartridge, magnetic rod cover and heating block
- Heating block designed with tight fit with conical materials for fast and efficient heat transfer

Brief workflow

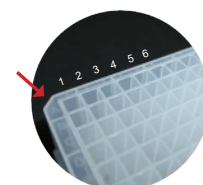
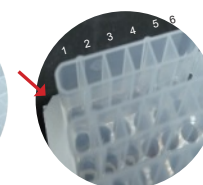


Plate Type Cartridge



Tube Type Cartridge

- 1 : Lysis well
- 2 : 1st washing well
- 3 : 2nd washing well
- 4 : 3rd washing + magnetic beads well
- 5 : Elution well
- 6 : 4th washing well

- The Tube Type Cartridge is designed for low to medium throughput, less than 8 samples. It is tailored to adjust the number of preps, contributing to efficient reagent saving.
- The Plate Type Cartridge enables the extraction of 16 samples, utilizing six consecutive wells for each extraction. These six wells are arranged horizontally, with each well housing specific reagents for the extraction process.
- Both kits can be used with same hardware allowing the users to switch between the two methods according to the requirements in sample.
- 1st (7th) wells contain lysis buffer which disrupts cell membranes and binds target DNA and RNA with magnetic beads.
- Magnetic beads, stored in the 4th (10th) are moved to the 1st (7th) well upon extraction initiation.
- 2nd, 3rd, 4th, 6th (8th, 9th, 10th, 12th) wells contain washing buffer in order to remove unwanted cell component and buffers.
- Elution buffer, housed in the 5th (11th) well facilitates the dissolution of nucleic acid molecules from the magnetic beads.

Carrier RNA

This kit is provided with Carrier RNA, which can be added at pre-treatment step if required. Carrier RNA can help improve the binding of viral nucleic acids to the magnetic bead, especially if very few target nucleic acids are present in the samples, and protect target nucleic acids from chances of degradation by residual RNase activity.

Protocol

1. Peel back the seal of reagents pre-filled cartridge.
2. Dispense 7 µl of dissolved Carrier RNA to 1st (7th) well.
 - * Note : To obtain a working solution of 1 µg/µl, add 370 µl of Nuclease-free water to the tube containing 370 µg of Carrier RNA. Dissolve the Carrier RNA thoroughly, divide it into conveniently sized aliquots, and store at -20°C. Do not freeze-thaw the aliquots of Carrier RNA more than 3 times.
3. Dispense 200 µl of samples to 1st (7th) well.
4. Load plate on the tray of GENTi™ Advanced Automatic Extraction Equipment.
 - * Note : Ensure that diagonally cut edge of Tube Rack faces the top left of the heating block and that the Tube Rack is placed evenly.
5. Insert magnetic rod cover to the end to strip bracket.
 - * Note : Ensure that magnetic rod cover is in the correct position.

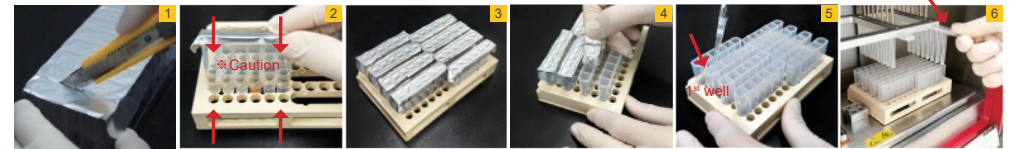
Extraction protocol of GENTi™ Advanced Automatic Extraction Equipment

| Protocol | Uses and purpose |
|---------------------------|---|
| Fast Protocol (17' 46") | <ul style="list-style-type: none"> • Time-saving, high-speed extraction for diagnostics PCR-ready nucleic acids • Validating the accuracy of samples confirmed positive post-POCT testing |
| Normal Protocol (29' 35") | <ul style="list-style-type: none"> • Standard procedure of nucleic acid extraction • Optimized for nucleic acid extraction from a variety of clinical samples |
| High Protocol (42' 12") | <ul style="list-style-type: none"> • High quality nucleic acid extraction (High yield & purity) • Accommodates complex clinical samples. (e.g., stool, swab, NGS-grade sample, etc.) |

