QIAcuity®
Digital PCR System

Fast. Scalable. Reliable.

Sample to Insight

The Magic is Inside

It's in the seamless integration of all digital PCR (dPCR) workflow components into an all-in-one walkaway instrument, delivering the speed and throughput every laboratory needs.

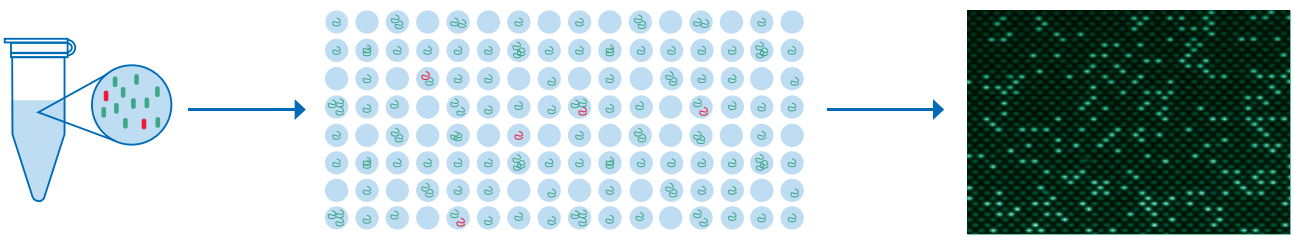
It's in the microfluidic nanoplate technology that puts every run ahead of the curve with its precision and sensitivity.

Got a needle in a haystack problem?

Digital PCR holds the answer.

You know the struggles of performing sensitive research applications to identify faint genetic event against a strong background, especially when the positives are lost in a dense pool of negatives. Finding that rare allele or mutant sequence is a typical needle in a haystack problem. This is where digital measurement comes in handy.

Digital PCR (dPCR) is a nucleic acid quantification technique that works by dividing a bulk qPCR-like reaction mixture into numerous individual reactions called partitions and then measuring the endpoint fluorescence of each partition to determine the presence (1) or absence (0) of the target. This makes digital PCR less reliant on the kinetics of the PCR reaction and eliminates the need for standard curves as in qPCR. Statistical methods (Poisson law) are then used to calculate the absolute concentration of the target based on the number of positive and negative partitions.

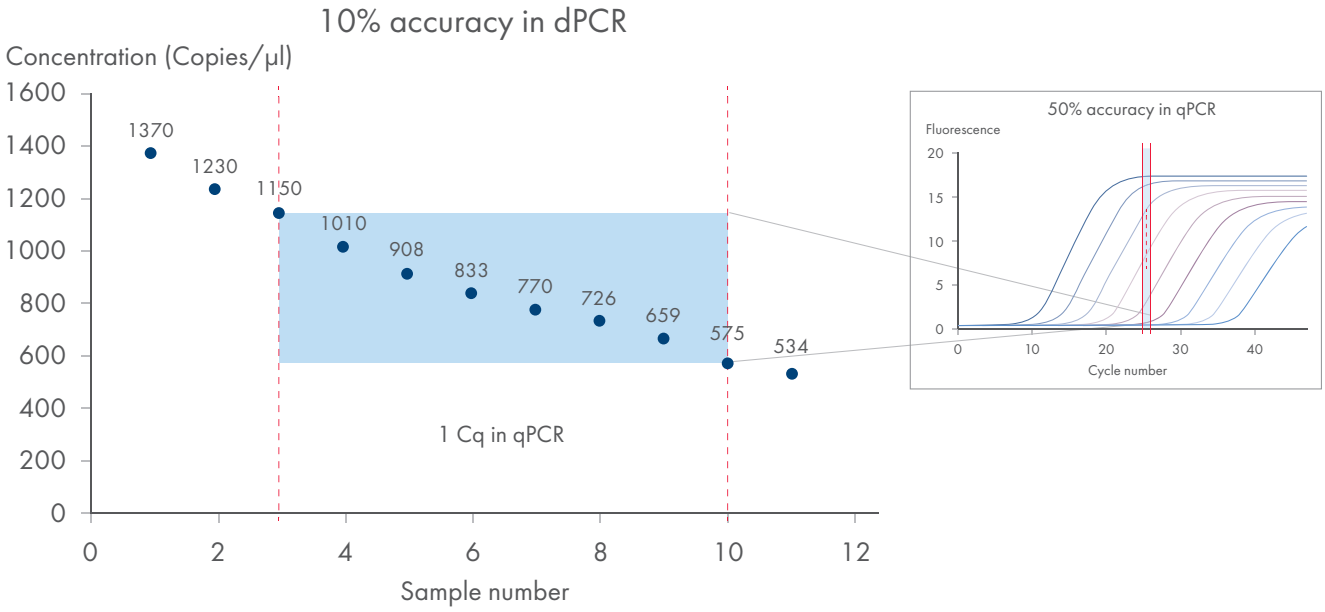


Red - Target and Green - Background (gDNA, cDNA; primers/probes; master mix)

Random distribution of molecules into partitions

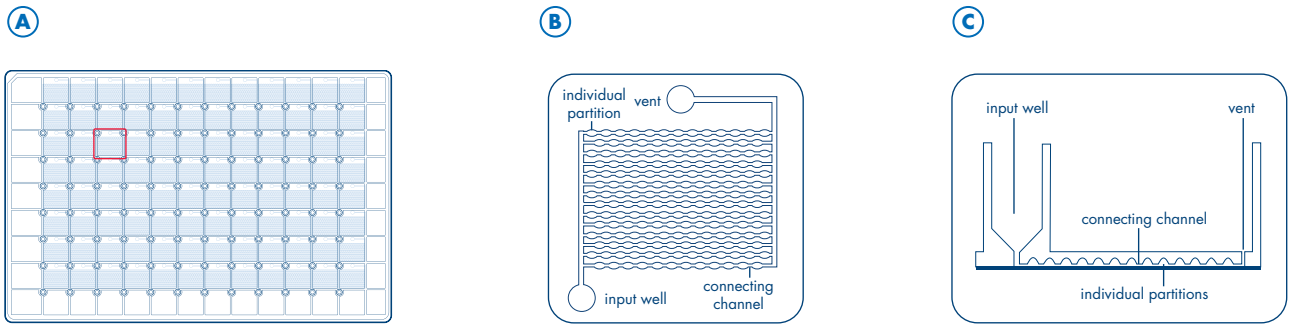
Absolute quantification: Copies/µl

Absolute quantification provides reproducible data that can be more easily compared between laboratories. Further, due to the linear response of the technology, dPCR offers a more precise measurement than qPCR and makes it surprisingly easy to detect the positives.



