

**BEHIND EVERY DIAGNOSIS,
THERE IS LIFE**

QuantStudio Dx Real-Time
PCR Instrument



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.

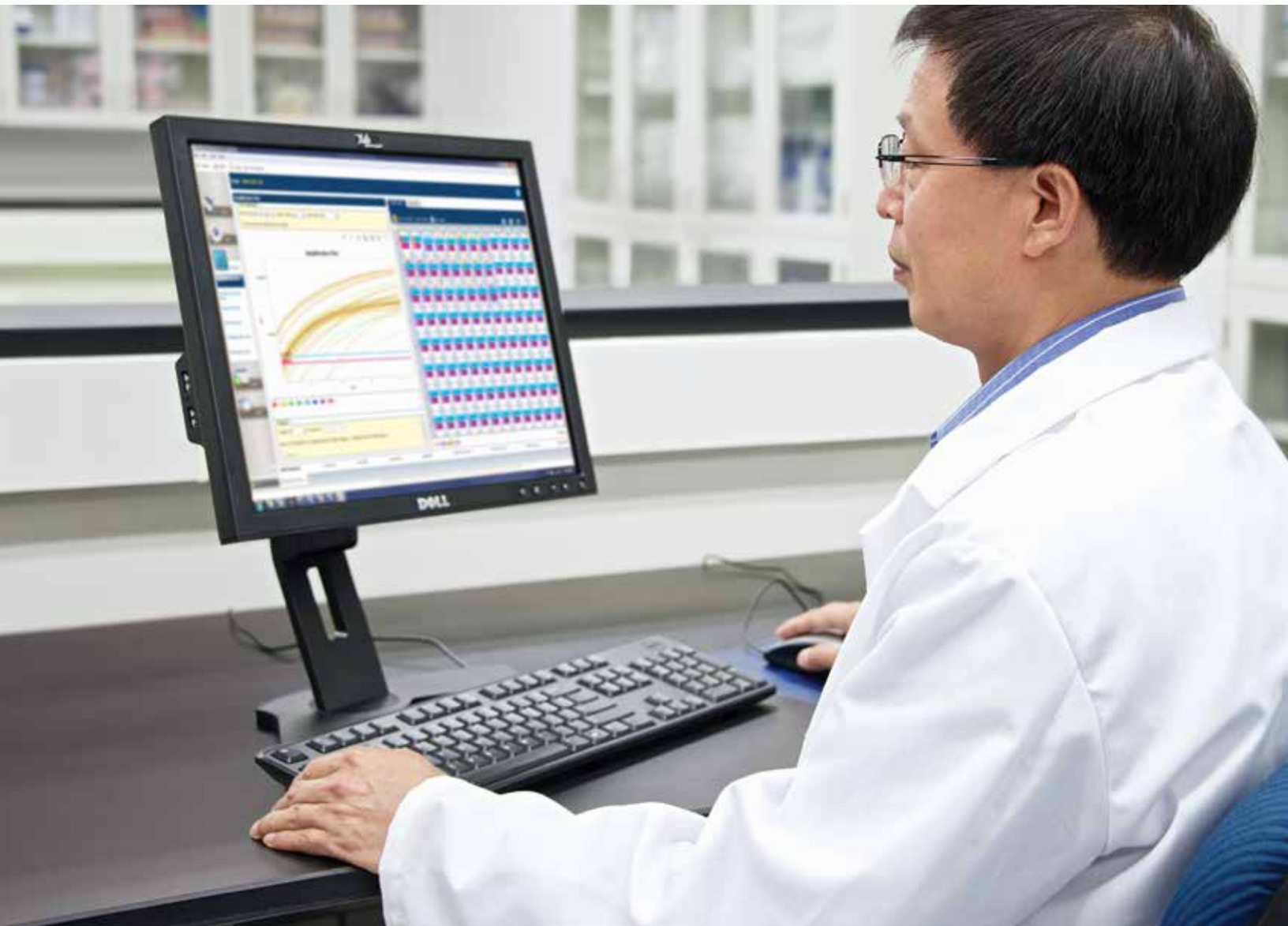
The path to diagnosis starts here.

In today's diagnostics 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 in 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 Applied Biosystems™ 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 real-time PCR (qPCR) innovation and our commitment to enhancing molecular diagnostic solutions. The QuantStudio Dx instrument provides your clinical laboratory with the performance you can trust, the security you demand, and the 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 with providing 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.

