

PANAMAX™ Viral DNA/RNA Extraction Kit

PNAK-1001



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Intended Use

The PANAMAX™ Viral DNA/RNA Extraction Kit is intended for *in vitro* diagnostic use, in combination with PANAMAX™ 48 Instrument, automated system that use silica-magnetic bead technology for isolation and purification of viral total nucleic acid from human cervical swab, vaginal swab, Nasal swab and Throat swab. The purified viral total nucleic acid is suitable for use in amplification-based *in vitro* diagnostic assays.

The product is intended to be used by professional users, such as technicians and physicians, who are trained in molecular biology techniques for *in vitro* diagnostic (IVD) purposes; it is intended for manual sample preparation purposes and gives no test results, qualitative or quantitative.

Principle and Overview

The PANAMAX™ Viral DNA/RNA Extraction Kit is used for automated nucleic acid purification of viral total nucleic acid from human cervical swab, vaginal swab, Nasal swab and Throat swab. It uses well-established silica dioxide-coated magnetic bead technology for purification of viral total nucleic acid from small sample volumes or sizes.

The procedure comprises 4 steps (lyse, bind, wash and elute) and is carried out using the selective binding properties of a silica dioxide-coated magnetic bead.

Kit Contents

- 432 PANAMAX™ Viral DNA/RNA Cartridges
- 60 Magnetic Covers
- 9 X 1.2 ml of Proteinase K
- 3 X 1.2 ml of PEB

Equipment and materials supplied by the user

- PANAMAX™ 48 Instrument
- Micro-centrifuge
- Pipettes and pipette tips for preprocessing sample transfer into prefilled reagent cartridges

Warnings and Precautions

- For *in vitro* diagnostic use only.
- Please read the instruction carefully and become familiar with all components of the kit prior to use.
- Material Safety Data Sheet (MSDS) is available upon request.

Reagent Storage and Handling

- Store the kit at 15-30°C. The kit is stable until the labeled expiration date.
- Do not use kit after their expiration dates.
- Once opened and reconstituted, the Proteinase K should be stored at 2-8°C
- Once opened, the remaining solutions are stable for up 90 days or until the expiration date, whichever comes first.
- Wear eye protection, laboratory coats and disposable gloves when handling any reagents. Avoid contact of these materials with the skin, eyes or mucous membranes.
- Do not pool reagents from different kits or lots.
- All samples should be handled as if infectious using good laboratory procedures.
- The use of sterile disposable pipettes, DNase-free pipette tips or DNase-free accessories is recommended to reduce the potential for contamination.
- Take care to avoid the formation of bubbles in the solution by shaking reagents vigorously.

- Carefully peel back the seal so that all plastic comes off the top of the cartridge.
- Do not expose cartridges with sealing film peeled off to air. Prolonged exposure to air, causing the solutions to evaporate and pH of the solutions to change, may impact purification efficiency.
- All solutions should be colorless and clear. Do not use solutions if the color is changed or solutions are opaque.
- After receiving the kit, check the kit components including PANAMAX™ Viral DNA/RNA Cartridges and Magnetic Covers for damage.
- Check that the automated instrument works correctly.
- Do not re-use PANAMAX™ Viral DNA/RNA Cartridges and Magnetic Covers.

Sample Collection and Handling

The PANAMAX™ Viral DNA/RNA Extraction Kit has been developed for use with human cervical swab, vaginal swab, Nasal swab and Throat swab.

Procedure

Preparing the reagent and cartridge

1. Place each cartridge to be used in the PANAMAX™ 48 Deck Tray with well #1 (the largest well in the cartridge) farthest away from the Elution Buffer in well #7.
2. Press down on the cartridge to snap it into position. Ensure both cartridge ends are fully seated in the deck tray. Carefully peel back the seal so that all plastic comes off the top of the cartridge.
3. Add 400 µl of sample and 20 µl of reconstituted Proteinase K reagent to the Lysis & Binding Buffer in well #1. Mixing is not required.
4. Place Magnetic Cover in well #6 (the blank well in the cartridge).

