PCR Enzymes

for Molecular Diagnostics

ISO 13485 : 2016

INNOBIZ

NANOHELIX
Reliable Partner for DNA Technologies

Who We Are

Established in 2008, NanoHelix began by producing research-use enzymes and now manufactures large-scale for molecular diagnostic applications. Utilizing an ICT-based smart factory system with ISO 13485:2016 and GMP facilities, we can produce 5 billion units of *Taq* DNA polymerase annually; equivalent to more than 2 billion PCR tests. NanoHelix continues to develop consistently reliable products, reinforcing our ability to supply 70% of Korea's COVID-19 MDx raw material reagents and putting us at the forefront of the pandemic response. We will maintain our reputation as an exceptional manufacturer and supplier of raw materials for molecular diagnostics and nucleic acid-based MDx kits.

Contract Manufacturer | Custom Development | OEM Business

Why NanoHelix?

Advanced Technology

Due to continuous and intensive investment in R&D, NanoHelix Co., Ltd. develops innovative technologies and products for molecular diagnostics; PMT Technology, fast real-time PCR, FMMA(Fluorescence-based multiple melting analysis), and novel POC NA purification technology(Punch-it™ NA-Sample Kit).
These novel and proprietary technologies would be applied to the custom diagnostic kits to enhance their performances and develop cutting-edge products.

Certified Management & Quality Assurance System

With an ISO 13485:2016 certified system, ICT-based smart factory with GMP facilities, and our dedicated professional staff, we ensure our products' quality measures up to the highest standard. EN ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices(including in-vitro diagnostic products) and related services that consistently meet both customers' and applicable regulatory requirements. All procedures related to R&D, manufacturing and QC/QA, including raw materials import/inspection, materials and data traceability, delivery, etc., are in compliance with NanoHelix's certified management and quality assurance system.

High Production Capability

NanoHelix manufactures 20+ different enzymes and proteins routinely. In the case of *Taq* polymerase, we can produce 5 billion units annually; equivalent to more than 2 billion PCR tests.

Over 10 years' experiences with hundreds of custom developments

As your custom development partner, NanoHelix leverages over 10 years' experiences, resources, and expertise to provide molecular diagnostic enzymes optimized for a wide range of special applications.

PCR Enzymes for MDx

- *Taq* polymerase
- *Taq* polymerase, glycerol-free
- *Hot-Taq* polymerase
- *Hot-Taq* polymerase, glycerol-free
- *Ab+Taq* polymerase
- *Ab+Taq* polymerase, glycerol-free
- *Premium-Taq* polymerase

Direct PCR / RT-PCR

- Direct PCR [3G]
- Direct RT-PCR [UDG System]
- Direct qPCR [Green]
- Direct qPCR [Probe]
- *DirectFast* qPCR
- *DirectFast* qRT-PCR

Conventional PCR / RT-PCR Premixes

- Multiplex PCR 2x Premix
- *Taq* 2x Premix
- *Hot-Taq* 2x Premix
- *Ab+Taq* 2x Premix
- One-Step RT-PCR Kit [*Hot-Taq*]
- One-Step RT-PCR Kit [*Ab+Taq*]

Real-Time PCR Premixes

- 2x qPCR Premix [Green]
- 2x qPCR Premix [Probe]
- *Premier* 2x qPCR Premix [Green]
- Superplex qPCR Premix [Probe]
- 1-sec qPCR Kit [Probe] (Ver. 2.0)

Real-Time RT-PCR Premixes

- 1-sec qRT-PCR [Probe] (Ver. 2.0)
- qRT-PCR Kit [Green]
- qRT-PCR Kit [Probe]
- qRT-PCR Kit [v4] [UDG System]
- qRT-PCR Kit [v6] [UDG System]

Enzymes for Molecular Diagnostics

- *Thermo* Reverse Transcriptase
- Uracil DNA Glycosylase
- Heat Labile UDG
- Cod UDG
- RNase Inhibitor (Recombinant)
- *Bst* DNA polymerase, LF (Ver. 3.0)
- *Phi29* DNA polymerase

