

qPCR

Empower your molecular diagnostics: The future is here

Innovative qPCR solutions for developers designing assays

Contents

Putting you in control of assay design	3
Which system fits your needs?	5
QuantStudio 7 Pro Dx Real-Time PCR System (CE-IVD, IVDR)	6
QuantStudio 5 Dx Real-Time PCR System (CE-IVD, IVDR)	8
Diomni software v4.0 (CE-IVD, IVDR)	10
Services and support	12
MicroAmp PCR plastics	14
TaqPath master mixes for real-time PCR	16
Commercial supply partnerships for MDx assay developers	20



Putting you in control of assay design

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

Assay developers face many complex challenges as molecular testing continues to rapidly evolve. The need for solutions that are flexible and efficient, and that support the delivery of high-quality results, is paramount.

We designed real-time PCR (qPCR) in vitro diagnostic (IVD) solutions with you in mind. Our innovative and complete workflow enables you to effectively respond to the assay design challenges you face in developing and commercializing products. Since 2008, we have been supporting your qPCR needs with a full workflow for assay developers. We now offer a comprehensive qPCR diagnostics portfolio, including instruments, master mixes and consumables, primers and probes, software solutions, and service and support.

Instruments: Powered by proven technology, the Applied Biosystems[™] QuantStudio[™] 7 Pro Dx Real-Time PCR System is an advanced, stand-alone qPCR platform that is versatile, highly expandable, and easy to use for a smart, assay-driven qPCR workflow, from setup to report.

The compact and flexible Applied Biosystems[™] QuantStudio[™] 5 Dx Real-Time PCR System is designed to streamline workflows and minimize training needs so you can get clinical answers quickly.









All of our high-quality Applied Biosystems™ QuantStudio™ IVD real-time PCR systems offer a small footprint, simple workflow and software, and world-class service and support plans.

Master mixes and consumables: Thermo Fisher Scientific is your trusted partner, from assay development, through validation and testing, to ultimate production. We offer a complete qPCR ecosystem that includes a broad range of custom primers and probes, GPR and GMP Applied Biosystems™ TaqPath™ master mixes, and PCR plastics.

Optimized to work synergistically, our flexible, high-performance solutions enable optimal PCR performance, giving you complete control and accelerating assay development, so you can bring high-quality diagnostic tests to market faster.

TagPath master mixes are designed to meet the needs of clinical diagnostic testing and are available for qPCR and one-step reverse transcription qPCR (RT-qPCR) in singleplex and multiplex formats.

Each reagent is manufactured in an ISO 13485-registered facility and rigorously tested to help ensure lot-to-lot reproducibility for C_a consistency and wide dynamic range.

Applied Biosystems[™] MicroAmp[™] PCR plastics are engineered to reduce cross-contamination and promote optimal heat transfer. Applied Biosystems[™] MicroAmp[™] General Purpose Laboratory Equipment (GPLE) reaction plates are ideal for use in diagnostic procedures and certified in an ISO 13485-registered facility to be free of DNA, RNase, 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.

Software solution: Designed to improve your lab's efficiency, Applied Biosystems™ Diomni™ Enterprise Software is an enterprise workflow solution that reduces time-toresults with interpretation, automated quality control, and configurable reporting.

Diomni software also provides a scalable solution by connecting to multiple instruments and supporting multiple concurrent users with centralized data management. In addition to integrating with QuantStudio real-time PCR systems, Diomni software reduces manual steps through integration with your laboratory information system (LIS)/laboratory information management system (LIMS), and the Thermo Scientific[™] KingFisher[™] Apex Dx sample prep instrument.

Diomni software is an open and flexible solution to support a variety of testing needs with traceability to help you meet compliance standards.

Service and support: We deliver peace of mind with the assurance that our diagnostic solutions are all backed by a proven, global leader in molecular testing; a reliable, single-source supplier with a robust supply chain; and unsurpassed service and support.







Which system fits your needs?

