The world leader in serving science

Challenge accepted

Custom solutions for molecular test development

Reagents, instruments, and plastics for real-time PCR workflows

ThermoFisher SCIENTIFIC

Whatever your project size, we'll help you achieve your commercialization goals

Our Commercial Supply team is your partner for successful commercial development of your future diagnostic, research, and applied products. We offer a superior combination of quality, globally distributed products, and professional commercial services to support and guide you at every step.

"The quality and performance of Applied Biosystems™ master mixes and Invitrogen™ custom oligos are key for our kit development. The Thermo Fisher Scientific team provided us with a one-stop solution for the entire process—from assay test design, assay optimization, and kit validation, to partnering on the development of our commercialization strategy."

—Patrick Burke, PhD, Executive Vice President, Emerging Products, Myriad Genetics

Contents

Introduction

If you're involved in the development of a commercial molecular assay, you've come to the right place. When you bring our experienced Commercial Supply team onboard, whether your project is large or small, your commercialization goals become our goals.

By leveraging our superior combination of quality, global distribution, and professional commercial services and support, you can maximize your efficiency and scale, while minimizing risk. More than just a partner for your project, you'll have an experienced, personal guide committed to your success at every stage of the product development and commercialization process.

Accelerate growth and differentiate yourself in the market with:

- Reagents available for incorporation into your assay
- Global installed base for validating your kit
- Instrument placement and reagent rentals
- Private label options

Commercial supply capabilities

Custom services and manufacturing

Your commercial assay is likely to require customization to fit your precise specificity, sensitivity, and workflow needs. Our products and services are not one-size-fits-all. When you partner with us, we work closely with you to build your assay components to your exact specifications. From assay design to workflow optimization—whatever your needs, our custom services team is there for you. In fact, many of our custom services and products are available exclusively to our commercial partners.

Custom services include:

- Assay design
- Workflow development and optimization
- Performance testing
- Bridging studies
- Guard banding
- Verification testing
- Analytical validation testing
- Stability studies

Manufacturing services:

- Lyophilization
- Kitting
- Fill and finish
- Custom packaging
- Private label

We can customize your products in a number of ways:

- Fill volume
- Formulation
- Packaging
- Private labeling
- Bulk ordering

Find out more at **thermofisher.com/mdxcustom**

Superior quality

When you rely on us for manufacturing, you'll gain the advantage of our uniquely robust processes. You can have confidence that the quality of your product will be manufactured in accordance with regulatory compliance guidelines and our commitment to manufacturing excellence.

Don't cut corners when it comes to standards. Manufacture with us and your product will go through rigorous testing to help ensure lot-to-lot consistency and reproducibility of your final supplies. You'll benefit from our uncompromising quality management system, which requires our suppliers to undergo a high level of scrutiny, including thorough audits and quality control (QC) on incoming raw materials.

Bring your vision into being in our state-of-the-art manufacturing centers. True to our company-wide commitment to advancing life science, your products will be manufactured in facilities that help guarantee your:

- Innovation
- Flexibility
- Reproducibility
- Efficiency
- Scalability

Compliance*

- Six Sigma and Lean Manufacturing processes
- Certified quality system with ISO 9001, ISO 13485, and ISO 14001 status
- US 21 CFR Part 820 Quality System (current good manufacturing practice (cGMP))
- Manufacturer of Class I, II, and III medical devices
- Manufacturer of general-purpose reagents
- Under USDA guidelines
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Good laboratory practice (GLP)–accredited

* Certain regulatory standards are available at specific sites only.

Robust security of supply

You shouldn't have to worry about changes in raw materials that may require you to retest your product. Partnering with us helps ensure the security of your raw materials supply, which is crucial to developing and manufacturing a reliable commercial product. We have strong safeguards in place to help you reduce risk and avoid delays and setbacks in manufacturing, including:

- Advanced change control notifications
- Supply agreements
- A global manufacturing footprint
- Comprehensive controls over raw materials and processes
- Multiple manufacturing sites
- Financial stability
- Confidentiality

Domain expertise

Any company—especially a smaller or newer company—can benefit greatly from working closely with us early in the product development process. That's because we have extensive expertise in developing and commercializing products, and we can leverage our leading-edge technologies to benefit you.

Your dedicated Business Development Manager will serve as your project champion and help connect you with the right resources in R&D, manufacturing, regulatory affairs, and more. Having a dedicated professional from Thermo Fisher on your team to guide you through the process of bringing a product to market can help you maximize your efficiency and avoid costly missteps.

We have partnered with companies who have developed assays in countless focus areas, including:

- Oncology
- Infectious disease
- Reproductive health
- Neurobiology
- Cardiovascular disease
- Hematology
- Cell therapy
- Agricultural and environmental
- Food safety
- Research tools

Molecular analysis workflow

Nucleic acid extraction

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We offer a one-stop shop for molecular test development. All of our products are highly optimized to work in concert with one another, to help ensure compatibility between product lines. Choose from our trusted brands, including Thermo Scientific, Applied Biosystems, and Invitrogen. The products mentioned in this handbook represent those most commonly used by our molecular testing partners. If you can't find exactly what you need, or would like assistance selecting the right product for your workflow, contact us and we will guide you.

"The broad range of genetic analysis products is only one of the many reasons we chose Thermo Fisher as our strategic partner for developing molecular tests. Its dedicated team—including field engineers, bioinformaticians, key account managers, CFDA registration experts, and global leaders—has been a great resource in helping us expand our business."

—Junquan Xu, President, CapitalBio Technology

Nucleic acid extraction

We offer a wide range of extraction solutions for your unique assay or application, including Invitrogen™ Dynabeads™ magnetic beads, customizable for your workflow; or turnkey Applied Biosystems™ MagMAX™ kits, optimized for easy integration with your existing workflow. Both Dynabeads magnetic beads and MagMAX kits work seamlessly with Thermo Scientific™ KingFisher™ instruments for high-throughput genomic analysis. For more unique or demanding applications, our R&D scientists will work closely with you to customize our beads and buffers to your exact specifications.

Dynabeads magnetic beads

Dynabeads products offer many unique benefits and are widely used for specific capture and detection of nucleic acids. Our beads are monodisperse, with tight coefficient of variation (CV) specifications and unmatched batch-to-batch reproducibility.

Table 1. Catalog Dynabeads products for capture of nucleic acids.

Capture	Dynabeads	Surface	Bead size	Characteristics and uses
Generic	MyOne SILANE	Silica-like	1.1 µm	• Rare or abundant target capture • High-efficiency capture • Generic en-masse purification
Generic	MyOne Carboxylic Acid	Hydrophilic	1.1 µm	• High-efficiency capture • Generic en-masse purification
Specific	MyOne Carboxylic Acid	Hydrophilic	1.1 µm	• Oligonucleotide coupling
Generic	M-270 Carboxylic Acid	Hydrophilic	2.8 µm	• High-efficiency capture • Generic en-masse purification
Specific	M-270 Carboxylic Acid	Hydrophilic	2.8 µm	• Oligonucleotide coupling
Specific	MyOne Streptavidin C1	Hydrophilic	1.1 µm	• Isolation and handling of biotinylated targets
Specific	MyOne Streptavidin T1	Hydrophilic	1.1 µm	
Specific	M-270 Streptavidin	Hydrophilic	2.8 µm	
Specific	M-280 Streptavidin	Hydrophilic	2.8 µm	
Specific	M-270 Oligo $(dT)_{25}$	Hydrophilic	2.8 µm	• Direct isolation of RNA

In addition to a wide portfolio of off-the-shelf Dynabeads products, our proprietary technology and know-how enable customized product development that can include:

Proof-of-concept services
- Custom coupled prototypes
- Workflow optimization
- Automation consultation
- Manufacturing scale-up consultation

Derivative product
New product derived from generic changes to existing products, e.g.:
- Bioconjugation

Custom product
New product based on existing beads with customer-specific modifications, e.g.:
- Coupling of oligo, antibody, or other bioreactive ligand of your choice

New bead
Development of a new bead or bead platform, e.g.:
- New surface coating
- New size
- New bead technology

Customization

"Securing access to Invitrogen™ Dynabeads™ MyOne™ magnetic beads and reagents for our second-generation colorectal cancer blood test enabled us to reduce the complexity of the kit significantly. The high-quality materials were able to improve reproducibility and robustness of our method."

—Uwe Staub, PhD, Chief Operating Officer, Epigenomics

MagMAX kits

Our MagMAX kits are designed for the purification of high-quality nucleic acids from a variety of sample types suitable for a range of downstream applications (Table 2). Each kit is optimized for use with KingFisher instruments to reduce overall handling and processing times, while increasing consistency of sample preparation. Each kit contains the necessary beads and solutions for lysis/binding, wash, and elution.

Table 2. MagMAX kits for nucleic acid purification.

	Nucleic acid isolated	Application	Sample types	Features
MagMAX *mir*Vana Total RNA Isolation Kit	True total RNA (small RNA–enriched total RNA)	RNA-based oncology or infectious disease	Works with most samples of interest, including plasma, serum, whole blood, cell culture, tissue, and urine	• No need to buy multiple kits to work with specific samples • Phenol-free (no organic extraction) • Verified for use with Applied Biosystems™ TaqMan® Advanced miRNA Assays
MagMAX DNA Multi-Sample Ultra 2.0 Kit	Genomic DNA	Genotyping for inherited disease, oncology, and infectious disease	Compatible with common sample types (whole blood, tissue, saliva, buccal swabs, and oral rinse)	• Streamlined protocols for numerous noninvasive biological samples
MagMAX Cell-Free DNA Isolation Kit	Cell-free DNA	Noninvasive prenatal testing (NIPT), liquid biopsy	Whole blood	• Can enrich for cell-free DNA fraction
MagMAX Cell-Free Total Nucleic Acid Isolation Kit	Cell-free DNA and RNA	NIPT, liquid biopsy	Whole blood	• Enrichment of all nucleic acid species present in cell-free biological samples such as plasma
MagMAX FFPE DNA/RNA Ultra Kit	DNA and RNA	Genotyping and gene expression for solid tumors	FFPE samples	• No sample splitting (RNA and DNA from same FFPE section)
MagMAX Pathogen RNA/DNA Kit	DNA and RNA	Infectious disease	Serum and plasma; nasal, tracheal, and cloacal swabs; ear samples; whole blood; semen; oral fluid; feces	• Purification from viruses and easy-to-lyse bacteria and parasites • Low and high sample input volumes
MagMAX Saliva gDNA Isolation Kit	Genomic DNA	A variety of molecular protocols, particularly for consumer genomics	Saliva	• Scalable and automatable protocol for the isolation of genomic DNA (gDNA) from fresh and stabilized saliva

Learn more about MagMAX kits at **thermofisher.com/magmax**

Featured MagMAX kits

MagMAX Saliva gDNA Isolation Kit

The Applied Biosystems™ MagMAX™ Saliva gDNA Isolation Kit is the fastest, most user-friendly saliva purification kit on the market. With minimal steps, an affordable price, and comprehensive support, users can process more samples with consistent results. Saliva is much more stable at room temperature compared to other sample types; and it yields a greater quantity of gDNA compared to buccal swabs, and does so more consistently.

