

qPCR



qPCR


# Step into the future of molecular diagnostics

QuantStudio 5 Dx Real-Time PCR System  
(CE-IVD, IVDR) and innovative qPCR tools

For *In Vitro* Diagnostic Use.

applied biosystems



Step into the future of molecular diagnostics  [thermofisher.com/quantstudio5dx](https://thermofisher.com/quantstudio5dx)

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# Putting you in control of clinical molecular diagnostics

At Thermo Fisher Scientific, we understand that the future of clinical diagnostics is molecular testing. Molecular diagnostics (MDx) tests have become indispensable tools, and the use of molecular-based assays will continue to grow in number and importance for vitally important diagnostic tests.

As the world of molecular testing rapidly evolves, clinical and hospital labs face many complex challenges, including an evolving *in vitro* diagnostic (IVD) regulatory environment. You need solutions that are flexible and efficient so you can focus on delivering high-quality results.


Our innovative, complete real-time PCR (qPCR) workflow puts you in command, enabling you to effectively respond to challenges you may face now and in the future. When you partner with us, you gain access to the largest portfolio of diagnostics products and services in the industry, including instruments, master mixes and consumables, and primers and probes.

**Instruments:** The compact and flexible Applied Biosystems™ QuantStudio™ 5 Dx Real-Time PCR System is designed to streamline workflows and minimize training needs, helping you get clinical answers quickly by fitting seamlessly into your established workflow. This instrument was recently updated with software, firmware, and algorithmic analysis to meet recent *In Vitro* Diagnostic Regulation (IVDR) requirements. We also fortified its cybersecurity to increase protection of sensitive information and to provide better integration with laboratory IT networks. Additionally, the touchscreen interface comes with English, French, German, Italian, and Spanish options.

All of our high-quality Applied Biosystems™ IVD qPCR instruments offer a small footprint, simple workflows and software, and world-class service and support plans.

**Services and support:** Thermo Fisher Scientific offers a comprehensive range of services and support to keep your QuantStudio 5 Dx Real-Time PCR System performing at peak level.

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**Master mixes and consumables:** Thermo Fisher is your trusted partner. We offer a complete qPCR ecosystem, including a broad portfolio of master mixes and PCR plastics.

Applied Biosystems™ TaqPath™ qPCR master mixes are IVD-ready reagents designed for use in molecular diagnostic assay development and testing. These reagents are manufactured in an FDA-registered, ISO 13485–certified facility following GMP principles. TaqPath master mixes provide superior quality control (QC) standards and an optimized formulation, producing greater lot-to-lot consistency. In addition, comprehensive supporting documentation is available, such as stability statements and change notifications, simplifying the IVD assay submission process and providing peace of mind.

Applied Biosystems™ MicroAmp™ PCR plastics are engineered to reduce cross-contamination and promote optimal heat transfer. Applied Biosystems™ MicroAmp™ reaction plates are ideal for use in diagnostic procedures and certified in an ISO 13485–certified facility to be free of DNA, RNases, and PCR inhibitors.

**Primers and probes:** Applied Biosystems™ custom primers and probes offer unprecedented assay design flexibility while delivering the quality, performance, and reliability of gold-standard Applied Biosystems™ TaqMan™ chemistry. All primers and probes are manufactured in an ISO 13485–certified facility to provide assay reproducibility and lot-to-lot consistency.

Discover how we can put you in control of molecular diagnostics—now and in the future.

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# QuantStudio 5 Dx Real-Time PCR System (CE-IVD, IVDR)

Designed to meet IVDR requirements for higher quality and safety for medical devices, the QuantStudio 5 Dx Real-Time PCR System fits seamlessly into your established workflow so you can get up and running quickly. You'll enjoy its compact footprint and ease-of-use, as well as its industry-leading technology, which includes enhanced cybersecurity.



