Diamond *Taq*® family

Ultra pure *Taq* DNA POLYMERASES

Suited for Diagnostic and Demanding Research PCR & qPCR

Diamond *Taq*®

Hot Diamond *Taq*®

HGS Diamond *Taq*®

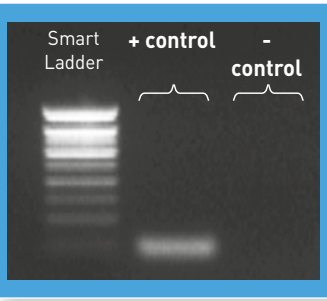
EGT GROUP
ANASPEC

Eurogentec
Experience true partnership

See additional benefits in the description of each individual enzyme.

General Benefits

- **Ultra-low residual DNA content:** <1 fg of genomic *E. coli* DNA / *Taq* Unit. Typically < 0.01 fg or 0.002 *E. coli* genome copies / *Taq* Unit
- **Pure:** High purity (> 98 %) and ultra-low bioburden (< 10 CFU/ml). Typically = 0 CFU/ml
- **Exceptional reproducibility:** GMP process and stringent QC ensuring lot-to-lot & results reproducibility
- **Sensitive:** Amplification of DNA templates even at very low concentrations
- **Full traceability:** Quality Management System fully compliant to ISO 13485 Medical Device standards and FDA's Quality System Regulations
- **GMP compliant:** Highly suited for Diagnostic kits, Lab Services (with ASRs) and demanding Research
- **Suited for ISO 15189 accredited laboratories**
- **GMP manufacturing & purification processes:** Minimize the risk of false positive results due to high leftover of residual DNA contamination (bacterial & fungal)
- **Complete:** PCR reaction buffer & $MgCl_2$ included
- **Documentation:** Technical Data Sheet & Certificate of Analysis
- **Customized Fill & Finish:** Cost-effective tailored solution
- **Batch reservation** (on request)
- **Particularly recommended** for Diagnostic PCR & qPCR applications that require ultra-low levels of bacterial & fungal DNA



Residual DNA content: Diamond *Taq*® was evaluated using positive control (10 ng of *E. coli* DNA) and negative control (no DNA). PCR products were analyzed by gel electrophoresis. No detectable *E. coli* DNA was observed after PCR on bacterial 16s DNA.

Introduction

With 25 years experience, Eurogentec Genomics is a leading supplier of high-quality reagents for genomic research to bench scientists around the globe. Eurogentec is also an experienced Contract Manufacturing Organization (CMO), operating GMP and ISO 13485-certified manufacturing facilities in Belgium, USA and Japan. We offer a wide range of oligonucleotide-based components for Diagnostic and Therapeutic applications.
In addition, Eurogentec Genomics has joined forces with Eurogentec Biologics, a leader in GMP manufacturing of biopharmaceuticals, to offer a growing range of ultrapure *Taq* DNA Polymerases highly suited for Diagnostic and demanding Research PCR & qPCR.

Why Partner with Eurogentec?

Choosing a manufacturing partner early in the assay development process is an important step towards successful assay validation and product commercialization. Eurogentec's ability to provide a complete custom solution makes the difference.

Experience
- 25 years experience in oligonucleotide synthesis
- Over 16 years experience in GMP protein manufacturing
- Fully trained and skilled staff

Quality commitment
- Organization-wide QMS implementation
- Comprehensive risk analysis and mitigation
- Classified cleanroom facility

Supply chain reliability
- Optimized and validated instruments & processes
- Full traceability for regulatory compliance
- Comprehensive archival batch records

Regulatory compliance
- Full compliance to ISO 13485:2003
- Full compliance to FDA cGMP/QSR (21 CFR Part 820)
- EU IVD Directive 98/79 EC compliance

Flexibility - Complete custom solutions
- CMO for manufacturing of bulk reagents
- GMP oligonucleotides and master mixes
- Fill & Finish, labeling & packaging

