



**BEHIND EVERY DIAGNOSIS,  
THERE IS A LIFE**

Applied Biosystems®



QuantStudio™ Dx Real-Time  
PCR Instrument

CE IVD



# Behind every diagnosis, there is a promise

You believe in molecular medicine. So do we. We are committed to providing you with comprehensive solutions that help deliver quality results to those who rely on you most.

## The path to diagnosis starts here.

In today's diagnostic laboratory, molecular tests are increasingly integrated into standard practice for identifying and managing disease, predicting the risk of developing disease or recurrence, and informing decisions that help guide lifestyle choices and behavior. These tests have become indispensable tools, both in the practice of modern medicine and the ongoing quest to positively impact patient outcomes. The use of molecular-based assays will only continue to grow in number and importance.

Building on an outstanding history of successful innovations and expertise in real-time PCR, we have developed the QuantStudio™ Dx Real-Time PCR Instrument, designed to address the evolving needs of the clinical laboratory.



The QuantStudio™ Dx Real-Time PCR Instrument represents 20 years of qPCR innovation and our commitment to enhancing molecular diagnostic solutions. The QuantStudio™ Dx instrument provides your clinical laboratory with performance you can trust, security you demand, and flexibility you need for your workflow.





Behind every diagnosis,  
there is trusted performance

## Empowering you to impact outcomes for the better

### **Performance you can trust**

The QuantStudio™ Dx instrument's proven performance, security, and reliability—combined with the outstanding sensitivity and specificity of real-time PCR—help you deliver the right answers that help result in better outcomes.

### **Security you demand**

The QuantStudio™ Dx Software enables you to maintain secure access to instruments, specify user access to various software functions, record all actions completed by users, and sign data electronically. In addition, the onboard software for the QuantStudio™ Dx Real-Time PCR Instrument assists with compliance for 21 CFR Part 11.

### **Flexibility you need**

In test development mode, the QuantStudio™ Dx instrument enables the creation of new assays in 96- or 384-well plates and qPCR microfluidic card formats.

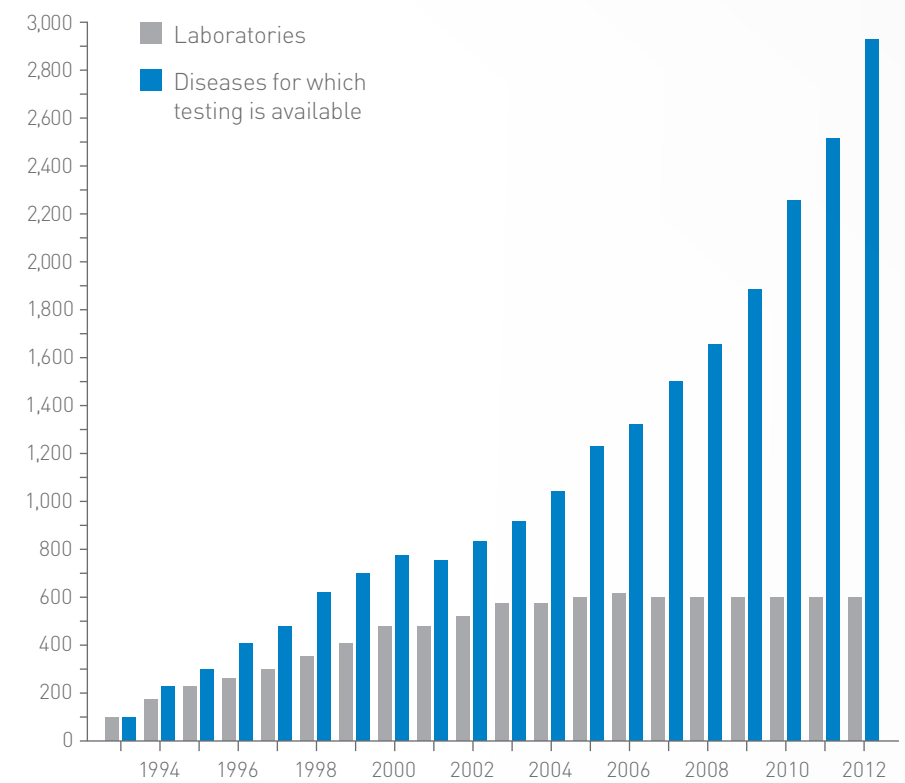
## Proven performance

Real-time PCR is well-established as the technology of choice for qualitative and quantitative molecular diagnostic tests that are rapid, accurate, and sensitive. With a track record spanning decades, we remain dedicated to delivering excellence in real-time PCR technology to clinical laboratories across the globe.