No droplets. No chips. No crystals. Digital PCR in nanoplates.

The QIAcuity Digital PCR System uses a microfluidic nanoplate technology to overcome challenges with inconsistent droplet generation, complex workflow, slow droplet readout, and limitations concerning the uncertainty of assays.



A Nanoplate with 96 well **B** Single well detail **C** Cross section view of the partitions

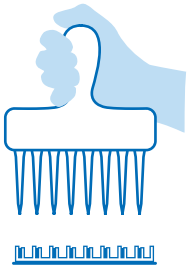
5 reasons why

- Fixed partitions prevent variation in size and coalescence, maximizing consistency
- Sealed nanoplates eliminate the risk of contamination
- Simultaneous reading of all partitions/well allows quicker time-to-result
- qPCR-like plates provide a more familiar workflow, improving ease of use
- Plates are amenable to front-end automation (e.g., on the QIAgility), minimizing hands-on steps

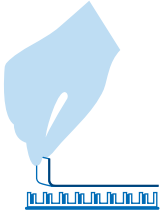
A simple and rapid workflow

The nanoplate-based QIAcuity Digital PCR System provides a qPCR-like workflow, in which sample preparation includes the transfer of diluted samples and the addition of master mix, probes and primers to a 96- or 24-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.

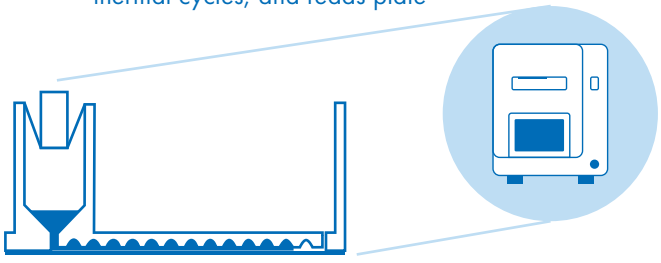
1 Pipette reaction mixtures to dPCR plate



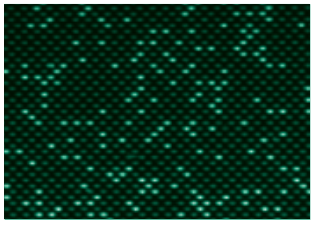
2 Apply rubber plate seal to dPCR plate and place in instrument



3 Instrument automatically partitions, thermal cycles, and reads plate



4 Analyze results



Explore a virtual workflow demo: **www.qiagen.com/qiacuity-demo**

QIAcuity Digital PCR System

Features and benefits

With a fully integrated design, walk-away automation, ease of use, advanced multiplexing, scalable instrument and flexible plate configuration for high throughput and highly sensitive detection, the QIAcuity system can displace qPCR, ddPCR and existing dPCR systems as the method of choice for quantification of nucleic acid targets.

- **Scalable design**
  The QIAcuity system comes in scalable instrument configurations with a single thermal cycler and capacity to run up to 4 plates or a dual thermal cycler and capacity to run up to 8 plates.

- **The highest throughput digital PCR system ever**
  An 8-plate capacity allows up to 1248 samples to be analyzed in a single workday using a 96-well nanoplate.

- **Ultra-high multiplexing**
  Up to 6 channels (including one reference channel) can be configured for multiplex quantification of up to 5 target DNA or RNA molecules in a given assay, saving time and reagents.

- **Fully automated digital PCR**
  The QIAcuity system integrates reaction partitioning, thermal cycling and imaging into a single fully automated instrument that takes users from sample to result of up to 96 samples in 2 hours and up to 768 samples in 5 hours.

- **Simplified transition from qPCR**
  The QIAcuity system is compatible with qPCR detection chemistries such as hydrolysis probes and EvaGreen dye, simplifying the transition from qPCR assays.

QIAcuity instruments

	QIAcuity One	QIAcuity Four	QIAcuity Eight
Plates processed	1	4	8
Detection channels (multiplexing)	2 or 5	5	5
Thermocycler(s)	1	1	2
Time to result	Approx. 2 h	First plate approx. 2 h Every ~60 min a following plate	First plate approx. 2 h Every ~30 min a following plate
Throughput (samples processed in a work day)	Up to 384 (96-well) Up to 96 (24-well)	Up to 672 (96-well) Up to 168 (24-well)	Up to 1248 (96-well) Up to 312 (24-well)

Detection channels and fluorophores

Detection channels	Recommended dyes
Green	FAM
Yellow	VIC, HEX
Orange	TAMRA
Red	ROX
Crimson	Cy5

You see the most with the QIAcuity Nanoplate 26K

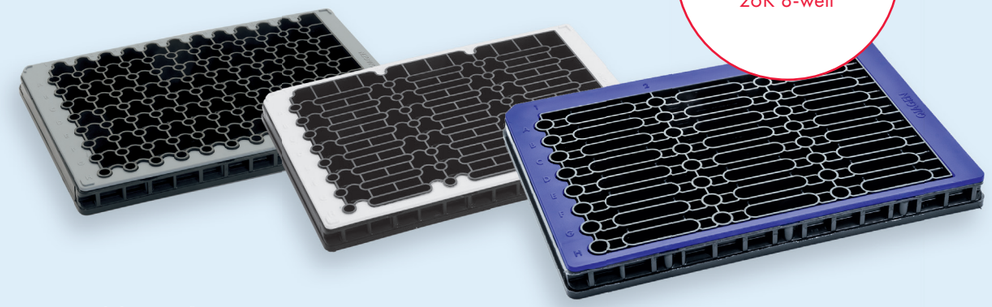
Finding a rare event (<10–20 copies per reaction) means confirming the presence or absence of a signal and not just precise quantification. Loading volume is critical when applied to samples with rare targets.