## An instrument with premium performance at an affordable price

- **Ease of use**—touchscreen can be operated in multiple languages
- **Ready for IVDR**—updated to meet IVDR requirements and technical documentation requirements
- **Results you can trust**—detect differences in target quantity as small as 1.5-fold in singleplex reactions, and obtain 10 logarithmic units of linear dynamic range
- **Simple, powerful software**—allows users to set up a run, lay out assays, control the instrument, and conduct plate analysis within a single, easy-to-use software interface
- **Designed with the clinic in mind**—interactive diagnostic instrument with short run times and minimal maintenance that uses existing plastic consumables
- **Security**—security, auditing, and e-signature (SAE) functionalities and the ability to support multiple clients, plus maintain centralized SAE settings that can be applied to multiple instruments on the same network, allowing better control for your IT department
- **Peace of mind**—IVD test menu allows only authorized tests to be run through IVD mode, helping to reduce the risk of unauthorized use and accidental or intentional misuse
- **Flexibility you need**—diagnose or develop, the choice is yours with software options that guide you through every step of test development\* and IVD modes
- **Maximize benchtop space**—compact instrument footprint and plate loading drawer at the front
- **Superior support**—services and support are available globally by highly skilled, customer-focused staff
- **QuantStudio system performance**—the reliability, sensitivity, and accuracy you expect, coupled with an intuitive and simple-to-use interface that allows users of any experience level to easily operate the system

\* Development mode is For Research Use Only. Not for use in diagnostic procedures.

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Learn more at [thermofisher.com/quantstudio5dx](https://thermofisher.com/quantstudio5dx)

## Specifications

QuantStudio 5 Dx system	
Sample capacity	96 wells
Reaction volume	96-well, 0.2 mL block: 10–100 µL
Excitation source	Bright white LED
Filter or color combinations	6 decoupled filters, CMOS camera
Excitation/detection range	450–680 nm/500–730 nm
Multiplexing	5-plex with 1 passive reference; 6-plex with no passive reference
Maximum block ramp rate	6.5°C/sec
Average sample ramp rate	3.66°C/sec
Temperature uniformity	±0.4°C
Temperature range	4–99.9°C
Heating and cooling method	Peltier
Independent temperature zones	6 Applied Biosystems™ VeriFlex™ Blocks zones (5°C zone-to-zone)
Chemistries	Fast and standard
Run time	<30 min
Compatible dyes	FAM, SYBR Green, VIC, ABY, NED, TAMRA, JUN, ROX, Mustang Purple, and Cy5 dyes
SAE features	Included
Automation compatible	No
Footprint (H x W x D)	40 x 27 x 50 cm
Weight	26 kg
CE-IVD certification	Class A under IVDR

## Features to help maintain quality and security



### Maintenance and calibration reports

Records are updated automatically with maintenance and calibration events and can be printed on demand, documenting that the system has been maintained and calibrated to vendor specifications.



### E-signature history

SAE software records test events, actions taken, dates, user names, user roles, and activity performed, for documentation and archiving purposes.



### Reagent tracking

Stores and archives information about reagents used with each test, including lot number and expiration date, with each run. Archived files can be retrieved when required to track samples that were tested with a given set of reagents.



### Diagnostic test results

Report IVD output records details for documentation, archiving, and review-at-a-glance needs, including clinical test name, barcode, file name, time stamps (creation, run start, run finish, duration, and modifications), instrument name, serial number, test type, results summary, plate layout image, standard curves, results table, quality control (QC) summary plate, set of reagents, run date and time, and data files.



### Sample tracking

The system tracks sample name and type; captures critical sample data, with parameters customizable to fit the laboratory's needs; and enables laboratories to more easily track samples associated with a particular plate, set of reagents, run date and time, and data files.

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# Simple, secure qPCR software

**Standardized and secure software to meet IVDR requirements for the clinical laboratory, enabling you to:**

- Run molecular testing in an updated and secure software environment
- Specify user access to various software functions
- Record all actions completed by users
- Operate within a secure interface with enhanced cyber security

SAE functionalities offer the ability to run preoptimized protocols for users operating in a secure environment. Security features such as user login, user permission settings, system auditing, and e-signature approvals are customizable to fit a range of security needs.