QuantStudio IVD real-time PCR systems





	QuantStudio 7 Pro Dx system	QuantStudio 5 Dx system	
Formats	96-well, 0.2 mL	96-well, 0.2 mL	
Tomato	384-well	oo woll, c.2 me	
User-interchangeable blocks	Yes	No	
Colors	Up to 6 colors (21 filter combinations)	Up to 6 colors (21 filter combinations)	
Touchscreen	21.5 cm	21.5 cm	
Applied Biosystems [™] VeriFlex [™] Blocks temperature control	Yes, 6 zones*	Yes, 6 zones	
Security, auditing, electronic signature (SAE)	Yes	Yes	
Dimensions (H x W x D)	55 x 34 x 53 cm	40 x 27 x 50 cm	
Weight	38 kg	26 kg	
Regulatory status	CE-IVD, IVDR; US-IVD	CE-IVD, IVDR; US-IVD	
Block format	Customer interchangeable 96-well 0.2 mL and 384-well	Fixed 96-well, 0.2 mL	
Software	Diomni software solution RUO, IUO, and IVD modes	Diomni software solution RUO, IUO, and IVD modes	
Integration	APIs for hardware integration Diomni software for LIMS compatibility	Diomni software for LIMS compatibility	
Footprint	Benchtop (55 x 34 x 53 cm); stand-alone	Benchtop (40 x 27 x 50 cm); computer required	
Performance	Up to 6 colors, 21 filter combinations; 6-zone VeriFlex Block temperature control*	Up to 6 colors, 21 filter combinations; 6-zone VeriFlex Block temperature control	
Standardization and security	Security, auditing, electronic signature	Security, auditing, electronic signature	

^{* 96-}well block only.







Take command of assay design

QuantStudio 7 Pro Dx Real-Time PCR System (CE-IVD, IVDR)

The QuantStudio 7 Pro Dx Real-Time PCR System is an In Vitro Diagnostic Regulation (IVDR)-compliant qPCR platform for the future, combining modern hardware and software in a compact footprint and enabling assay developers in molecular diagnostics to achieve maximum efficiency, smarter productivity, and higher accuracy from their workflow. The system enables flexible throughput with interchangeable 96-well and 384-well blocks, and it features an RUO mode for development and an IVD mode for routine diagnostics.



Smart instrument, smart features, and smart productivity enabled by connectivity

- IVDR—meets 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 orders of magnitude of linear dynamic range
- Simple, powerful software—users can set up a run, lay out assays, control the instrument, and analyze plates within a single, easy-to-use touchscreen interface; no computer is needed
- Proven performance—over 10 years of clinical real-time PCR instrument manufacturing
- Efficient—shorter run times compared to those with previous QuantStudio Dx systems, minimal maintenance, and compatibility with existing plastic consumables
- Enhanced security—SAE functionalities that assist with compliance and have the ability to support multiple clients; maintain centralized SAE settings that can be applied to multiple instruments on the same network, allowing better control for your IT department
- Instrument monitoring—use a mobile app to check instrument availability and monitor run progress
- Voice command—enables selected hands-free operation by voice control (Alexa[™] services)
- Smart help and remote support—Smart Help enables you to report issues or request instrument services to reduce downtime; remote access to device for troubleshooting

Automatable

The application programming interface (API) enables integration with a robotic plate mover, a liquid handler, and a third-party system.

The QuantStudio 7 Pro Dx instrument is a stand-alone system

The graphical user interface (GUI) enables an end-to-end IVD workflow, offering the following features:

- · Run setup with predefined assays
- · Instrument controls
- Run monitoring
- Post-run data analysis, exporting, and reporting
- Maintenance and support
- SAE features to assist with regulation compliance

The instrument is Internet of Things (IoT) - enabled (Thermo Fisher™ Connect Platform)

- · Voice-activated controls
- Smart support
- · Remote run monitoring

Routine testing at scale

Diomni software supports the use of multiple instruments and users with centralized data management.