Imagine analyzing a DNA eluate containing a very rare event of 0.1 cp/µl, i.e., 3 cp in a 30 µl eluate. How many copies can you detect by digital PCR?

The QIAcuity Nanoplate 26K allows more loading, allowing you to see the most compared to that offered by any other dPCR method, including comparable plate methods.

QIAcuity Nanoplates

Coming soon!
QIAcuity Nanoplate
26K 8-well



Features and benefits

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

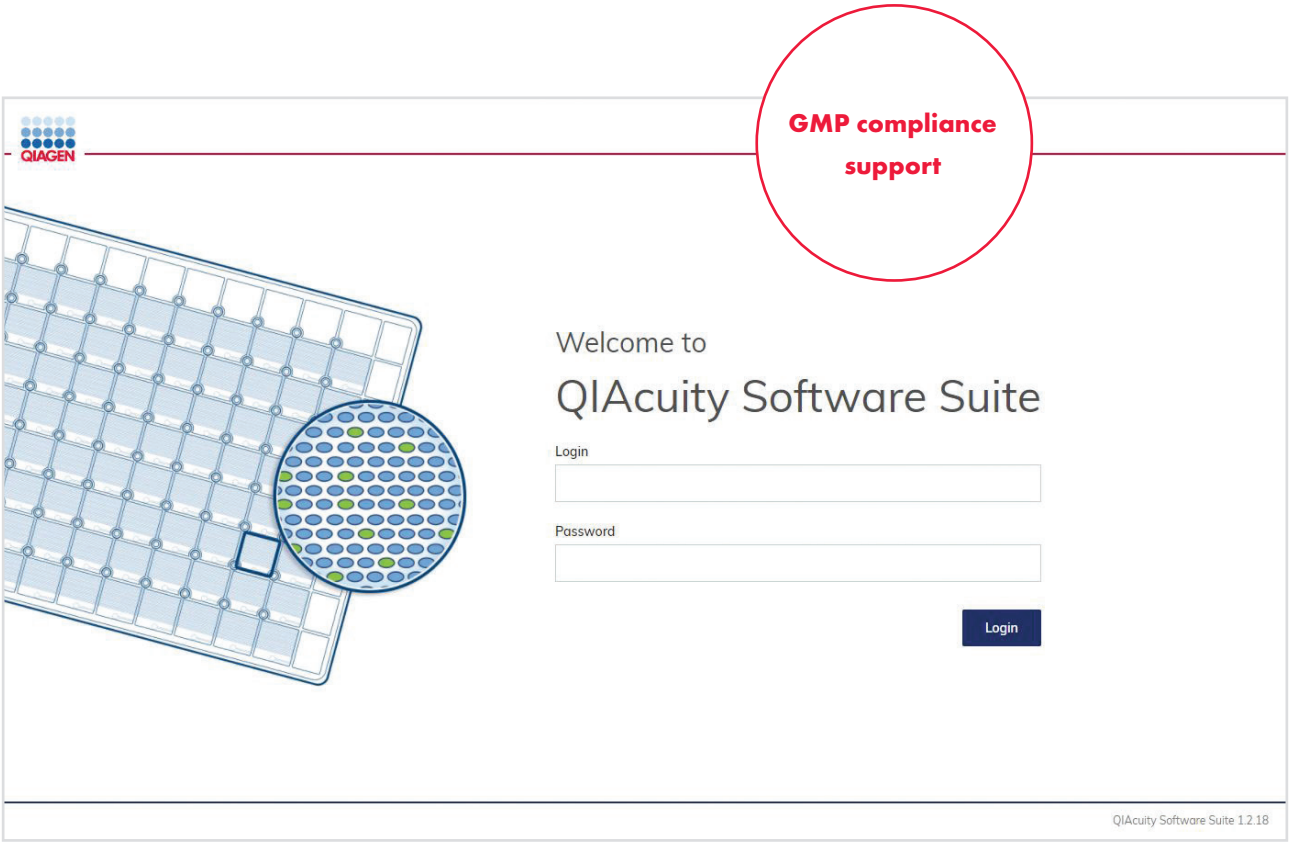
Plate type	Samples/plate	Partitions/well	Input volume	Key application
Nanoplate 26K 24-well	24	approx. 26,000	40 µl	Rare mutation detection, liquid biopsy, and more
Nanoplate 8.5K 96-well	96	approx. 8500	12 µl	CNV detection, NGS library, quantification, and more

	QIAGEN Nanoplate 26K	MAP16 dPCR plate	ddPCR	
	40 µl	9 µl	20 µl	Reaction volume
	26 µl	6 µl	13 µl	Possible sample volume from the 30 µl eluate (assuming 4x master mix and 10x assay)
	20 µl	8.5 µl	16 µl (assuming 16K droplets)	Volume analyzed
3 cp in the eluate	2.6 cp	0.6 cp	1.3 cp	Copies transferred
	1.3 cp	0.57 cp	1.04 cp	Copies analyzed
10 cp in the eluate	8.7 cp	2 cp	4.3 cp	Copies transferred
	4.3 cp	1.9 cp	3.46 cp	Copies analyzed

QIAcuity Software

The QIAcuity Control Software is an integral part of the QIAcuity system. It offers a GUI (graphical user interface) for basic functionalities such as plate setup, changing the order of plates to be processed, and monitoring the status of runs in real time. After a run is completed, the data are stored on the instrument's memory and are sent to the connected QIAcuity Software Suite for analysis.

The QIAcuity Software Suite provided with the instrument and installed on a separate computer controls one or multiple QIAcuity instruments, either connected directly to one instrument or using an existing local area network (LAN).
When integrated into a local area network, the computer is hosting the QIAcuity Software Suite function as a server that is accessible via LAN to other computers serving as clients.
This enables multiple users to access the software from other rooms or offices and analyze data via a standard browser without the need to install the software on multiple computers or access and exchange data via internet connections.