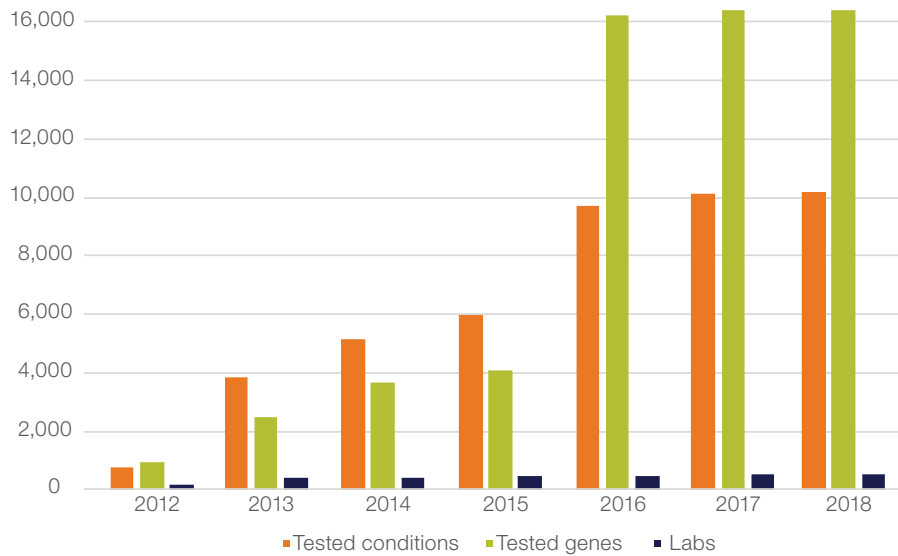
Proven performance

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 400,000 publications describe the use of real-time PCR in clinical, research, and diagnostics
- More than 40,000 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 diseases for which genetic 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 several years, indicating an increasing acceptance of molecular assays in the clinic. Source: Rubinstein WS, Maglott DR, Lee JM, et al. (2013) The NIH genetic testing registry: a new, centralized database of genetic tests to enable access to comprehensive information and improve transparency. *Nucleic Acids Res* 42(D1):D925–D935.



A diagnostic platform that can grow with you

A growing list of assays

The list of available assays for your testing needs continues to grow, including *C. difficile*, influenza A + B, RSV + hMVP, HSV 1 + 2/VZV, and other assays in the United States.

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.^{†‡} You can also use the proprietary Applied Biosystems™ 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 analyses, or high-resolution melt analysis.^{§,††}

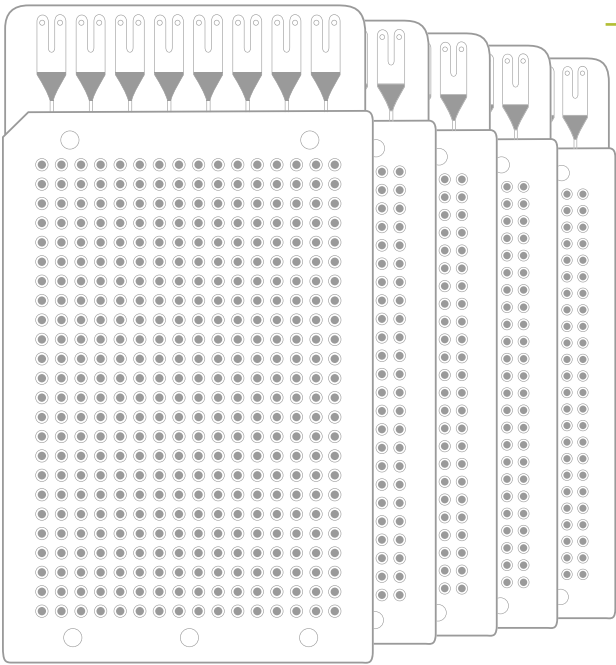
* The QuantStudio Dx Real-Time PCR Instrument is for distribution in the United States and specific European and non-European countries only. The QuantStudio Dx Real-Time PCR Instrument with QuantStudio Dx Software is intended to perform fluorescence-based PCR to provide detection of nucleic acid sequences 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.

