



July 2024

## Product Sheet

# QIAcuityDx<sup>®</sup> Nanoplate 26k 24-well

Version 1

**IVD**

For In Vitro Diagnostic Use  
For use with QIAcuityDx Four  
For Laboratory Use



**REF**

260001



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R1 **MAT**

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# Kit Contents

<b>Cat. no.</b> <b>260001</b>	<b>Qty.</b>
QIAcuityDx Nanoplate 26k 24-well	10
QIAcuity Nanoplate Seals	11

## Materials Required but Not Provided

- QIAcuity® Roller (911106)
- QIAcuity Nanoplate Tray (cat. no. 250098)
- The QIAcuityDx Nanoplate 26k 24-well (10) product is optimized for use with the QIAcuityDx Universal MasterMix Kit and compatible assay(s).

# Shipping and Storage

The QIAcuityDx Nanoplate 26k 24-well product is shipped at ambient temperature (15–25°C). Upon receipt, product should also be stored at ambient temperature. When stored correctly, the QIAcuityDx Nanoplate 26k 24-well product can be used until the expiration date printed on the outer packaging.

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

# Intended Use













The QIAcuityDx Nanoplate 26K 24-well product is a single use disposable, that partitions samples and reaction mixes using a microfluidic plate-based technology to enable the QIAcuityDx Four instrument to be used as intended. The QIAcuityDx Nanoplate is used in conjunction with the QIAcuity Nanoplate Seal to establish a closure that allows air displacement to push samples into the partitioning area of the QIAcuityDx Nanoplate during priming.

The QIAcuityDx Nanoplate 26K 24-well is intended for *in vitro* diagnostic use.

The QIAcuityDx Nanoplate 26K 24-well is not an automated device.

# Symbols

The following symbols may appear in the Instructions for Use or on the packaging and labeling:

	This product fulfills the requirements of the European Regulation (EU) 2017/746 for in vitro diagnostic medical devices (IVDR).
	In vitro diagnostic medical device
	Catalog number
	Material number
	Lot number
	Global Trade Item Number
	Unique Device Identifier
	Contains
	Component
	Number
<b>R<sub>n</sub></b>	R is for revision of the Product Sheet and n is the revision number
<b>V<sub>n</sub></b>	V is for version of the Product Sheet and n is the version number
	To be used by
	Temperature limitations



Manufacturer

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Consult instructions for use

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Keep away from sunlight

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Do not re-use

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# Safety Information

When working with chemicals and biological substances, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at [www.qiagen.com/safety](http://www.qiagen.com/safety), where you can find, view, and print the SDS for each QIAGEN® kit and kit component.

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.

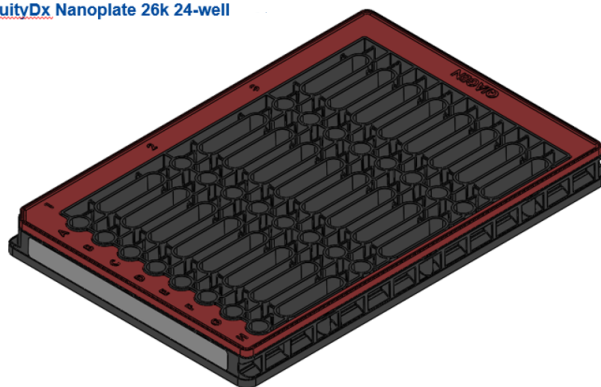
Specimens and samples are potentially infectious. Discard sample and assay waste according to your local safety procedures.

# Description and Principle

The QIAcuityDx Nanoplate 26k 24-well product, hereafter referred to as "QIAcuityDx Nanoplate (s)" are single use disposables which deliver sample partitioning prior to amplification and imaging. QIAcuityDx Nanoplates are supplied with QIAcuity Nanoplate Seals, which are adherent elastic top-seals that support this partitioning process. The top-seal is a multi-layered seal which 'closes' the QIAcuityDx Nanoplate after sample loading. This closure is essential to support air displacement that pushes samples into the partitioning area of the QIAcuityDx Nanoplates during the priming step that takes place on the QIAcuityDx Four instrument.

A full list of materials to be used with the QIAcuityDx Nanoplates can be found in the QIAcuityDx System Instructions for Use.

[QIAcuityDx Nanoplate 26k 24-well](#)



**Figure 1.** QIAcuityDx Nanoplate contains rows A-H and columns 1–3.

# Procedure

QIAcuityDx Nanoplates are intended for use as part of the QIAcuityDx System, which includes instrumentation, chemistry and software. For detailed procedural steps see *QIAcuityDx System User Manual* or specific assay Instructions for Use.

# Disposal

QIAcuityDx Nanoplates may be used for the detection of infectious substances. All QIAcuityDx Nanoplate contents used for this purpose should be discarded in line with local and national regulations. Individual assay and/or reagent Instructions for Use should be consulted for specific guidance on disposal.

# Quality Control

Since QIAcuityDx Nanoplates are used in the QIAcuityDx System, please refer to the specific assay Instructions for Use used in combination for related quality control procedures.

# Limitations

This product is intended to be used only by trained professionals who are specially instructed and trained in *in vitro* diagnostics and on the use of the QIAcuityDx System.

Since QIAcuityDx Nanoplates are used in the QIAcuityDx System, please refer to the QIAcuityDx System User Manual or specific assay Instructions for Use for any warnings and precautions or product limitations

# Troubleshooting

For troubleshooting, refer to the *QIAcuityDx System User Manual* which can be found on the QIAGEN website, [www.qiagen.com](http://www.qiagen.com)

If further assistance is required, contact QIAGEN Technical Services using the contact information below, which will direct you to country specific contact details:

Website: [support.qiagen.com](http://support.qiagen.com)

# Ordering Information

Product	Contents	Cat. no.
QIAcuityDx Nanoplate 26k 24-well (10)	24-well dPCR Nanoplate with 26K partitions and 40 $\mu$ L reaction volume per well, 10 Nanoplates w/ 11 seals	260001

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



# Document Revision History

Date	Changes
07/2024	Initial release.

### Limited License Agreement for QIAcuityDx<sup>®</sup> Nanoplate 26k 24-well (10)

Use of this product signifies the agreement of any purchaser or user of the product to the following terms:

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