Example run and analysis views in the software

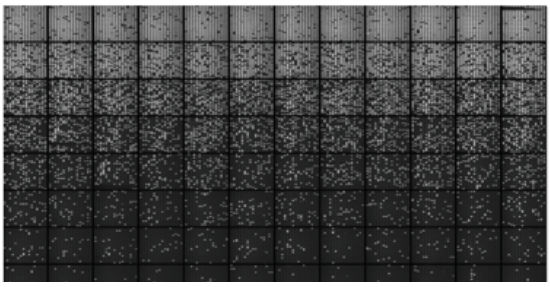
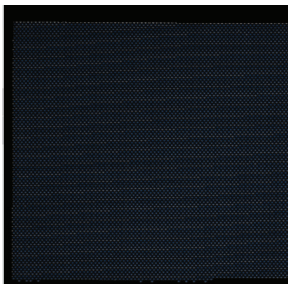
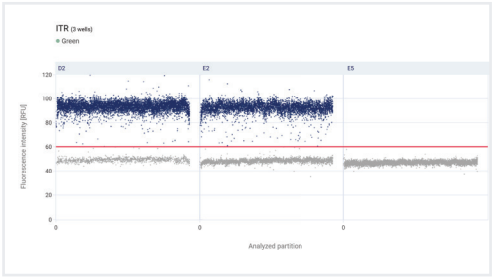


Plate image



Signal map

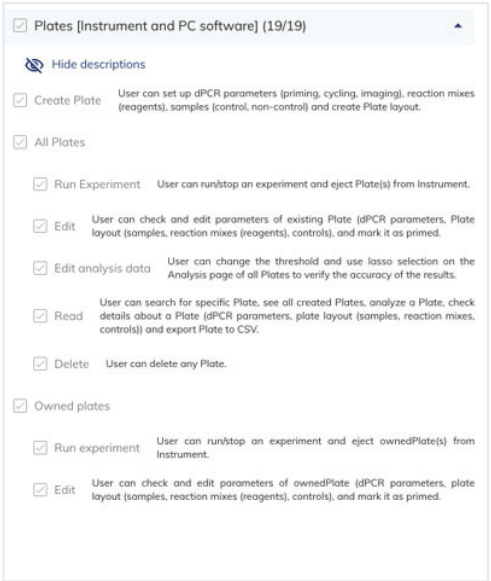


1D Scatterplot

Heat map

Features and benefits

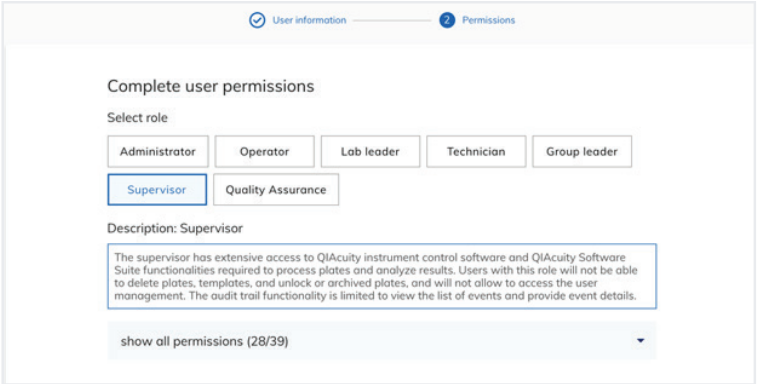
Easy to use – access, design and analyze from anywhere



Enables 21 CFR Part 11 compliance support in a GMP setting

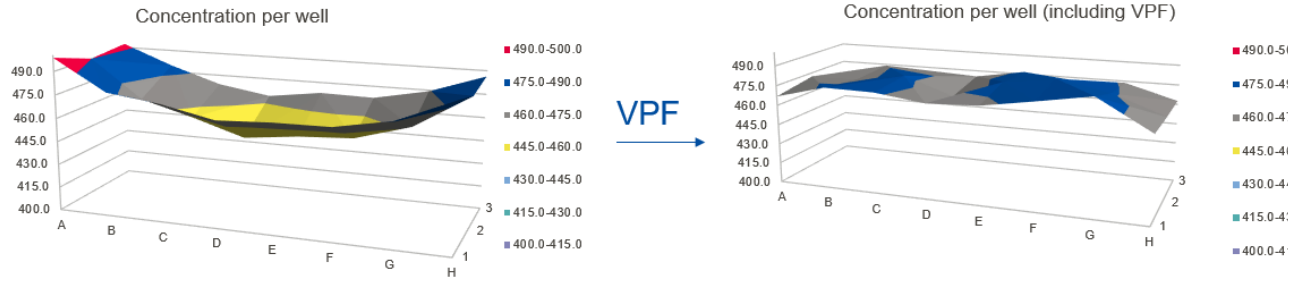
- Audit trail and traceability
- Advanced user management with customized roles and permissions*
- Electronic signatures*

*Available in software v2.1



Improving precision of concentration results by using a volume precision factor (VPF)

A precise determination of the cycled sample volume is needed to calculate target concentrations in dPCR. In general, nanoplates provide partitions of fixed sizes that enable an exact and reproducible sample concentration calculation. To compensate for even the slightest volume variations between different wells of a plate or between different plate batches, a volume precision factor (VPF) is available for each plate. The VPF is a set of factors for each well included in the software. It consists of 96 individual factors that can address the well-to-well variability and reduce variations between different molding forms resulting in batch-to-batch variability. This increases the precision of concentration measurements in dPCR, particularly for sensitive applications such as rare mutation analysis.



Expected concentration copies/µl	477.5
Mean concentration copies/µl	472.1
SD	13.6
CV%	2.9%

Expected concentration copies/µl	477.5
Mean concentration copies/µl	472.8
SD	6.3
CV%	1.3%

Hyperwell option added to certain analysis for higher accuracy

Multiple wells can be grouped and analyzed as a single well to achieve higher accuracy. For the analysis, hyperwells are treated as a single well but with more partitions. This may be helpful for rare event detection if the sample volume to be analyzed exceeds the volume that can be loaded into a single well.

For more information about QIAcuity Digital PCR System, visit: **www.qiagen.com/qiacuity**

QIAcuity Reagents

The QIAcuity system is optimized for hydrolysis probes and EvaGreen dye, allowing you to expand applications using flexible dPCR chemistry.