- The first peer-reviewed paper describing a diagnostic test using real-time PCR was developed on an Applied Biosystems® instrument\*
- Today, over 70,000 publications describe the use of real-time PCR in clinical, research, and diagnostics
- More than 20,000 Applied Biosystems® real-time PCR instruments are installed in laboratories worldwide

\*Lee LC, Connell CR, Block W (1993), Allelic discrimination by nick-translation PCR with fluorogenic probes, *Nucleic Acids Res* 21(16): 3761-3766.

Number of genetic diseases for which testing was available and number of laboratories offering genetic testing by year



The number of approved diagnostic real-time PCR assays has accelerated over the past 18 years, indicating an increasing acceptance of molecular assays in the clinic. Source: Gene Tests: Medical Genetics Information Resource [database online]. Copyright University of Washington, Seattle. 1993-2012. Available at: <http://www.genetests.org>





## A diagnostic platform that can grow with you

### A growing list of assays

Through our partnership with Quidel Corporation, you can find access to a growing list of assays for your testing needs. The first available assays include the Molecular Direct *C. difficile*, influenza A + B, and RSV + hMPV assays in the United States, with a menu that will continue to expand in the future. Additional available assays may include a test for HSV 1+2/VZV and other infectious disease agents, as well as tests for oncology and inherited diseases.

### Flexible software designed to meet your needs

Have confidence in an instrument that helps ensure compliance for fully regulated laboratories in the United States and Europe.\* QuantStudio™ Dx Software runs IVD tests in a secure mode with set parameters for run and analysis.

In test development mode, the flexible QuantStudio™ Dx Software enables you to create new assays and perform clinical research using the 96-well standard and Fast blocks, the 384-well block, or the qPCR microfluidic card block.†

### Easily multiplex samples

In test development mode, use the proprietary Life Technologies™ qPCR microfluidic card to perform 8 x 48 simultaneous reactions without the need for liquid-handling robots.

