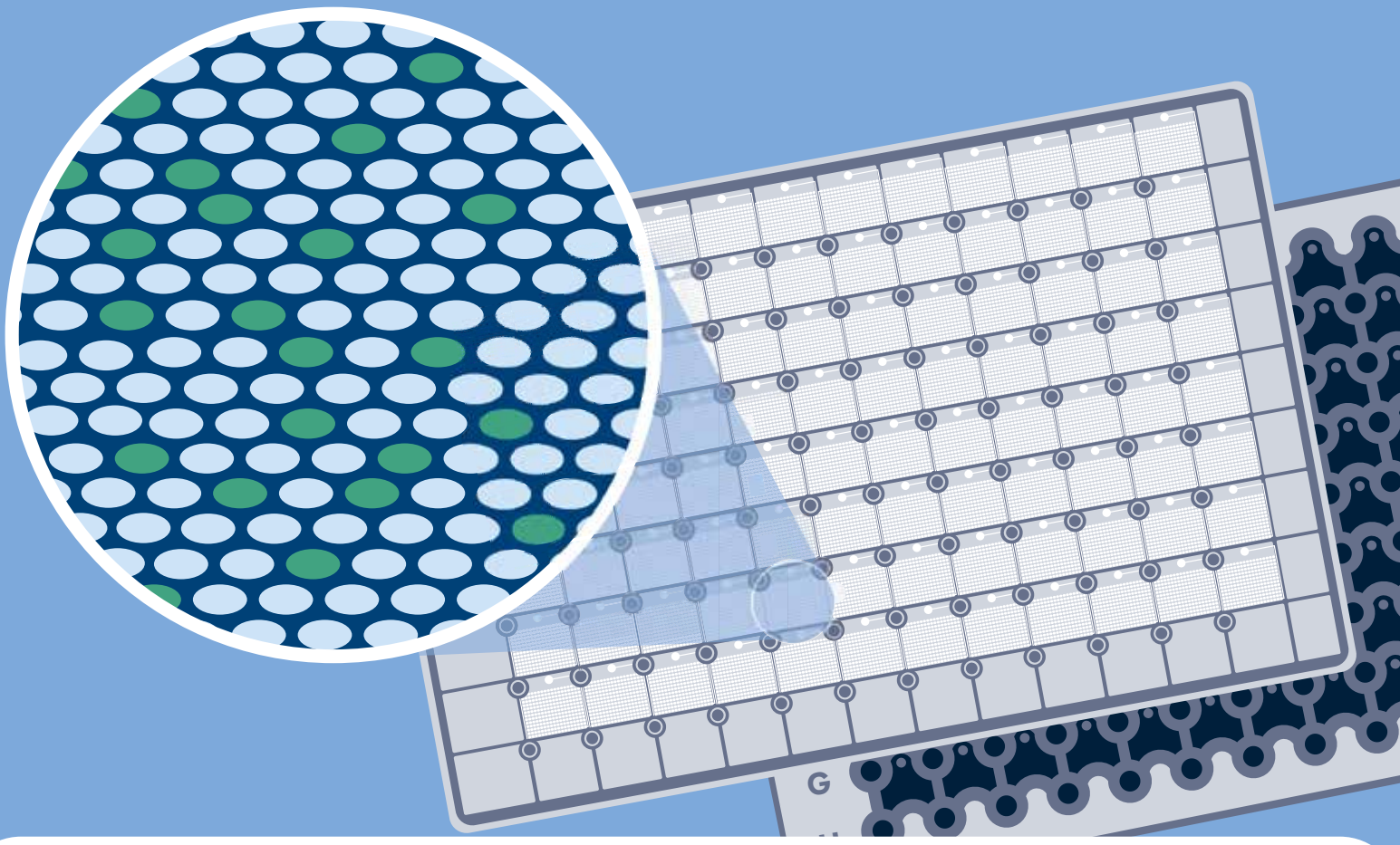


The magic is inside

Nanoplate-based digital PCR system

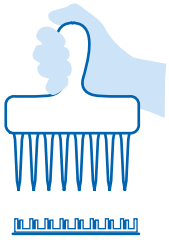
No droplets. No chips. No crystals.
6 reasons to love nanoplate-based digital PCR

- Enables a qPCR-like workflow, improving ease of use
- Plates are amenable to front-end automation (e.g., on the QIAgility®), minimizing hands-on steps
- Sealed nanoplates eliminate the risk of contamination
- Simultaneous reading of all partitions/well allows quicker time-to-result
- Fixed partitions prevent variation in size and coalescence, maximizing consistency and uniformity
- Simultaneous analysis of up to 12 targets in one reaction (12 plex) saves precious samples

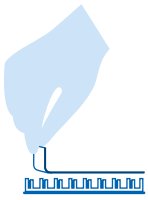
A simple and rapid workflow

The nanoplate-based QIAcuity® System provides a qPCR-like workflow. Sample preparation includes the transfer of diluted samples and the addition of master mix, probes and primers to an 8-, 24- or 96-well nanoplate. The system then automates a fully integrated dPCR workflow – partitioning, thermocycling and imaging – enabling walk-away operation and delivering results in about two hours.