A reagent for every need

- Optimized for best performance in nanoplate microfluidic
- Includes special reference dye needed for dPCR analysis and counting analyzable partitions
- Highly concentrated master mixes enabling larger sample volumes
- All mixes for single-plex and multiplex use
- QIAcuity OneStep Advanced Probe Kit with thermostable RT (HotStart) enabling multi-plate runs in high throughput

Dye-based
QIAcuity EG PCR Kit

Probe-based
QIAcuity Probe PCR Kit
QIAcuity OneStep Advanced Probe Kit

QIAcuity Assays

Thanks to the high sensitivity and superior precision and accuracy, a wide range of samples and applications can benefit from digital PCR.

Wet-lab verified dPCR assays on GeneGlobe

- For DNA targets; for detection of copy number variation or mutations related to cancer and oncogenesis
- For quantification of microRNA targets
- For quantification of RNA/lncRNA targets and gene expression studies
- For detection of bacterial 16S rRNA and fungal ribosomal rRNA sequences; for species identification, detection of virulence genes and antibiotic resistance genes

Rare mutation detection
dPCR LNA Mutation Assays

Pathogen detection
dPCR Microbial DNA Detection Assays

Copy number variation
dPCR Copy Number Assays

Gene expression
QuantiNova LNA PCR Assays

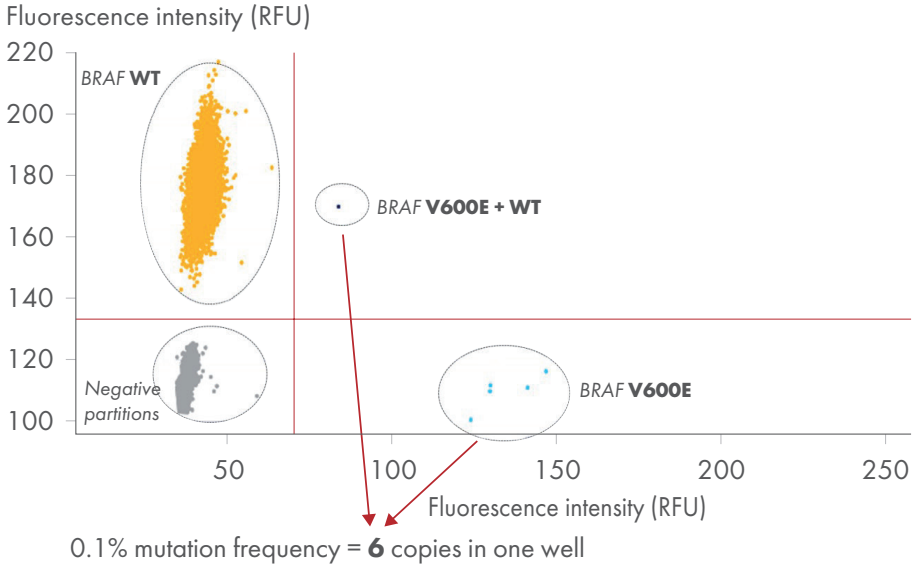
miRNA detection
miRCURY LNA miRNA PCR Assays

Cell and gene therapy
AAV Gene Therapy Assays
Coming soon

Find and configure your dPCR assay with ease at
www.geneglobe.qiagen.com/products/analysis-type/analysis-type-dpcr

dPCR LNA Mutation Assays

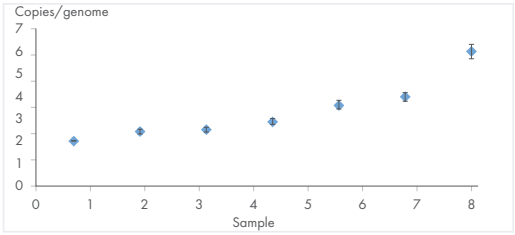
- Locked nucleic acid (LNA) technology increases assay specificity and sensitivity
- Duplex assay design detects mutated and wild-type sequences
- Two dye combinations allow detection of two targets in the same reaction



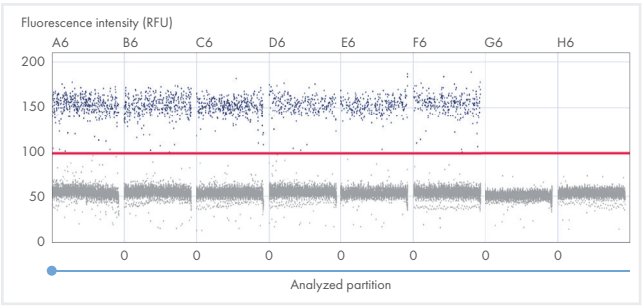
***BRAF* V600E detection at 0.1% in FFPE samples**. Test sample with 0.1% mutation frequency was created by spiking 0.3 ng Horizon™ FFPE samples into 30 ng healthy WT gDNA. The measured mutation frequency was 0.13% with 0.24 copies/µl. The figure shows the 2D scatter plot of a single well with 6 positive copies detected in the green channel (FAM).

dPCR Copy Number Assays

- Predesigned assays for all genes in the human genome deliver reliable results
- Three design locations per gene – 5′, middle, 3′– to amplify your region of interest
- Simple and straightforward EvaGreen-based dPCR format enhances usability



***MYC* copy number determination in MCF-7 cell line.** Copy number plot of *MYC* normalized with TERT as reference. The samples S1–S7 are WT/MCF-7 mixtures containing increasing amounts of MCF-7 DNA: S1=0%, S2=11%, S3=20%, S4=33%, S5=43%, S6=50% and S7=100%. MYC copy number determined using the QIAcuity System matched the expected numbers: S1=2, S2=2.4, S3=2.8, S4=3.3, S5=3.7, S6=4 and S7=6. The WT, MCF-7 and mixture samples were analyzed with 4 ng/reaction.

