PerkinElmer® Nucleic Acid Extraction Kit

Instructions for Use

Product Name

PerkinElmer® Nucleic Acid Extraction Kit

Cat. No.

SY609 (KN0212)

Contents

For 48 tests

Intended Use

The PerkinElmer® Nucleic Acid Kit is designed for RNA extraction and purification from oropharyngeal swab, nasopharyngeal swab, plasma and serum specimens using magnetic beads. The kit is intended to be used for *in vitro* diagnostics with PerkinElmer diagnostic assays, for example the PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay.

Product Description

The PerkinElmer® Nucleic Acid Kit is designed for extracting nucleic acids from oropharyngeal swab, nasopharyngeal swab, plasma and serum specimens using magnetic beads. The specimen is mixed with the Lysis/Binding Buffer and Magnetic Beads, at which step the DNA/RNA will be released from cells and binds to the beads. Then the beads are collected and washed by Wash Buffer A and B sequentially to get rid of salts and proteins. Finally, DNA/RNA binds to the beads is eluted by the Elution Buffer provided with the kit. Eluted DNA/RNA is ready to be used for downstream *in vitro* diagnostic assays.

Kit Components

Component	Volume		Ingredients
Lysis/Binding Buffer	44.8 mL	×1	Guanidine isothiocyanate, Sodium perchlorate, Sodium acetate, Tween-20, Ethanol
Magnetic Beads	840 µL	×1	Magnetic beads
Wash Buffer A	44.8 mL	×1	Sodium perchlorate, Sodium acetate, Ethanol
Wash Buffer B	44.8 mL	×1	Ethanol
Elution Buffer	5 mL	×1	Tris-HCl

Please note that components from different batches cannot be used interchangeably.

Storage & Handling Requirements

1. Store the reagents at 10℃ to 30℃.
2. Use the reagents within 12 months from its production, expiration date is stated on kit label and component labels.
3. Precipitate can be seen in the Lysis/Binding Buffer when the buffer is stored at low temperature as it contains high concentration of salts. Please heat the buffer at 55℃ for 10-15 minutes to completely dissolve the salts before use.

Instruments

PerkinElmer® Pre-NAT II Automated Workstation

Chemagic™ 360

Materials Required but not Supplied

For extraction using Pre-NAT II or Chemagic 360, these following consumables are required but not provided with the kit:

Items	Cat. No.	Pre-NAT II	Chemagic 360
900 µL conductive tip Sterilized	AF01MP-9-XS	√	
175 µL conductive tip Sterilized	AF200P-9-XS	√	
50 µL conductive tip Sterilized	ATO5OP-9-XS-LB	√	
150 mL Reagent Trough	C3040016	√	
33 mL Reagent Trough	CJ222161115	√	
2 mL U type 96 deep-well plate	DP20UR-9-N	√	√
Magnetic rods disposable tips	CMG-550	√	√
Deep-well plate sealing film	HY3020011	√	√

Specimen Requirements

Specimens should be collected, transported, stored, and processed according to the relevant regulatory requirements.

Specimens should be stored at 2°C to 8°C until tested. If specimens cannot be tested within 72 hours after collection, they should be frozen at -70°C or colder until tested. Repeated freezing and thawing specimens should be avoided and limited to no more than 5 times.

Extraction Procedure

1. Manual Extraction Procedure

1) Place specimens in a biological safety cabinet. If the specimen is frozen, completely thaw it at room temperature before use;
2) Add 800 µL Lysis/Binding buffer into a 1.5 mL Eppendorf tube, then add 400 µL specimen, appropriate amount of Internal Control (if applicable for the downstream assay) and 15 µL Magnetic Beads, vortex for 15 minutes;

3) Place the tube on a magnet to collect the beads to the bottom which takes about 2 minutes. Keep the tube on the magnet and carefully remove the liquid;
4) Add 800 µL Wash Buffer A to the tube, vortex mix for 2 minutes. Then briefly centrifuge the tube to collect the liquid to the bottom of the tube, and repeat step 3;
5) Wash the beads with 800 µL Wash Buffer B as described in step 4;
6) Open the tube cap and keep it in biological safety cabinet for 5~10 minutes to dry the beads;
7) Add 60 µL Elution Buffer into the tube, vortex mix for 2 minutes, incubate the tube at 55℃ for 5~10 minutes, then place the tubes on a magnet until the solution to be clear (takes about 5 minutes). Carefully take the supernatant to another tube and discard the beads.
8) Proceed to downstream assay with the extracted nucleic acids or store the nucleic acids at -25°C to -15°C.

2. Extraction procedure with Pre-NAT II

Please follow Pre-NAT II Automated Workstation User Manual for extraction setup. A quick-start instruction is described as below.