Running the method on the PANAMAX™ 48

1. Turn on the PANAMAX™ 48 Instrument. The instrument user interface will start automatically, and the instrument will process through a self-check and home all moving parts.
2. Select the method for type of nucleic acid and sample (DNA/Viral or RNA/Swab/PBS) to be run.
3. Transfer the deck tray containing the prepared cartridges to the instrument deck. Ensure that the deck tray is placed in the instrument with the Elution Buffer closest to the door. The deck tray will only fit in the instrument in this orientation. If you have difficulty fitting the deck tray on the platform, check that it is in the correct orientation. Ensure that the deck tray is level on the instrument deck.
4. Confirm all indicated preprocessing has been performed, and touch "NEXT" to close the door and start processing.
5. The instrument will immediately begin the purification run. The screen will display the steps performed and the approximate time remaining in the run.
6. When the automated purification run is complete, the user interface screen will display a message that the method has ended. "Complete".

End of Run

1. Touch "Complete" and "Door" to open the door. Verify that magnetic covers are located in well #6 of the cartridge at the end of the run.
2. Remove the deck tray from the instrument and transfer eluted viral total nucleic acid immediately to prevent evaporation of the eluates.
3. Remove the deck tray from the instrument.

Note: Following the automated purification procedure, the stage block of PANAMAX™ 48 Instrument may be warm. To remove the rack from the instrument platform, hold the deck tray. Ensure samples are removed from the instrument before running UV sanitization to avoid damage to the purified nucleic acid.

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4. Remove the cartridges and magnetic covers from the deck tray, and discard as hazardous waste according to your institution's procedures. Cartridges and magnetic covers are intended for single use. Do not re-use PANAMAX™ Viral DNA/RNA Cartridges or Magnetic Cover.

Post-Purification

The volume of eluate recovered depends on the nature of the sample.
It is the user's responsibility to optimize the elution volume by adding PEB provided separately into the eluted total nucleic acid for any procedures used in their laboratory.

Quality Control

Each lot of PANAMAX™ Viral DNA/RNA Extraction Kit is tested against predetermined specifications to ensure consistent product quality in accordance with PANAGENE's ISO 9001 & 13485-certified Quality Management System.


Performance Characteristics

Cross Contamination

The risk of cross contamination was evaluated using PCR assay. A checker-board pattern of alternating positive and negative samples was processed.
All the results showed no cross contamination was detected.

Contact Information

For any questions including technical support or concerns, please contact the distributors or the manufacturer.











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Endnotes

The kit itself or any of the components in the kit cannot be modified, re-sold or transferred without the approval of manufacturer. Information in this document is subject to change.

Explanation of Symbols on the Label

The following symbols may appear on the packaging and labeling.

Symbol	Symbol definition
	In Vitro Diagnostic Medical Device
	Batch code
	Catalogue number
	European conformity
	Manufacturer
	Consult instructions for use
	Contains Sufficient for <n> tests
	Temperature limit



Used by (YYYY.MM.DD)



Danger

Hazard Statements

- H225 Highly Flammable liquid and vapor
H302 Harmful if swallowed
H305 May be fatal if swallowed and enters airways
H315 Causes skin irritation
H319 Causes serious eye irritation
H335 May cause respiratory irritation
H340 May cause genetic defects
H350 May cause cancer

Precautionary Statements

- P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat, hot surface, sparks, open flames and other ignition sources. - No smoking.
P223 Do not allow contact with water.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ventilating/lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353 IF ON SKIN (or hair): Take off Immediately all contaminated clothing. Rinse SKIN with water [or shower].
P370+P378 In case of fire: Use a fire extinguisher to extinguish.
P281 Use personal protective equipment as required.
P308 + P313 IF exposed or concerned: Get medical advice/attention
P405 Store locked up.
P403+P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents/ container to an approved waste disposal plant.



Instruction manual for product # PNAK-1002
Doc. No.: PNG-PMVDUM001
Instruction Version: 1.2
Issued date: Mar. 2020