Highlights:

- Fast, easy, and budget-friendly automated sample prep for saliva gDNA
- 96 samples in a ~20 minute instrument run with less than 45 minutes of hands-on time
- Compatible with top 10 saliva collection devices
- Consistent gDNA recovery (Figure 1)

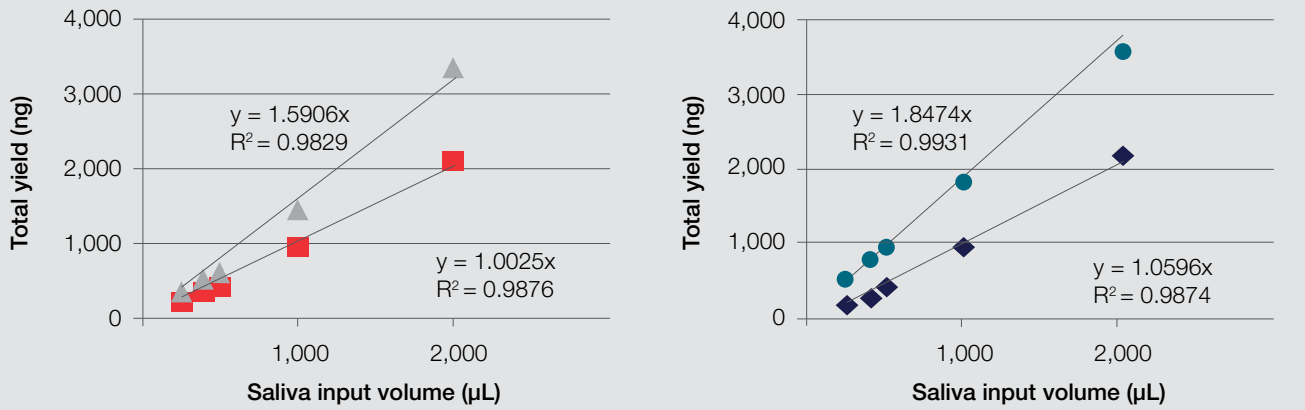


Figure 1. Linear recovery of gDNA across a wide range of volume inputs. gDNA was extracted from 4 donors using the MagMAX Saliva gDNA Isolation Kit with the KingFisher Flex instrument. A total of 200 µL, 400 µL, 500 µL, 1 mL, and 2 mL of stabilized saliva from each donor was purified and measured for total DNA yield.

Find out more at **thermofisher.com/saliva**

The Applied Biosystems™ MagMAX™ Cell-Free DNA Isolation Kit is designed for enrichment of circulating cell-free DNA (cfDNA) and optimized for use with biological samples such as serum and plasma. The kit is based on Applied Biosystems™ MagMAX™ magnetic bead technology, enabling reproducible recovery of high-quality DNA that is suitable for a broad range of applications, including downstream analysis of circulating tumor DNA, or fetal DNA.

Highlights:

- Flexible sample volume inputs ranging from 500 µL to 10 mL of plasma, serum, or urine
- No gDNA contamination; phenol-free extraction
- Purified cfDNA in less than 45 min when used with KingFisher instruments
- Specifically recovers short DNA, shorter than 800 bp (Figure 2)

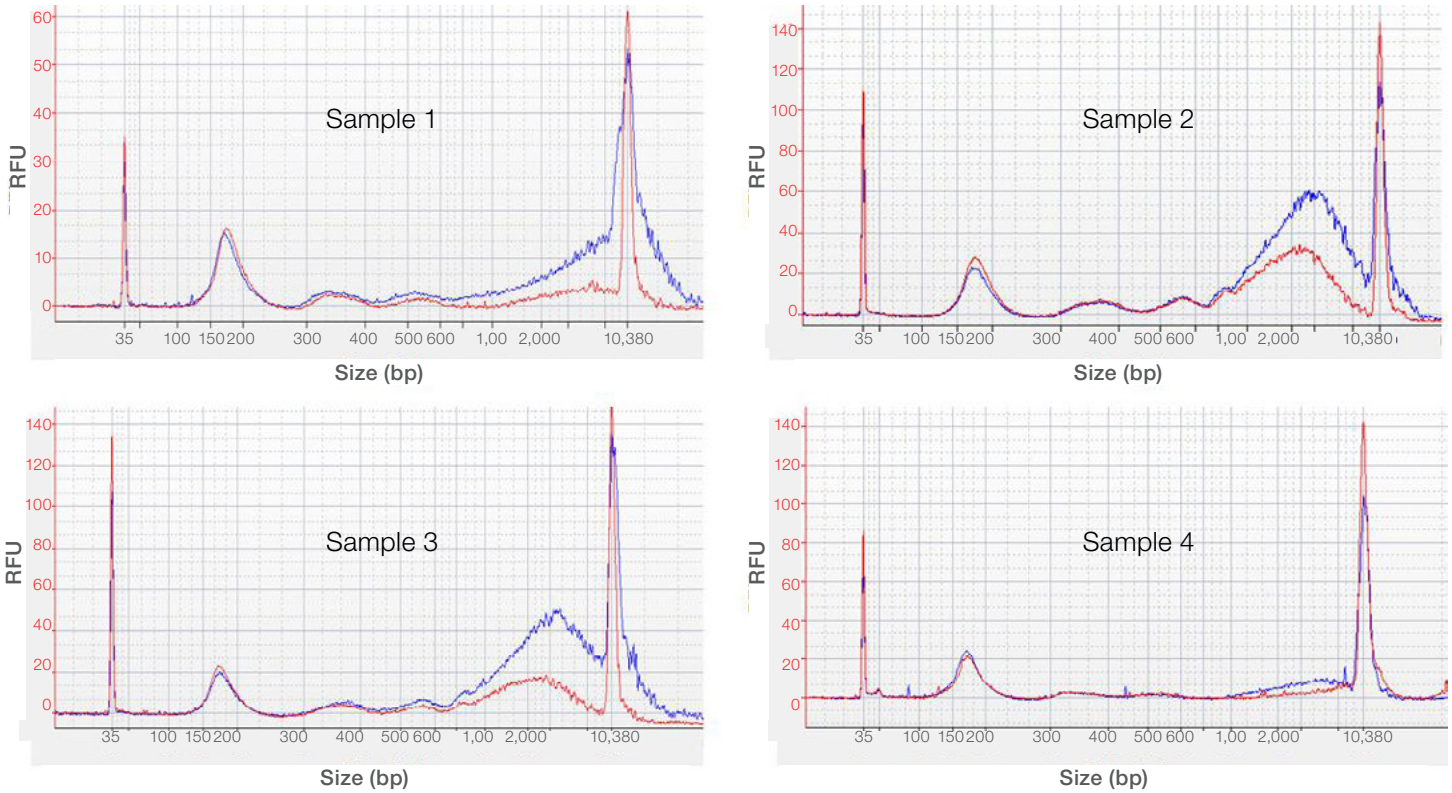


Figure 2. Enrichment of cfDNA following extraction from plasma samples. Cell-free plasma was separated from 4 normal blood samples by centrifugation for 20 minutes at 2,000 x *g*, then for 30 minutes at 6,000 x *g*. DNA was extracted from 4 mL plasma using either the MagMAX Cell-Free DNA Isolation Kit (red trace) or kit Q (blue trace). The eluted DNA was loaded onto a High Sensitivity DNA Chip and run on the Agilent™ Bioanalyzer™ 2100 system.

Find out more at **thermofisher.com/cfdnaisolation**

KingFisher instruments

KingFisher purification systems automate and increase the throughput of bead-based purification protocols. Designed to deliver high-quality results with minimal hands-on time, KingFisher systems use permanent magnetic rods and disposable tip combs to collect, transfer, and mix magnetic particles. KingFisher instruments support more applications than any other single sample preparation instrument. They are elegantly designed to use multiple magnetic bead reagents in 96- or 24-well plate format (Table 3).

- Throughput: 6–96 samples per run
- Plate format: 96- or 24-well plates
- Protocols: optimized protocols from trusted reagent brands, or custom protocols
- Reagents: supports multiple magnetic bead reagents

Table 3. KingFisher instruments for automated sample preparation.

	Duo Prime	Flex	Presto
Instrument format	Compact benchtop	Benchtop	Benchtop + robotic liquid handler
Throughput level	Low to medium	Medium to high	Ultrahigh
Samples per run/plate format	6 or 12 per run	96 or 24 per run	96 or 24 per run
Heating or cooling options	Heating and cooling	Heating only	Heating only

Find a model that supports you best at **thermofisher.com/kingfisher**

Amplification

Reverse transcriptases

We offer a comprehensive portfolio of reverse transcriptases (RTs), from the wild-type Moloney murine leukemia virus (M-MuLV) RT to the Invitrogen™ SuperScript™ line of RTs with superior characteristics such as enhanced sensitivity and reduced reaction time (Table 4). Our proprietary technology of *in vitro* protein evolution has enabled the introduction of multiple favorable mutations into the traditional M-MuLV RT. This has dramatically improved the enzyme thermostability, tolerance for inhibitors, and processivity.

Benefits:

- Robust performance with challenging samples
- Enhanced thermostability and processivity
- High efficiency and sensitivity, even in the presence of inhibitors
- Minimal false-positive results with low residual host-cell DNA
- Lyophilization compatibility with lyo-ready formulation

Table 4. RT selection chart.

Characteristics	SuperScript IV RT	SuperScript III RT	Maxima RT	RevertAid RT (M-MuLV)
Optimal reaction temperature	50°C	50°C	50°C	42°C
RNase H activity	No	No	Yes	Yes
RNase H$^-$ version available	No	No	Maxima H Minus RT	RevertAid H Minus RT
Reaction time	10 min	50 min	30 min	60 min
Inhibitor tolerance	++++	+	+++	+
Sensitivity	++++	+++	+++	++
Lyo-ready*	Yes	Yes	Yes	Yes

* Lyo-ready is a lyophilization-compatible enzyme composition without glycerol.

+ = poor; ++ = medium; +++ = good; ++++ = recommended choice.

Find out more at **thermofisher.com/reverse-transcription**

Featured RT: SuperScript IV RT

Invitrogen™ SuperScript™ IV RT is an M-MuLV RT mutant with superior robustness and reliability in cDNA synthesis. This RT enzyme exhibits strong inhibitor tolerance, high processivity, thermostability, highly efficient full-length cDNA synthesis, and reduced RNase H activity. SuperScript IV RT demonstrates its ability to carry out reliable cDNA synthesis in the presence of common PCR reaction inhibitors, which are typical in situations where biological samples of optimal quality are not available.

