

Dedicated to Molecular Diagnostics

For Europe



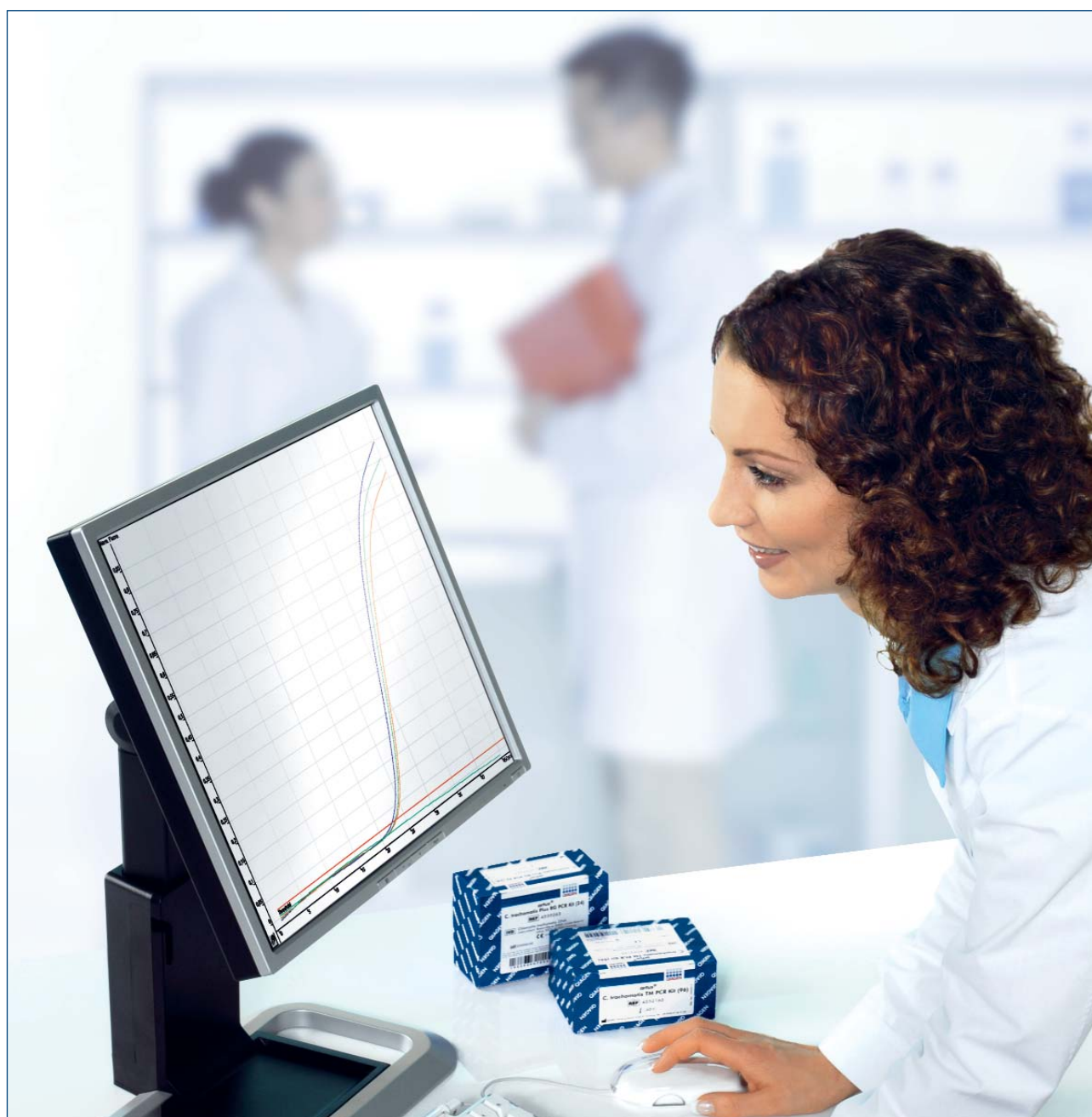
Sample & Assay Technologies

QIAGEN's growing role in molecular diagnostics

At QIAGEN, one of our key goals is to support clinical decision-making and improve patient healthcare. We recognize the increasing importance of molecular diagnostics and are committed to expanding our role in this field.

By combining sample preparation and assay technologies, QIAGEN is able to provide integrated, standardized systems required for molecular diagnostics. Automated solutions enable further standardization and streamlined laboratory workflows. A broad range of CE-IVD-marked sample and assay technologies provides integrated, validated systems for molecular diagnostics.

Our extensive product portfolio is complemented by expert technical service, including training, on-site support, and tailored solutions from sample to result. QIAGEN continues to expand in the field of molecular diagnostics through partnerships and acquisitions, remaining a key player in the global molecular diagnostics market.



Expert tools, service, and support for molecular diagnostics

QIAGEN is a major supplier of reagents for molecular diagnostic laboratories, including the broadest range of test systems for detection of viruses and bacteria. While innovative products and technologies plus rigorous manufacturing standards are key components of QIAGEN's molecular diagnostics capabilities, expert service and support provide the additional resources needed in this important and growing field.