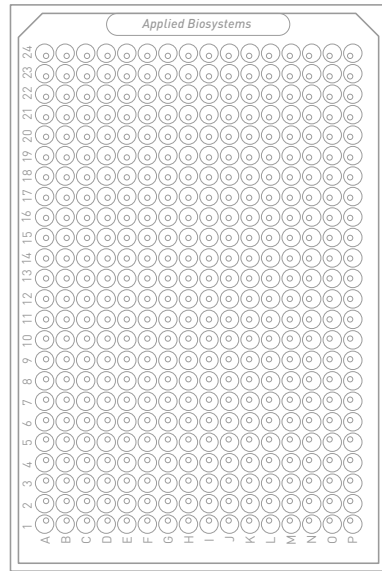
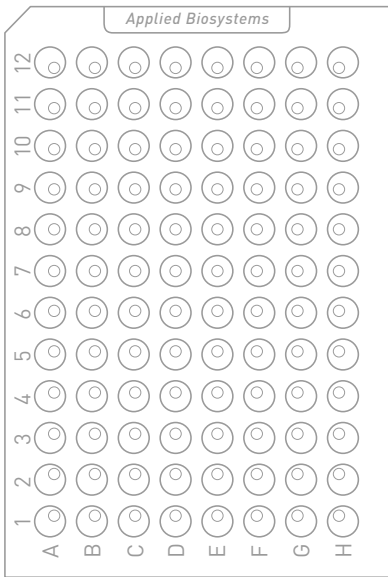
‡ These blocks in Test Development Mode are RUO in the United States.

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

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



qPCR microfluidic card



qPCR 96- and 384-well plates



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

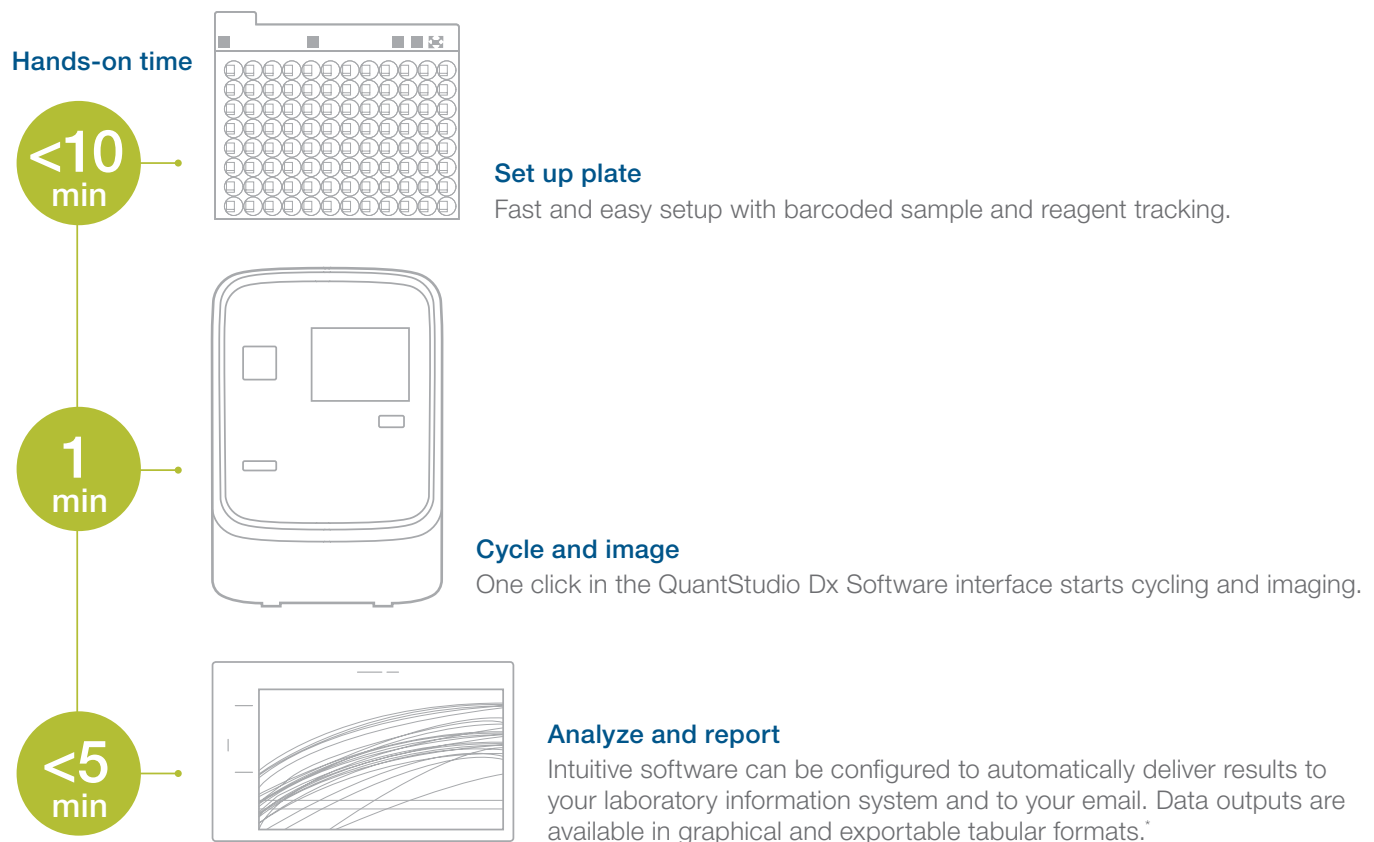
Streamline your laboratory process

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 setup 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 Microsoft[™] Excel[™] files to minimize data entry errors.