Raw Materials for MDx

Lyophilized Premixes

- qPCR Lyo-Dot/Cake [Probe]
- qPCR Lyo-Dot/Cake [Probe] [UDG System]
- qRT-PCR Lyo-Dot/Cake [Probe]
- qRT-PCR Lyo-Dot/Cake [Probe] [UDG System]
- qPCR Lyo-Cake [Green]
- qRT-PCR Lyo-Cake [Green]
- FastLAMP Lyo-Dot/Cake
- Fast RT-LAMP Lyo-Dot/Cake
- FastLAMP Lyo-Dot/Cake (V3)
- FastLAMP Lyo-Cake [Green] (V3)
- Fast RT-LAMP Lyo-Dot/Cake (V3)
- Fast RT-LAMP Lyo-Cake [Green] (V3)

LyoReady Premixes

- 2.5x qPCR LyoReady Premix [Probe]
- 2.5x qPCR LyoReady Premix [Probe] [UDG System]
- 2.5x qRT-PCR LyoReady Premix [Probe]
- 2.5x qRT-PCR LyoReady Premix [Probe] [UDG System]
- 2.5x FastLAMP LyoReady Premix
- 2.5x Fast RT-LAMP LyoReady Premix
- 2.5x FastLAMP LyoReady Premix (V3)
- 2.5x Fast RT-LAMP LyoReady Premix (V3)

Isothermal Amplification

- FastLAMP Kit (Ver. 2.0)
- Fast RT-LAMP Kit (Ver. 2.0)
- pH-Sensing LAMP/RT-LAMP

Diagnostics Kits

DirectFast™

- SARS-CoV-2 Multiplex assay
- HPV28 Genotyping Kit

HelixDtec™

- SARS-CoV-2 & Flu Detection Kit
- SARS-CoV-2 & Omicron Detection Kit
- SARS-CoV-2 Omicron Assay
- COVID/Flu/RSV Combo Kit
- COVID/Flu/RSV Assay Kit
- COVID, Flu A/B Assay Kit
- ASFV Real-Time PCR Assay
- CSFV Detection & Typing Kit
- CSFV & ASFV Assay
- Fireblight/Black Shoot Blight Pathogen Detection Kit
- Fireblight(*E.amylovora*) Dual Detection Kit
- Rice Planthopper ID LAMP Kit

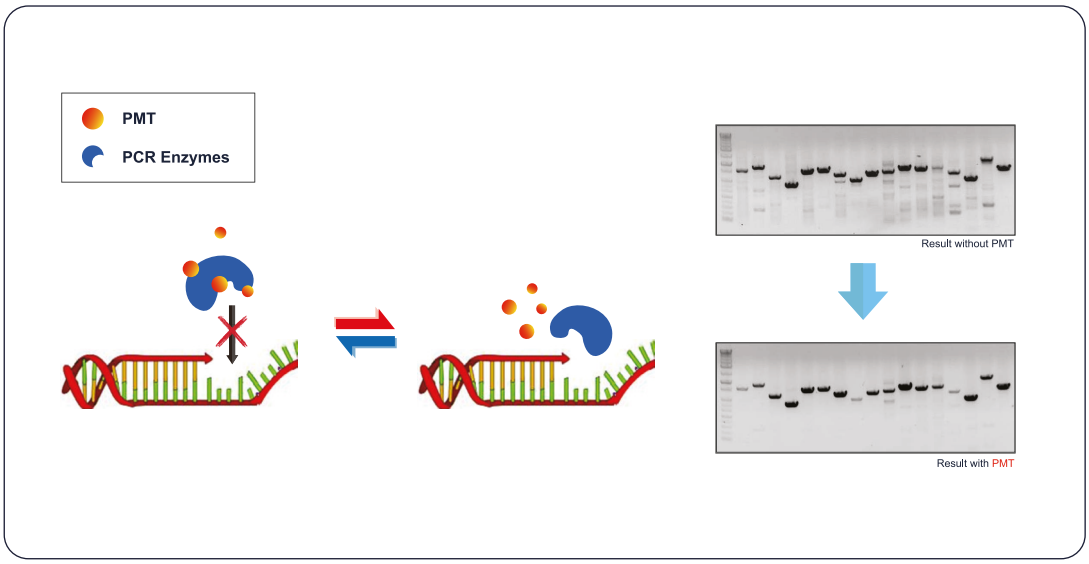
RealHelix™

- Pathogenic Amoeba Detection Kit
- Rice-22 FMMA Kit

Core Technologies

PMT Technology

- **PMT**(Polymerase Modulator on Temperature) is a chemical that maximizes the effect of the hot-start PCR
- Reversible according to temperature
- Highly specific amplification while minimizing the primer-dimer formation