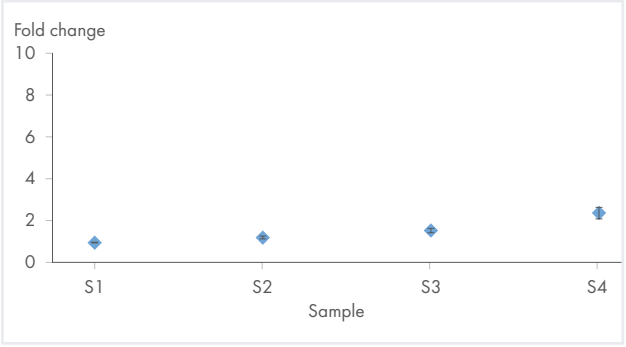


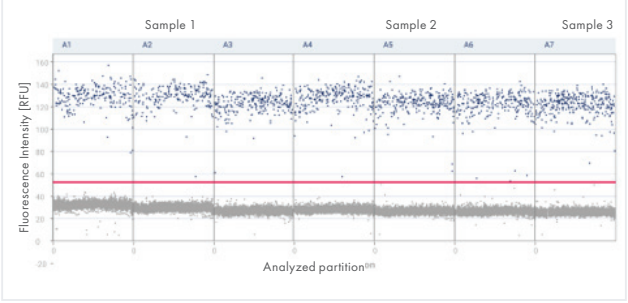
dPCR Copy Number Assay validation. 1D scatter plot showing single-well assay validation data of dPCR Copy Number Assay MYC with different human gDNA input amounts (**A6–C6**: 6 ng/reaction, **D6–F6**: 4 ng/reaction, **G6**: NTCs; Green channel for EvaGreen detection).

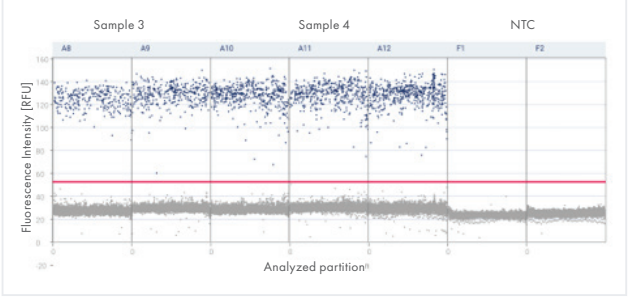
QuantiNova LNA PCR Assays

- Over 1.3 million assays detect any human, mouse or rat mRNA or lncRNA
- Short LNA-enhanced primers provide exceptional sensitivity and specificity
- EvaGreen-based dPCR allow accurate and convenienttranscript analysis

IL-4 gene expression analysis – detecting small expression changes with the highest precision. Synthetic IL4 RNA was spiked into non-IL4 expressing Universal Human Reference RNA (Thermo Fisher Scientific). IL4 fold-expression changes in samples S2, S3 and S4 were calculated using S1 as reference sample and HPRT as reference target.
The mean fold change (from 3 technical replicates/sample) in IL4 expression: S1=0 (reference), S2=1.3, S3=1.5 and S4=2.3.



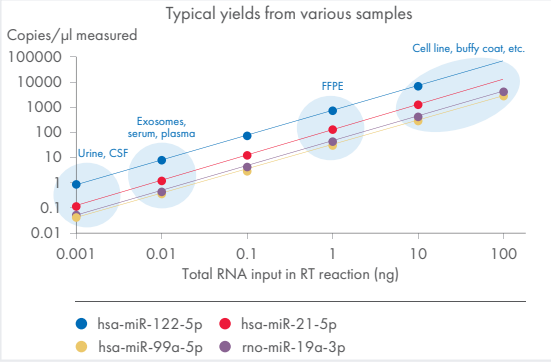




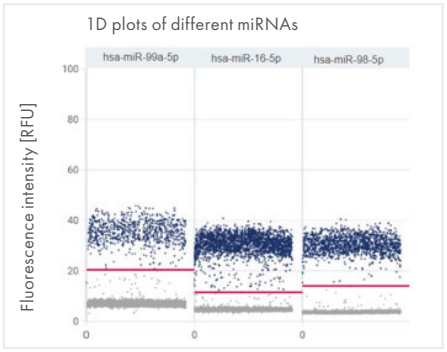
1D Scatter Plot of IL4 QuantiNova LNA PCR Assay showing the resolution

miRCURY LNA miRNA PCR Assays

- One RT reaction for all miRNA and two LNA-enhanced miRNA-specific primers for highest specificity
- EvaGreen-based dPCR allow absolute quantification of miRNA expression changes
- Full miRBase coverage enables miRNA profiling from any organism



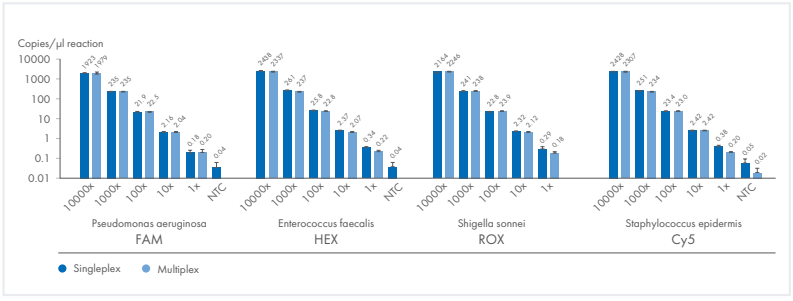
Reliable miRNA detection from different samples at 1 pg RNA input without pre-amplification



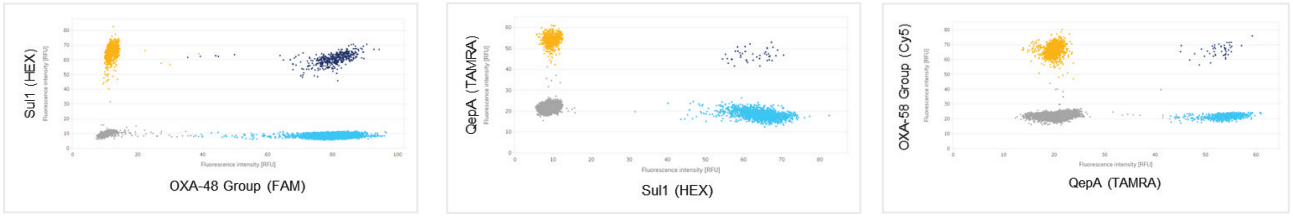
Good separation between negative and positive partitions and precise thresholding of the positives

dPCR Microbial DNA Detection Assays

- Assays for more than 680 targets detecting microbial species, virulence genes, viruses or antibiotic resistance genes
- Dye selection enables multiplexing of up to 5 targets per reaction
- Combine microbial DNA and viral RNA targets in one reaction using the QIAcuity OneStep Advanced Probe Kit



Microbial detection in multiplex on the QIAcuity. Single-plex versus multiplex setup quantifying four different bacterial targets. The data shows a very similar and precise quantification of all targets for concentrations between 0.2–2500 cp/µl.



