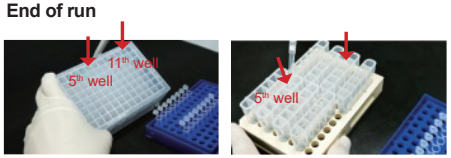
End of run



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 60 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.
- The extracted nucleic acid is stable at 2~8°C for 7 days. For long-term storage, 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.
- Be mindful of contamination with DNase 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%

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

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GENEALL BIOTECHNOLOGY CO., LTD.

2024.06
www.geneall.com

Ver 1.2

GeneAll®

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

CE IVD

GENTi™ Advanced
Blood DNA Extraction Kit (Tube Type/Plate Type)

Description

The GENTi™ Advanced Blood DNA Extraction Kit provides efficient genomic DNA extraction, in conjunction with magnetic bead-based GENTi™ Advanced Automatic Extraction Equipment.
Available extraction protocols for genomic DNA 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 Blood DNA Extraction Kit is formulated to extract genomic DNA from a wide range of samples including whole blood (EDTA, heparin), blood swab, dried blood spot, body fluid using GENTi™ Advanced Automated Nucleic Acid Extraction Equipment.
The extracted nucleic acid is suitable for various downstream applications such as PCR, qPCR, sanger sequencing, NGS and other molecular diagnostic tests.

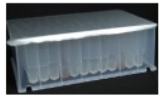
Kit contents

Components	Quantity	
	903-048A	903-096A
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
Proteinase K 24 mg **	1 ea	2 ea
PK-Storage buffer 1.5 ml	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 Proteinase K by adding 1.2 ml of PK-Storage buffer (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

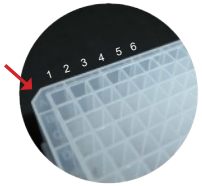
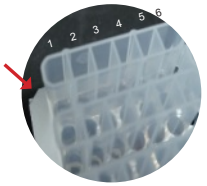


Plate Type Cartridge



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 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.

Proteinase K solution (20 mg/ml) at first use

This kit is provided with Proteinase K which is provided in freeze-dried format. Thus, it should be reconstituted thoroughly with PK-Storage buffer.
To obtain a solution of 20 mg/ml of Proteinase K, add appropriate amount of the PK-Storage buffer.
Reconstituted enzyme should be stored at 4˚C for its stability. For long-term storage, storage below -20˚C is recommended.

Preparation of sample

Sample	Max. amount per prep	Preparation
Whole blood	300 µl	Direct use
Body fluid	300 µl	Direct use
Buffy coat	300 µl	Direct use
Dried blood spot	3 dots (5 mm diameter) 9 dots (3 mm diameter)	1. Place samples in a 2 ml microcentrifuge tube 2. Add 300 µl of distilled water (not provided), 20 µl of Proteinase K solution 3. Vortex 1 min 4. Transfer all of the supernatant (200~300 µl)
Cultured cell or lymphocyte	5 x 10^6	5 x 10^6 cells in 200 µl of 1X PBS
Blood swab	1 ea	1. Add 400 µl of 1X PBS and vortex 2. Incubate at room temperature for 1 min 3. Transfer 200~300 µl of the supernatant

Protocol

1. **Peel back the seal of reagents pre-filled cartridge.**
2. **Dispense 15 µl of dissolved Proteinase K solution to 1st (7th) well.**
   *** Note : To obtain a working solution of 20 mg/ml, add 1.2 ml of PK-Storage buffer to the tube containing 24 mg of Proteinase K.**
3. **Dispense 1~200 µl of samples to 1st (7th) well.**
4. **Load cartridge 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 magnetic rod cover slot.**
   *** Note : Ensure that magnetic rod cover is in the correct position.**

Notice

Tips for improving yield and purity
1. Gently mix whole blood at room temperature or 37˚C for about 10 min.
2. Vortex strongly for 10 sec before use.

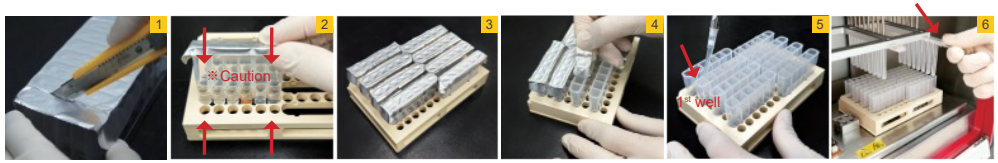
Extraction protocol of GENTi™ Advanced Automatic Extraction Equipment

Protocol	Uses and purpose
Fast Protocol (16' 58")	• Time-saving extraction for PCR-ready nucleic acids
Normal Protocol (28' 06")	• Standard procedure of nucleic acid extraction • Optimized for nucleic acid extraction from a variety of sample types
High Protocol (37' 07")	• Excellent yields of highly-pure DNA • Accommodates complex clinical samples. (e.g., blood swab, dried blood spot, etc.)

Progression of normal protocol

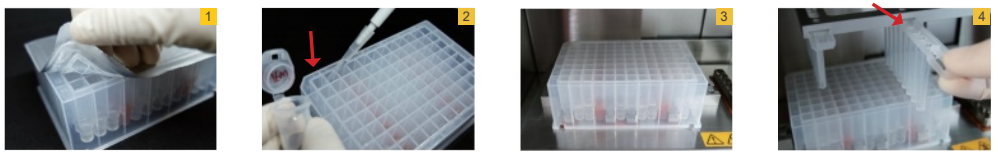
Step	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7	Step 8	Step 9
Well	4	1	2	3	4	6	6	5	4
Name	Bead TF	Lysis	Wash 1	Wash 2	Wash 3	Wash 4	Dry	Elution	Reclaim
Mixing	0:00	12:00	1:30	1:30	1:00	0:30	0:00	3:10	0:10
Volume	600	600	600	600	600	600	100	80	50
Block Tm	Off	65˚C	Off	Off	Off	Off	Off	75˚C	Off

Preparation of Tube Type Cartridge



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

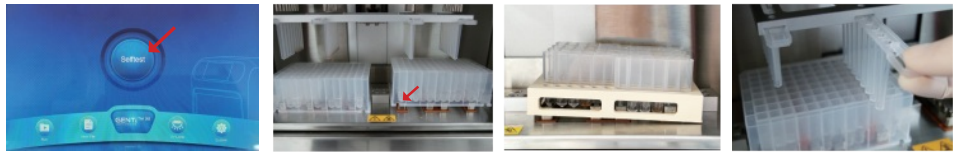
Preparation of Plate Type Cartridge



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 <28 min>, 3) High <37 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.