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# Keep advancing with new technology. We've got your back.

Get superior service and support to maximize your investment



## A standard of support that's a cut above

Thermo Fisher Scientific offers a comprehensive range of services and support to keep your QuantStudio 5 Dx Real-Time PCR System performing at peak level. Your instrument purchase comes with a standard 1-year manufacturer warranty, customer concierge services, SmartStart Orientation, and an advanced digital service ecosystem built right into the instrument. Extended warranty coverage is also available at the time of purchase for total peace of mind.

### Get started with our global customer concierge services\*

Count on our dedicated customer concierge services for an exceptional and seamless experience implementing your QuantStudio 5 Dx Real-Time PCR System. From order placement through installation and training, our team is here to streamline and simplify the process by:

- Preparing your laboratory space for a successful installation providing critical documentation and checklists
- Connecting your IT department with our IT specialists to ensure an easy and secure network connection so you can take advantage of cutting-edge features and advanced digital support
- Coordinating instrument installation with a highly skilled field service engineer (FSE)
- Scheduling interactive SmartStart Orientation training with an experienced field application scientist (FAS)

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\* Concierge services are available in certain geographies.

### SmartStart Orientation enables your success

Every QuantStudio 5 Dx Real-Time PCR System comes with SmartStart Orientation to help your team quickly become proficient using the new software features and instrumentation. Led by an experienced FAS, this interactive course is a 1-day instrument- and software-based training that covers the principles of quantitative real-time PCR, and how to use the QuantStudio 5 Dx Real-Time PCR System, Diomni Software, and SAE features. The course will cover the following topics:

- Proper experimental technique
- Basic workflow
- Software features and data analysis features
- Discussion of instrument maintenance

## Comprehensive warranty and service plans to protect your investment

Choose from a range of extended-coverage service plans to meet your budget and needs for the QuantStudio 5 Dx Real-Time PCR System. In addition to the standard 1-year warranty, these plans offer:

- Preventive maintenance to extend the life of your instrument and help keep it running at peak performance
- Qualification services completed by certified field service engineers
- Prioritized response time with fast repair turnaround time from manufacturer-trained and certified field service engineers

To build your personalized service quote, go to [thermofisher.com/serviceselector](https://thermofisher.com/serviceselector)



**98%  
uptime  
guarantee**  
with the AB Platinum  
service plan\*

\* Terms and conditions apply.  
For complete details, go to the [AB Platinum terms and conditions](#).



## Enjoy premium coverage with our premier service plan: AB Platinum

The AB Platinum plan is our top-tier total solution designed not only to optimize instrument performance and uptime, but also to provide a seamless experience and prompt resolutions.

Key features of the AB Platinum plan include:

- 98% uptime guarantee\*
- Comprehensive repair coverage
- Rapid-response on-site support\*\*
- Priority Technical Support†
- Planned maintenance
- Qualification services
- Digital remote support
- Training

Find out more about the AB Platinum service plan at [thermofisher.com/abplatinum](https://thermofisher.com/abplatinum)

\* Terms and conditions apply. For complete details, go to the [AB platinum terms and conditions](#).

\*\* Rapid-response on-site support within next-business day is subject to regional availability.

† Priority Technical Support is available in the English language only.

## Qualification services

Instrument hardware qualifications for your QuantStudio 5 Dx Real-Time PCR System for the clinical market include installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) services to verify and document your instrument's ability to meet manufacturer design specifications for performance. Our qualification specialists will partner with you to deliver timely, cost-effective, and trusted qualification services that include reliable, audit-style documentation that will help ensure that your instruments meet regulatory requirements.

Contact an instrument qualification specialist at [thermofisher.com/iqoqpg](https://thermofisher.com/iqoqpg)



Most  
qualifications in  
**1 day**  
with a  
**100%**  
success rate

# High-performance PCR plastics for optimal qPCR results

## MicroAmp qPCR plastics

Applied Biosystems™ PCR plastics have been designed and tested to work with our instruments and enable optimal performance.