### One instrument, multiple applications

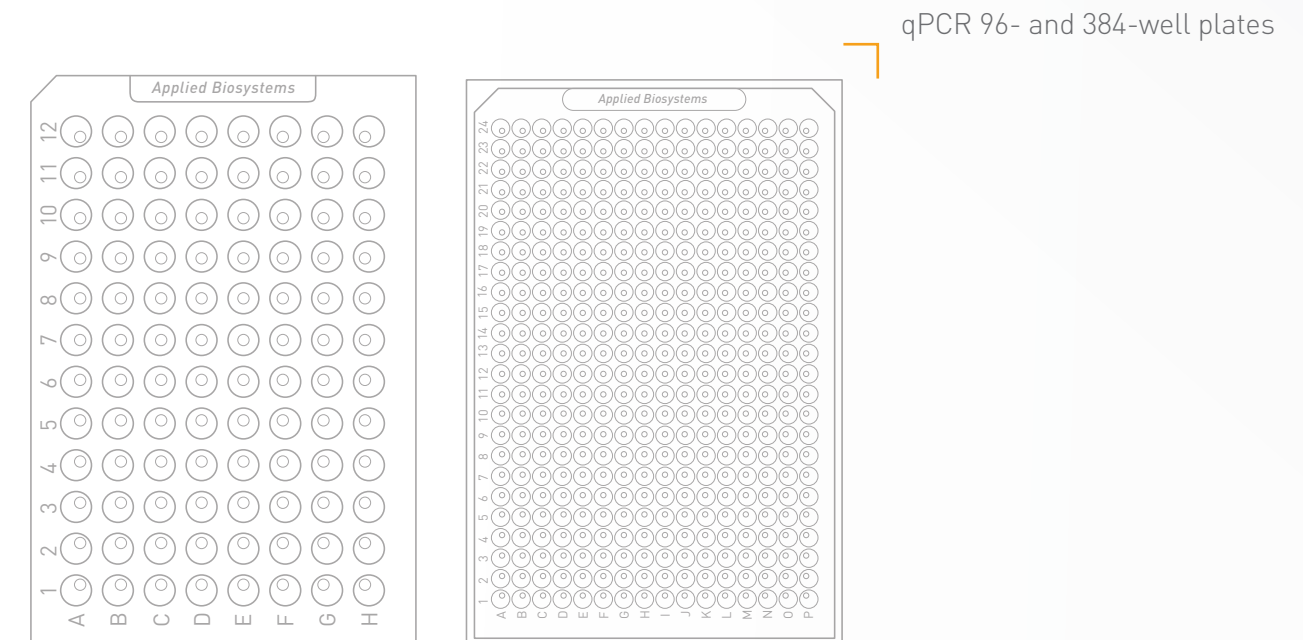
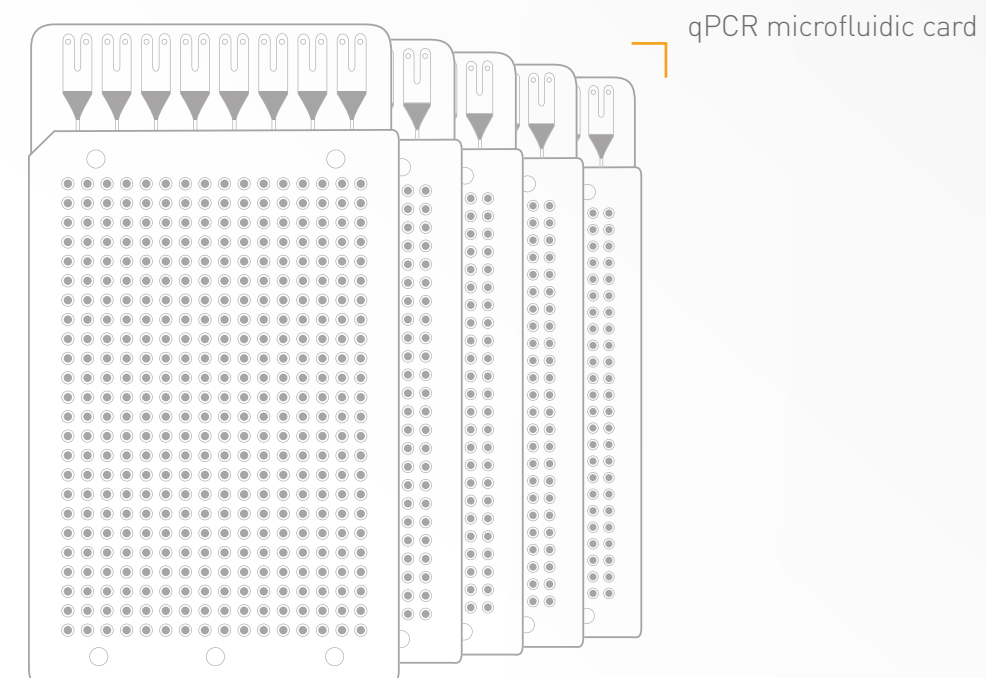
The QuantStudio™ Dx instrument has you covered across several applications—whether you perform pathogen detection, gene expression analysis, SNP genotyping, copy number analysis, mutation detection with castPCR™ technology, microRNA and other noncoding RNA analysis, or high-resolution melt analysis.§‡

\*The QuantStudio™ Dx Real-Time PCR Instrument is for distribution and use in the United States and specific European countries only. The QuantStudio™ Dx Real-Time PCR Instrument with QuantStudio™ Dx Software is intended to perform fluorescence-based PCR to provide detection of nucleic acid sequences in human-derived specimens in IVD-labeled tests. The QuantStudio™ Dx Real-Time PCR Instrument with QuantStudio™ Dx Software is intended for *In Vitro* Diagnostic use by trained laboratory technologists in combination with nucleic acid reagent kits/tests manufactured and labeled for diagnostic purposes on this instrument. The QuantStudio™ Dx Real-Time PCR Instrument and accessories also meet the requirements of the EU *In Vitro* Medical Devices Directive (98/78/EC).