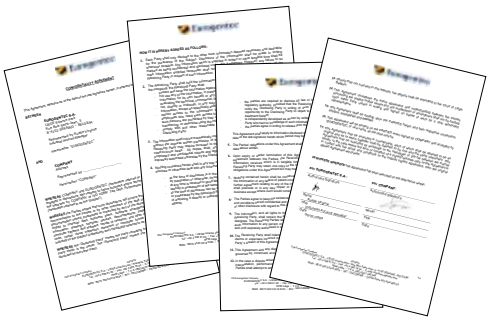
Enzyme Selection Guide

Page		Free Sample#	PCR	qPCR	Yield	Sensitivity Low copy template	Specificity	Difficult template (GC & AT rich)	Long template
	Recombinant *Taq*								
p.5	**Diamond *Taq*®**	TAQ-I020-100	***	*	++	++	++	*	**
	Hotstart *Taq*								
p.6	**Hot Diamond *Taq*®**	TAQ-I032-100	***	**	+++	+++	+++	***	***
p.7	**HGS Diamond *Taq*®**	TAQ-I010-100	***	***	+++	+++	+++	**	**

#Free samples can be requested at diagnostic.taq@eurogentec.com

* Weakly recommended
** Recommended
*** Highly recommended

\+ Low
++ Medium
+++ High



Quality

The entire process is performed under controlled conditions; in class 10,000 cleanroom for purification (ISO 7 with < 100 cfu/m³) and in class 100 laminar flow hoods for fill & finish (ISO 5 in with < 1 cfu/m³). Final product is released by our Quality Assurance Department with a formal Certificate of Analysis. Full batch records are maintained and can be reviewed during customer or regulatory audits.

Quality System Management

- → High level of education and training
- → Strict process segregation and employee gowning policy
- → Supplier qualification and evaluation
- → Comprehensive batch records with full traceability
- → IQ/OQ/PQ maintenance and calibration standards
- → Dedicated equipment
- → Stringent document change control procedures
- → Deviation management
- → Process control
- → Exhaustive analytical method validation
- → Critical analysis & documentation rationale
- → Independent QC department for assuring exact specifications prior to release
- → Routine internal audits
- → Customer quality audits
- → Sample retention to facilitate troubleshooting
- → Quality and/or Supply Agreements as extension of the manufacturing contracts to clearly define our responsibilities to our partners
- → Project-specific details are discussed and documented.

Professional support for manufacturers of diagnostic assays

First and foremost, the Eurogentec Diagnostic team believes that knowing its customer needs and expectations is essential to the success of any collaboration. Long-term relationships with our customers are built on trust and mutual respect. All projects are handled with complete confidentiality (CDA).

Product description

Specifications

Diamond *Taq*® Family

Parameters	Specifications
Appearance*	Colorless solution
Identity (SDS-PAGE)	MW approx. 95 kDa
Volume activity	≥5 U/µl
Purity (SDS-PAGE)	>98 %
Performance test: PCR - λ DNA*	0.5 kb fragment positive down to 5 pg
Performance test: PCR - 18 S DNA*	0.1 kb fragment positive down to 10 pg
Ribonucleases (up to 10 U, 1 h, 37 °C)	Not detectable
Endonucleases (up to 30 U, 16 h, 65 °C)	Not detectable
Exonucleases (up to 30 U, 16 h, 65 °C)	Not detectable
Nicking activity (up to 30 U, 16 h, 65 °C)	Not detectable
E.coli residual DNA	< 1 fg / *Taq* Unit
Bioburden*	≤ 10 CFU/ml
Stability*	24 months (at -20 °C) from date of manufacture
Animal-derived additives*	None

* Also for buffer & $MgCl_2$

Additional HGS Diamond *Taq*® specification	
HotStart	No detectable amplification without 95 °C activation

Additional Hot Diamond *Taq*® specification	
Performance test PCR-Numb DNA	0.3 kb fragment positive down to 10 pg

Diamond *Taq*® is a highly thermostable enzyme produced and purifed from recombinant *Escherichia coli* bacteria containing the *Thermus aquaticus* DNA polymerase gene. This thermophilic eubacterium strain lacks *Taq*I restriction endonuclease. The expressed enzyme shows very good fidelity and catalyzes 5'→3' synthesis of DNA with no detectable 3'→5' exonuclease activity. The enzyme has the 3' extendase activity allowing TA cloning.

Order & Shipping conditions

Diamond *Taq*® family enzymes can be ordered & shipped following two processes:

IVD process: Order to **diagnostic.taq@eurogentec.com**

- Shipping on dry ice.
- Full traceability from production, storage to shipment of the product.
- Tracking number sent to customer the day of the shipment.