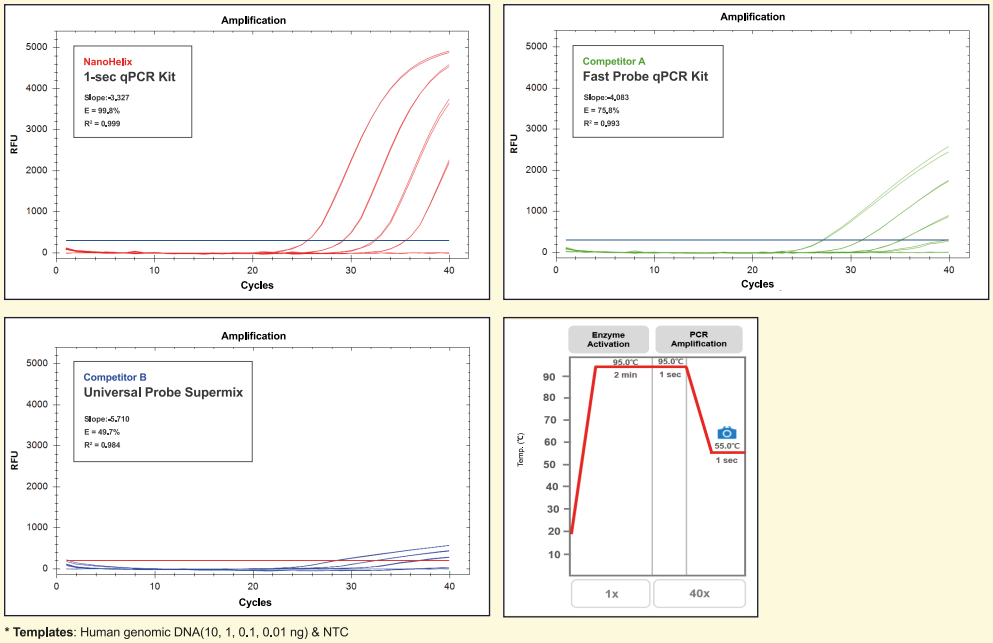


Fast Real-Time PCR/RT-PCR

- Probe-based real-time PCR and RT-PCR kit
- Fast real-time assay: 20 ~ 40 minutes for 40 cycles
- Multiplex: Up to 5-plex probes in a reaction
- Fast, specific, sensitive and reliable
- Unique buffer system and antibody-mediated hot-start enzyme

29 minutes / 40 cycles

* **Instrument**: CFX96(Bio-Rad)

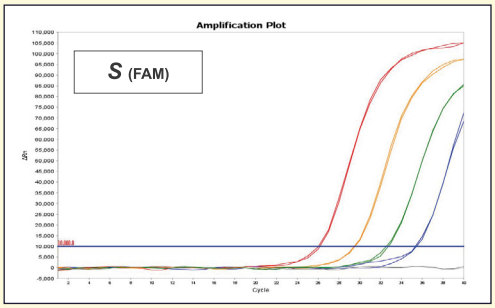


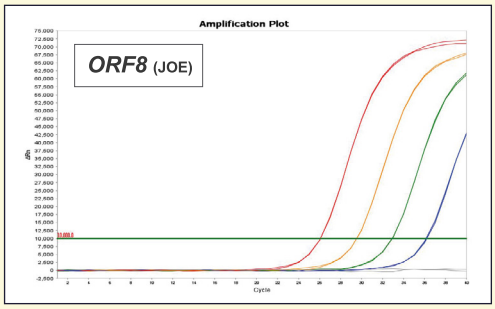
* **Templates**: Human genomic DNA(10, 1, 0.1, 0.01 ng) & NTC

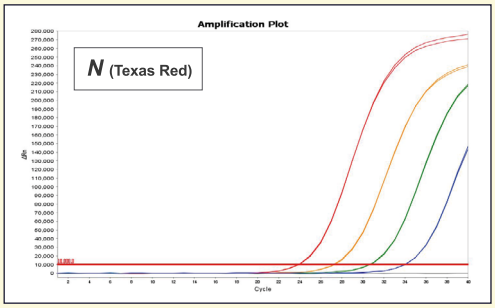
An Ultrafast Application : qRT-PCR

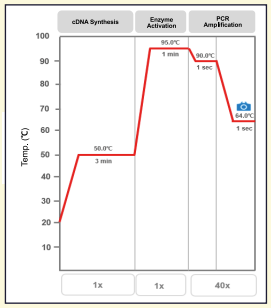
21 minutes / 40 cycles

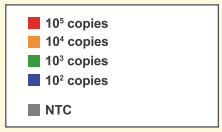
* **Instrument**: QuantStudio 5(Applied Biosystems)