†These blocks are CE-marked in Europe.

‡Applications are intended for use in research use only (RUO) mode.

§High-resolution melt analysis requires purchase of an additional software license.





## Behind every diagnosis, there is confidence

A streamlined instrument and assay workflow, combined with intuitive software, simplifies molecular testing and enhances efficiency—from sample processing to reporting

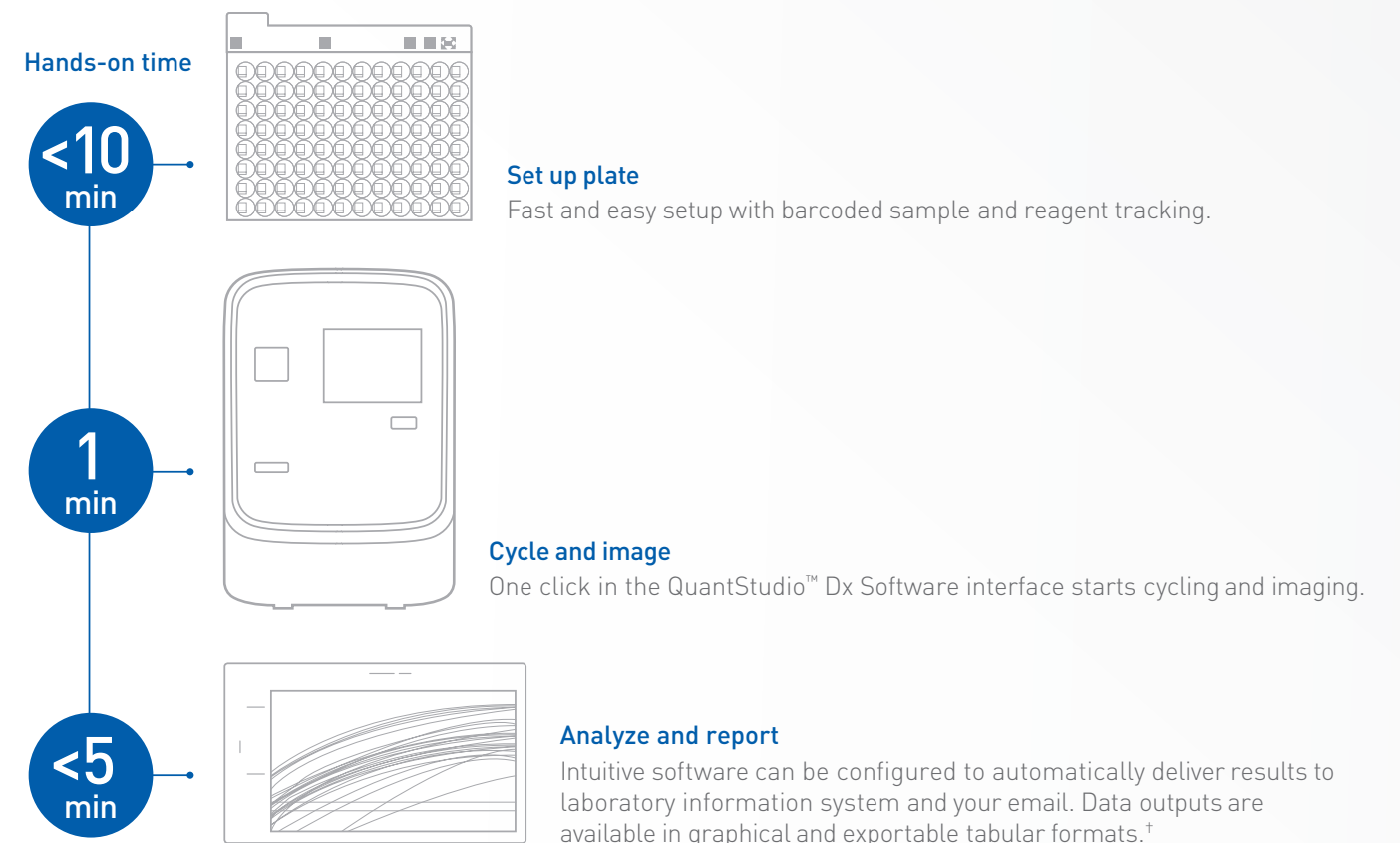
### Streamline your laboratory process

Take advantage of a simplified workflow that requires no instrument programming. IVD tests are conducted using a test definition document with predefined run and analysis parameters to minimize run set-up time and effort. In addition, the QuantStudio™ Dx instrument delivers results to a laboratory information system, helping reduce the workload for busy technologists.

### Improve quality by automated data entry and tracking

Reagent and patient information can be tracked by assay for quality control purposes. Reagents and other critical information can be entered by barcode. In addition, patient information may be uploaded from Excel® files to minimize data entry errors.

### QuantStudio™ Dx instrument time to results in <60 minutes\*



\*The Quidel® Molecular Direct *C.difficile* Assay can be analyzed on the QuantStudio™ Dx instrument in less than 60 minutes. Influenza A + B and RSV + hMPV assay run times will be dependent on each individual assay's protocol.  