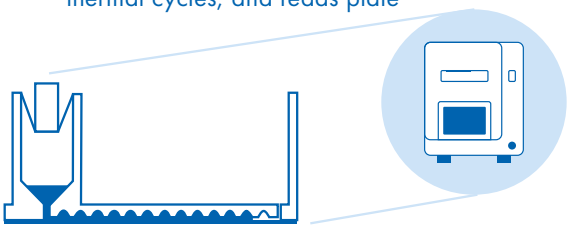
1 Pipette reaction mixtures to dPCR plate



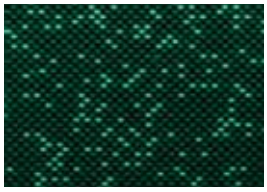
2 Apply rubber plate seal to dPCR plate and place in instrument



3 Instrument automatically partitions, thermal cycles, and reads plate



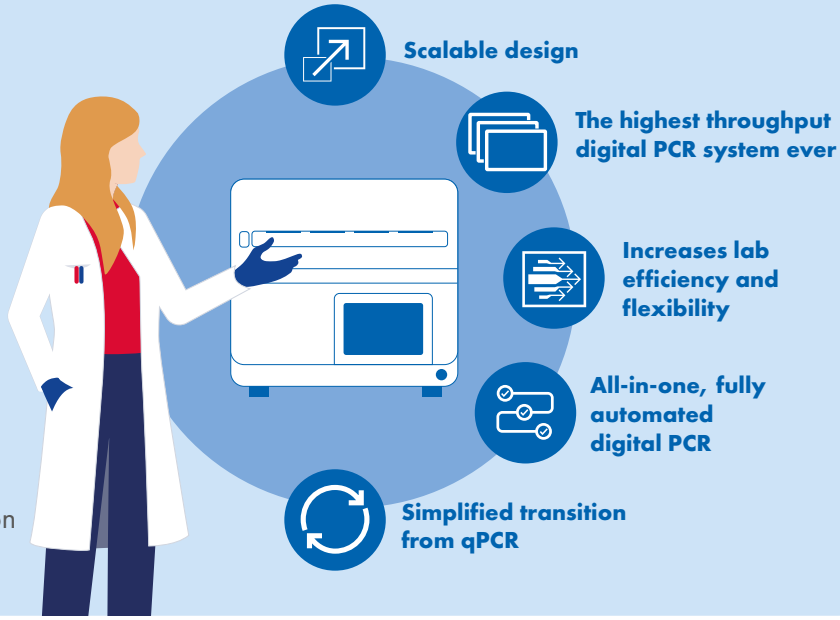
4 Analyze results



The magic of QIAcuity

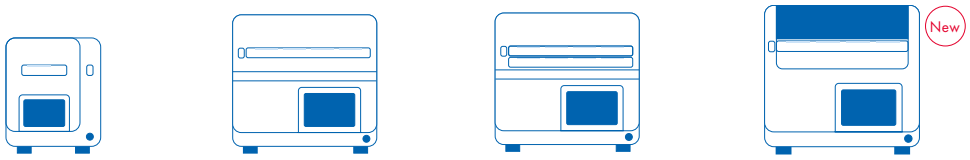
QIAcuity offers a fully integrated design, walk-away automation and ease of use. It delivers high throughput and highly sensitive detection through multiplexing, scalability, continual loading and flexible plate configuration.

Its capabilities are ideal for replacing qPCR, ddPCR and existing dPCR systems as the method of choice for quantification of nucleic acid targets.



The QIAcuity instruments and nanoplates

A fully integrated digital PCR solution for absolute quantification



	QIAcuity One*	QIAcuity Four*	QIAcuity Eight*	QIAcuityDx® Four †
Plates processed	1	4	8	4
Detection channels	2 or 8[1] (6+2 hybrid[2])	8[1] (6+2 hybrid[2])	8[1] (6+2 hybrid[2])	5
Multiplexing capability	4 or 12[3][1]	12[3][1]	12[3][1]	5
Thermocycler(s)	1	1	2	1
Time to result	Approx. 2 h	First plate approx. 2 h Every ~80 min a following plate	First plate approx. 2 h Every ~40 min a following plate	First plate approx. 2h Every ~80 min a following plate
Throughput (samples processed in an 8-hour shift, including overnight run)	Up to 480 (96-well) Up to 120 (24-well)	Up to 768 (96-well) Up to 192 (24-well)	Up to 1536 (96-well) Up to 384 (24-well)	Up to 768 (96-well) ‡ Up to 192 (24-well)
Purpose	For non-clinical applications only	For non-clinical applications only	For non-clinical applications only	IVD medical device

1) Requires use of QIAcuity High Multiplex Probe PCR Kit in case of multiplexing >5plex
2) Hybrid channels are used for Long Stokes Shift (LSS) dyes
3) Detection of 12 targets in parallel can be achieved by using amplitude multiplexing in the six standard channels. When combining hybrid channels for single plex LSS dyes and amplitude multiplexing, the total possible multiplex can be increased to 14. However, this combination is not recommended due to the optimization demand for all assays used in a reaction mix and their corresponding crosstalk compensation.