Highlights:

- Robust cDNA synthesis with a variety of gene targets, including degraded RNA and RNA samples of suboptimal purity
- High sensitivity and linearity in a 10-minute reaction
- Linear dynamic range across a broad range of RNA input (Figure 3), crucial for detection of low-abundance targets
- Extensive quality testing (Table 5)

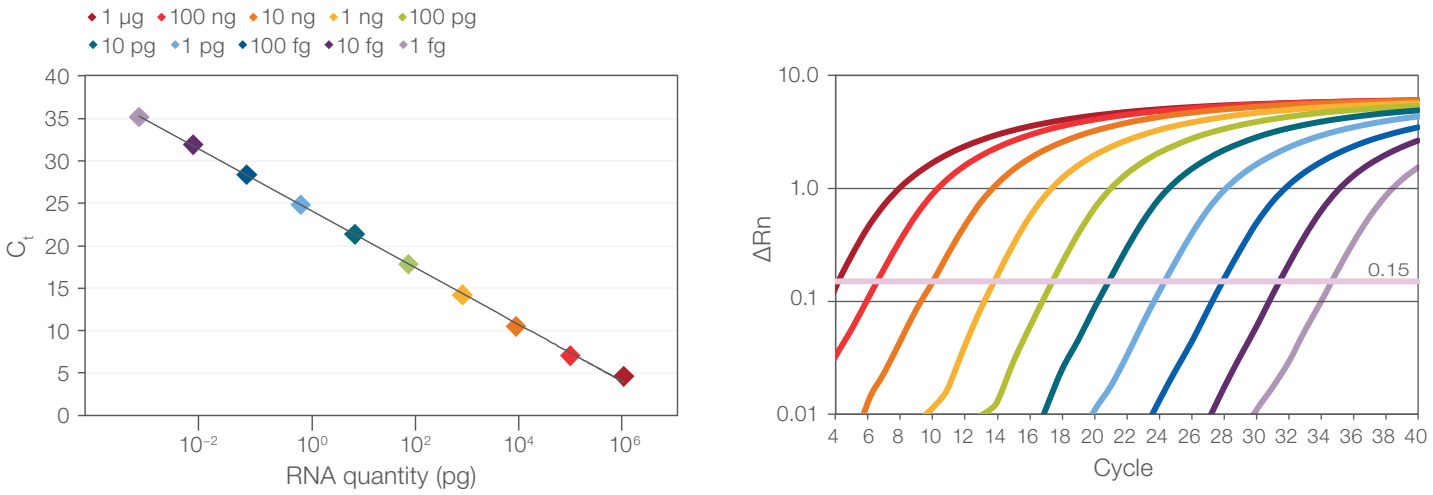


Figure 3. Linearity across 10 orders of magnitude of RNA input. RT-qPCR targeting human 18S rRNA was performed using Invitrogen™ SuperScript™ IV VILO™ Master Mix and an Applied Biosystems™ TaqMan® Assay with 1 fg–1 µg HeLa total RNA input. E = 94.2%, R^2 = 0.999.

Table 5. Quality testing to help ensure high performance of the RT in your RNA-based assays.

Parameter	Method used
Unit concentration	One unit of the enzyme incorporates 1 nmol of dTMP into a polynucleotide fraction in 10 min at 37°C
Endo- and exodeoxyribonucleases	Incubation of radiolabeled, single- and double-stranded oligonucleotides with enzyme
Endodeoxyribonucleases (nicking activity)	Incubation of supercoiled plasmid DNA with enzyme
Ribonucleases	Incubation of radiolabeled RNA transcript with enzyme
Functional testing	Functionally tested in first-strand cDNA synthesis
Human gDNA*	Quantitative PCR test, which uses amplification of selected human gDNA fragments
E. coli gDNA*	Quantitative PCR test, which uses amplification of *E. coli* 23S rRNA gene fragment

* Scope of standard quality-control program may vary for a specific enzyme.

Find out more at **thermofisher.com/ssiv**

DNA polymerases

Taq DNA polymerases

We are dedicated to providing PCR enzymes that meet the most demanding customer requirements. Our knowledge and expertise in enzymology and *in vitro* evolution allow us to develop enzymes with new or improved properties. Our customers can select enzymes from a spectrum of DNA polymerases based on a combination of hot-start technology, speed, level of tolerance for PCR inhibitors, or lyophilization compatibility (Table 6). A high level of performance, lot-to-lot consistency, and extensive quality-control testing enable the highest sensitivity, accuracy, and reproducibility of PCR and real-time PCR (qPCR) assays developed with our enzymes.

Benefits:

- High sensitivity and specificity for detection of low-copy DNA targets
- Minimal activation time for faster time-to-results
- Robust amplification of difficult-to-amplify targets, including those of suboptimal purity
- Lyophilization-compatible (lyo-ready) formulations available

Table 6. *Taq* DNA polymerase selection chart.

Characteristics	Platinum II *Taq* DNA Polymerase	Platinum *Taq* DNA Polymerase, DNA-free	AmpliTaq Gold DNA Polymerase	LibertyTaq DNA Polymerase	Wild-type *Taq* DNA polymerase	Phire Hot Start II DNA Polymerase
Hot-start PCR	Antibody-based	Antibody-based	Chemically modified	Proprietary	No	Affibody-based
TaqMan probe–compatible	Yes	Yes	Yes	Yes	Yes	No
Reactivation time	2 min	2 min	10 min	0 min	0 min	0 min
Extension rate	15 sec/kb	30–60 sec/kb	30–60 sec/kb	30–60 sec/kb	30–60 sec/kb	10–15 sec/kb
Sensitivity	++++	++++	+++	+	+	+
Specificity	++++	++++	+++	+	+	++
Inhibitor tolerance	++++	+	+	+	+	+
Multiplexing	Yes	Yes	Yes	Yes	No	Yes
Lyo-ready*	Yes	Yes	On request	Yes	Yes	Yes

* Lyo-ready is a lyophilization-compatible enzyme composition without glycerol.

+ = poor; ++ = medium; +++ = good; ++++ = recommended choice.

Find out more at **thermofisher.com/pcrenzymes**

Featured *Taq* DNA polymerase: Platinum II *Taq* Hot-Start DNA Polymerase

Invitrogen™ Platinum™ II *Taq* Hot-Start DNA Polymerase combines an enzyme engineered for speed and inhibitor tolerance with a proprietary buffer that allows for a universal primer annealing temperature. These attributes, combined with a robust hot-start feature, open new possibilities in DNA- and RNA-based assay designs (Figure 4).

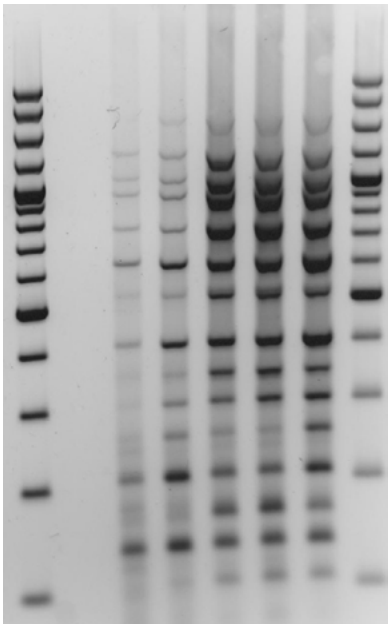


Figure 4. Multiplex PCR with Platinum II *Taq* Hot-Start DNA Polymerase. Fifteen targets (99, 131, 160, 199, 251, 300, 345, 400, 516, 613, 735, 908, 1,005, 1,190, and 1,606 bp) were simultaneously amplified from 0, 1.6, 8, 40, 200, and 1,000 ng of human genomic DNA, in 50 µL reactions. The Thermo Scientific™ GeneRuler™ 100 bp Plus DNA Ladder was used as a size standard/marker (M).

Highlights:

- Universal primer annealing buffer reduces tedious optimization steps and saves time by enabling co-cycling of all assays
- Engineered *Taq* DNA polymerase allows fast cycling, even in the presence of inhibitors
- Platinum hot-start technology offers superior specificity, sensitivity, and yields
- Extensive quality testing (Table 7)

Table 7. Quality testing to help ensure high performance of DNA polymerases in your assays.

Parameter	Method used
Unit concentration	Incorporation of radiolabeled dNTP into polynucleotide fraction by enzyme during the selected time interval
Endo- and exodeoxyribonucleases	Incubation of radiolabeled, single- and double-stranded oligonucleotides with enzyme
Ribonucleases	Incubation of radiolabeled RNA transcript with enzyme
Residual activity assay	Extension of labeled, double-stranded oligonucleotides by enzymes without heat activation
Functional testing	Quantitative PCR containing 10-fold dilutions over 5 orders of magnitude of human and *E. coli* gDNA
Human gDNA	Quantitative PCR test, which uses amplification of selected human gDNA fragments
E. coli gDNA	Quantitative PCR test, which uses amplification of *E. coli* 23S rRNA gene fragment

Find out more at **thermofisher.com/platinumiitaq**

High-fidelity DNA polymerases

Thermo Scientific™ and Invitrogen™ high-fidelity DNA polymerases are designed to amplify DNA fragments with exceptional robustness and fidelity, and to generate PCR products with high accuracy and speed, even with the most difficult templates. Choose from a collection of our high-fidelity enzymes: their formats, buffers, and dNTP solutions vary depending on the sophistication of your DNA-based assay and your needs for flexibility (Table 8).

Benefits:

- Highest fidelity on the market (>100x *Taq* polymerase)
- Robust amplification of versatile targets, up to 20 kb
- Exceptional tolerance of PCR inhibitors
- Shorter cycling times for faster time-to-results
- High yields without optimization
- Minimal nonspecific amplification
- Available as a stand-alone enzyme or in a master mix format

Table 8. High-fidelity DNA polymerase selection chart.

Characteristics	Platinum SuperFi DNA Polymerase	Phusion Hot Start II DNA Polymerase	Phusion U Hot Start DNA Polymerase	Phusion High-Fidelity DNA Polymerase
Fidelity compared to *Taq* polymerase	>100x	52x	25x	52x
Hot-start PCR	Antibody-based	Affibody-based	Affibody-based	No
Extension rate	15–30 sec/kb	15–30 sec/kb	15–30 sec/kb	15–30 sec/kb
Inhibitor tolerance	++++	+++	++	++
dUTP tolerance	No	No	Yes	No
Multiplexing	Yes	Yes	Yes	No
Lyo-ready*	Yes	Yes	On request	On request

* Lyo-ready is a lyophilization-compatible enzyme composition without glycerol.

+ = poor; ++ = medium; +++ = good; ++++ = recommended choice.

Find out more at **thermofisher.com/pcrenzymes**

Featured high-fidelity DNA polymerase: Platinum SuperFi DNA Polymerase

Invitrogen™ Platinum™ SuperFi™ DNA Polymerase is designed for success in PCR, combining the highest fidelity with trusted Invitrogen™ Platinum™ hot-start technology. Featuring >100x *Taq* fidelity, Platinum SuperFi DNA Polymerase is ideally suited for applications benefiting from supreme sequence accuracy.

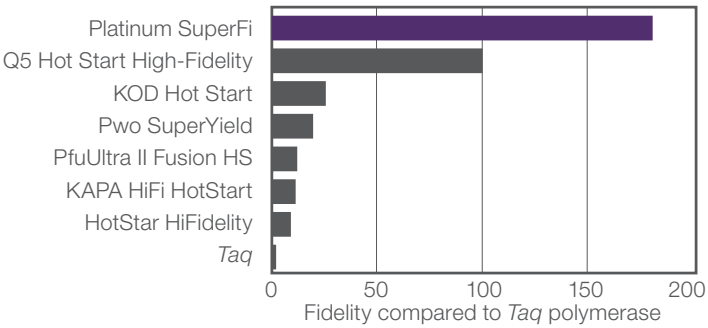


Figure 5. Relative fidelity values of different DNA polymerases. The fidelity of DNA polymerases was measured by next-generation sequencing. The background level of experimental errors was estimated from PCR-free library sequencing data. The polymerase fidelities were normalized to *Taq* polymerase. It is difficult to determine the fidelity values that are greater than 100x *Taq* polymerase in a statistically significant manner, because the extremely low error rates are at the background level.

