



Revision 1, September 2024

Product Sheet

PyroMark® Q24 Plate

**IVD**

For In Vitro Diagnostic Use

This Instructions for Use is applicable for:

		<b>REF</b>	Version
PyroMark Q24 Plate	100	979301	V2



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## Materials required but Not Provided

- Heating Block capable of attaining 80°C
- Pipettes (adjustable) and sterile pipette tips
- 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).

## Shipping and Storage

The PyroMark Q24 Plate is shipped at ambient temperature and should be stored upon receipt at room temperature (15–25°C). The PyroMark Q24 Plate is for single use only.

When stored correctly, PyroMark Q24 Plate is valid for use until the expiration date printed on outer package and plastic label.

Do not use PyroMark Q24 Plate if stored outside the specifications, if the packaging has been damaged, or if other signs of deterioration or malfunction are visible.

Once opened, plates can be stored in their original packaging at room temperature until use or expiry date.

## Intended Use

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

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

The PyroMark Q24 Plate is not an automated device.

## Active ingredients

The PyroMark Q24 Plate 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 in vitro 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
	Do not re-use

Description and Principle

The PyroMark Q24 Plate is a 24-well sequencing reaction plate for use with PyroMark Q24 MDx System, to perform DNA sequencing using pyrosequencing technology.

Safety Information


When working with chemicals and biological 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.

The following hazard and precautionary statements apply to PyroMark Q24 Plate:

<div>WARNING</div> <div></div>	<div>Hot surface</div> <div>The plate holder and the heating block (for annealing) can reach temperature of up to 80°C (176°C). Avoid touching them when they are hot.</div>
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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 Plate is for single use only.
- Ensure that the plate is kept in the same orientation (e.g., beveled corner used as a guide) all along the procedure.
- Prewarm one PyroMark Q24 Plate Holder (supplied with the PyroMark Q24 Vacuum Workstation) by placing it (without a plate) on a heating block at 80°C.
- Leave a second PyroMark Q24 Plate Holder at room temperature (15–25°C) and use it as support when preparing and moving the plate.

### Filling the PyroMark Q24 Plate

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

### Annealing of sequencing primers to samples

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).

### 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).

## 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 Plate is tested against established procedures to ensure consistent product 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 Plate (100)	Plate for sequencing reaction.	979301
<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.

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# Document Revision History

Date	Changes
R1, 09/2024	Initial release.

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