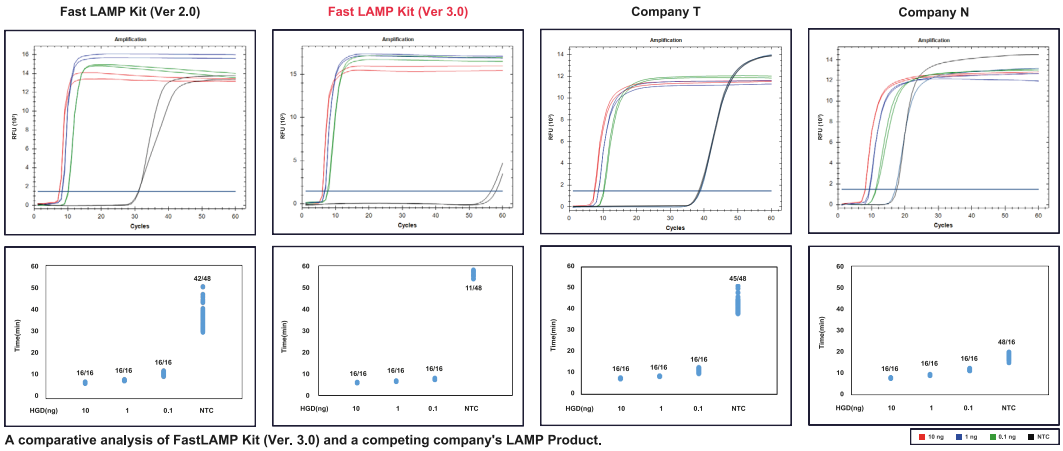




	S gene (FAM)		*ORF8* (JOE)		*N* gene (Texas Red)	
	Ct	Avg. Ct	Ct	Avg. Ct	Ct	Avg. Ct
10^5	26.05	**26.01**	26.04	**26.03**	23.68	**23.77**
	25.97		26.02		23.85	
10^4	29.52	**29.47**	29.54	**29.54**	27.07	**27.10**
	29.42		29.54		27.12	
10^3	32.59	**32.68**	32.91	**32.92**	30.43	**30.48**
	32.77		32.92		30.53	
10^2	35.72	**35.60**	36.12	**36.17**	33.83	**33.87**
	35.47		36.22		33.91	

