

DIAMOND *Taq*™

Ultra-low
DNA



cGMP *Taq* DNA POLYMERASE
For use in highly sensitive
research-based applications

PRODUCT DESCRIPTION AND INTENDED USE

Eurogentec's *Taq* DNA Polymerase, originally supplied for Research Use Only (GoldStar®), is now also manufactured according to a cGMP process, resulting in an exhaustively characterized and lot-to-lot reproducible enzyme.

This *Taq* DNA Polymerase, named Diamond *Taq*™, is a highly thermostable enzyme produced and purified from recombinant *Escherichia coli* bacterium 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' proof reading exonuclease activity.

Key Benefits



Ultra low residual DNA content (only 0.002 *E. coli* genome copies / *Taq* Unit in the batch currently sold)

- ✓ Efficiently amplifies DNA templates even at very low concentrations
- ✓ Purity higher than 98 % and low bioburden due to production in a GMP-Pharma facility
- ✓ The Quality Management System is fully compliant to the ISO13485:2003 Medical Device standard and FDA's Quality System Regulations (21 CFR 820)
- ✓ PCR reaction buffer & MgCl₂ are included
- ✓ Reproducible results, GMP process and stringent QC combined with rigorous analytical method ensure exceptional lot-to-lot reproducibility.

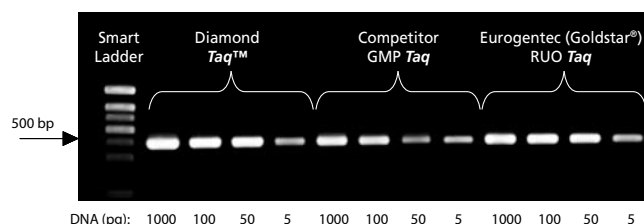
SPECIFICATIONS

| Parameter | Specification |
|--|--|
| Appearance | Clear, colorless solution |
| Identity (SDS-PAGE) | MW approx. 95 kDa |
| Volume activity | ≥ 5 U/μl |
| Purity (SDS-PAGE) | > 98 % |
| Performance test: PCR on λ DNA | 0.5 kb fragment positive down to 5 pg |
| Performance test: PCR on genomic DNA | 0.1 kb fragment positive down to 5 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 |
| <i>E. coli</i> residual DNA | < 1 fg / <i>Taq</i> Unit |
| Bioburden | ≤ 10 CFU/ml |
| Stability | 24 months (at -20 °C) from date of manufacture |
| Animal-derived additives | None |

Some results

Performance test

Diamond *Taq*™ is a highly sensitive polymerase that efficiently amplifies DNA even at very low concentration. The higher yield of amplification products allows increasing the performance of the assays.



Performance test: *Taq* DNA Polymerases were evaluated for their ability to amplify different amounts of a PCR template (0.5 kb fragment of λ DNA). PCR products were analyzed by gel electrophoresis.

Residual *Escherichia coli* DNA Content

The entire process (production, purification and fill & finish) is performed under controlled conditions in a GMP-Pharma facility, leading to the release of a product with a low bioburden level.

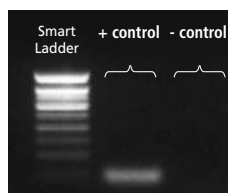
Moreover, the highly optimized purification processes used permit to obtain an extremely low level of residual DNA content (including host) that allows amplification of a wider range of targets, including *Escherichia coli*.

Comparison with competitor

| | fg of DNA / <i>Taq</i> ml | fg of DNA / <i>Taq</i> Unit | <i>E. coli</i> Genome copies / <i>Taq</i> Unit |
|---------------------------|---------------------------|-----------------------------|--|
| Diamond <i>Taq</i> ™ | 50 | 0.01 | 0.002 |
| Competitor GMP <i>Taq</i> | 29 000 000 | 5 800 | 1 160 |

Residual *E. coli* DNA content: DNA from *E. coli* was quantified in GMP *Taq* DNA Polymerases (at 5 U/μl).

No detectable *Escherichia coli* DNA was observed after Polymerase Chain Reaction on bacterial 16S RNA and genomic 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.

DIAMOND TAQ™ PRICE TABLE

| Ref# | Pack size (Units) | Price USD |
|-----------------|-------------------|-----------|
| TAQ-I020-100 | 100 | 39 |
| TAQ-I020-1000 | 1 000 | 280 |
| TAQ-I020-5000 | 5 000 | 1050 |
| TAQ-I020-10000 | 10 000 | 1800 |
| TAQ-I020-25000 | 25 000 | 4000 |
| TAQ-I020-100000 | 100 000 | 13000 |

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