Signal separation between channels in multiplex on the QIAcuity. Four assays targeting four bacterial resistance genes were run in multiplex reactions. 2D scatter plots of various dye combinations from the 4-plex runs.

Download the **QIAcuity Application Guide** for detailed information about setting up experiments and analyzing results for applications, including copy number variation analysis, rare mutation detection and gene expression.

QIAcuity Services

Our instrument service plans are offered at various levels, so you can choose the one that best fits your needs and budget. Let our highly-skilled certified service team keep your instrument maintained so you can focus on results

- Maximize uptime and productivity
- Receive priority support and service
- Reduce the risk of non-compliance
- Control costs
- Minimize disruption of laboratory performance

All parts, labor and travel costs are included for standard repairs, and the annual preventive maintenance gives you peace of mind.

Get a full overview of the QIAcuity service solutions at **www.qiagen.com/qiacuity-services**

Digital MIQE guidelines

As part of the PCR community, you're well aware of the reproducibility crisis in research and the daily challenges in a molecular biology laboratory using qPCR, dPCR, or any comparable techniques.

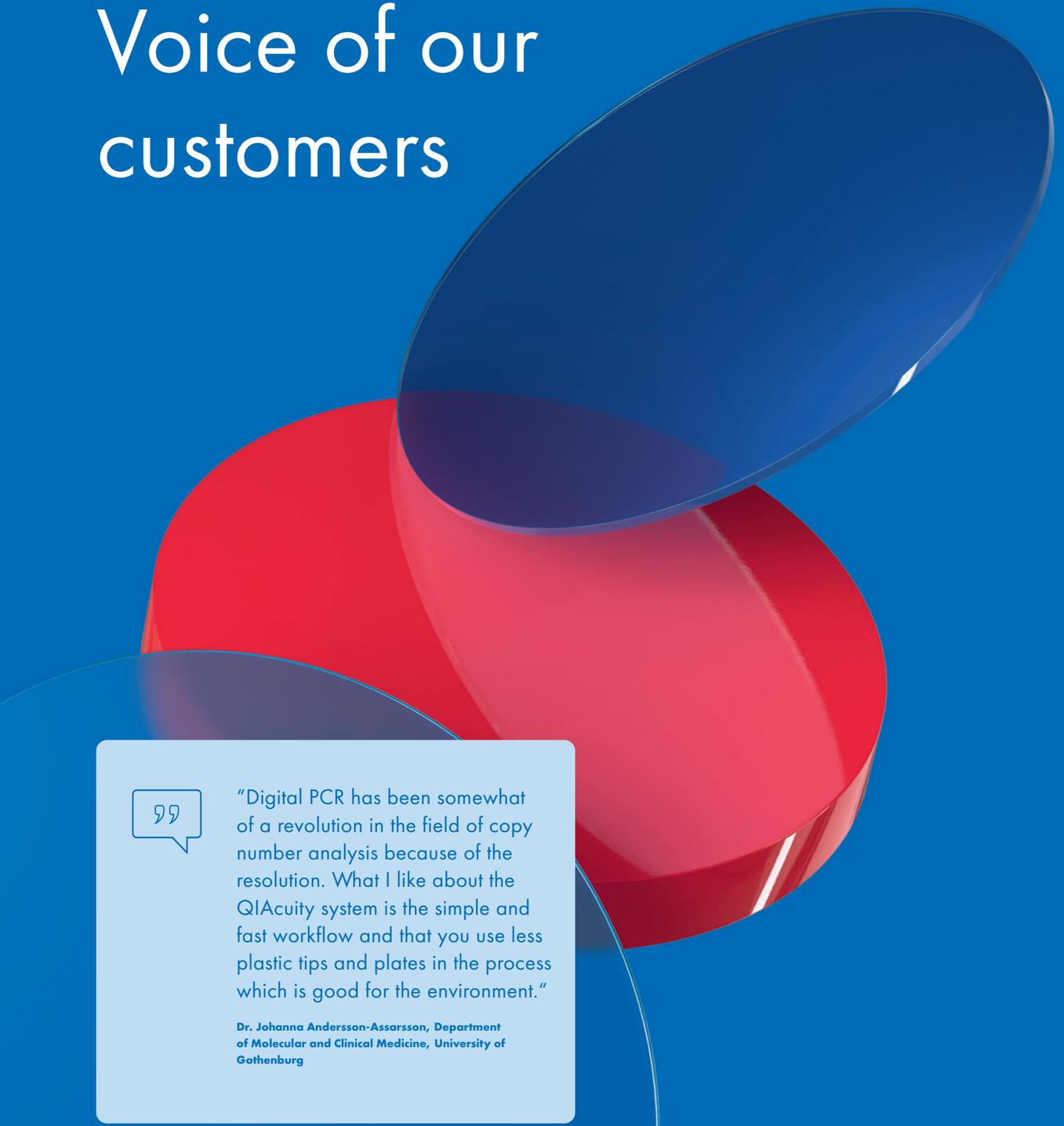
To support the community, a group of experts published the Minimum Information for Publication of Quantitative Real-Time PCR Experiments (MIQE) guidelines in 2009, targeting the reliability of results for credible publications, promoting reproducibility between laboratories, and increasing experimental transparency.

Fast forward to 2013, owing to a growing interest in dPCR because of its accessibility and affordability, the Minimum Information for Publication of Quantitative Digital PCR Experiments (dMIQE) guidelines were published to ensure global standardization. The guidelines were further updated in 2020.

- Why do we need such guidelines?
- What are these guidelines?
- How are these guidelines revolutionizing dPCR experiments?

Watch an on-demand webinar to find out.

Voice of our customers



"Digital PCR has been somewhat of a revolution in the field of copy number analysis because of the resolution. What I like about the QIAcuity system is the simple and fast workflow and that you use less plastic tips and plates in the process which is good for the environment."

