

Technical Information

QIAGEN® Forensic DNA Grade Quality

QIAGEN is a forerunner in quality initiatives for human identity testing and forensics. Industry-leading quality control systems, exacting manufacturing standards and rigorous product validation ensure that your work meets the highest quality standards.

High-quality Investigator® solutions

In compliance with ISO 18385, QIAGEN ensures that each of its Investigator Kits meets a range of dedicated quality measures to guarantee superior product quality.

- QIAGEN Quality Management System
- Production and supplier quality standard
- Automated manufacturing and EO (ethylene oxide) treatment
- Risk analysis of manufacturing processes
- Environmental human DNA monitoring
- Post-production testing for absence of human DNA

- QIAGEN Exclusion Database Service
- Certificate of Analysis
- Product validation

Our Forensic DNA Grade and Forensic DNA Grade EO labels denote the sum of these quality assurance activities and our dedication to the strictest of quality control measures for human identity and forensic testing. QIAGEN has held ISO 18385 certification since 2017. Furthermore, QIAGEN is an active contributor at DIN and ISO towards future international standards and their implementation.



Figure 1. QIAGEN Forensic DNA Grade.

Investigator products that undergo an EO treatment are labeled accordingly.

QIAGEN Quality Management System

QIAGEN operates an effective quality management system (QMS) to ensure consistent delivery of high-quality products. Our systems are designed and maintained according to regulatory requirements defined by leading QMS standards, including for example:

- ISO 9001
- ISO 18385
- ISO 13485
- USA FDA 21CFR Part 820
- Medical Device Audit Program (MDSAP)
- MHLW Ministerial Ordinance No. 169 of Japan
- Directives including (IVDR)
 - Regulation EU 2017/746

- Technical Cooperation Program (TCP) Taiwan
- Other international regulations and standards

As part of the stringent and process-oriented quality management system, all Investigator Kits are manufactured in an ISO-certified facility. This ensures that they comply with the applicable regulatory requirements. To further ensure consistent high quality, each kit lot is tested against predetermined specifications. QIAGEN aims to continually improve the quality of our solutions and services, to guarantee complete customer satisfaction.



Figure 2. Automated manufacturing.
Automated manufacturing line at QIAGEN Hilden.



Figure 3. Spin-column production.
Close-ups of the spin-column production processes.

Production and supplier quality standard

Investigator products are manufactured in clean rooms that comply to ISO 14644 standard (minimum standard: ISO class 8) and EU guidelines on Good Manufacturing Practice of Medicinal Products for Human and Veterinary Use. Critical operations are performed under laminar flow.

As the quality of raw material supplies can impact the final kit quality, QIAGEN has established a program for the selection, evaluation and re-evaluation of suppliers, contractors and service providers. In compliance with the ISO 18385 standard section 5.4, QIAGEN evaluates and selects suppliers only based on their ability to supply products in accordance with QIAGEN's requirements. They are regularly subjected to inspections and audits, and their certifications are reviewed periodically. Quality assurance agreements are finalized only with suppliers whose materials, equipment and services meet QIAGEN's quality demands and standards.

Automated manufacturing and EO treatment

Handling and primary packaging of chemicals and consumable devices are conducted, where feasible, on automated production systems. QIAGEN also employs ethylene oxide (EO) as an additional measure to control exogenous DNA in the manufacturing process. Those products are labeled accordingly with "Forensic DNA Grade EO" seals. QIAGEN continually monitors the applicability of EO treatment and progressively expands its utilization for Investigator Kits and relevant finished plastic accessories.

Risk analysis of manufacturing processes for potential exogenous human DNA

QIAGEN maintains an ongoing process for identifying, estimating and evaluating the risk of introducing human DNA contamination into products, controlling these risks and monitoring the effectiveness of controls. Therefore, QIAGEN collects and periodically reviews relevant product and process information to evaluate if any previously unrecognized risks are present or if a previously identified risk is no longer acceptable. If either of these occurs, the impact on previously implemented risk assessment and control measures are evaluated and the risk control measures are updated as necessary.

Post-production testing for absence of human DNA

QIAGEN's quality control system includes a release process that tests the performance, reproducibility and absence of exogenous human genomic DNA in finished lots of Investigator Kits. Exogenous human genomic DNA is quantified by a sensitive real-time PCR assay that amplifies highly ubiquitous human DNA sequences. All kit components of the Investigator portfolio for qPCR and multiplex STR PCR undergo negative control testing (no-template control). Only kit lots meeting the specifications are released for sale.

QIAGEN Exclusion Database Service

Since 2005, QIAGEN has maintained a staff DNA profile database managed by an independent custodian from a German forensic institute. This database comprises anonymous STR profiles of staff working in operations at all our international locations, where testing reagents and plastics of the “Investigator” product line are produced. It is regularly updated. The service works on a per-request basis and is open for our customer base worldwide. Inquiries can be initiated by reporting STR profiles to the QIAGEN Technical Service team at www.qiagen.com/exclusiondatabase.

For our customers’ convenience, QIAGEN maintains a **Profile Summary Report** consisting of individual profiles either reported to be found in an Investigator-branded product and matched with the QIAGEN Exclusion Database or observed independently by more than one laboratory using QIAGEN products.

Certificate of Analysis

Lot-specific Certificates of Analysis (CoA) for Investigator Kits are available on request. They can be ordered **online**. The CoA documents list the quality controls tested and their acceptance criteria (e.g., determination of enzyme activity, conductivity and performance of buffers, size testing of magnetic particles, etc.).

Product validation

Investigator Kits are intended for molecular biology applications in forensic, human identity and paternity testing. They are used in forensic casework analysis and developed specifically for rapid and reliable generation of DNA profiles from blood, buccal swabs and forensic stains. The performance of Investigator Kits is evaluated for various sample types and conditions commonly encountered in forensic and parentage laboratories. Where feasible, the validation study is based on the recommendations of the European Network of Forensic Science Institutes (ENFSI) and the Revised Validation Guidelines of the Scientific Working Group on DNA Analysis Methods (SWGDM).



Learn about human identity and forensic solutions at: www.qiagen.com/HID



Learn about QIAGEN’s Forensic DNA Grade Quality at: www.qiagen.com/forensicgrade

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services or your local distributor.

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