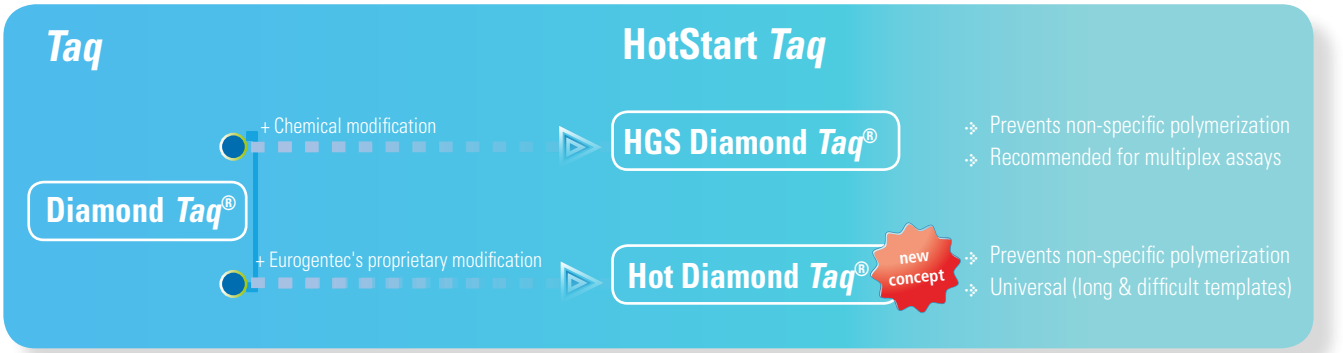
Classical process: Order to **order@eurogentec.com**

- Shipping at room temperature*.
- Full traceability from production to storage of the product.

Traceability

	Production	Storage	Order	Shipment	Shipping Tracking number
IVD Process	Yes	Yes	Yes	Yes (shipment at -20 °C)	Yes (Sent to customer the day of the shipment)
Classical Process	Yes	Yes	No	No (shipment at room temperature*)	No

* Except for Hot Diamond *Taq*®



Diamond *Taq*®

Product description and intended use

GoldStar® *Taq* DNA Polymerase, originally supplied for Research applications, is now manufactured according to a GMP Process resulting, in the Diamond *Taq*® enzyme that is highly suited for use in *in vitro* Diagnostic and demanding Research PCR & qPCR applications.

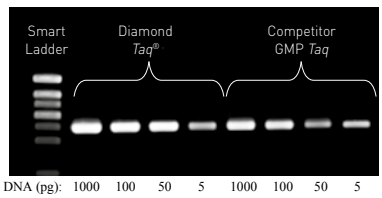
See also general benefits page 2

Additional Benefits

- ✔ **Proven performance in many applications:** Same enzyme as extensively validated GoldStar®.
- ✔ **Customized Fill & Finish:** On request Diamond *Taq*® enzyme can be provided with:
  - ➜ An activity from 5 to 200 U/µl
  - ➜ A glycerol level from 1 to 50%

Experimental results

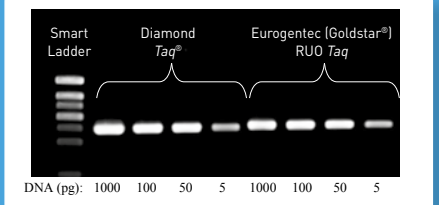
Diamond *Taq*® compared to competitor GMP *Taq*



Diamond *Taq*® was evaluated against competitor GMP *Taq* for its ability to amplify different amounts (from 5 to 1000 pg) of a 0.5 kb PCR template (λDNA). PCR products were analyzed by gel electrophoresis.

➜ Diamond *Taq*® performance is similar or higher than competitor GMP *Taq*

Diamond *Taq*® compared to GoldStar® *Taq*



Diamond *Taq*® was evaluated against Eurogentec's GoldStar® *Taq* for its ability to amplify different amounts (from 5 to 1000 pg) of a 0.5 kb PCR template (λDNA). PCR products were analyzed by gel electrophoresis.

- ➜ Same enzymes
- ➜ Same performances
- ➜ Higher qualities

Additional information

➜ Package content

Diamond *Taq*® is provided at a concentration of 5 U/µl with 10x reaction buffer and $MgCl_2$ solution.
10x Reaction buffer: 750 mM Tris-HCl, 200 mM $(NH_4)_2SO_4$, 0.1 % (v/v) Tween 20 and stabilizer, pH 8.8 (at 19 °C).
$MgCl_2$ solution: 25 mM $MgCl_2$.
Enzyme storage buffer: 20 mM Tris-HCl, 1 mM DTT, 0.1 mM EDTA, 0.1 M KCl, 0.5 % (v/v) Nonidet P40, 0.5 % (v/v) Tween 20, 50 % (v/v) glycerol and stabilizer pH 8.0 (19 °C).