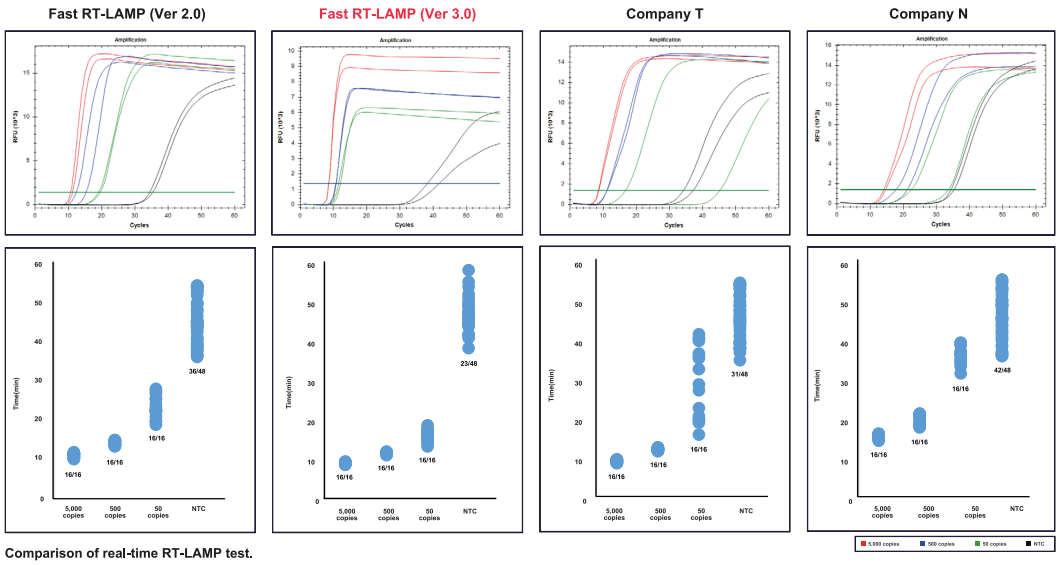
Fast LAMP Kit/RT-LAMP Kit

- Lightning-fast **DNA** amplification/**one-step RNA** amplification: **8 minutes** to threshold
- **Unparalleled sensitivity**: As few as 10 to 50 copies of the target DNA/RNA in a reaction
- **Unmatched specificity**: Guarantee clear differentiation from background amplifications
- Ensuring **accurate** and **reliable** results: Experience next-level isothermal amplifications



A comparative analysis of FastLAMP Kit (Ver. 3.0) and a competing company's LAMP Product.

Real-time isothermal amplifications of the BRCA gene were conducted from serially diluted human genomic DNA. The reactions were carried out at 65℃ for 60 minutes and analyzed using a real-time instrument(Bio-rad CFX96) by monitoring fluorescence signals. The kit exhibited exceptional results, demonstrating both the fastest amplification and the highest level of specificity.

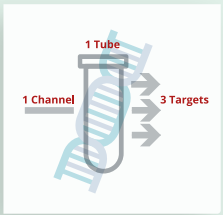


Comparison of real-time RT-LAMP test.

Serially diluted SARS-CoV-2 RNAs were analyzed using the **Fast RT-LAMP Kit (Ver. 3.0)** and other company products. Reaction were incubated at 60°C for 60 minutes and monitored with LAMP fluorescence dye in the SYBR/FAM channel of a real-time instrument. The **Fast RT-LAMP Kit (Ver. 3.0)** shows highest specificity amplification.

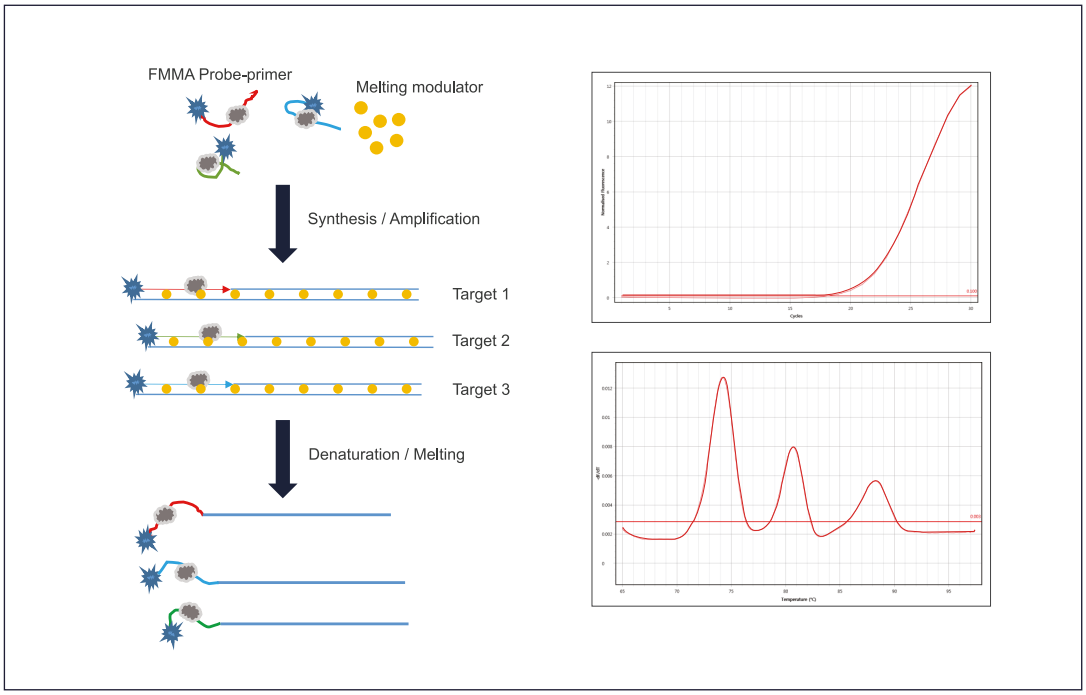
* **Instrument**: CFX96(Bio-Rad)