Highlights:

- Exceptionally high fidelity (>100x higher fidelity than *Taq* polymerase) (Figure 5)
- High specificity and increased yields with Platinum hot-start technology
- Robust amplification of a wide range of targets with tolerance of common PCR inhibitors (Figure 6)
- Convenient workflow with room-temperature reaction setup and 24-hour benchtop stability of preassembled reactions
- Extensive quality testing (Table 9)

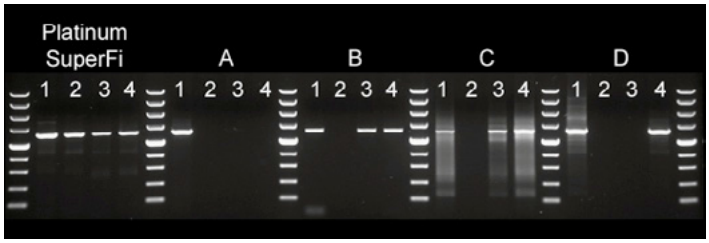


Figure 6. Tolerance of inhibitors. Amplification of a 2 kb human gDNA fragment using Platinum SuperFi DNA Polymerase or high-fidelity DNA polymerases from other suppliers (A–D) in reaction mixtures containing: 1 = no inhibitor, 2 = heparin (0.15 µg/µL), 3 = xylan (0.5 µg/µL), or 4 = humic acid (0.5 ng/µL).

Table 9. Quality testing to help ensure optimal performance of high-fidelity DNA polymerases.

Parameter	Method used*
Unit concentration	One unit of enzyme incorporates 10 nmol of dNTPs into a polynucleotide fraction at 74°C in 30 min
Endodeoxyribonucleases	Incubation of supercoiled plasmid DNA with 10 U of enzyme at 37°C for 4 hr and analysis on agarose gel
Residual activity assay	Extension of labeled, double-stranded oligonucleotide with 5′-overhangs for 4 hr at 37°C in the presence of dNTPs
Functional testing in PCR	PCR amplification of 7.5 kb fragments from human gDNA and 20 kb fragments from lambda DNA, and analysis on agarose gel
Human gDNA	Quantitative PCR test, which uses amplification of selected human gDNA fragments

* Scope of standard quality-control program varies for different enzymes.

Find out more at **thermofisher.com/platinumsuperfi**

Single-use manufacturing

We have developed a manufacturing process using single-use system (SUS)–based technology with extensive quality control testing to help drastically reduce the risk of DNA contaminates in the PCR reagents for commercial supply. The result is the same high level of performance and lot-to-lot consistency that is expected for our standard conventional PCR reagents. DNA-free reagents are the perfect choice for PCR assays where higher sensitivity and specificity are needed to minimize ambiguous or false-positive results.

The first enzyme we manufactured utilizing a closed SUS-based technology was DNA-free Invitrogen™ Platinum™ *Taq* DNA Polymerase. We can apply this technology for a wide range of DNA polymerases and reverse transcriptases in our portfolio. Please contact us and we will work with you to meet your requirements.

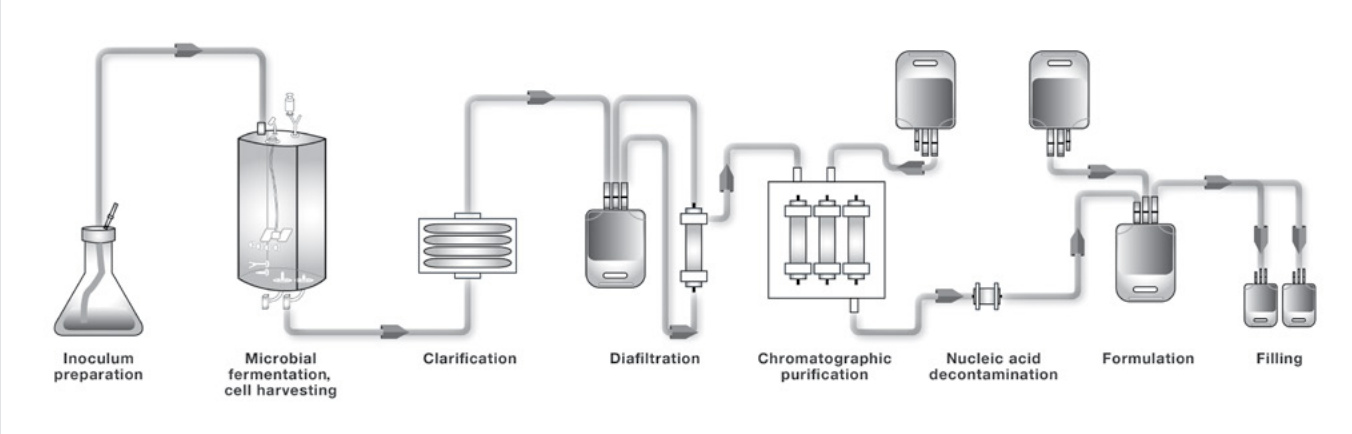


Figure 7. Closed SUS–based manufacturing process for recombinant enzymes. A completely closed system using disposable single-use bags, tubes, and connectors reduces the potential for cross-contamination or contamination from the environment or a human operator to a negligible level.

DNA-free Platinum *Taq* DNA polymerase

DNA-free Platinum *Taq* DNA Polymerase is manufactured using a novel, closed SUS aimed at minimizing the risk of DNA contamination, which can compromise sensitivity and specificity in nucleic acid–based assays. Proprietary quality control tests, relying on highly sensitive qPCR assays, are used to confirm that nucleic acid contaminants are absent from the manufactured enzyme.

Highlights:

- Exceptional sensitivity and specificity of qPCR assay (Figure 8)
- Manufactured in an ISO 13485–certified facility and extensively tested (Table 10)

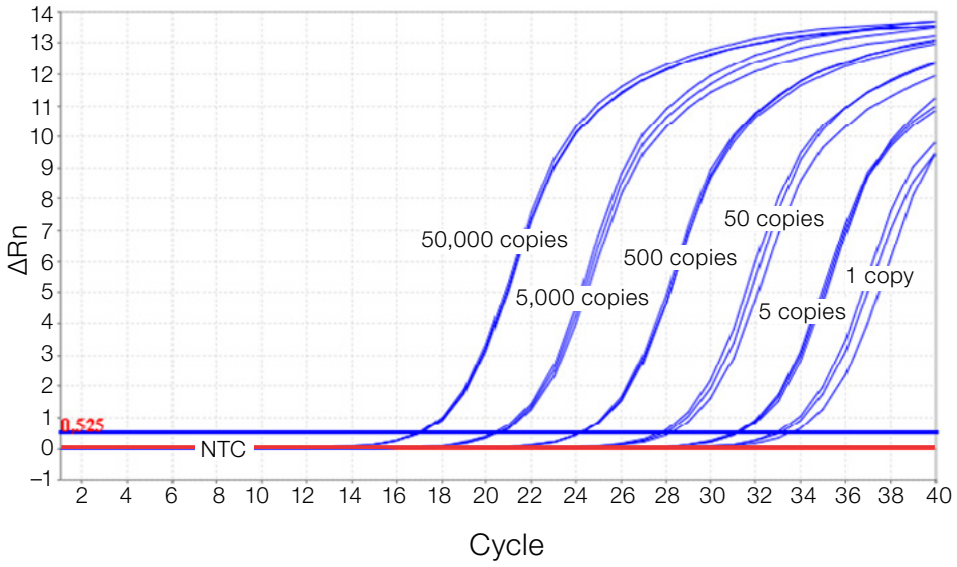


Figure 8. Assay sensitivity. The performance of DNA-free Platinum *Taq* DNA Polymerase in qPCR assays was evaluated using universal primers targeting the bacterial 16S rRNA gene, varying amounts of *E. coli* input DNA (blue line), and no-template control (NTC, red line).

Table 10. Extensive testing helps ensure the quality of DNA-free Platinum *Taq* DNA Polymerase.

Purity test	Requirement
***Taq* DNA polymerase purity**	Exonucleases and endonucleases: undetected
	RNases: undetected
DNA contamination detection	Bacterial gDNA (16S rRNA gene detection): <0.01 copy per enzyme unit
	Human gDNA (*Alu* sequence detection): <0.001 copy per enzyme unit
	Plasmid DNA (ori1 sequence detection): <0.01 copy per enzyme unit

Find out more at **thermofisher.com/dna-free**

EquiPhi29 DNA Polymerase

Thermo Scientific™ EquiPhi29™ DNA Polymerase is a proprietary phi29 isothermal DNA polymerase mutant developed through *in vitro* protein evolution. This enzyme is significantly improved over phi29 DNA polymerase in protein thermostability, reaction speed, product yield, and amplification bias, while retaining all the benefits of the wild-type enzyme, including high processivity (more than 70 kb), strong strand displacement activity, and 3′ to 5′ exonuclease (proofreading) activity acting preferentially on single-stranded DNA or RNA.

Highlights:

- Lowest amplification bias offered in the market (Figure 9)
- Extremely high yields of amplified DNA, even from minute amounts of template
- Highly accurate DNA synthesis in a short amount of time

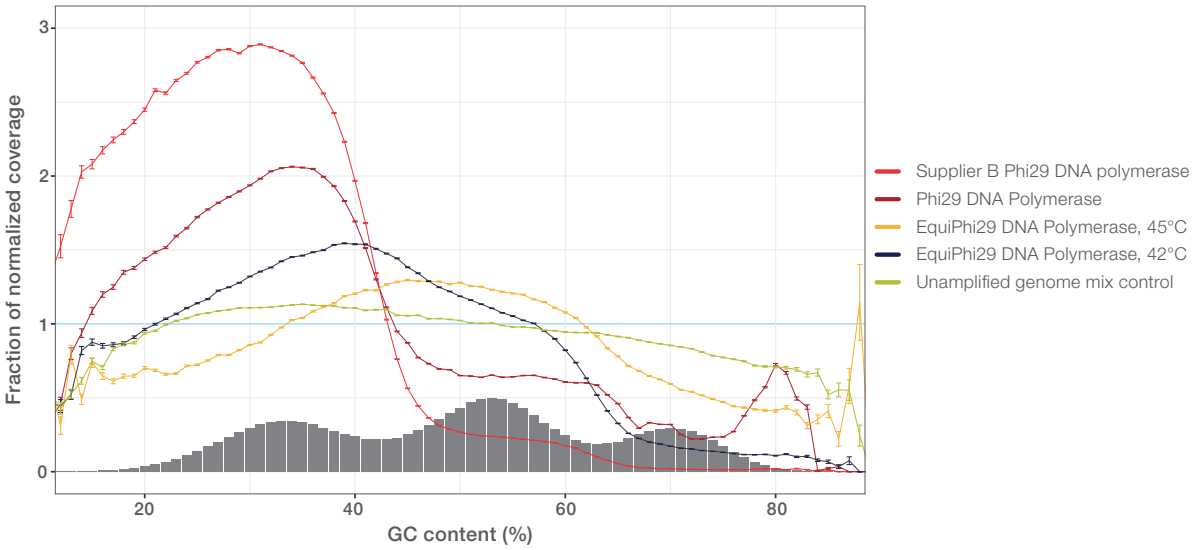


Figure 9. EquiPhi29 DNA Polymerase demonstrates low bias when amplifying 3 bacterial genomes. A mixture of bacterial genomes with low-GC (*S. aureus*, 33% GC), moderate-GC (*E. coli*, 51% GC), and high-GC (*P. aeruginosa*, 68% GC) content was amplified using EquiPhi29 and Phi29 DNA Polymerases as well as a DNA polymerase from another supplier. For each genome, the GC content of the reference genome, in 100 bp windows indicated in gray, was plotted versus the coverage normalized to the unamplified genome mix, indicated in green. In the absence of sequencing bias, all windows should be equally distributed close to the normalized coverage of 1, indicated in light blue. The normalized coverage obtained after amplification using different polymerases is shown. EquiPhi29 DNA Polymerase amplifies DNA with the lowest bias across all GC contents when compared to other DNA polymerases.