Learn more at thermofisher.com/quantstudio7prodx







Specifications

	QuantStudio 7 Pro Dx system
Sample capacity	96 wells, 384 wells
Reaction volume	96-well, 0.2 mL block: 10–100 μL; 384-well block: 5–20 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	±0.5°C
Temperature range	4–99.9°C
Heating and cooling method	Peltier
Independent temperature zones	6 VeriFlex Blocks zones (5°C zone-to-zone)
Chemistries	Fast and standard
Run time	<30 min (fast mode)
Compatible dyes	Applied Biosystems [™] FAM [™] , SYBR [™] Green, VIC [™] , ABY [™] , NED [™] , TAMRA [™] , JUN [™] , ROX [™] , Mustang Purple [™] , and Cy5 [®] dyes
SAE features	Included
Automation compatible	Yes
Footprint (H x W x D)	55 x 34 x 53 cm
Weight	38 kg

Features to maintain data quality and integrity



Automated quality control

Run data are systematically analyzed based on predefined settings pertaining to each test, such as validity of internal positive and negative controls. Assessment for failed samples can be configured based on assay characteristics.



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.

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, a set of reagents, a run date and time, and data files.



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

Test results

Report records details for documentation, archiving, and review-at-a-glance needs, including experiment name, barcode, file name, time stamps (creation, run start, run finish, duration, and modifications), instrument name, serial number, experiment type, results summary, plate layout image, standard curves, results table, and QC summary.



Cybersecurity

The system has passed penetration testing that fulfills FDA cybersecurity guidance.







An easy-to-use, reliable, IVD qPCR system to put you in control

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

Designed to simplify workflows and minimize training needs, the QuantStudio 5 Dx Real-Time PCR System can help you get to your clinical answers quickly by fitting seamlessly into your established workflow. This compact, flexible system provides confidence in performance and supports both development and IVD modes.



An instrument with premium performance at an affordable price

- 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
- Proven performance—more than 25 years of real-time PCR instrument manufacturing and more than 10 years of clinical instrument manufacturing
- Designed with the clinic in mind—an interactive diagnostic instrument, with short run-times and minimal maintenance, that uses existing plastic consumables
- **Security**—SAE functionalities and the ability to support multiple clients, plus centralized SAE settings that can be applied to multiple instruments on the same network, allowing better control for your IT department

- Peace of mind—the 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—a compact instrument footprint and a 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

Learn more at thermofisher.com/quantstudio5dx







^{*} Test development mode is for Research Use Only.

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 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

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.



Reagent tracking

The system 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.



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, a set of reagents, a run date and time, and data files.



E-signature history

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



Experimental results

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







Streamline your assay design

Diomni software v4.0

Diomni software makes assay design on QuantStudio instruments more efficient, from development and verification to validation and launch.

Single encapsulation for assay workflow into one setup file:

- Define the assay-specific run protocol, QC parameters, analysis settings, and result interpretation in one place—start in development phase, iteratively adjust for verification and validation, and submit your validation evidence with your assay submission
- Choose the workspace designed specifically for your assay stage—each assay has a development status that can be used as your assay moves through the development process by choosing the RUO/IUO/IVD workspace that corresponds to each stage; functionalities in each workspace are optimized to support the matching objectives
 - RUO workspace—support iterative changes to the assay definition during the assay development phase; routine RUO tests
 - IUO workspace—support verification and validation runs for product development
 - IVD workspace—support routine testing for IVD tests
- Expand test menu with speed—new tests (ADFs) may be added to the system without requiring software upgrade

Assay-driven runs:

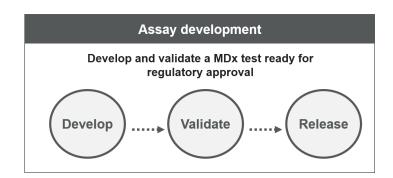
- Use of predefined protocols to reduce time and error in run setup
- Result interpretation according to your ADF and automated QC saves time and effort for data review
- Problematic data callout and QC tools make data review quicker and easier

Easily integrated into development workflows:

- Self-certify assays—ADFs can be published in Diomni software to lock down parameters and prevent user error when ready for clinical trials and after regulatory approval
- Customized data input and output—make data transfer between LIS simple and flexible
- Configurable reporting—tailor the PDF report to your needs
- Integrate with LIS/LIMS—reduce manual steps to transfer data through configurable and automated sharing of results; additional traceability through ASTM communication to receive sample and test information available with full integration
- IT friendly—the client server deployment model will enable your lab to maintain the software with ease and manage your lab in a secured, centralized location

Specifications:

- Microsoft[™] Windows[™] 10 operating model designed for setup on local network system
- Supported browsers: Google[™] Chrome[™], Microsoft[™] Edge[™], Apple[™] Safari[™] (OS X), and Mozilla[™] Firefox[™]
- Client server model designed for setup on local network
- SAE Administrator Console Dx v1.2
- Instrument compatibility: Applied Biosystems[™] QuantStudio[™]
 7 Pro series and QuantStudio[™] 5 series real-time PCR systems



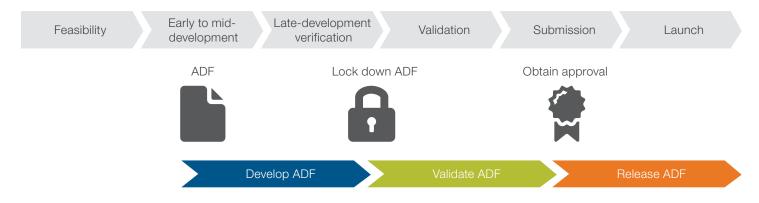
Learn more at thermofisher.com/diomni







Reduce time-to-market with the assay developer workflow in Diomni software



You're in control of assay design with the Diomni software self-certifying process to seamlessly transition through the test development stages. Once your assay has obtained approval for IVD use, the ADF can be locked and distributed as a final product for easy plug-and-play use. Your customers will reduce setup time and reduce error using your supplied IVD-labeled ADF.

Develop your assay, then run it with ease using the Diomni software workspaces



^{*} Investigational use only. Performance evaluation is only available upon request.

Security features fit for molecular diagnostics

Each instrument is equipped with a security, audit, and electronic signature (SAE) module to assist in compliance with regulatory requirements that involve a quality management system (QMS), GMPs, cybersecurity, and electronic records and signatures.

- · Secure access to instruments and data
- Role-based permissions for different lab personnel







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 real-time PCR IVD systems performing at peak level. Your instrument purchase comes with a standard 1-year factory 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 real-time PCR IVD systems. 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 help 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)

SmartStart Orientation enables your success

Both QuantStudio 5 Dx and QuantStudio 7 Pro Dx Real-Time PCR Systems come 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 7 Pro Dx instrument, 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
- · Certificate of Training Completion for up to three users







^{*} Concierge services are available in certain geographies.

Comprehensive warranty and service plans to protect your investment

Choose from a range of extended-coverage service plans to meet your budget and needs. In addition to the standard 1-year warranty, these plans offer:

- Preventive maintenance
- Access to advanced troubleshooting features, including Smart Help and Remote Support
- Prioritized response time

To build your personalized service quote, go to thermofisher.com/serviceselector

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[†]
- · Qualification services
- Digital remote support
- Additional FAS training (2-hour virtual consultation)

Find out more about the AB Platinum service plan at thermofisher.com/abplatinum



- * Terms and conditions apply. For complete details, go to AB Platinum terms and conditions.
- ** Rapid-response on-site support within the next business day is subject to regional availability.
- † Priority Technical Support is available in the English language only.

Digital services and support ecosystem and on-demand support at your fingertips

Your new QuantStudio 7 Pro Dx Real-Time PCR System is equipped with a state-of-the-art ecosystem of digital services and support so you can access our network of over 2,000 trained professionals at the touch of a button. With Smart Help you can easily share log and run files to speed up service troubleshooting and, if needed, request a service visit. Remote Support features enable our technical team to see your instrument in real time and interact with you on the instrument screen to resolve issues virtually.

Find out how our digital support helps resolve up to 70% of cases in minutes, not days, enabling you to focus on your next scientific breakthrough.

thermofisher.com/digitalserviceecosystem





Learn more at thermofisher.com/instrumentservices







High-performance PCR plastics for optimal qPCR results

MicroAmp qPCR plastics

Applied Biosystems™ MicroAmp™ 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, GPLE			
Formats	96-well 96-well Fast 384-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		