### MicroAmp qPCR plastics are:

- Verified on Applied Biosystems™ thermal cyclers for optimal fit and performance
- Designed to perform on all Applied Biosystems IVD qPCR instruments
- Designed for optimal heat transfer, with thin-walled polypropylene wells
- Designed to reduce cross-contamination, with raised well rims for effective sealing



## Which qPCR plastic is right for you?

Find the plastic format with the throughput and features for your application

Applied Biosystems™ MicroAmp™ EnduraPlate™ optical microplates	
Format	96-well
DNA-, RNase-, and PCR inhibitor-free	Yes
ANSI/SBS standard dimension color	Clear
Instrument compatibility	Use our plastics selection tool*
Barcode	Yes (3 sides)
Multiple applications	Yes
Optical compatibility	Yes

\* [thermofisher.com/us/en/home/life-science/pcr/pcr-plastics/plastics-selection-guide.html](https://thermofisher.com/us/en/home/life-science/pcr/pcr-plastics/plastics-selection-guide.html)

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## Find the plastics and accessories you need for your instrument quickly

Product	Cat. No.	QuantStudio 5 Dx system
<b>96-well, 0.2 mL reaction plates</b>		
MicroAmp Optical 96-Well GPLE Reaction Plates (10 plates)	4481191	•
MicroAmp Optical 96-Well GPLE Reaction Plates with Barcode (10 plates)	4481192	•
MicroAmp EnduraPlate Optical 96-Well Clear GPLE Reaction Plates with Barcode (20 plates)	4483348	•
MicroAmp EnduraPlate Optical 96-Well Clear GPLE Reaction Plates with Barcode (500 plates)	4483351	•
<b>Seals and covers</b>		
Optical Adhesive Covers GPLE (25 films)	A49767	•
<b>Accessories</b>		
Splash-Free 96-Well Base	4312063	•
MicroAmp 96-Well Support Base	4379590	•

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# TaqPath master mixes for qPCR

## Delivering confidence and performance

TaqPath master mixes are designed to deliver confidence and performance for even your most demanding clinical applications. With IVD-ready qPCR reagents, we are committed to providing trusted, versatile, and innovative tools for molecular diagnostic applications.

TaqPath master mixes feature fluorogenic 5' nuclease chemistry and are General Purpose Reagents labeled For Laboratory Use. They are manufactured in an FDA-registered, ISO 13485–certified facility using GMP principles.

### TaqPath qPCR Master Mix, CG, for DNA detection

Applied Biosystems™ TaqPath™ qPCR Master Mix, CG is a 2X formulation designed for gene expression and miRNA analysis, containing a thermostable fast DNA polymerase and dNTPs in an optimized buffer solution for maximum robustness and reproducibility.

### TaqPath 1-Step RT-qPCR master mixes

Applied Biosystems™ TaqPath™ 1-Step RT-qPCR master mixes are 4X formulations designed for one-step processing of RNA and DNA targets optimized for use in molecular diagnostics testing and pathogen detection. Versions with Invitrogen™ ROX™ passive reference dye, and versions designed specifically for multiplexing and formulated with either Applied Biosystems™ Mustang Purple™ passive reference dye or without ROX dye, are available.

Both the Mustang Purple dye–containing mix and the “no ROX dye” mix can be used in conjunction with Applied Biosystems™ TaqMan™ probes with Applied Biosystems™ FAM™, VIC™, ABY™, and JUN™ dyes and Applied Biosystems™ QSY™ quenchers to provide detection of four targets in a single reaction.

### TaqPath BactoPure Microbial Detection Master Mix

Applied Biosystems™ TaqPath™ BactoPure™ Microbial Detection Master Mix is for clinical customers who need a rapid method for detection of low-level pathogen DNA from a variety of targets using complex samples. We offer the BactoPure master mix which—unlike competitors' mixes—offers the lowest limit of detection across common microbial targets of interest (e.g. bacteria, as demonstrated by a 16S rRNA assay).