Progression of normal protocol

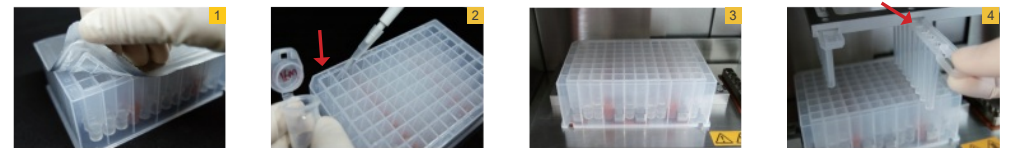
| Step | Step 1 | Step 2 | Step 3 | Step 4 | Step 5 | Step 6 | Step 7 | Step 8 | Step 9 |
|----------|---------|--------|--------|--------|--------|--------|--------|---------|---------|
| Well | 4 | 1 | 2 | 3 | 4 | 6 | 6 | 5 | 4 |
| Name | Bead TF | Lysis | Wash 1 | Wash 2 | Wash 3 | Wash 4 | Dry | Elution | Reclaim |
| Mixing | 0:00 | 10:10 | 1:30 | 1:30 | 1:10 | 1:10 | 0:00 | 5:00 | 0:15 |
| Volume | 700 | 1000 | 600 | 700 | 700 | 700 | 100 | 100 | 50 |
| Block Tm | Off | 35°C | Off | Off | Off | Off | Off | 85°C | Off |

Preparation of Tube Type Cartridge

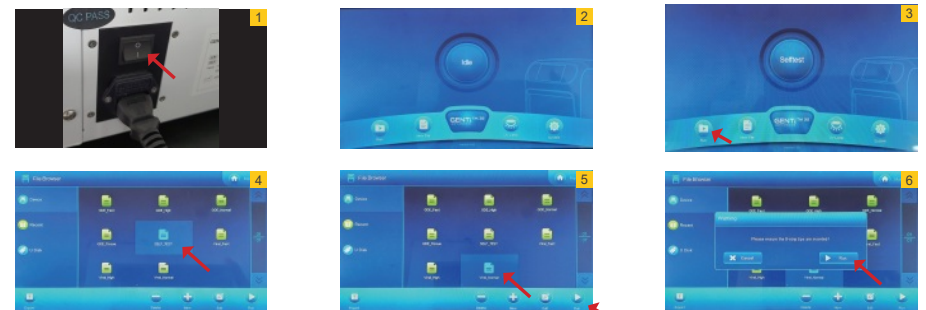


Cut the cartridge as much as necessary and install it in the GENTi™ Advanced Tube Rack.

Preparation of Plate Type Cartridge

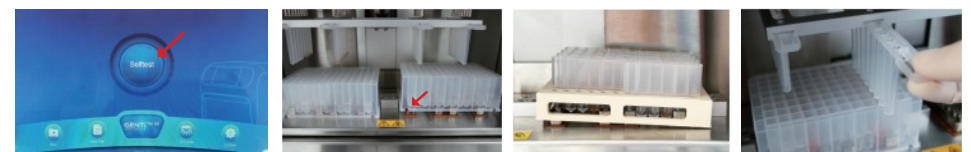


Equipment run



1. Turn on the 'Power switch' located on the right rear of the GENTi™ Advanced Automatic Extraction Equipment.
2. Touch the 'RUN' button when the home screen appears.
3. Select the 'Self Test' at the File Browser menu and then touch the 'RUN' button to run a self-test.
4. After self test completes, select the extraction protocol and then touch the 'RUN' button for the protocol operation. (Optimal protocol of the three options, 1) Fast <17 min>, 2) Normal <29 min>, 3) High <42 min>)
* Note : If 'Warning' message appears, check the system and touch the 'RUN' button again.

Precautions for use of equipment



Self-test

The self-test starts automatically when the equipment turns on.

Mounting the Plate/Tube Type Cartridge

Gently mount the Tube Rack on the equipment with caution.

Mounting magnetic rod cover

When installing the magnetic rod cover, push it to the end of magnetic rod cover slot.