1) Turn on the Pre-NAT II instrument, double click the “Pre-NAT II” software icon, select username and enter password to start, then follow software guidance to initialize the instrument.
2) After initialization, click “Program Input” to choose a protocol.
3) In the same window, input the number of specimens that are going to be processed at the indicated box. Then click “Set Complete” to proceed to loading guidance for reagents and consumables.
4) Remove the lids from reagents, controls and specimens, load the consumables, reagents, specimens, and controls according to software guidance, then double confirm that all items are at the positions indicated by software. Close instrument door after finish loading. Click “Run” to start the protocol.
5) Pre-NAT II conduct both nucleic acid extraction and PCR setup procedure, prepared PCR mix can be capped and directly loaded into a PCR instrument to start amplification.

3. Extraction procedure with Chemagic 360

Please follow Chemagic 360 User Manual for extraction setup. A quick-start instruction is described as below.

1) Turn on the Chemagic 360, double click the software icon “Chemagic 360”. Select username and enter password to start. Follow the Chemagic 360 User Manual to select a protocol.
2) Load the magnetic sleeves onto the deck according to the number of specimens being tested (count positive and negative controls in if applicable).
3) Add reagents to deep-well plates and load the plates at the positions indicated in the below table.

Please note that specimens and Magnetic Beads should be thoroughly vortex mixed before use.

Chemagic 360 layout：

Position 1	Magnetic rods disposable tips
Position 3	deep-well plate: add 60-80 μL Elution Buffer
Position 4	deep-well plate: add 800 μL Wash Buffer B
Position 5	deep-well plate: add 800 μL Wash Buffer A
Position 6	deep-well plate: add 400 μL specimen, 800 μL Lysis/Binding Buffer, 15 μL Magnetic Beads and indicated amount of Internal Control for the downstream assay if applicable

4) Double check the positions and directions of all consumables.
5) Click “Start” to start the extraction process.
6) Proceed to downstream assay with the extracted nucleic acids or store the nucleic acids at -25°C to -15°C.

Precautions

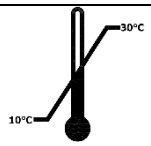
1. This kit is for *in vitro* diagnosis use.
2. Protective equipment accessories (goggles, work clothes, hats, shoes, gloves, etc.) should be worn during operation.
3. All specimen to be tested should be considered as infectious substances and processed strictly in accordance with laboratory biosafety requirements.
4. Use sterile centrifuge tubes and filter-tips for sample preparation.
5. Tubes and tips should be disposed into a waste bin containing a 10% sodium hypochlorite solution to disinfect the consumables.
6. After the operation, the work area surface and the instrument surface should be disinfected with a freshly prepared 10% sodium hypochlorite solution, and then cleaned with 75% ethanol or pure water. Finally, turn on UV light (if available) to disinfect working surfaces for 30 minutes.
7. Precautions for Pre-NAT II usage
   1) Read Pre-NAT II Automated Workstation User Manual thoroughly before use.
   2) The consumables, such as tips, deep-well plates, etc. are part of a complete system of Pre-NAT II, and cannot be replaced with other similar consumables which are not specified in the User Manual to avoid unreliable result.
   3) The specimens, reagents and consumables must be loaded to the correct positions according to the specific extraction protocol to avoid instrument running error.
   4) After the completion of extraction, the instrument should be cleaned and/or maintained according to Pre-NAT II Automated Workstation User Manual.

References

1. Yang G, Erdman DE, Kodani M, Kools J, Bowen MD, Fields BS, 2011, Comparison of commercial systems for extraction of nucleic acids from DNA/RNA respiratory pathogens. J Virol Methods, 171(1):195-9.
2. Witt S, Neumann J, Zierdt H, Gébel G, Röscheisen C, 2012, Establishing a novel automated magnetic bead-based method for the extraction of DNA from a variety of forensic samples. Forensic Sci Int Genet. 6(5):539-47.
3. Pan S, Gu B, Wang H, Yan Z, Wang P, Pei H, Xie W, Chen D, Liu G, 2013, Comparison of four DNA extraction methods for detecting Mycobacterium tuberculosis by real-time PCR and its clinical application in pulmonary tuberculosis. J Thorac Dis. 5(3):251-7.

Symbol Explanation

IVD	*In vitro* diagnostic medical device
	Consult instructions for use
	Manufacturer
	This way up
	Recyclable
	Date in produced
LOT	Lot number
REF	List number
	Expiration date
EC REP	Authorized Representative



Temperature limitation

Basic Information

EC REP

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Approval date and version: 29-03-2020 V1