

AutoXT PGS DNA/RNA Kit

INTRODUCTION

The AutoXT PGS DNA/RNA Kit is used with the Miracle-AutoXT Nucleic Acid Extraction System (IMC-NC15PLUS) to purify DNA and RNA of pathogens such as bacteria and virus from fresh / frozen blood, serum, other cell-free body fluids, virus culture, cultivated cell, tissue homogenate and stool swab homogenate. DNA/RNA are easily bound to the surface of the magnetic beads and release using a proprietary buffer system.

To run the Virus protocol, you should have Miracle-AutoXT ver. 1.3 (or higher version) firmware installed on your Miracle-AutoXT Nucleic Acid Extraction System, and you should use the Miracle-AutoXT high strength magnetic rod and Plunger Tip. The DNA/RNA purification procedure is a simple method with the minimal handling before automated purification.

The eluted fraction is used to generated high-guality viral DNA/RNA suitable for use in downstream applications such as PCR/RT-PCR, real-time PCR/RT-PCR, etc.. The AutoXT PGS DNA/RNA kit provides the reagents required for processing the samples and uses prefilled cartridges or well plate for purification, maximizing simplicity and convenience. The Miracle-AutoXT Nucleic Acid Extraction System Instruments can process from 1 to 32 samples in under an hour.

INTENDED TO USE

This product is intended to be used by professional users, such as technicians and physicians that are trained in molecular biological techniques.

Tissue, cell culture, blood and serum in the presence of pathogen nucleic acid extraction and detection of its research.

PRODUCT COMPONENTS AND STORAGE CONDITIONS

| Cat. No. | Product | | Туре | Size |
|-------------|------------------------|------------------------------|--|---------|
| 17168-48 | AutoXT PGS DNA/RNA Kit | (Individual) | Cartridge | 48 T |
| 17168-96 | AutoXT PGS DNA/RNA Kit | (Well plate) | Plate | 96 T |
| * Cartridge | e (Individual) Type | • 2: • 3: • 4: • 5: | ents] Lysis Buffer Washing Buffe Washing Buffe Bead Solution Elution Buffer | r 2 |
| | | • 48 | idual type] Prefilled Cartri Plunger Tips | dges |
| | | • 6 6 | e Type] Prefilled Well pla Plunger Tips | ates |
| 1 2 3 | 456123456 | Shipp | age Conditions] bing and Stora om temperature | ige dry |

※ Storage Conditions

Upon receipt, store the kit components at room temperature (15~25°C) for up to 24 months without showing any reduction in performance and quality.

※ Safety Information

The reagent Cartridges or Plates contain ethanol which is flammable. Guanidine thiocvanate and Guanidine hydrochloride (which are components of the Lysis Buffer and Washing Buffer 1) are harmful and irritants.

Always wear protective gear during handling chemical materials and the test should be handled by professionally trained person.

MATERIALS REQUIRED BUT NOT PROVIDED

 Miracle-AutoXT Nucleic Acid Extraction System



Cartridge Rack (Individual type only)



- · Pipette and air barrier tip
- · Disposable gloves
- 1.5 ml micro tube
- · General lab equipment

PRODUCT WARRANTY AND SATISFACTION GUARANTEE

All products are undergone extensive guality control test and are warranted to perform as described when used correctly. Immediately any problems should be reported. Satisfaction guarantee is conditional upon the customer providing full details of the problem to iNtRON within 60 days, and returning the product to iNtRON for examination.

NOTICE

- 1. This product is intended to be used by professional users, such as technicians and physicians that are trained in molecular biological techniques.
- 2. The product is developed, designed and tested for both Research purposes (RUO) and in vitro diagnosis (IVD).
- 3. Always wear protective gear during handling chemical materials and the test should be handled by professionally trained person.
- 4. Be careful and prevent the contamination and direct contact from the test samples .
- 5. Surface of workspace and pipette should be regularly sterilized by 10% bleach solution.
- 6. All the waste should be sterilized before discarding.
- 7. The contamination should be considered very seriously. The work station should be kept with extreme cleanness not to have false-positive. Use RNase WiPER (iNtRON. Cat. 21131) to clean the desk or 1/20 diluted household bleach can be used alternatively.