Find the plastics and accessories you need for your instrument quickly

Product	QuantStudio 7 Pro Dx system	QuantStudio 5 Dx system	Cat. No.
96-well, 0.2 mL reaction plates			
MicroAmp Optical 96-Well GPLE Reaction Plate (10 plates)	•	•	4481191
MicroAmp Optical 96-Well GPLE Reaction Plate with Barcode (10 plates)	•	•	4481192
MicroAmp EnduraPlate Optical 96-Well GPLE Clear Reaction Plates with Barcode (20 plates)	•	•	4483348
MicroAmp EnduraPlate Optical 96-Well GPLE Clear Reaction Plates with Barcode (500 plates)	•	•	4483351
384-well reaction plates			
MicroAmp Optical 384-Well GPLE Reaction Plate with Barcode (50 plates)	•		4481195
MicroAmp EnduraPlate Optical 384-Well GPLE Clear Reaction Plates with Barcode (20 plates)	•		4483319
Seals and covers			
MicroAmp Optical Adhesive Covers GPLE (25 films)	•	•	A49767
Accessories			
Splash-Free 96-Well Base	•	•	4312063
96-Well Support Base	•	•	4379590







TaqPath master mixes for real-time PCR

Delivering confidence and performance

TagPath master mixes are designed to deliver confidence and performance for even your most demanding clinical applications. With over 10 years of leadership in clinical real-time PCR, we are committed to providing trusted, versatile, and innovative tools.

All TagPath qPCR master mixes are:

- Designed using fluorogenic 5' nuclease chemistry
- General purpose reagents (GPRs) registered with the US FDA
- Manufactured in ISO 13485-certified facilities under cGMP
- Supported by a comprehensive compliance document package
- Labeled "For Laboratory Use" applications
- · Quality controlled to help ensure lot-to-lot consistency
- Ready for IVD assay development and regulatory body submission

TaqPath qPCR Master Mix, CG

Applied Biosystems[™] TagPath[™] 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.

TagPath 1-Step RT-gPCR Master Mix, CG

Applied Biosystems[™] TaqPath[™] 1-Step RT-qPCR Master Mix, CG, is a 4X formulation designed for one-step processing of RNA and DNA targets. Versions with ROX passive reference dye, and versions designed specifically for multiplexing, are available. TagPath 1-Step RT-gPCR Master Mix, CG, formulated with either Mustang Purple passive reference dye or without ROX dye, allows for additional targets or controls to be run simultaneously. All versions are optimized to be highly tolerant to challenging inhibitors commonly found in clinical samples, while providing high specificity and a dynamic range down to six orders of magnitude.

TagPath BactoPure Microbial Detection Master Mix

Applied Biosystems™ TaqPath™ BactoPure™ Microbial Detection Master Mix is for clinical customers who need a rapid method for low-level DNA pathogen detection on a variety of targets using complex samples. We offer the TagPath 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). TagPath BactoPure master mix is available with or without ROX to be compatible with higher-order multiplexed assays.

TagPath ProAmp Master Mix

Applied Biosystems[™] TaqPath[™] ProAmp[™] Master Mix is for high-throughput genotyping and copy number variation protocols requiring uncompromising reliability and accuracy, even in the presence of inhibitors commonly found in clinical samples. It is designed to deliver sensitive and confident results from genomic DNA targets on a broad range of qPCR instrument platforms. TagPath ProAmp Master Mix is manufactured under a strong ISO 13485 quality management system and is designed to produce consistent product performance lot after lot.

Learn more at thermofisher.com/qpcrmm









	TaqPath 1-Step RT-qPCR Master Mix, CG	TaqPath BactoPure Microbial Detection Master Mix	TaqPath ProAmp Master Mix	TaqPath qPCR Master Mix, CG
	Applied 2000 Miles Tourism Control of the Control o	STATE OF THE PARTY	Stoled Stoled	Trade of the trade
Recommended applications	Pathogen detection Gene expression	Microbial detection	SNP genotyping Copy number variation	Gene expression MicroRNA analysis
Target	RNA	DNA	gDNA	cDNA
Multiplexing	With ROX dye (up to 3 targets)			
and passive reference dye	No ROX dye (>3 targets)	No ROX dye (>3 targets)	With Mustang Purple dye (>3 targets)	
	With Mustang Purple dye (>3 targets)			
Assay recommendation	TaqPath qPCR assays			
	Request a sample			







TaqMan probes

The gold standard for qPCR research 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 are synthesized using the same raw materials and manufacturing know-how as predesigned Applied Biosystems™ TagMan™ Assays 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 TagMan probes when designing your next molecular test or analyte-specific reagent (ASR).

