



Revision 1, September 2024

Product Sheet

# PyroMark® Q24 Cartridge

**IVD**

For In Vitro Diagnostic Use

This Instructions for Use is applicable for:

		<b>REF</b>	Version
PyroMark Q24 Cartridge	3	979302	V4



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## Materials Required but Not Provided

- PyroMark Q24 MDx System

**Note:** The PyroMark Q24 System includes the Pyromark Q24 MDx instrument (cat.no. 9001513), the PyroMark Q24 software (cat.no., 9019062), the PyroMark Q24 Vacuum Workstation (cat.no., 9001515 [220V] (or 9001517 for U.K.) plus any PyroMark Q24 kits or Reagents).

- Pipettes (adjustable) and sterile pipette tips (without hydrophobic filter)
- High-purity water (Milli-Q® 18.2 MΩ x cm or equivalent)
- Lint-free tissue
- PyroMark Q96 HS Tip Holder Box (cat. no. 9019074)

## Shipping and Storage

The PyroMark Q24 Cartridge is shipped at ambient temperature.

It should be stored upon receipt at room temperature (15–25°C), protected from dust and light. PyroMark Q24 Cartridge can be cleaned and re-used for up to 30 runs. After first use, we recommend storing the cartridges in the PyroMark Q96 HS Tip Holder Box (cat. no. 9019074).

When stored and cleaned correctly, the PyroMark Q24 Cartridges are valid for use until the expiration date printed on outer package and cartridge label.

Do not use if stored outside the specifications, if the packaging has been damaged, or if other signs of deterioration or malfunction are visible.

## Intended Use

The PyroMark Q24 Cartridge is a plastic consumable used to perform DNA sequencing using Pyrosequencing® technology – a process intended to detect changes in specified variable positions in human DNA that may have clinical relevance.

The PyroMark Q24 Cartridge is intended to be used in combination with QIAGEN® in vitro diagnostics products for which the PyroMark Q24 Cartridge is listed as an accessory.

The PyroMark Q24 Cartridge is intended to be used only by professionals specially instructed, trained for molecular biology techniques, and familiar with the device technology. The device procedure is to be implemented in a diagnostic laboratory environment.







The PyroMark Q24 Cartridge is intended for in vitro diagnostic use.

The PyroMark Q24 Cartridge is not an automated device.

## Active ingredients

The PyroMark Q24 Cartridge is a plastic consumable and does not contain active ingredients.

## Symbols

<b>CE</b>	This product fulfills the requirements of the European Regulation (EU) 2017/746 for <i>in vitro</i> diagnostic medical devices (IVDR).
<b>IVD</b>	<i>In vitro</i> diagnostic medical device
<b>REF</b>	Catalog number
<b>LOT</b>	Lot number
<b>GTIN</b>	Global Trade Item Number
<b>UDI</b>	Unique Device Identifier
<b>CONT</b>	Contains
<b>COMP</b>	Component
<b>NUM</b>	Number
<b>Rn</b>	R is for revision of the Product Sheet and n is the revision number
	To be used by
	Temperature limitations
	Manufacturer
	Consult instructions for use
	Contains reagents sufficient for <N> reactions
	Keep away from sunlight
<b>INSTRUM-PARAM</b>	Instrument parameters
<b>METHOD</b>	Method settings

Description and Principle


The PyroMark Q24 Cartridge is used in the dispensing unit of the PyroMark Q24 System, to perform DNA sequencing using Pyrosequencing® technology. The cartridge is divided into compartments that are filled with Reagents supplied for use with the PyroMark Q24 system.

Safety Information

When working with chemicals substances, always wear a suitable lab coat, disposable gloves, and protective goggles.

The user should also refer to regional, as well as institute specific guidelines. Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and the regulatory authority in which the user and/or the patient is established.

Specimens and samples are potentially infectious. Discard sample and assay waste according to your local safety procedures.

<p>WARNING</p> 	<p><b>Sharp needles</b></p> <p>Do not touch the sharp needles at the bottom of the reagent cartridge. Handle the needles with care. Small particles and fibers may obstruct the needles.</p>
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For safety information relative to all other "Materials Required but Not Provided" (as listed in section above), please refer to the respective SDS – for reagents – and to the relevant instrument user manuals.

## Procedure

### Important points before starting

- The PyroMark Q24 Cartridges must be handled with care to avoid personal injury and damage to the needles.
- When handled according to instructions in this product sheet, a PyroMark Q24 Cartridge can be used for up to a total of 30 runs.
- For protection, PyroMark Q24 Cartridges are shipped with needles capped. Remove the cap before using the cartridge for the first time. We do not recommend recapping the needles since replacing and removing the cap may damage the needles (refer to section below "Cleaning and testing the PyroMark Q24 Cartridge").
- We recommend cleaning and testing of the cartridge before using it for the first time (see dedicated section below), and also if it has not been used in 4 weeks or longer, to remove any particles that may have accumulated.