Find out more at **thermofisher.com/equiphi29**

PCR-grade dNTPs

We are one of the few primary manufacturers of nucleotides. Our deoxyribonucleotide triphosphates (dNTPs) have been extensively tested and verified for use in a wide variety of molecular biology applications, including highly sensitive techniques such as RT-qPCR and next-generation sequencing.

Highlights:

- Greater than 99% purity confirmed by HPLC (Table 11)
- Manufactured using dedicated equipment for each dNTP
- Free of contaminating RNases, DNases, and qPCR, PCR, and RT inhibitors
- High stability with a 48-month shelf life at –20°C; stable after >100 freeze/thaw cycles
- No limitations to manufacturing scale
- Available as individual dNTPs, sets, or mixes

Table 11. dNTP specifications.

Parameter	Method
Appearance	Colorless solution
pH	7.3–7.5
Concentration	100 mM
Base purity (HPLC)	>99.5% deoxynucleoside
Purity (HPLC)	≥99% triphosphate
Pyrophosphate	<0.003 pmol PPi/pmol dNTP
Endodeoxyribonuclease and nicking activity	Undetectable after incubation of supercoiled plasmid DNA with dNTP
Endo- and exodeoxyribonucleases	Undetectable after incubation of single- and double-stranded radiolabeled oligonucleotides with dNTP
Ribonucleases	Undetectable after incubation of RNA transcript with dNTP
Human DNA	Undetectable via qPCR, which uses amplification of *Alu* repeats in human gDNA
E. coli DNA	Undetectable via qPCR, which uses amplification of *E. coli* 23S rRNA gene fragment
Functional test	Functionally tested in 2-step RT-qPCR using different starting amounts of RNA transcript in reverse transcription reactions followed by amplification with hot-start *Taq* DNA polymerase

Find out more at **thermofisher.com/dntps**

Master mixes

Real-time PCR master mixes

Applied Biosystems™ TaqPath™ and TaqMan® master mixes provide turnkey solutions for real-time PCR (Table 12). They contain buffer, dNTPs, passive reference dye, thermostable hot-start DNA polymerase, and other components formulated for reliable 5′ nuclease probe–based real-time PCR. Just add your sample and Applied Biosystems™ TaqMan® Assay components, and start your reactions.

We offer a range of real-time PCR master mixes optimized for specific applications, and provide TaqMan master mixes for Research Use Only (RUO) and TaqPath master mixes, which are general purpose reagents (GPRs), for laboratory use.

Benefits of TaqPath master mixes:

- Reagents developed, manufactured, and supported by the world leader in qPCR for over 20 years
- Closely controlled for lot-to-lot reproducibility so you observe consistent, reliable results
- Manufactured under an ISO 13485 quality management system to meet your quality assurance needs
- Optimized for a variety of applications, customizable to meet your specific requirements

The master mixes listed in this handbook represent those that are most commonly used; please inquire if you have other specifications, and we will find a solution to suit your needs.

Table 12. TaqPath and TaqMan master mixes provide turnkey solutions for real-time PCR.

	TaqPath ProAmp Master Mix and Multiplex Master Mix	TaqPath qPCR Master Mix	TaqPath 1-Step RT-qPCR Master Mix and Multiplex Master Mix	TaqMan Fast Advanced Master Mix and Multiplex Master Mix	TaqMan Fast Virus 1-Step Master Mix
Application	Genotyping and copy number variation	DNA detection and 2-step gene expression analysis	RNA virus detection and 1-step gene expression analysis	DNA detection and 2-step gene expression analysis	RNA virus detection and 1-step gene expression analysis
GPR*	Yes	Yes	Yes	No	No
Passive reference dye	ROX, Mustang Purple	ROX	ROX, Mustang Purple, or none	ROX	ROX
Features/ advantages	Accurate genotyping calls in the presence of inhibitors	Linear, reproducible results over a wide dynamic range	Sensitive, reproducible detection, even in the presence of inhibitors	Wide linear dynamic range with reduced run times	Sensitive and linear results, even in the presence of inhibitors

* TaqPath qPCR master mixes are classified as General Purpose Reagents (GPRs) by the FDA, designated for laboratory use, and are recommended for many commercial applications. Lyo-ready master mixes for qPCR and 1-step RT-qPCR are also available. See pages 31–32 for details.

Genotyping master mixes

Applied Biosystems™ TaqPath™ ProAmp™ Master Mixes are versatile master mixes developed for high-throughput genotyping and copy number variation (CNV) analysis protocols that require accurate results from samples containing PCR inhibitors. TaqPath ProAmp Master Mixes are designed to deliver accurate and reproducible results from genomic DNA targets. The simple workflow and reproducible performance even in the presence of inhibitors offer confidence in results (Figure 10).

Highlights:

- High specificity, call accuracy, and reproducibility for genotyping and copy number determination
- More robust inhibitor tolerance than comparable universal and genotyping master mixes
- Multiplexing made possible by a formulation without ROX dye, which enables detection of up to four targets per reaction
- Manufactured with strict controls for lot-to-lot consistency in an ISO 13485–certified facility

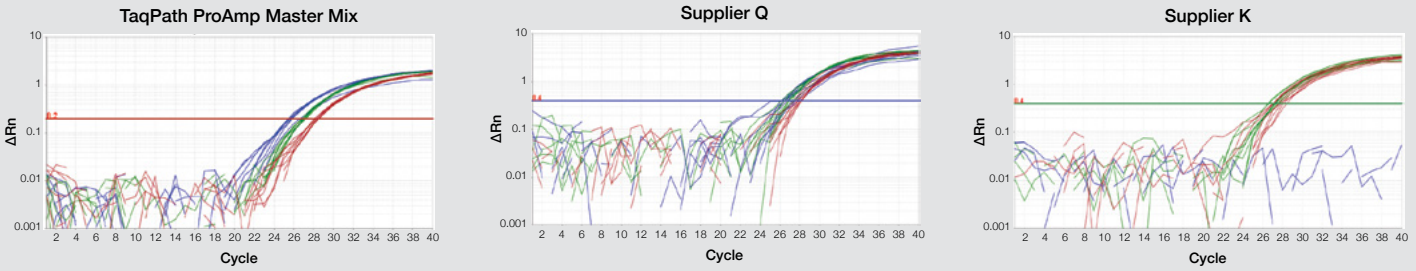


Figure 10. Inhibitor tolerance of TaqPath ProAmp Master Mix and other commercial master mixes. Crude lysates of blood samples isolated in sodium citrate (green), EDTA (red), or heparin (blue) BD Vacutainer™ tubes were used in the experiment and constituted 30% of reaction volume. Eight replicate genotyping reactions were run to assess the magnitude and standard deviation of C_t values in the presence of these PCR inhibitors. Amplification plots for reactions are shown. TaqPath ProAmp Master Mix yields lower C_t values in the presence of inhibitors, and lower standard deviations for replicates. No amplification was observed using Supplier K's mix with the heparinized sample.

Find out more at **thermofisher.com/proamp**

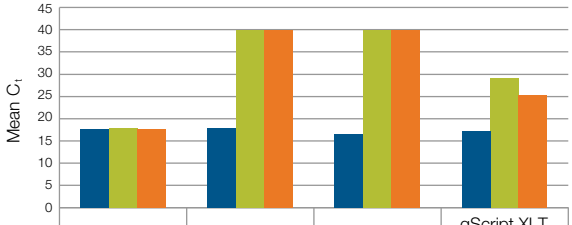
Gene expression analysis master mixes

Depending on your workflow, you may choose to perform reverse transcription and amplification in one or two reactions, and would need a 1-step or 2-step gene expression master mix, respectively.

Applied Biosystems™ TaqPath™ qPCR Master Mix, CG, is an ideal reagent for 2-step gene expression. For the best performance, use SuperScript IV VILO Master Mix to prepare cDNA prior to amplification with the TaqPath qPCR Master Mix.

Featured gene expression master mix: TaqPath 1-Step RT-qPCR Master Mix

For highly reproducible 1-step gene expression analysis, Applied Biosystems™ TaqPath™ 1-Step RT-qPCR Master Mix provides sensitive, low-copy target detection, even in the presence of inhibitors. It is also available with Mustang Purple dye or without reference dye, making it ideal for higher-order multiplexing applications that enable you to get more data out of each reaction. While the single-tube, 4X format facilitates easy reaction setup and increases sensitivity even in low-volume reactions, the product's stringent quality control minimizes lot-to-lot variation, helping to ensure confidence in results.



	TaqPath 1-Step Multiplex Master Mix	iTaq Universal Probes One-Step Kit	QuantiTect Virus Kit	qScript XLT One-Step ToughMix master mix
No inhibitor	17.6	17.6	16.6	17.3
10 µM hematin	17.9	40.0	40.0	29.0
0.0625 U/µL heparin	17.6	40.0	40.0	25.2

Figure 11. Inhibitor tolerance of TaqPath 1-Step Multiplex Master Mix and kits from other suppliers. Two inhibitors (hematin and heparin) were added to RT-qPCR reactions run on the Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System to assess the magnitude of C_t shifts caused by these inhibitors. C_t values for reactions without and with inhibitors are shown.

Highlights:

- Tolerance of inhibitors commonly found in biological samples (Figure 11)
- Ability to detect up to four targets in one reaction
- High sensitivity to detect low-copy targets with reproducible C_t values
- Wide dynamic range compatible with multiplexing applications
- Manufactured with stringent process controls to help ensure lot-to-lot consistency (Figure 12)

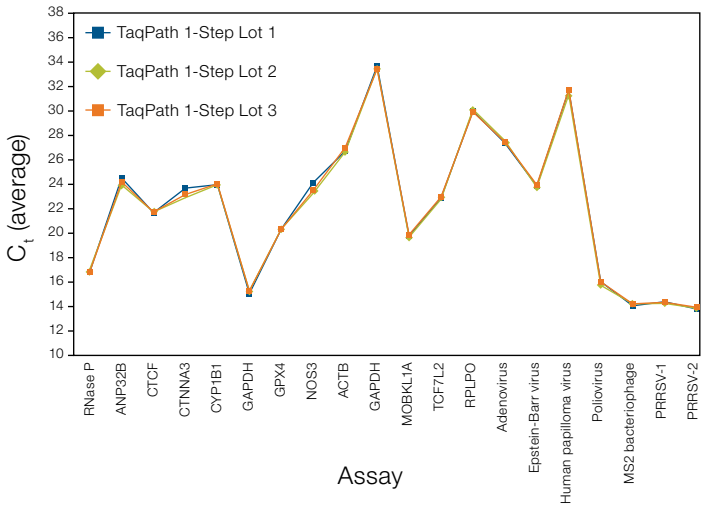


Figure 12. Consistency of C_t values across multiple assays for three unique lots of TaqPath 1-Step RT-qPCR Master Mix. Total RNA was amplified using a panel of human and viral gene expression assays and three distinct lots of TaqPath 1-Step RT-qPCR Master Mix. Excellent C_t concordance is seen across the three lots for a representative subset of the assays used.