QuantStudio Dx instrument time to results in <60 minutes*

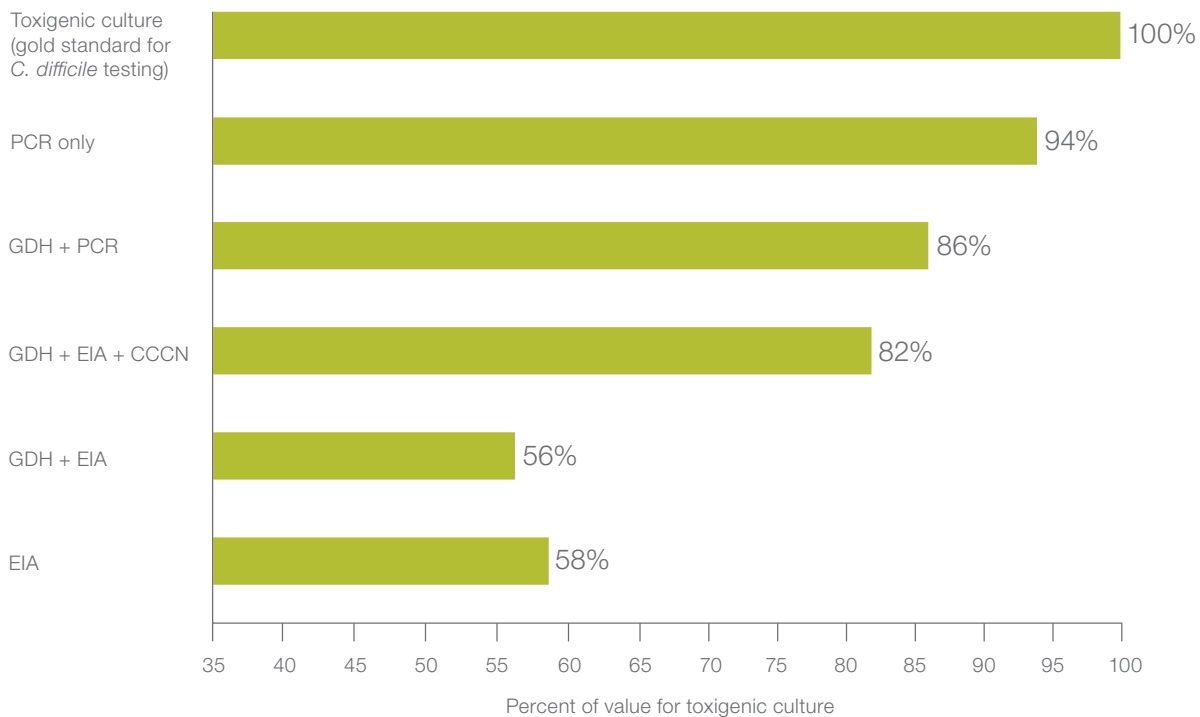


* The amplification curves for qualitative real-time PCR look different than those for quantitative.

“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, EIA = enzymatic immunoassays, and CCN = cell culture cytotoxicity neutralization.



Find one trusted partner.
Find a better path to diagnosis.

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 (Cat. No. 990500)—a quick method for validating laboratory assays *in silico*.

Applied Biosystems™ Service Plans:

The QuantStudio™ Dx Real-Time PCR Instrument is supported by:

- Professional installation
- Premium Package Training conducted by field scientists
- Worldwide application, technical, and field-training support

Qualification service versus system performance check

	Applied Biosystems™ Assurance Plan with Qualification Service	Applied Biosystems™ Assurance Plan with System Performance Check
Onsite response time for repairs	Guaranteed 2 business days	Guaranteed 2 business days
Remote instrument monitoring and diagnostics	+	+
Priority phone and email access to instrument support	+	+
Instrument operating software upgrades	+	+
Instrument qualification services	+	NA
Instrument system performance check	NA	+
Planned maintenance	+	+
Parts, labor, and travel	+	+

NA = not applicable

applied
biosystems



For more information about the QuantStudio Dx Real-Time PCR Instrument, contact your representative or go to thermofisher.com/quantstudiodx

ThermoFisher
SCIENTIFIC