Dr. Johanna Andersson-Assarsson, Department of Molecular and Clinical Medicine, University of Gothenburg

"With the new, high-throughput QIAcuity Eight, we were able to detect new variants of SARS-CoV-2 in wastewater samples successfully. This fast and scalable technology can provide a valuable addition to our environmental, biological testing services, which we will offer to our clients in the near future."

Dr. Franz Durandet, President of I.A.G.E. in Montpellier, France

"When working with low microbial biomass concentrations, qPCR is a good tool for quantification, but dPCR is the best approach. The QIAcuity dPCR instrument allows us to consistently detect and quantify microorganisms in soil, rock and water."

Prof. John R. Spear, Department of Civil and Environmental Engineering, Colorado

"Digital PCR has higher detection rates at low DNA concentrations and can handle high concentrations of PCR inhibitors present in marine coastal ecosystems. We found the QIAcuity especially straightforward and fast. It can quantify eDNA from invasive species with more accuracy and sensitivity, independent of the amplification efficiency."

Per Sundberg, CEO, SeAnalytics AB, Gothenburg, Sweden

"Our lab loves using the QIAcuity digital PCR system for absolute quantification of targets from a wide range of samples. The workflow is straightforward, easy to learn, and generates incredibly consistent and sensitive results."

Drew Capone and colleagues, University of North Carolina at Chapel Hill, NC

Ordering Information

Product	Contents	Cat. no.
QIAcuity One, 2plex Platform System FUL-1	One-plate digital PCR instrument for detecting up to 2 fluorescent dyes, notebook computer, Nanoplate Roller, USB flash memory, and QIAcuity Software Suite: includes installation, training, full agreement for 1 year with a 2-business day response time, and 1 preventive maintenance visit	911015
QIAcuity One, 5plex Platform System FUL-1*	One-plate digital PCR instrument for detecting up to 5 fluorescent dyes, notebook computer, Nanoplate Roller, USB flash memory, and QIAcuity Software Suite: includes installation, training, full agreement for 1 year with a 2-business day response time, and 1 preventive maintenance visit	911035
QIAcuity Four Platform System FUL-1*	Four-plate digital PCR instrument for detecting up to 5 fluorescent dyes, notebook computer, barcode scanner, Nanoplate Roller, USB flash memory, and QIAcuity Software Suite; Includes installation, training, full agreement for 1 year with a 2-business day response time, and 1 preventive maintenance visit	911045
QIAcuity Eight Platform System FUL-1*†	Eight-plate digital PCR instrument for detecting up to 5 fluorescent dyes, notebook computer, barcode scanner, Nanoplate Roller, USB flash memory, and QIAcuity Software Suite: includes installation, training, full agreement for 1 year with a 2-business day response time, and 1 preventive maintenance visit	911055
QIAcuity Nanoplate 26k 24-well (10)	24-well dPCR Nanoplate with 26K partitions and 40 µl reaction volume per well, including Nanoplate seals	250001
QIAcuity Nanoplate 26k 24-well (50)	24-well dPCR Nanoplate with 26K partitions and 40 µl reaction volume per well, including Nanoplate seals	250002

Ordering Information

Product	Contents	Cat. no.
QIAcuity Nanoplate 8.5k 24-well (10)	24-well dPCR Nanoplate with 8.5K partitions and 12 µl reaction volume per well, including Nanoplate seals	250011
QIAcuity Nanoplate 8.5k 24-well (50)	24-well dPCR Nanoplate with 8.5K partitions and 12 µl reaction volume per well, including Nanoplate seals	250012
QIAcuity Nanoplate 8.5k 96-well (10)	96-well dPCR Nanoplate with 8.5K partitions and 12 µl reaction volume per well, including Nanoplate seals	250021
QIAcuity Nanoplate 8.5k 96-well (50)	96-well dPCR Nanoplate with 8.5K partitions and 12 µl reaction volume per well, including Nanoplate seals	250022
Nanoplate Seals (11)	Nanoplate seal for sealing QIAcuity Nanoplates	250099
Nanoplate Tray (2)	Nanoplate Tray improving plate-handling during pipetting or carrying	250098
QIAcuity Probe PCR Kit (1 ml)	1 ml 4x concentrated QIAcuity Probe Mastermix, 2 x 1.9 ml Water	250101
QIAcuity Probe PCR Kit (5 ml)	5 x 1 ml 4x concentrated QIAcuity Probe Mastermix, 8 x 1.9 ml Water	250102
QIAcuity Probe PCR Kit (25 ml)	5 x 5 ml 4x concentrated QIAcuity Probe Mastermix, 4 x 20 ml Water	250103
QIAcuity EG PCR Kit (1 ml)	1 ml 3x concentrated QIAcuity EvaGreen Mastermix, 2 x 1.9 ml Water	250111
QIAcuity EG PCR Kit (5 ml)	5 x 1 ml 3x concentrated QIAcuity EvaGreen Mastermix, 8 x 1.9 ml Water	250112
QIAcuity EG PCR Kit (25 ml)	5 x 5 ml 3x concentrated QIAcuity EvaGreen Mastermix, 4 x 20 ml Water	250113
QIAcuity OneStep Advanced Probe Kit (1 ml)	1 ml OneStep Advanced Probe Master Mix (4x), 45 µl OneStep RT Mix (100x), 1 ml Enhancer GC, 20 µl QN Internal Control RNA, 2 x 1.9 ml RNase-free water; for 100 reactions in Nanoplate 26K and 333 reactions in Nanoplate 8.5K	250131
QIAcuity OneStep Advanced Probe Kit (5 ml)	5 x 1 ml OneStep Advanced Probe Master Mix (4x), 5 x 45 µl OneStep RT Mix (100x), 5 x 1 ml Enhancer GC, 1 x 20 µl QN Internal Control RNA, 8 x 1.9 ml RNase-free water; for 500 reactions in Nanoplate 26K and 1666 reactions in Nanoplate 8.5K	250132

* Additional instrument and Service bundles are available.

† For all systems, Installation and Training is included but are additionally available as separate service offerings. For specific catalog numbers and additional information, visit www.qiagen.com or contact your local sales representative.

To learn more about QIAGEN's dPCR technology visit **www.qiagen.com/dPCR**

The products mentioned here are intended for molecular biology applications. These products are not intended for the diagnosis, prevention, or treatment of a disease.

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