Find out more at **thermofisher.com/taqpath**

PowerUp SYBR Green Master Mix

The Applied Biosystems™ PowerUp™ SYBR™ Green Master Mix is a preformulated, optimized universal 2X master mix ideal for more economical assays in less demanding applications. Coupled with user-supplied primer sets and template, PowerUp SYBR Green Master Mix is designed to amplify targets for accurate gene expression analysis. It uses SYBR Green dye (a double-stranded DNA binding dye) to detect PCR products as they accumulate.

Highlights:

- A dual hot-start mechanism for excellent specificity
- Highly reproducible C_t values over a broad dynamic range
- Inclusion of uracil DNA glycosylase (UDG) to help prevent carryover contamination
- Stability of preassembled reactions for up to 72 hours
- Compatibility with most real-time PCR instruments

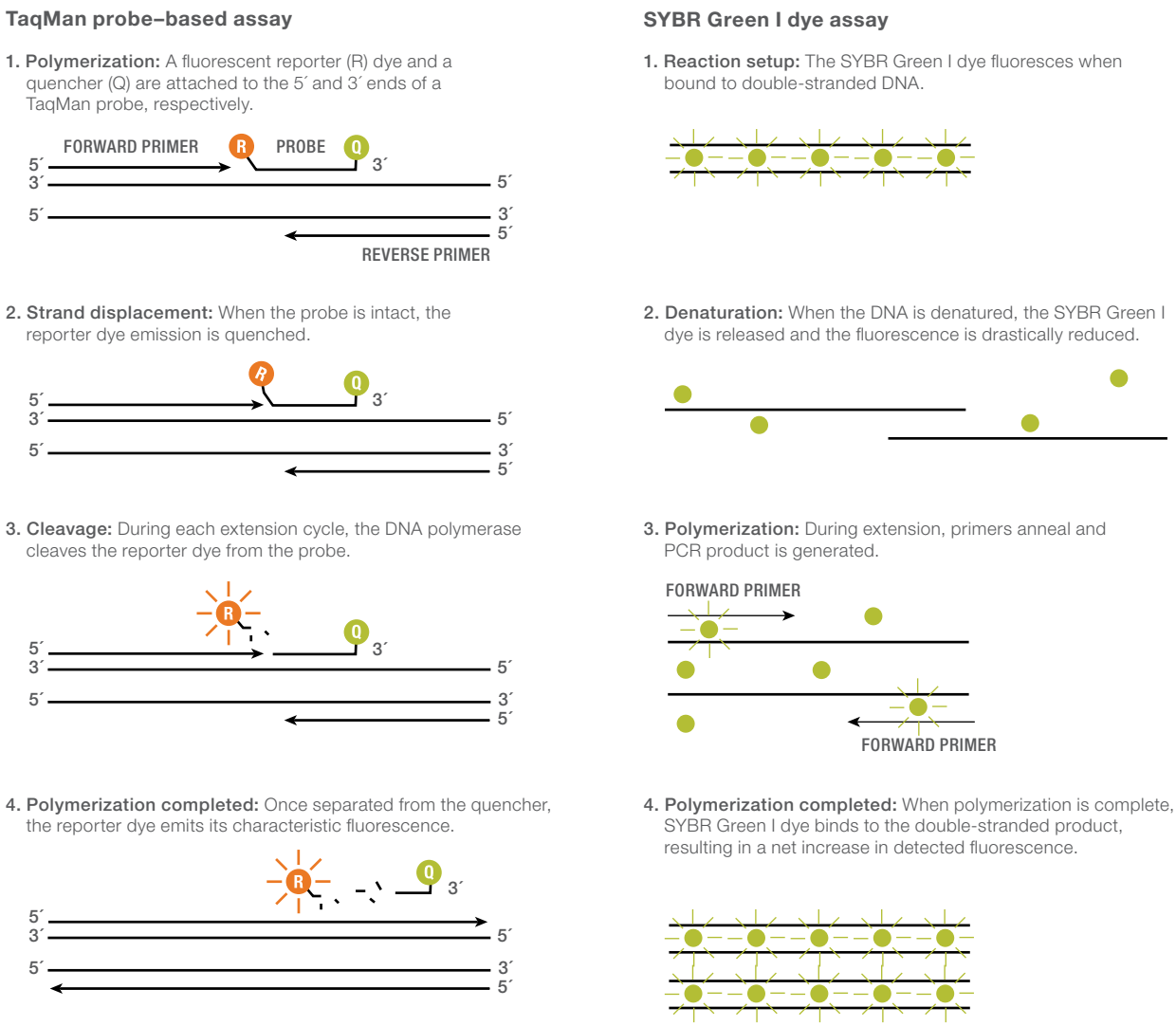
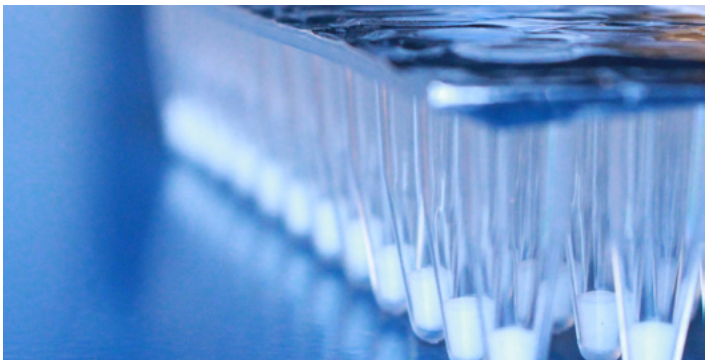


Figure 13. Comparison of workflows based on TaqMan and SYBR Green detection technologies.

Find out more at **thermofisher.com/sybr**

Lyo-ready enzymes and master mixes



We provide ready-to-lyophilize versions of many of our most popular enzymes and qPCR master mixes, as well as services to lyophilize your final assay into PCR plates or strip tubes. Our concentrated, convenient master mixes include enzyme, dNTPs, buffer, and an optional passive reference dye, ready for the addition of primers, probes, and excipients for lyophilization. For those who prefer to formulate their own reaction mixtures, we provide a variety of low-glycerol, lyophilization-ready (lyo-ready) enzymes.

Benefits:

- **High concentration**—allows flexibility in final formulations with primers, probes, and excipients
- **Convenience**—end users only have to add their sample
- **Cost savings**—room-temperature shipping and longer shelf life of the assay
- **Performance**—same excellent results you expect from wet master mix formulations

Lyo-ready enzymes

From Invitrogen™ SuperScript™ reverse transcriptases (RTs) to Platinum II *Taq* DNA Polymerase, we offer a large portfolio of lyo-ready enzyme formats to meet the performance requirements of RT-qPCR and qPCR assays in dry formats (Table 13). These enzymes are formulated without glycerol and perform consistently across different formats—standard glycerol, lyo-ready, lyophilized, and reconstituted.

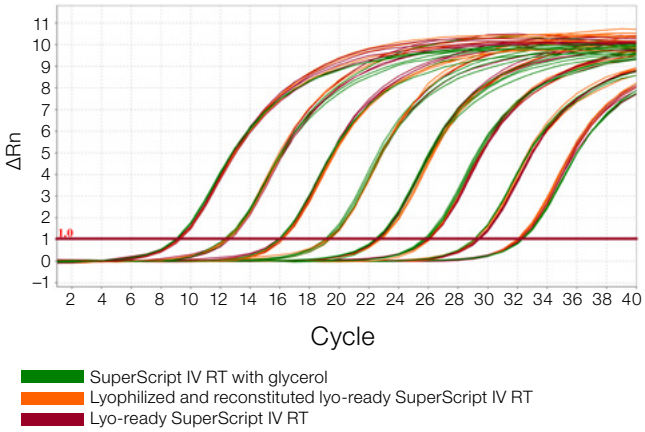


Figure 14. Lyo-ready Invitrogen™ SuperScript™ IV Reverse Transcriptase provides reliable performance across a wide dynamic range. 1.25 ng to 0.125 fg of 1.3 kb GAPDH RNA was used in 20 µL RT reactions with oligo(dT)$_{20}$ and random hexamers. Thermo Scientific™ Luminaris™ HiGreen qPCR Master Mix, low ROX (Cat. No. K0972) with GAPDH gene-specific primers was used for qPCR. cDNA composed 10% of the qPCR mixes. Lyophilized and reconstituted lyo-ready SuperScript IV RT showed equivalent performance to wet lyo-ready and glycerol-containing RTs. Lyo-ready enzymes show high linearity with R^2 ≥0.999 and reaction efficiency of 100% across a wide dynamic range.

Table 13. Selection of lyo-ready enzymes for molecular assays.*

Reverse transcriptases (RTs)	DNA polymerases
SuperScript IV RT	Platinum II *Taq* DNA Polymerase
SuperScript III RT	Platinum SuperFi DNA Polymerase
RevertAid (M-MuLV) RT	LibertyTaq DNA Polymerase
Maxima H Minus RT	Platinum *Taq* DNA Polymerase
Maxima RT	Phire HS DNA Polymerase
	Phusion HS DNA Polymerase

* Additional lyo-ready RTs and DNA polymerases are also available.

Find out more at **thermofisher.com/lyoreadyenzymes**

Lyo-ready master mixes

Our low-glycerol, lyo-ready qPCR master mixes are one-tube solutions that are ready to be mixed with primers, probes, and excipients, for the subsequent lyophilization step. There is no need for time-consuming development, optimization, and sourcing of multiple separate qPCR reaction components. These reagents retain the reproducibility, sensitivity, and specificity required for commercial assays (Figure 15). Once lyophilized, the assays demonstrate little to no loss of sensitivity or specificity, and have been shown to reproducibly detect a single copy of target per reaction and provide a linear dynamic range of over seven logarithmic units.

Once lyophilized, assays also exhibit higher stability, thus reducing waste due to reagent and assay expiration. Figure 16 shows consistent stability of three batches of lyophilized assay using TaqMan Lyo-Ready 1-Step Master Mix for four targets tested.

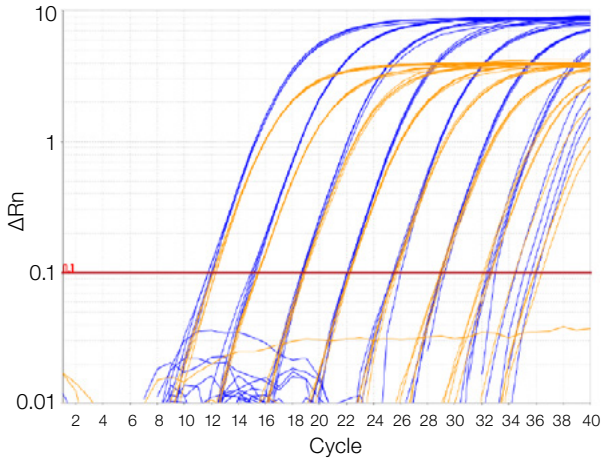


Figure 15. Comparison of qPCR amplification curves using Applied Biosystems™ TaqMan® Lyo-Ready 1-Step Master Mix and Applied Biosystems™ TaqMan® Fast Virus 1-Step Master Mix. The Applied Biosystems™ VetMAX™ Xeno™ Internal Positive Control was used as the target, in a dilution series over 7 orders of magnitude. The TaqMan Lyo-Ready 1-Step Master Mix maintains or exceeds the performance of TaqMan Fast Virus 1-Step Master Mix in C_t and fluorescence (ΔRn) values. The TaqMan Lyo-Ready 1-Step Master Mix can be formulated with Applied Biosystems™ ROX™ passive reference dye (as shown here) or without the passive reference dye.