†The amplification curves for qualitative real-time PCR look different than those for quantitative.

# Behind every diagnosis, there is an enhanced molecular workflow

QuantStudio™ Dx instrument + Quidel® Molecular Assays  
= the power of molecular diagnostics



We distribute Quidel® real-time PCR kits for identifying infectious disease agents. Unlike other methods, Quidel® Molecular Assays offer workflow benefits that deliver results in 60–75 minutes after sample preparation. The kits are approved for use on the Applied Biosystems® QuantStudio™ Dx instrument and the 7500 Fast Dx Real-Time PCR System. The Quidel® Molecular Direct *C. difficile*, Influenza A + B, and RSV + hMPV assays are currently the only approved assays for use in the United States, with additional assays in development. Approved assays for use in Europe include the Molecular Direct *C. difficile*, Influenza A + B, RSV + hMPV, and HSV 1+2/VZV assays.

## Developed to support an easy workflow

### One-step reagent preparation

Just add rehydration solution to the lyophilized master mix and pipette it into the assay plate.

### Room-temperature setup

Prepare your assays at room temperature, and eliminate the need for ice buckets or cooling blocks.

### Regulatory compliance

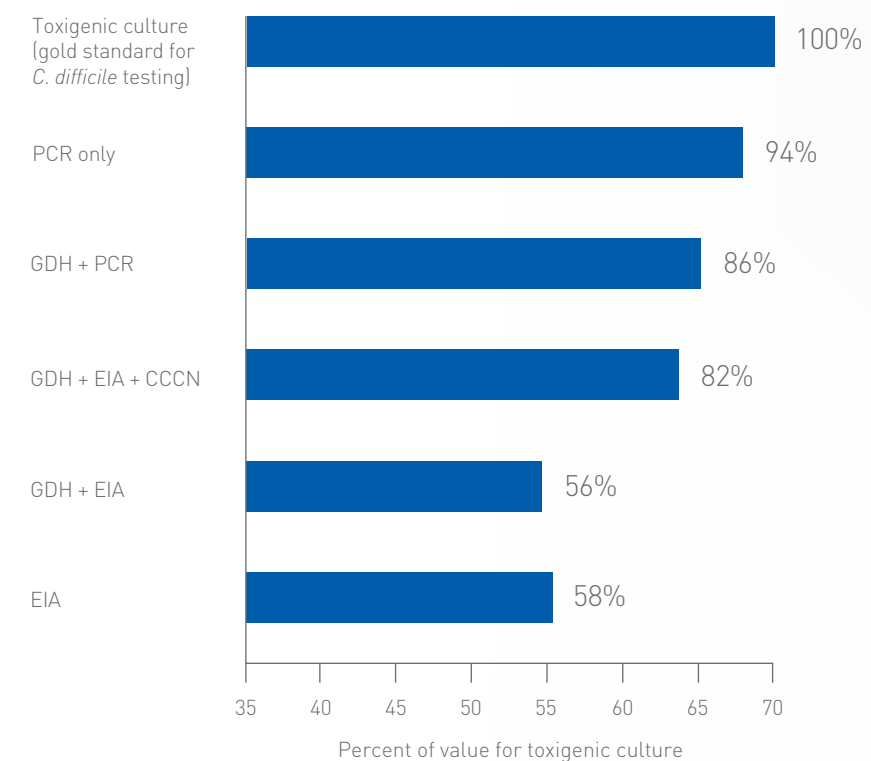
The Quidel® kits are IVD/CE-IVD labeled.\*