TaqMan MGB Probes

Applied Biosystems™ TagMan™ MGB Probes are dual-labeled probes with a 5' reporter and a 3' nonfluorescent quencher (NFQ) (Figure 1). What sets TagMan 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.

TagMan QSY Probes

Applied Biosystems[™] TagMan[™] QSY Probes provide the perfect complement to TagMan 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).

TagMan 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 four dyes are optimized for the filter sets and work together with minimal spectral overlap for optimal performance.

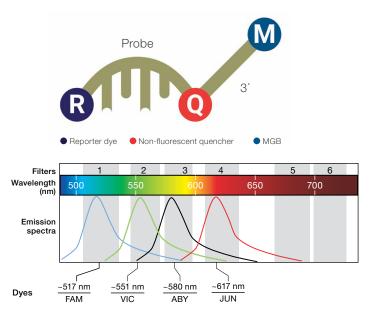


Figure 1. Fluorescence emission spectra of FAM, VIC, ABY, and JUN dyes used for multiplex real-time PCR. Gray zones represent the filters available on Applied Biosystems real-time PCR systems: 1 through 6 for the QuantStudio Dx instruments.

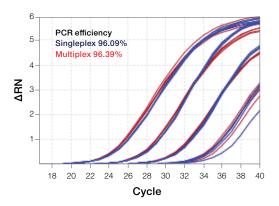


Figure 2. Comparable results for singleplex and multiplex assays. The amplification plot shows linear portions of the curves for 4 EGFR assays amplified in singleplex (blue) and 4-plex (red) reactions in a dilution series from 20,000 pg to 2 pg of reference colon cDNA per 10 µL reaction. PCR efficiencies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

Learn more at thermofisher.com/customprobes









TaqMan TAMRA Probes

Applied Biosystems[™] TaqMan[™] TAMRA Probes feature a 5' fluorescent reporter dye (FAM, VIC, or 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, NED dyes	FAM, VIC, ABY, JUN dyes	FAM, VIC, 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

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.

For more information, email gmp-oligos@thermofisher.com







Commercial supply partnerships for MDx assay developers

Leveraging our state-of-the-art genetic sciences tools and solutions, the Licensing and Commercial Supply (LCS) team helps our partners commercialize assays within a wide range of applications, including infectious disease and oncology. Our team is aligned to help you navigate potential speed bumps on your path to commercialization by providing you value beyond just products in our partnerships. Our team also specializes in providing support for those in the ideation and feasibility phases.

We bring the right mix of solutions you need to help you on your path and combine these solutions with the quality you can expect from Thermo Fisher Scientific.

Example client assay development process

We begin working with your leadership team in the development of a value proposition to identify the solution best suited for your success. Your innovation can receive the highest benefit from partnering during the feasibility and development stages, prior to locking in your design. Our support varies depending on where you are in your development process and includes:

- · Commercial use rights
- Compliance documentation support
- Custom assay development
- Custom manufacturing
- Globalized footprint

- · High-efficiency technology transfer
- Novel content and technology
- Product optimization
- · Quality products and services
- · Security of supply



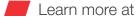
As part of Thermo Fisher, our global regulatory team with expertise in established quality management systems; FDA-, NMPA-, CE-IVD (including IVDR)—compliant facilities; manufacturing quality standards; and global trade compliance can support your business, allowing you the freedom to focus on your priorities.







For In Vitro Diagnostic Use.



thermofisher.com/qpcr-molecular-diagnostics

applied biosystems

For *In Vitro* Diagnostic Use. © 2020–2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. TaqMan is a trademark of Roche Molecular Systems, Inc., used under permission and license. Cy3, Cy5, and Cy5.5 are registered trademarks of GE Healthcare. Cy is a registered trademark of Cytiva. BHQ is a trademark of Biosearch Technologies Inc. Alexa is a trademark of Amazon Technologies, Inc. Microsoft, Edge, and Windows are trademarks of Microsoft Corporation. Google and Chrome are trademarks of Google LLC. Mozilla and Firefox are trademarks of the Mozilla Foundation. Apple and Safari are trademarks of Apple Inc. COL35715 0623