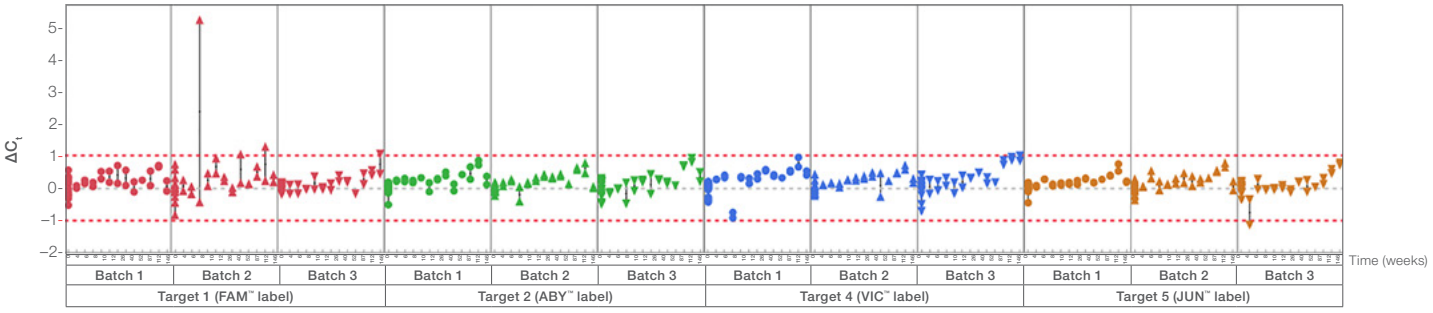


Figure 16. Stability testing of different batches of TaqMan Lyo-Ready 1-Step Master Mix. Three batches of a lyophilized multiplex arbovirus assay using TaqMan Lyo-Ready 1-Step Master Mix were stored at ambient temperature (24°C) and tested for their stability at regular intervals. Stability results for all batches of the lyophilized 1-step master mix with four targets showed that the ΔC_t values ($C_{t\ (test\ point)} - C_{t\ (time\ 0)}$) remained within the specified metric of ±1 over 146 weeks (2.8 years).

Lyophilization services

We can lyophilize your master mix, assay, and excipients into a plate or strip tube for you. By sourcing your reagents and your lyophilization services from the same supplier, you can drastically reduce the complexities in your supply chain. Your assay will be delivered to you, ready to go. We have heavily invested in our own lyophilization and manufacturing capabilities, so that you don't have to.

Our products are manufactured in clean room facilities, which are certified according to EU directives and ISPE guidelines, and in compliance with ISO 9001, ISO 13485, ISO 14001, and OHSAS 18001 certification. Lyophilization is performed in an environmentally controlled room.

Optimizing your assay into a dry format

We work with you to optimize your assay with lyo-ready reagents in a wet format. Then, we begin manufacturing smaller amounts of lyophilized assay to ensure performance of the dry assay. Once it is optimized, we scale up manufacturing so that you can perform validation on the dry assay.

Test/develop with wet lyo-ready reagents	Verify performance of lyophilized assays	Assay validation
• Confirm assay performance with lyo-ready reagents • Optimize assay and cycling parameters	• Confirm lyophilized assay performance • Lock down assay formulation, specifications, and test parameters	• Confirm and document that the test works as intended • Confirm the validity, utility, sensitivity, and specificity of the test

Primers, probes, and oligonucleotides

TaqMan MGB probes

Applied Biosystems™ TaqMan® probes include a minor groove binder (MGB) moiety at the 3′ end that increases the primer melting temperature (T_m) of the probe and stabilizes probe–target hybrids, enabling shorter probe length. The nonfluorescent quencher (NFQ) absorbs (quenches) signal from the fluorescent dye label at the other end of the probe. The properties of the NFQ combined with the short length of the MGB probe result in lower background signal than with non-MGB NFQ probes. Lower background signal means increased sensitivity and precision in your data (Figure 17).

MGB probes and unlabeled primers are also available as analyte-specific reagents (ASRs) to help meet requirements for test development. Applied Biosystems™ probe and primer ASRs are manufactured in a registered facility in accordance with current good manufacturing practices (cGMPs) with a quality management system certified to ISO 13485:2003.

TaqMan probe outperforms non-MGB probe in real-time PCR: in dynamic range, sensitivity, and reproducibility

	C_t		Standard deviation	
Input	TaqMan Assay	Non-MGB assay	TaqMan Assay	Non-MGB assay
10 ng	9.72	13.35	0.02	0.15
1 ng	13.36	16.82	0.04	0.18
0.1 ng	16.76	20.23	0.07	0.13
10^{-2} ng	20.19	23.72	0.04	0.13
10^{-3} ng	23.64	27.31	0.03	0.10
10^{-4} ng	27.01	30.66	0.04	0.12
10^{-5} ng	30.24	32.82	0.13	0.19

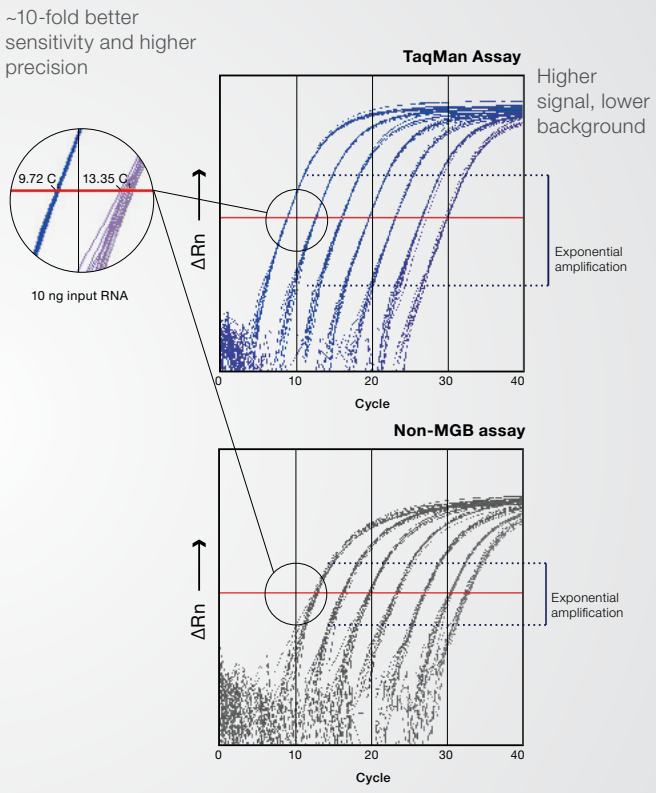


Figure 17. TaqMan probes provide better sensitivity and precision. Comparison of two 5′ nuclease PCR assays for 18S rRNA. Ten-fold dilutions of Invitrogen™ Universal Human Reference RNA (10 to 10^{-5} ng) were prepared and analyzed in 11 replicate real-time PCR reactions using either the Applied Biosystems™ TaqMan® Gene Expression Assay (FAM dye–labeled, with NFQ) or the non-MGB assay (FAM dye–labeled, with BHQ). Real-time PCR was run according to the respective manufacturers' recommended conditions. Across a 6-log range of input template, the TaqMan Assay displayed lower C_t values and better reproducibility across all data points. In addition, the TaqMan Assay had higher signal and lower background, resulting in better sensitivity and higher precision.

TaqMan QSY probes for multiplexing

Applied Biosystems™ TaqMan® QSY™ probes incorporate a proprietary 3′ QSY quencher to provide maximal PCR performance in a multiplex format. TaqMan QSY probes are available with Applied Biosystems™ FAM™, VIC™, and our proprietary ABY™ and JUN™ dyes, allowing amplification of up to four targets in a single reaction. All four dyes are optimized for the filter sets on Applied Biosystems™ real-time PCR instruments and work together with minimal spectral overlap for optimal performance (Figure 18).

Multiplexing with TaqMan QSY probes enables cost savings and preservation of limited samples, and also yields comparable results between reactions performed in individual tubes or in 4-plex reactions for a gene quantification experiment (Figure 19).

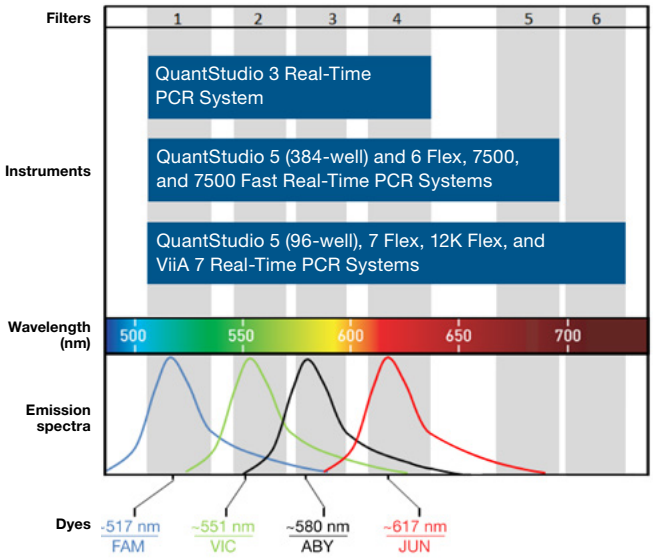


Figure 18. Fluorescence emission wavelengths used for multiplex real-time PCR. Emission spectra for FAM, VIC, ABY, and JUN dyes are shown in relation to regions of the spectrum detected by six filters available on Applied Biosystems real-time PCR instruments.

TaqMan real-time PCR assays

TaqMan Assays are optimized primer and probe sets in one convenient tube. We provide a complete range of custom-synthesized oligonucleotide primers and probes, all built to your specifications. Simply identify your target of interest or exact sequence, and our team can design your assay.

Benefits:

- Advanced primer and probe sequence selection criteria generate highly specific amplification and detection of your target
- The NFQ on TaqMan probes minimizes background, enabling detection of fewer than 10 copies
- Reproducible results from well to well, day to day, and lab to lab—even across manufacturing lots
- Wide dynamic range from a handful to millions of target molecules with the same reaction setup
- All assays use a single, universal thermal cycling profile

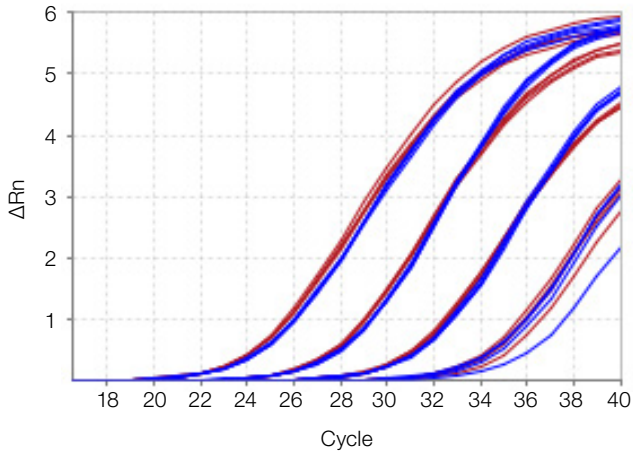


Figure 19. Comparable results for singleplex and multiplex assays. The amplification plot shows linear portions of the curves for 4 EGFR assays amplified in singleplex (blue) and 4-plex reactions (red) in a dilution series from 20,000 pg to 2 pg of reference colon cDNA per 10 µL reaction. PCR efficiencies are 96.09% for EGFR singleplex and 96.39% for EGFR 4-plex reactions.