### Filling the PyroMark Q24 Cartridge

- The detailed procedure is described in the handbooks of the IVD-validated assays to be used with the PyroMark Q24 MDx (related products are described in the "Ordering Information" section).

**Important note:** The PyroMark Q24 Cartridge must be oriented with the label facing you when filling the cartridge.

## Starting a Pyrosequencing run

The detailed procedure is described in the *PyroMark Q24 MDx User Manual* and in the handbooks of the IVD-validated assays to be used with the PyroMark Q24 MDx (related products are described in the “Ordering information” section).

**Important note:** The filled reagent cartridge must be oriented with the label facing out when loading it into the instrument.

## Cleaning and testing the PyroMark Q24 Cartridge

If the cartridge is to be reused, it must be cleaned immediately after use.

1. Discard any solutions remaining in the PyroMark Q24 Cartridge.
2. Rinse the PyroMark Q24 Cartridge 4 times with high-purity water.
3. Spray the outside of the needles with high-purity water.
4. Check that the cartridge needles are not blocked or damaged. Completely fill the compartments with high-purity water. Hold the cartridge over a sink or beaker while pressing firmly on top of each compartment with a finger (wear powder-free gloves). A jet of water should come straight out of the tip of each needle.
5. If a needle is blocked, follow step 5a. If the jet of water comes out of a needle at an angle, instead of parallel to the direction of the needle, follow step 5b. If all needles are working properly, proceed to step 6.
  - 5a. If a needle is blocked (for example, if the reagent cartridge was left overnight without cleaning), fill the compartments with high-purity water and immerse the PyroMark Q24 Cartridge in a beaker with enough high-purity water to cover the needles. Leave the cartridge in the beaker for 1 h, then rinse, and repeat step 4.
  - 5b. If the jet of water comes out at an angle, refill the compartment with high-purity water and repeat step 4. If the water still comes out at an angle, discard the PyroMark Q24 Cartridge. Otherwise, proceed to step 6.



Observe all federal, state, and local environmental regulations for disposal of laboratory waste.

6. When all needles have been rinsed, tested and their integrity confirmed, discard any remaining water and let the PyroMark Q24 Cartridge dry on a lint-free tissue.
7. Before using the cartridge, ensure that the needles are dry. Do not dry the needles with tissue. Liquid droplets, lint, or particles remaining on the needle tips will affect cartridge performance.
8. Once dry, store the PyroMark Q24 Cartridge in the PyroMark Q96 HS Tip Holder Box.

## Disposal

Dispose used and unused products in compliance with local and national regulations.

For disposal information relative to all other "Materials Required but Not Provided", please refer to the respective SDS – for reagents – and to the relevant instrument user manuals.

## Quality control

In accordance with QIAGEN's ISO-certified Quality Management System, each lot of PyroMark Q24 Cartridge is tested against predetermined specifications to ensure consistent quality.

## Limitations

This product is to be used only by personnel specially instructed and trained in in vitro diagnostics and on the PyroMark Q24 MDx System. All operations must be performed according to PyroMark Q24 MDx system instructions, as provided through dialog messages appearing on the screen of the PyroMark Q24 MDx, the associated user manuals, handbooks, and technical support from QIAGEN, and within the limits set by the technical specifications. Materials for sample preparation before Pyrosequencing analysis are not included in the product. The product is intended solely for use on the PyroMark Q24 MDx System. Strict compliance with the instrument user manual and this product sheet is required for optimal results. Attention should be paid to expiration dates and storage conditions printed on the box and labels of all components. Do not use expired or incorrectly stored components. Results from the PyroMark Q24 MDx System must be interpreted within the context of all relevant clinical and laboratory findings.

## Ordering Information

Product	Contents	Cat. no.
PyroMark Q24 Cartridge (3)	Cartridge for dispensing nucleotides and reagents.	979302
<b>Related products</b>		
Pyromark Q24 MDx System	Sequence-based detection platform for Pyrosequencing of 24 samples in parallel	9001513
PyroMark Q24 Software	Application software	9019063
PyroMark Q24 Vacuum Workstation		9001515 [220V] (or 9001517 for U.K)
PyroMark Q24 kits or Reagents		Refer to QIAGEN website

All due care and attention should be exercised in the handling of the products. We recommend all users of QIAGEN® products to follow any applicable local regulation and we also recommend to follow any applicable standards and guidelines.

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at [www.qiagen.com](http://www.qiagen.com) or can be requested from QIAGEN Technical Services or your local distributor.

# Document Revision History

Date	Changes
R1, 09/2024	Initial release.

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