FMMA Fluorescence-based Multiple Melting Analysis



- Single-channel, multiple target detection in a real-time PCR machinery
- 10+ target detection in a reaction
- Relatively sharp melting peak(narrow peak base)
- Wide range of Tm distribution: 70°C ~ 95°C

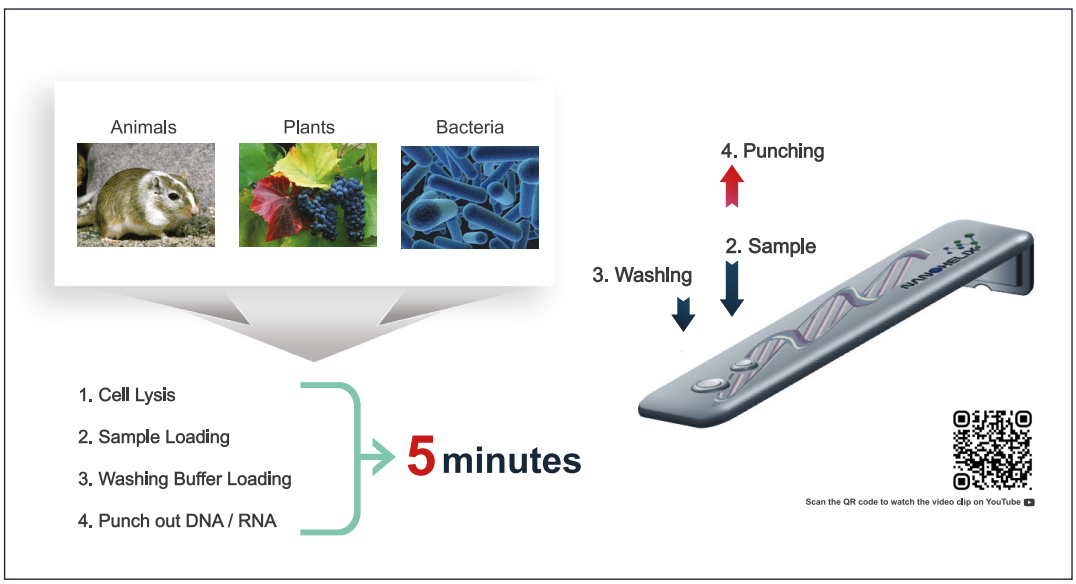
FMMA is a NanoHelix's novel technology for super-plex target identification in a single real-time PCR reaction. **FMMA** provides multi-target detection in a single fluorescence channel, and more than 10 targets could be analyzed using multiple melting analysis in a reatcion. This technology is currently patent pending and could be applied to any multiplexing MDx including pathogen detection, genotyping, SNP analysis, food ingredients analysis, GMO detection, etc.



NA-Sample Kit

- Novel POC nucleic acid sample preparation kit
- Easy to handle and does not need an electric instrument
- Total **5 minutes** handling time to obtain DNA and RNA
- Direct preparation of nucleic acid for molecular diagnostics

Punch-it™ NA-sample Kit is designed for straightforward isolation of nucleic acid from a small amount of biological samples such as animal tissues, plant tissues, blood, serums, swabs, water, soil, bacteria, viruses, etc. It is easy to handle and does not need any equipment.
This kit is suitable for the direct preparation of nucleic acids for molecular diagnostics using PCR or RT-PCR technologies.