TaqPath general purpose reagent	Application	Passive reference dye
TaqPath BactoPure Microbial Detection Master Mix	Microbial detection and quantitation	ROX
TaqPath BactoPure Microbial Detection Master Mix, No ROX	Microbial detection and quantitation	None
TaqPath ProAmp Master Mix	Genotyping and copy number variation (CNV)	ROX
TaqPath ProAmp Multiplexing Master Mix	Genotyping and CNV	Mustang Purple
TaqPath qPCR Master Mix, CG	Two-step gene expression	ROX
TaqPath 1-Step RT-qPCR Master Mix	One-step pathogen detection and gene expression	ROX
TaqPath 1-Step Multiplex Master Mix	One-step pathogen detection and gene expression	Mustang Purple
TaqPath 1-Step Multiplex Master Mix (No ROX)	One-step pathogen detection and gene expression	None

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Learn more at [thermofisher.com/qpcrmm](https://www.thermofisher.com/qpcrmm)

# TaqMan primers and probes

## The gold standard for qPCR applications

The Thermo Fisher Scientific portfolio of custom fluorophores and quenchers offers unprecedented flexibility during assay development, while delivering the quality, performance, and reliability of gold-standard TaqMan chemistry. Our probes deliver outstanding signal-to-noise ratio and reproducibility, and they are synthesized using the same raw materials and manufacturing know-how as pre-designed Applied Biosystems™ TaqMan™ Assays, which are featured in over 300 patents and more than 40,000 publications. Additionally, our GMP oligos service provides the traceability you need to meet all your regulatory requirements. Leverage the expertise and flexibility of TaqMan probes when designing your next laboratory-developed test (LDT) or analyte-specific reagent (ASR).

### TaqMan MGB probes

Applied Biosystems™ TaqMan™ MGB probes are dual-labeled probes with a 5' reporter and a 3' nonfluorescent quencher (NFQ). What sets TaqMan MGB probes apart from other probe-based chemistries is the inclusion of a minor groove binder (hence the name "MGB") moiety at the 3' end that increases the melting temperature ( $T_m$ ) of the probe and stabilizes probe-target hybrids. This means that TaqMan MGB probes can be significantly shorter than traditional probes, providing better sequence discrimination and flexibility to accommodate more targets.

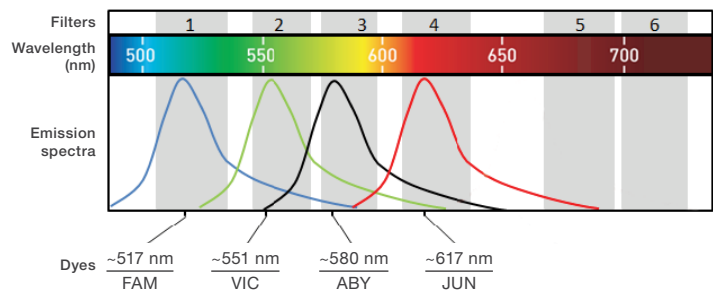
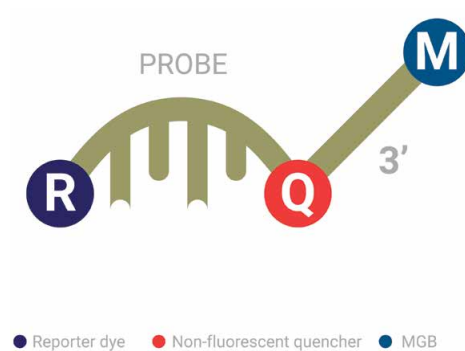
### TaqMan QSY probes

Applied Biosystems™ TaqMan™ QSY probes provide the perfect complement to TaqMan MGB probes for multiplexing several targets within a single reaction. Multiplexing enables cost savings and preservation of limited samples, while yielding comparable results between reactions performed in individual tubes and in 4-plex reactions (see Figure 2).