➜ Documentation

Enzymes are provided with Technical Data Sheet & Certificate of Analysis with the QC data released by a QC authorized person and based on review of the complete batch record.

➜ Storage conditions

Storage at -20 °C is recommended.

See also general benefits page 2

Additional Benefits

- ✔ **Universal:** Amplification of long & difficult templates.
- ✔ **Specific:** Prevents non-specific polymerization as primer-dimer formation and increases the PCR yield of specific products.
- ✔ **Very short activation time:** Minimum 20 seconds.

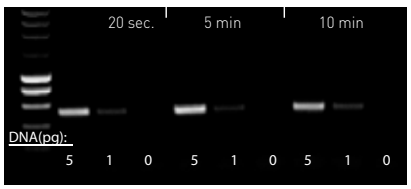
Hot Diamond *Taq*®

Product description and intended use

The enzyme exhibits unique HotStart characteristics and represents a completely new "HotStart concept". HotStart characteristics are neither accomplished through chemical modification nor a blocking antibody but a proprietary agent which prevents non-specific polymerization; thereby preventing primer-dimer formation and increasing the PCR yield of specific products. Hot Diamond *Taq*® shows no amplification at room temperature and gives very high yield of specific products. The enzyme needs very short activation time (100 % activated during the first PCR cycle) but is compatible with all existing protocols (from 20 seconds to 15 minutes at 95 °C).

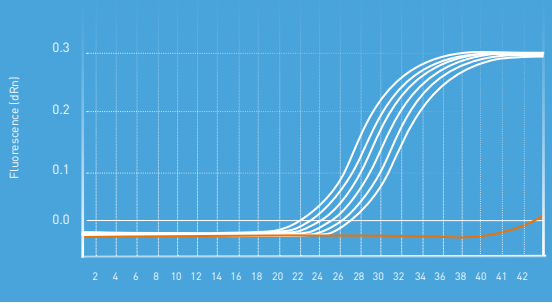
Experimental results

Activation time



Hot Diamond *Taq*® was evaluated using from 20 secondes to 10 minutes as activation time for its ability to amplify 1 and 5 pg of λ DNA. PCR products were analyzed by gel electrophoresis.

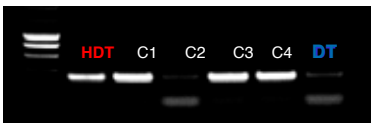
Hot Diamond *Taq*® needs very short activation time



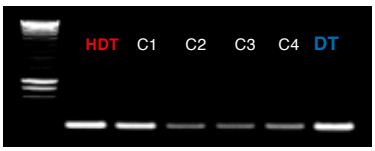
High quality results obtained using the Hot Diamond *Taq*® (twice serial dilutions) on ß-actin cDNA performed in singleplex Taqman assay.

Hot Diamond *Taq*® compared to HotStart competitors

Performance test on difficult template:
gDNA NUMB (306b)



Performance test on GC rich template:
SCO3449 (152b) – 72 % GC



Hot Diamond *Taq*® (HDT) & Diamond *Taq*® (DT) were evaluated against HotStart competitors (C1, 2 & 4 – Chemical modification; C3 - Antibody) for their ability to amplify difficult and GC rich templates. PCR products were analyzed by gel electrophoresis.

Hot Diamond *Taq*® is highly suitable for difficult and GC rich template amplifications

Additional information

Package content

Hot Diamond *Taq*® is provided at a concentration of 5 U/µl with 10x reaction buffer and $MgCl_2$ solution.
10x Reaction buffer: 750 mM Tris-HCl, 200 mM $(NH_4)_2SO_4$, 0.1 % (v/v) Tween 20 and stabilizer, pH 8.8 (at 19 °C).
$MgCl_2$ solution: 25 mM $MgCl_2$
Enzyme storage buffer: 20 mM Tris-HCl, 1 mM DTT, 0.1 mM EDTA, 0.1 M KCl, 0.5 % (v/v) Nonidet P40, 0.5 % (v/v) Tween 20, 50 % (v/v) glycerol and stabilizer, pH 8.0 (19 °C).

Documentation

Enzymes are provided with Technical Data Sheet & Certificate of Analysis with the QC data released by a QC authorized person and based on review of the complete batch record.

