PANAMAX™ FFPE DNA Extraction Kit

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Intended Use

The PANAMAX™ FFPE DNA 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 purifica tion of genomic DNA from human formalin-fixed, paraffin-embedded (FFPE) tissue sample. The purified genomic DNA 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™ FFPE DNA Extraction Kit is used for automated nucleic acid purification of genomic DNA from human FFPE tissue sample . It uses well -established silica dioxide-coated magnetic bead technology for purification of genomic DNA from small sample volumes or sizes.
The procedure comprises 6 steps (paraffin removal , lysis, heat, bind, wash and elute) and is carried out using the selective binding properties of a silica dioxide-coated magnetic bead.

Kit Contents

- 48 PANAMAX™ FFPE DNA Cartridges
- 12 Magnetic Covers
- 2 × 12 mg of Proteinase K
- 1.5 ml of Proteinase K Buffer
- 10 ml of FIB
- 2 × 8 ml of FLB
- 10 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
- 1.5 - 2.0 ml tubes for incubation of samples
- Heating blocks set at 70°C
  ***Note**: The heat block should be set to the needed temperature.*
- Razor blades
  ***Note**: Use caution when using razor blades to scrape sample from the slide.*

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 reagent should be stored at 2 -8°C and is stable for up to 90 days or until the expiration date, whichever comes first.
- 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™ FFPE DNA Cartridges and Magnetic Covers for damage.
- Check that the automated instrument works correctly.
- Do not re -use PANAMAX™ FFPE DNA Cartridges and Magnetic Covers.

Sample Collection and Handling

The PANAMAX™ FFPE DNA Extraction Kit has been developed for use with 1 to 10 5-µm sections of human FFPE tissue specimen.

Procedure

Preparing reagent and FFPE samples.

1. Prepare the reconstitute d Proteinase K reagent by adding 600 µl of Proteinase K Buff er into the vial of Proteinase K . Mix by inverting the vial 5 to 10 times.
2. Place section into 1.5 ml micro -centrifuge tube. If using slide-mounted tissue sections, scrape section o ffof slide using a clean razor blade.
3. Add 180 µl of FIB and 20 µl of reconstituted Proteinase K reagent to the sample tubes.
4. Heat the samples to 70°C for overnight.

Preparing the cartridge

1. Place each cartridge to be used in the PANAMAX™ 48 Deck Tray with well #1 (the la rgest 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 300 µl of FLB to the sample tubes. Vortex for 5 seconds.
4. Add 500 µl of sample to the Binding Buffer in well #1. Mixing is not required.
5. Place Magnetic Cover in well # 6 (the blank well in the cartridge).

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Running the method on the PANAMAX™ 48

1. Turn on the PANA MAX™ 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/FFPE) 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 genomic DNA 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 genomic DNA.*
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™ FFPE DNA 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 genomic DNA for any procedures used in their laboratory.

Quality Control

Each lot of PANAMAX™ FFPE DNA Extraction Kit is tested against predetermined specifications to ensure consistent product quality in accordance with PANAGENE’s ISO 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.

Explanation of Symbols on the Label

The following symbols may appear on the packaging and labeling.

Symbol	Symbol definition
IVD	*In Vitro* Diagnostic Medical Device
LOT	Batch code
REF	Catalogue number
	Manufacturer
EC REP	Authorized European representative
	Consult instructions for use
Σ	Contains Sufficient for <n> tests
	Temperature limit
	Used by (YYYY.MM.DD)

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.

IVD CE 15°C 30°C

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