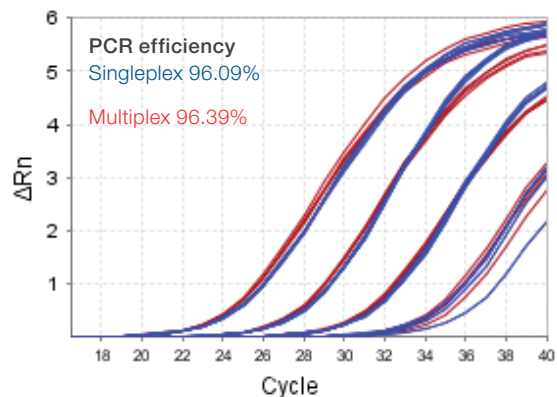
TaqMan QSY probes are also ideal for direct conversion of BHQ probe designs and can be ordered with FAM, VIC, and our proprietary ABY and JUN dyes, allowing amplification of up to 4 targets in a single reaction. All 4 dyes are optimized for the filter sets on the QuantStudio 5 Dx Real-Time PCR System and work together with minimal spectral overlap for optimal performance (Figure 1).

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**Figure 1. Fluorescence emission spectra of FAM, VIC, ABY, and JUN dyes used for multiplex real-time PCR.** Gray zones represent the filters available on Applied Biosystems real-time PCR systems: 1 through 6 for the QuantStudio Dx instruments.



**Figure 2. Comparable results for singleplex and multiplex assays.** The amplification plot shows linear portions of the curves for 4 *EGFR* assays amplified in singleplex (blue) and 4-plex reactions (red) in a dilution series from 20,000 pg to 2 pg of reference colon cDNA per 10  $\mu$ L reaction. PCR efficiencies are 96.09% for *EGFR* singleplex and 96.39% for *EGFR* 4-plex reactions.

## TaqMan TAMRA Probes

Applied Biosystems™ TaqMan™ TAMRA probes feature a 5' fluorescent reporter dye (FAM, VIC, or Applied Biosystems™ TET™ dye) and 3' fluorescent quencher (TAMRA dye). TaqMan TAMRA probes, which were some of the first TaqMan probes to be developed, continue to be offered in support of legacy products and protocols featuring this quencher.

### Probe specifications

	MGB	QSY	TAMRA
5' reporter dye options	FAM, VIC, TET, and NED dyes	FAM, VIC, ABY, and JUN dyes	FAM, VIC, and TET dyes
Form	Liquid		
Includes	Probe set		
Purification	HPLC		
Shelf life	12 months from manufacturing date		
Green features	Less waste and sustainable packaging		

## Customize TaqMan primers and probes your way

Our Specialty Manufacturing service offers even more customized solutions for those truly challenging real-time PCR assay designs and formats. From off-catalog dye offerings to specialized formulation and volume requirements to specific assay plating arrangements, our Specialty Manufacturing team will work with you to design your perfect assay.

For more information, email [specialty\\_oligos@thermofisher.com](mailto:specialty_oligos@thermofisher.com).

Need GMP oligos? Powered by more than 100 years of combined experience, we offer dedicated ordering and fulfillment services that can be integrated into your organization's systems and processes. Our capabilities extend to the production of GMP oligonucleotide components for IVD tests and ASRs.

For more information, email [GMP-oligos@thermofisher.com](mailto:GMP-oligos@thermofisher.com).

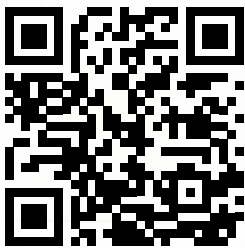
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Learn more at [thermofisher.com/customprobes](https://www.thermofisher.com/customprobes)

# qPCR resources

## For enhanced training and support

PCR-based applications are essential to many laboratory workflows and techniques. Fortunately, we offer qPCR training courses just for you. For more detailed course information and to enroll, go to [thermofisher.com/educationconnect](https://thermofisher.com/educationconnect)\*



\* Thermo Fisher account required.

Learn more at [thermofisher.com/quantstudio5dx](https://thermofisher.com/quantstudio5dx)

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