Storage conditions

Storage at -20 °C is recommended.

HGS Diamond *Taq*®

Product description and intended use

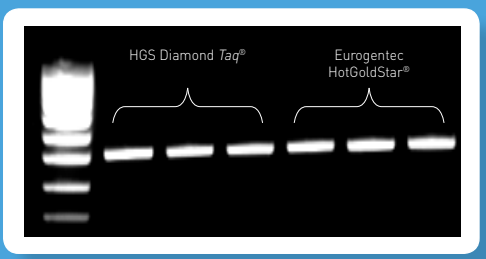
HotGoldStar® *Taq* DNA Polymerase, originally supplied for Research applications, is now manufactured according to a GMP Process resulting in the HGS Diamond *Taq*® enzyme that is highly suited for use in *in vitro* Diagnostic & demanding Research PCR & qPCR applications.
HGS Diamond *Taq*® is a chemically modified HotStart *Taq* DNA Polymerase requiring a thermal activation of 10 minutes at 95 °C to reach maximal initial activity. Before activation the enzyme completely lacks any activity below 74 °C. This avoids non-specific priming at low temperature. During the PCR, the rest of its activity is released. HGS Diamond *Taq*® is more heat-stable than commonly used *Taq* DNA Polymerases.
DNA fragments as long as 2 kb can be efficiently amplified. HGS Diamond *Taq*® DNA Polymerase provides efficient amplification of specific products without amplifying non-specific products or primer dimers.

See also general benefits page 2

Additional Benefits

- ✔ **Specific:** Prevents non-specific polymerization as primer-dimer formation and increases the PCR yield of specific products.
- ✔ **Proven performance in many applications:** Same enzyme as EGT's extensively validated HotGoldStar®.
- ✔ **Customized Fill & Finish:** On request HGS Diamond *Taq*® enzyme can be provided with:
  - ➜ An activity from 5 to 50 U/µl
  - ➜ A glycerol level from 1 to 50 %

HGS Diamond *Taq*® compared to Hot GoldStar® *Taq*



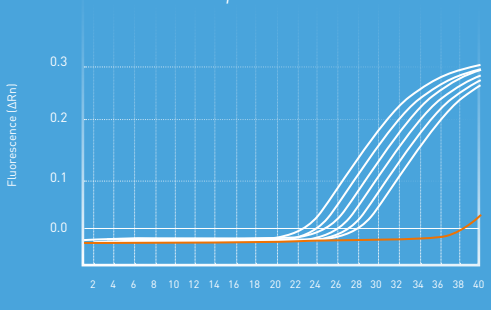
HGS Diamond *Taq*® was evaluated against Eurogentec's HotGoldStar® (HGS) for its ability to amplify in triplicate 5 pg of a 0.5 kb PCR template (λDNA). PCR products were analyzed by gel electrophoresis.

- Same enzymes
- Same performances
- Higher qualities

HGS Diamond *Taq*®

HGS Diamond *Taq*® was evaluated for its ability to amplify a PCR template of 0.5 kb (λDNA) for several activation times. PCR products were analyzed by gel electrophoresis.

- HGS Diamond *Taq*® needs 5 min. activation time to amplify DNA fragment



High quality results obtained using the HGS Diamond *Taq*® (twice serial dilutions) on ß-actin cDNA performed in singleplex Taqman assay.

Additional information

Package content

HGS Diamond *Taq*® DNA Polymerase is provided at a concentration of 5 U/µl with 10x reaction buffer and $MgCl_2$ solution.
10x Reaction buffer: 150 mM Tris-HCl, 500 mM KCl and stabilizer, pH 8.5 (at 19 °C).
$MgCl_2$ solution: 25 mM $MgCl_2$.
Enzyme storage buffer: 20 mM Tris-HCl, 1 mM DTT, 0.1 mM EDTA, 0.1 M KCl, 0.5 % (v/v) Nonidet P40, 0.5 % (v/v) Tween 20, 50 % (v/v) glycerol and stabilizer pH 8.0 (19 °C).

Documentation

Enzymes are provided with Technical Data Sheet & Certificate of Analysis with the QC data released by a QC authorized person and based on review of the complete batch record.

Storage conditions

Storage at -20 °C is recommended.

Eurogentec, your manufacturing partner of choice

For inquiries, please contact the Eurogentec Diagnostic *Taq* team:

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