PROTOCOLS

REF 17168-48 248 REF 17168-96 296 15°C CE IVD

- * Before You Begin
- 1. Power on the Miracle-AutoXT Nucleic Acid Extraction System Instrument. [Note] It is recommended that the equipment is maintained through ultraviolet ravs prior to use.

2. A suitable number of Plunger Tip is combined into the tip socket.



[Correct way of inserting Plunger Tip in the tip socket of device]

3. Attach the Cartridges to Cartridge Rack (or prefilled Well Plate), then mount on the Block with attention to the orientation.



[Combined Prefilled Cartridges to Rack for individual preparation]

- ※ Sample Preparation
- 1. Cultured Cell: 0.1 ~ 2.0 × 10⁶ cells per 200 µL suspension
- 2. Bacteria Culture : Centrifuge the 1 ~ 3 OD bacteria culture, then resuspend the pellet with 200 µL of media or buffer.
- 3. Tissue : Grind the 10 ~ 50 mg of tissue with 200 µL of PBS Buffer
- 4. Swab : To collect swab sample, scrape the swab to the specimen and air-dry the swab at least 2hr after collection. Then resuspend the swab with 500 µL of PBS Buffer.
- 5. Stool : Resuspend 20 ~ 200 mg of stool samples with 1ml of PBS buffer.
- 6. Blood, Serum, Body fluids : 200 µL of specimen

* DNA/RNA Extraction

- 1. Peel of the cover seal from the AutoXT PGS DNA/RNA Kit
- 2. Add the 200 µL of Specimen to the each first well



[The adding well-position of the specimen]



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3. Insert Prefilled Well-Plate or Cartridge Rack combined with Prefilled Cartridge on Heating Tray as shown figure below. Make sure the position of the diagonally cut edge of plate forward on the Heating Tray. If it is inserted incorrectly or upside down it may cause operating error and extraction may not work.



[Correct way of inserting Heating Tray in the device]

4. Close the front door and ready to start.

- 5. Press the 'menu / Cell' button on the touch display of the Miracle-AutoXT Nucleic Acid Extraction System to select the extraction type.
- Select 'VIRUS' icon for viral DNA/RNA extraction as shown figure below. [Note] If you select a program 'VIRUS (Fast)', you can shorten the total running time. However, we recommend that you check whether 'VIRUS (Fast)' program is satiable for your testing conditions.

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|----------------|---------|-----------|----------------|--------------------|----------------------|-----------------|
| | L.M. | | Å more | Cutared Cet | Bully Cost 7 Sumb | LBO |
| Miracle-AutoXT | 9 | U li | 8 04 2 Tene | VIRUS | вастерна | venus (Peeti |
| hueld | UV LAMP | TEST MODE | Belon) | BACTEPIA (Field | | |

7. Press the 'Start' button to perform the extraction.

[Note] It will be started automatically and indicates the remaining time on the screen (Refer to Figure below). After completion, it gives a beep. You can check the progress of step on window of touchscreen. Current process is indicated with blue color icon and remained process is presented with white icon. Time on the LCD screen does not run during magnetic rod positioning. There are approximately 3~4 minutes of magnetic rod positioning during the operation. The instrument can be forcibly stopped by 'Pause' button. The whole operation is initialized if home button on right top corner of LCD screen in below Figure is pressed; LCD screen returns to home and magnetic rod moves to its original position. Opening the door during operation put it on hold and re-activated once closed.



8. After completion of device working, transfer the 70~100 μ L of Elution fraction (well position 6) to a new 1.5 ml Microtube. Then store the DNA/RNA at appropriate temperature (4°C : 1~2 days, -20°C : 1~4 weeks, -70°C : 1~6 month).