Find out more at **thermofisher.com/taqman**

Instrumentation

With Applied Biosystems™ thermal cyclers and real-time PCR platforms, you get exceptional value with excellent performance, reliability, and world-class support.

When you validate your assay on Applied Biosystems instruments, you can leverage the expansive, global installed base in end-user laboratories, or place our instruments in a reagent rental agreement. As an option, you can even have an Applied Biosystems instrument private-labeled and integrated into your workflow and deliver it to your customers with your own label attached. Your customers will also gain access to the same validation and IQ/OQ services that our direct instrument customers enjoy.

Thermal cyclers

We offer a broad portfolio of high-quality thermal cyclers for commercial applications (Table 14).

Table 14. Applied Biosystems thermal cycler selection chart.

	ProFlex PCR System	SimpliAmp Thermal Cycler	MiniAmp Plus and MiniAmp Thermal Cyclers	Automated Thermal Cycler
Thermal cyclers				
Key benefits	Ultimate flexibility and throughput	Elegantly simple and precise	Routine PCR, elevated	Designed for easy robotic integration
User interface	8.4 inch touchscreen	8.4 inch touchscreen	5.0 inch touchscreen	Automated via robotics
Max sample throughput	480,000 reactions	96 reactions	96 reactions	384 reactions
Max block ramp rate	6.0°C/sec	4.0°C/sec	MiniAmp Plus Thermal Cycler: 3.5°C/sec MiniAmp Thermal Cycler: 3.0°C/sec	3.5°C/sec
Temperature optimization	6-zone VeriFlex Block on 96-well system 2-zone VeriFlex Block on 3 x 32-well system	3-zone VeriFlex Block on 96-well system	MiniAmp Plus Thermal Cycler: 3-zone VeriFlex Block on 96-well system MiniAmp Thermal Cycler: none	None

Find out more at **thermofisher.com/thermalcyclers**

Real-time PCR instruments

The Applied Biosystems family of instruments is designed for compatibility with TaqMan Assays and master mixes. Our genetic analysis instruments support your lab's assay development needs along with a workflow to match your requirements. Table 15 lists our most popular instruments for assay development and commercialization.

Table 15. Applied Biosystems real-time PCR instruments for molecular assays.

	QuantStudio 5 system	QuantStudio 7 Flex system	7500 Fast system
			
Description	Modern, interactive, affordable, dual mode	A high-throughput platform that can grow with you	A widely used workhorse instrument
Footprint	27 x 50 x 40 cm (W x D x H)	53 x 70 x 75 cm (W x D x H)	34 x 45 x 49 cm (W x D x H)
Optical system	Bright white LED	White halogen lamp	White halogen lamp
Blocks	Fixed block: 96-well 0.2 mL	Interchangeable: 96-well 0.2 mL, 96-well 0.1 mL, 384-well, TaqMan Array Card	Fixed block: 96-well 0.1 mL

"Adding the Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System to the VERSANT™ kPCR Molecular Solution brings a new level of innovation to the market by providing more flexibility and customization to the molecular laboratory workflow. We are excited to strengthen our dedication to molecular laboratory innovations through our partnership with Thermo Fisher Scientific."

—David Stein, President of Molecular Diagnostics, Siemens

Find out more at **thermofisher.com/qpcrsystems**

PCR and qPCR plastics, seals, and accessories

For more than 25 years, we have been at the forefront of innovation in the manufacturing of high-grade plastic consumables, with a focus on providing plastic solutions for molecular biology applications, including PCR and qPCR.

We have the essentials to help ensure that your development and manufacturing projects are a success:

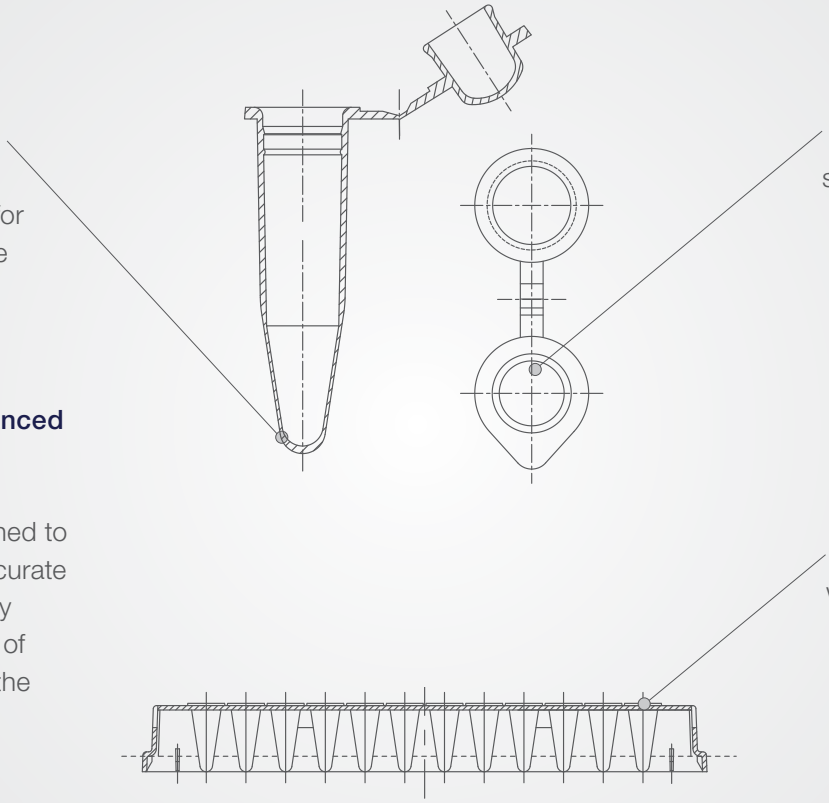
- State-of-the-art injection molding manufacturing facilities that meet Class 10,000 or 100,000 clean room standards
- Expertise in thin-walled polypropylene plastics and sealing films for PCR and qPCR, and sample storage
- Custom product design, rapid prototyping, and manufacturing
- In-house toolmaking and tool maintenance
- Barcoding options unique to your product, in any barcode format
- Customized product packaging and labeling
- Application-specific quality control
- ISO 9001 compliance, with complete traceability and process controls

Find out more at **thermofisher.com/oemplastics**

Innovative product design

High efficiency, reduced variability
Uniform, ultrathin walls enable maximum and consistent heat transfer for equally high performance from every sample.

White plastics for enhanced qPCR detection
Thermo Scientific™ white qPCR plastics are designed to provide sensitive and accurate fluorescence detection by preventing refraction out of the tube and increasing the signal-to-noise ratio.



Secure, easy sealing
Specially designed caps create a tight seal that is still easy to open and close. Tube strips with attached caps that open and close independently are also available.

Evaporation protection
Raised rim around each well enables secure sealing and safeguards against evaporation.

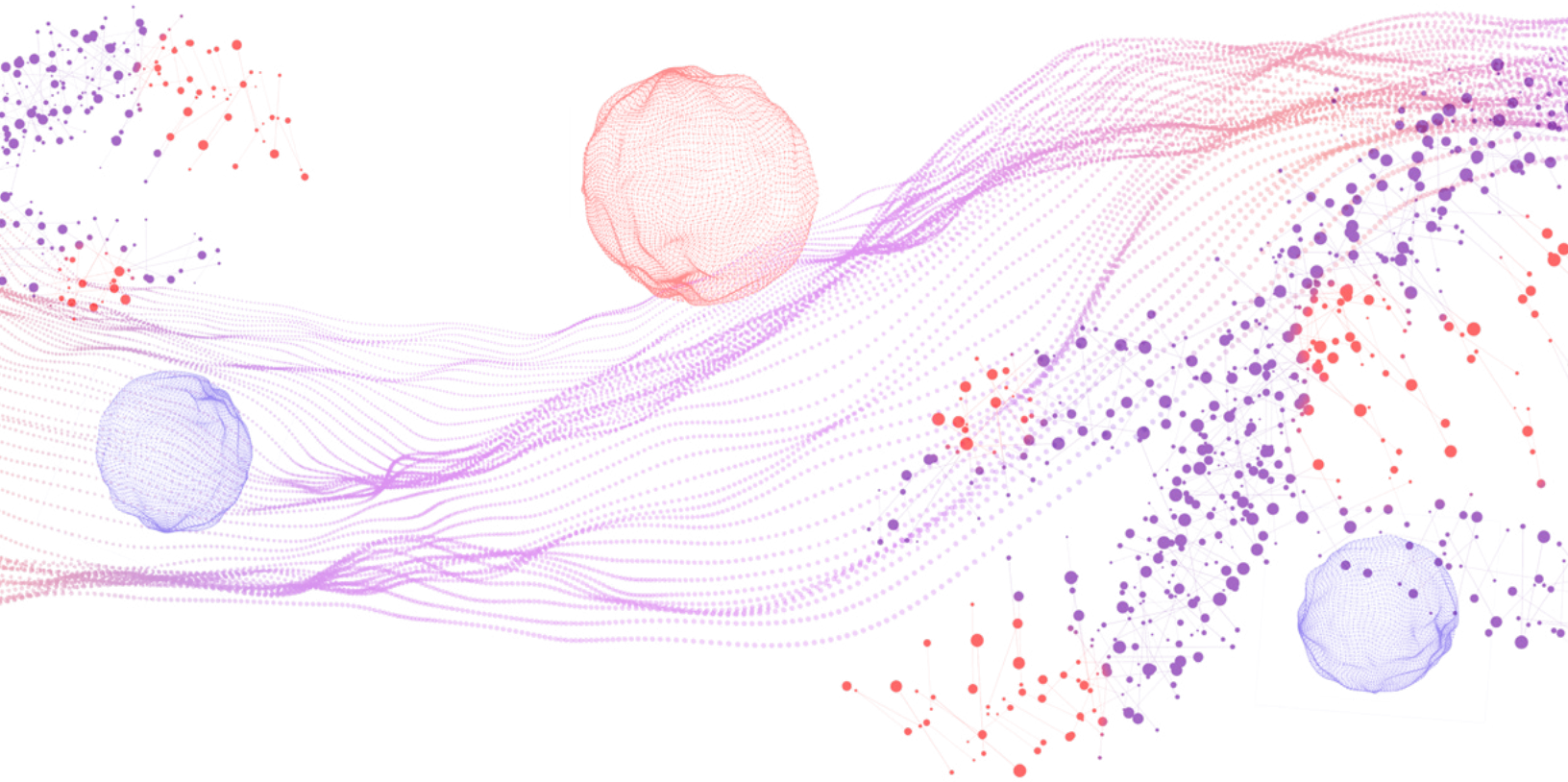
Custom manufacturing services

Streamline your supply chain and avoid investing in costly manufacturing capabilities, with our custom manufacturing services. We provide raw materials, manufacturing of components, and packaging of a molecular assay kit according your design and requirements.

- Choice of tube and bottle sizes
- Variety of plate formats
- Fill and finish
- Custom kit configurations
- Private labeling

We have expertise in OEM product development, formulation, aseptic processing, kit assembly, and packaging. We can bring individual components such as master mix, assay, and controls together in a skillfully designed package with your company logo.

Multiple levels of regulated manufacturing are available, e.g., cGMP, general purpose reagents, research use only, clean room, controlled environment, and advanced quality management systems ISO 9001 and ISO 13485.



Find out more at **thermofisher.com/oem**

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