# Products at QIAGEN manufactured under Good Manufacturing Practice (GMP) principles

At QIAGEN, we understand that using extensively characterized raw materials with high lot-to-lot consistency is crucial for research and diagnostic success. Our commitment to quality assurance is a top priority and ensures that our customers receive the best molecular biochemicals available.

The manufacturing process, quality control, and the documentation of QIAGEN®'s PCR enzymes and buffers are performed using Good Manufacturing Practice principles — thereby ensuring a constantly high-quality, standardized product for all of our customers, including those within the applied testing, pharmaceutical, and diagnostic industries.

**In brief, our GMP system for these products encompasses the following aspects:**

- QIAGEN has been certified under DIN ISO 9001 and ISO13485 quality standards since 1998. We have convincingly demonstrated the capability of consistently manufacturing products with the required quality and of complying with their required specifications.
- Raw materials used at QIAGEN meet the highest quality standards. Each supplier is managed according to QIAGEN's strict documented qualification program. ▶

- Our manufacturing processes are clearly defined and systematically reviewed. Manufacturing as well as testing documentation is under strict change control.
- Instructions and procedures are written in clear language using Good Documentation Practices [GDP]. Processes are documented via a sophisticated computerized document management system. Operators are trained to carry-out and document procedures.
- QIAGEN completely tracks products from raw material to customer. Records of manufacture (including distribution) demonstrate that all steps required by the defined procedures and instructions were taken, and that the quantity and quality of the product was as expected. These records enable the complete history of a batch to be traced and are retained in a comprehensible and accessible form.
- Manufacturing processes take place under clean room conditions (class 100.000) in an access controlled area. The critical process steps are performed under laminar flow class 100. The elevant production steps and associated clean rooms are continuously monitored for bioburden particle, temperature, and moisture. Our facilities are designed to a defined flow of personnel and material.
- A highly optimized purification process is used for the DNA polymerases and RT enzymes, enabling an extremely low level of residual DNA content (including host) that allows amplification of a wider range of targets, including *Escherichia coli*. All equipment that has direct contact with the product is sanitized or is disposable. All equipment is qualified to fulfil the process requirements and is dedicated wherever possible for a single product.

These elements, along with QIAGEN's strong commitment to the highest quality standards guarantee that you will receive a highly consistent product.

Products at QIAGEN manufactured using Good Manufacturing Practice (GMP) Principles are intended for further processing by manufacturers for laboratory-developed tests.



**Australia** ■ 1-800-243-800
**Austria** ■ 0800-281011
**Belgium** ■ 0800-79612
**Brazil** ■ 0800-557779
**Canada** ■ 800-572-9613
**China** ■ 800-988-0325
**Denmark** ■ 80-885945
**Finland** ■ 0800-914416
**France** ■ 01-60-920-930
**Germany** ■ 02103-29-12000
**Hong Kong** ■ 800 933 965
**India** ■ 1-800-102-4114
**Ireland** ■ 1800 555 049
**Italy** ■ 800-787980
**Japan** ■ 03-6890-7300
**Korea (South)** ■ 080-000-7145
**Luxembourg** ■ 8002 2076
**Mexico** ■ 01-800-7742-436
**The Netherlands** ■ 0800-0229592
**Norway** ■ 800-18859
**Singapore** ■ 1800-742-4368
**Spain** ■ 91-630-7050
**Sweden** ■ 020-790282
**Switzerland** ■ 055-254-22-11
**UK** ■ 01293-422-911
**USA** ■ 800-426-8157

**www.qiagen.com**