AutoXT PGS Program Conditions

1. Program main protocol

| STEP | Step 1 | Step 2 | Step 3 | Step 4 | Step 5 | Step 6 | Step 7 |
|-------------|------------------|------------------|--------|--------|--------|---------|-----------------|
| Well | 5 | 1 | 2 | 3 | 4 | 6 | 5 |
| Name | Bead Transfer | Lysis Binding | Wash 1 | Wash 2 | Wash 3 | Elution | Bead Reclaim |
| Running (s) | - | 600 | 180 | 180 | 180 | 180 | 20 |
| Speed | - | 1 | 1 | 1 | 1 | 2 | 1 |
| Volume (ul) | - | 800 | 800 | 800 | 800 | 100 | 100 |

2. Program fast protocol

| STEP | Step 1 | Step 2 | Step 3 | Step 4 | Step 5 | Step 6 | Step 7 |
|-------------|------------------|------------------|--------|--------|--------|---------|-----------------|
| Well | 5 | 1 | 2 | 3 | 4 | 6 | 5 |
| Name | Bead Transfer | Lysis Binding | Wash 1 | Wash 2 | Wash 3 | Elution | Bead Reclaim |
| Running (s) | - | 600 | 60 | 60 | 60 | 60 | 20 |
| Speed | - | 1 | 1 | 1 | 1 | 2 | 1 |
| Volume (ul) | - | 800 | 800 | 800 | 800 | 100 | 100 |

TROUBLE SHOOTING GUIDE

| Problem | Possible causes and comments |
|---|---|
| | Sample homogenization was incomplete. Incomplete homogenization samples results is loss of DNA/RNA yield within particulates and clump of debris The starting samples were compromised. Ensure that |
| Lower viral | samples (e.g., for customer-provided internal controls) were collected, shipped and stored according to recommended guidelines. |
| nucleic acid recovery than expected | The Miracle-AutoXT Nucleic Acid Extraction System Instrument was set for the wrong method. Ensure that the correct method is chosen in Virus Mode. |
| | Check that an Plunger Tip was added to the cartridge. Ensure that all cartridges are snapped into the rack properly before processing. |
| | Check amount and storage conditions of starting materials |
| | Check and ensure the block set temperature at 65°C. |
| Poor amplification | Paramagnetic particle carryover may cause interference in amplification reaction. Remove particles in Elution Tube by centrifugation. |
| Cross- contamination | Avoid splashing when adding lysates to cartridges. Cartridges may be removed from the rack for sample addition to minimize contamination of adjacent cartridges.se fresh plastic wares for each sample to prevent sample-to sample contamination. |
| Virus method not an option on the instrument | For the Miracle-AutoXT Nucleic Acid Extraction System Instrument, verify that the instrument is in Engineer mode. Verify that the instrument has firmware version 1.3 or higher, which includes the Viral method. |

TECHNICAL INFORMATIONS



Panel Previous, Previous Spin-Column Type Product; panel AutoXT PGS, AutoXT PGS DNA/RNA Kit, Lane M, DNA Marker; Lane 1 ~ 6, RT-PCR Detection Results tested by RNA extraction from 10-fold serial diluted (10⁻⁰ ~ 10⁻⁵) specimen.

* Reproducibility Test Data



[Lane Information]

Panel Set 1 ~ 3, Triplicated Testing; Lane M, DNA Marker; lane 1~6, RT-PCR Detection Results tested by RNA extraction from 10-fold serial diluted ($10^{-0} \sim 10^{-5}$) specimen.

RELATED PRODUCTS

| Cat. No. | Product | Size |
|-------------------|---|--------|
| 17168-48 | AutoXT PGS DNA/RNA Kit (Individual) | 48 T |
| 17168-96 | AutoXT PGS DNA/RNA Kit (Well plate) | 96 T |
| IMC-NC15PLUS | Miracle-AutoXT Nucleic Acid Extraction System | System |
| IMC-NC15PLUS.rack | Cartridge Rack (for Individual type) | 10 ea |
| IMC-NC15PLUS.TIP | Plunger Tip | 96 ea |



IVD In vitro diagnostic REF Product number

Consult Instructions For Use

Manufactured by

Manufacturing date

Sufficient for tests

Batch number

LOT

Document No. : QG-17168-R00

Date : 2020, 09, 01

EXPLANATION OF SYMBOLS

Do not reuse

 \otimes

Expire date

₹¤%•

Attention

47

Keep away from sunlight

Storage temperature limitation