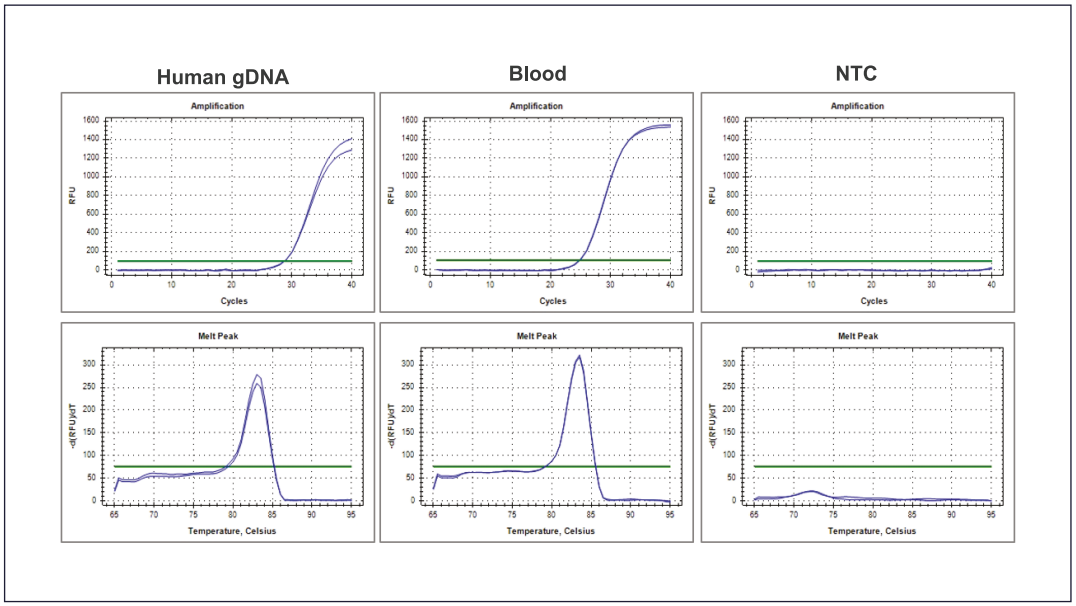


Direct qPCR

- Real-time amplification directly from whole blood, animal, and plant tissues
- Skip DNA purification
- Available to intercalating dyes and probes
- Time and cost saving
- POC diagnostic application

RealHelix™ Direct qPCR Kits are designed for quantitative real-time amplification directly from animal tissues, plant tissues, and various clinical samples, including whole blood, serum, urine, hair, and swab collections without any DNA purification processes.

RealHelix™ Direct qPCR Kits contain antibody-coupled hot-start *Taq* DNA polymerase, dNTPs, $MgCl_2$, stabilizer, and unique buffer system to resist various PCR inhibitors from tissue samples. These Kits are ideal systems for rapid on-site molecular diagnostics.

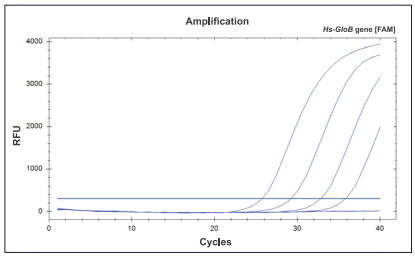


Lyophilized Reagents for NA Amplification

- Ready-to-use formulation
- Simplify assay setup and workflow
- Simplify logistics and reduce cost
- Minimize sample contamination
- Storage and shelf life: Minimum 1 year at 25°C

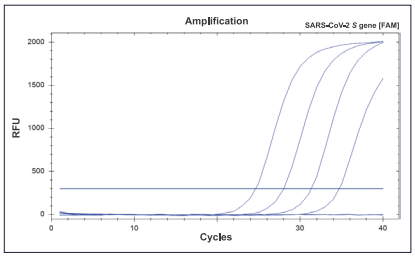
NanoHelix's **lyophilized reagents** are freeze-dried master mixes including RNA/DNA polymerase, dNTPs, salts, and other components. They are available in cake or bead format, allowing for ambient/room temperature shipping and storage prior to use. Versions for qPCR, qRT-PCR, LAMP and RT-LAMP in bead(Lyo-Dot) or cake(Lyo-Cake) formats are available.

qPCR Lyo-Dot



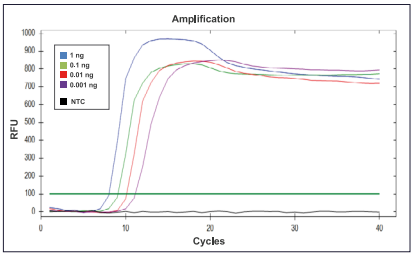
Template: Human genomic DNA(30, 3, 0.3, 0.03 ng)
Target gene & Probe label: *Hs-GloB* gene(FAM)
Instrument: CFX96(Bio-Rad)

qRT-PCR Lyo-Dot



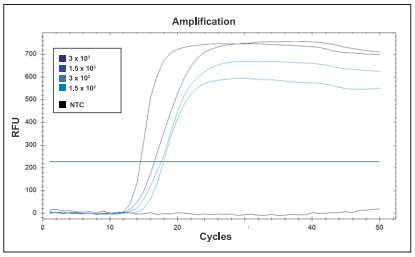
Template: SARS-CoV-2 viral RNA($3x10^4$, $3x10^3$, $3x10^2$, $3x10^1$ copies)
Target gene & Probe label: *S* gene(FAM)
Instrument: CFX96(Bio-Rad)