\*Not all Quidel® diagnostic kits are available in the US; see individual products for details. We distribute Quidel® real-time PCR kits for identifying infectious disease agents. Quidel® molecular assays offer workflow benefits that deliver answers 60–75 minutes after sample preparation. The kits are approved for use on the QuantStudio™ Dx instrument and the 7500 Fast Dx Real-Time PCR System. The Quidel® Molecular Direct *C. difficile*, Influenza A + B, and RSV + hMPV assays are currently the only approved assays for use in the US, with additional assays in development. Approved assays for use in Europe include the Molecular Direct *C. difficile*, Influenza A + B, RSV + hMPV, and HSV 1+ 2/VZV assays.

“More accurate and rapid diagnostics methods are essential for optimum patient management...In our experience, nucleic acid amplification methods...are emerging as tests of choice.”

Carroll K, Loeffelholz M (2011) Conventional versus molecular methods for the detection of *Clostridium difficile*. *J Clin Microbiol* 49(9 Suppl): S49–S52.\*

Observed sensitivity results for multiple *C. difficile* testing algorithms compared to toxigenic culture



Novak-Weekley SM, Marlowe EM, Miller JM et al. (2010) *Clostridium difficile* testing in the clinical laboratory by use of multiple testing algorithms. *J Clin Microbiol* 48(3): 889–893.\*

GDH = glutamate dehydrogenase, EOA = enzymatic immunoassays, and CCN = cell culture cytotoxicity neutralization.

\*Assay not performed with Quidel® Molecular Assay.



# Behind every diagnosis, there is trusted support

## You're covered

Every new instrument purchase comes with a one-year warranty that includes a full service plan. Longer-term service contracts are also available.

## Experienced field service to meet your needs and your budget

Protect your technology investment with a range of service plans that fit your laboratory requirements and budget needs. Highly trained, certified service engineers use the latest technology to diagnose and fix your instruments. And when you purchase a service plan up front, you can save substantially on instrument care.

## Award-winning remote services

You can maintain maximum uptime with remote services that let you track critical system parameters with real-time reporting. Proactively monitor, alert, and help diagnose and correct your instrument's performance. And with automatic alerts sent directly to your field service engineer, you can minimize unnecessary interruptions in laboratory operations.

## A trusted company—evolving with your needs

In addition to our rapidly expanding diagnostics portfolio, we offer a comprehensive list of diagnostic standards and controls through our AcroMetrix® product family. We also offer the AcroMetrix® EZValidation™ tool—a quick method for validating laboratory assays *in silico*.

## Affordable reagent rental program

For one affordable monthly payment, our Reagent Rental Program offers you the system, assay kits, support, and service you need to perform your diagnostic testing. All cleared assays are included in the program.



Find one trusted partner.

Find a better path to diagnosis.





For more information about the QuantStudio™ Dx Real-Time PCR Instrument or any of our molecular diagnostic products, contact your Life Technologies representative or go to [lifetechnologies.com/quantstudiodx](http://lifetechnologies.com/quantstudiodx)

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