The QIAcuity system offers distinct nanoplate configurations with flexible sample formats that accommodate a wide range of throughput and sensitivity requirements.

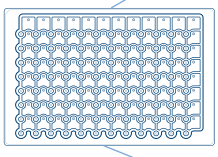


Plate type	Samples/ plate	Partitions/ well	Input volume	Purpose	Key applications
Nanoplate 26K 8-well §	8	approx. 26,000	40 µL	For molecular biology applications only	Rare mutation detection, liquid biopsy, gene expression analysis, pathogen detection and more
Nanoplate 26K 24-well	24	approx. 26,000	40 µL	For molecular biology applications only	Rare mutation detection, liquid biopsy and more
Nanoplate 8.5K 24-well	24	approx. 8500	12 µL	For molecular biology applications only	CNV detection, NGS library, quantification and more
Nanoplate 8.5K 96-well	96	approx. 8500	12 µL	For molecular biology applications only	CNV detection, NGS library, quantification and more
Nanoplate 26K 24-well	24	approx. 26,000	40 µL	IVD medical device	IVD applications

Non-clinical applications

Rare mutation detection
dPCR LNA® Mutation Assays

Gene expression
QuantiNova® LNA PCR Assays

Wastewater testing
QIAcuity OneStep Advanced Probe Kit

Pathogen detection
dPCR Microbial DNA Detection Assays
QIAcuity UCP Probe PCR Kit

Cell and gene therapy
QIAcuity CGT dPCR Assays
QIAcuity RCL Quant Kit
Viral Vector Lysis Kit
QIAcuity Residual DNA Quant Kits
QIAcuity Mycoplasma Quant Kit

Liquid biopsy
dPCR LNA Mutation Assays
dPCR CNV Probe Assays

Copy number variation
dPCR Copy Number Assays
dPCR CNV Probe Assays

miRNA detection
miRCURY® LNA miRNA PCR Assays

GMO detection
dPCR Copy Number Assays

IVD applications

Infectious disease
- Viral
- Bacterial
- Fungal
- Parasitic
- Oncology

Oncology
- Cancer biomarker detection
- Monitoring and MRD testing
- Liquid biopsy
- Cell and gene therapy

Genetic testing
- Quantify specific DNA sequences at low analyte concentration with high precision

Transplant rejection
- Molecular monitoring
- Chimerism

Unique features of the QIAcuityDx System as an IVD medical device

To deliver excellence in diagnostic compliance and fulfill the needs of clinical labs, we've developed QIAcuityDx with a valuable range of features and software elements

- IVD labeled medical device platform¶, nanoplate and dPCR probe mix coupled with compliant and flexible Universal MasterMix**
- Developed and manufactured according to quality standards††
- Software follows cybersecurity standards ‡‡
- Bi-directional LIMS interface §§
- Validated installation process (IQ, OQ, PQ)
- Exportable audit trails storing 53 distinct event types

Visit **www.qiagen.com/dPCR** to learn more about nanoplate-based PCR.
Or **www.qiagen.com/qiacuitydx** to learn more about dPCR for clinical testing.

* The QIAcuity is intended for molecular biology applications. This product is not intended for the diagnosis, prevention or treatment of a disease. Therefore, the performance characteristics of the product for clinical use (i.e., diagnostic, prognostic, therapeutic or blood banking) is unknown.
** Supplied with a separate tube of magnesium chloride to support product optimization processes.
† QIAcuityDx is intended for in vitro diagnostic use. Product availability may differ from country to country based on regulations and approvals. Contact your country representative for further details.
‡ When using nanoplates for molecular biology applications only in Utility Mode.
§ Not currently supported on QIAcuityDx Four.
¶ Complies with Regulation (EU) 2017/746 (IVDR) and is classified as a Class II Medical Device under FDA regulations.
†† Developed and manufactured in accordance with ISO 13485 Quality Management System (QMS) standard, 21 CFR 820 Quality System Regulation (QSR) and under ISO 14971 Risk Management program.
‡‡ Software developed following the IEC 62304 Software Development Lifecycle standard (SDLC) and adhered to the latest cybersecurity standards, including IEC 81001-5-1 and most recent FDA guidance on cybersecurity.
§§ Not available with software version 1.0. Available with software version 1.1, scheduled to release during Q1, 2025.

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