FastLAMP Lyo-Dot



Template: Lambda DNA(1, 0.1, 0.01, 0.001 ng)
Intercalating dye: 0.2X EvaGreen
Instrument: CFX96(Bio-Rad)

Fast RT-LAMP Lyo-Dot



Template: SARS-CoV-2 viral RNA($3x10^3$, $1.5x10^3$, $3x10^2$, $1.5x10^2$ copies)
Target gene: *ORF8* / **Intercalating dye:** 0.2X EvaGreen
Instrument: CFX96(Bio-Rad)

LyoReady Premix

- Ready for lyophilization
- Glycerol-free mix containing enzymes, buffer, dNTP, $MgCl_2$ and excipients
- Simply add primers/probes and lyophilize
- High performance and reproducible
- Versions for qPCR, qRT-PCR, LAMP and RT-LAMP are available

An advanced lyophilization-ready master mix revolutionizing molecular diagnostic tests.

There are several benefits of lyophilized molecular diagnostic mixes. They maintain stability for long durations, are stored and transported at ambient temperature, and are ideal for high-throughput, automated platforms or microfluidic systems with rapid rehydration requirements.

The LyoReady Premixes revolutionize lyophilization in molecular diagnostics, offering a glycerol-free, excipient-enhanced formula tailored for you to create lyophilized versions of qPCR, qRT-PCR, LAMP, and RT-LAMP master mixes including specific primers and probes.

The specialized excipients in the LyoReady Premixes safeguard enzymes during the lyophilization process, enabling fast rehydration and reactivation without compromising performance. Options with UDG and dUTP are available for effective prevention of carryover contamination.

Unlike traditional lyophilization processes with lengthy optimization phases, the LyoReady Premixes streamline the transition to lyophilized. This ready-to-use, one-tube solution eliminates the need for extensive development efforts. Simply mix primers and probes with the LyoReady Premixes for direct lyophilization.

Choose Nanohelix's LyoReady Premixes for a streamlined, sustainable, high-performance solution for lyophilizing your molecular diagnostics.

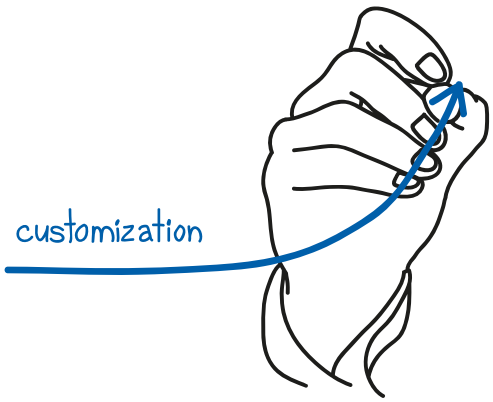
Services

Custom MDx Kit Development

Are you looking for free customization and/or how to save raw material costs?

If you need to customize your PCR based MDx kit and save raw material costs of PCR/Real-Time PCR enzymes, working with NanoHelix is the smart choice.

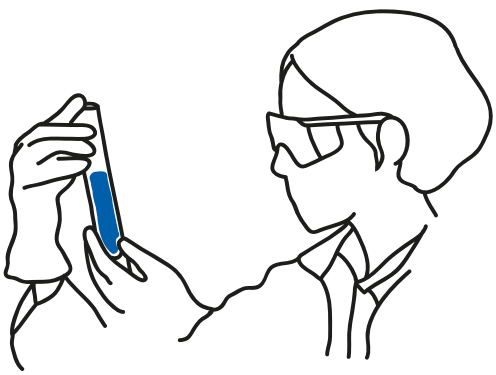
NanoHelix's MDx customization service is absolutely free. We need only direct and professional cooperation for the successful development of your customized MDx Kit. Not only will you receive free custom services, our affordable prices of supplying the enzymes for your diagnostic kit could save you up to 50% of the raw material cost.



OEM Supply

Production line can meet your requests for packaging under the logos you want.

NanoHelix's production line can meet your requests for packaging under the logos you want. If you want to add molecular biological reagents to your product portfolio without increasing the production line, consider the OEM supply from NanoHelix. For bulk users we can supply any amount of our products at very affordable prices and a Q.C certificate for each batch.



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