1984 QIAGEN founded in Düsseldorf, Germany

1994 Launch of the QIAamp® DNA Blood Mini Kit

Standardized solutions for sample and assay technologies are the central focus of QIAGEN's product portfolio, including integrated automated solutions for increased standardization and streamlined laboratory workflows. From sample-preparation kits to enzymes for standard and real-time PCR, QIAGEN continues to developing further new products for sample preparation and assays.

1999 ISO 9001 and EN 46001 certification

PEI (Paul-Ehrlich-Institute, Germany) validation for the QIAamp Viral RNA Mini Kit

PreAnalytiX founded, a joint venture with BD

The comprehensive line of products for HLA typing from QIAGEN includes CE-IVD-marked Olerup SSP™ Kits for high- and low-resolution typing and SBTexcellerator® HLA Kits for sequencing-based typing.

2002 Acquisition of GenoVision, with an extensive line of products for HLA typing

2004 Launch of first CE-IVD-marked sample preparation kit

Launch of the CE-IVD-marked BioRobot® MDx DSP system

2005 510 (k) clearance of PAXgene™ Blood RNA System in the USA

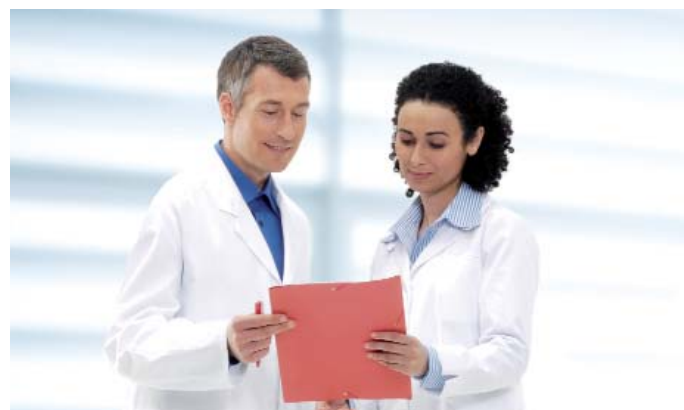
QIAGEN is one of only a few companies with a worldwide PCR license for diagnostics. Ready-to-use, CE-IVD-marked *artus*® real-time PCR kits are developed for sensitive detection of various infectious disease panels, including transplantation associated pathogens, respiratory disease or encephalitis pathogens, and others.

2005 Acquisition of *artus*, with the broadest range of real-time PCR pathogen test systems

2007 Launch of the CE-IVD-marked BioRobot EZ1™ DSP system

Launch of QIAplex Panels for multiplex analysis of respiratory pathogens and staphylococci

QIAGEN employs more than 1950 professionals in 16 countries around the globe, with a global network of sales professionals serving customers in more than 40 countries. With two cGMP-level manufacturing facilities, one in North America and one in Europe, QIAGEN assures the availability of quality products in any situation. Rigorous quality control and exacting manufacturing standards ensure standardized production and quality.



Sample collection & stabilization

Purification



Sample collection and stabilization

- Integrated system for blood collection, and stabilization and purification of intracellular RNA
- CE-IVD-marked and 510 (k) cleared
- Standardized sample processing



Automated purification

- Standardized automated solutions from low to high throughput
- CE-IVD-marked systems for a range of applications
- IQ/OQ and validation support services



Manual purification

- Reliable sample preparation from a wide range of sample types
- CE-IVD-marked manual sample preparation systems
- Purified DNA or RNA ready to use in downstream assays

Analysis



Pathogen detection by quantitative PCR

- Broadest range of real-time PCR kits for pathogen detection
- CE-IVD-marked assays
- Reliable, sensitive, and accurate detection and quantitation



Multiplex pathogen detection

- Multiplex detection of pathogens in a single reaction
- Molecular differential detection
- High sensitivity with robust PCR amplification



HLA typing

- High- and low-resolution HLA typing
- CE-IVD-marked assays for HLA typing by SSP (sequence-specific primers)
- Fast sequencing-based typing with data-analysis software to resolve ambiguities





Expert technical service and support

QIAGEN's molecular diagnostics experts provide exceptional service and technical support for molecular diagnostics customers. Molecular diagnostics specialists in QIAGEN Technical Services and sales are extensively trained in molecular diagnostic applications.

QIAGEN Instrument Service provides comprehensive support services. Application Services and Training Programs give the freedom and flexibility to adapt systems to specific or changing research needs. ISO 9001/ISO 13485 certification and an international team of highly qualified and experienced Support Specialists guarantee high-quality service.

Molecular diagnostics application laboratories in Germany (2 labs), the USA, and Singapore provide a range of expert services, including on-site demos, validation support, and protocol adaptations. Training programs are available for automation of molecular diagnostics applications, tailor-made to meet customer needs.

Molecular diagnostics PCR training at QIAGEN provides both theoretical and practical training on major real-time PCR cyclers. Theoretical training includes an introduction to pathogen detection, key features of *artus* real-time PCR Kits, validation requirements, programming of thermal cyclers, and general troubleshooting. Hands-on practical training in the laboratory includes sample preparation, pathogen detection and quantification, plus detailed analysis of results.

CE-IVD-marked *artus* PCR Kits, Olerup SSP Kits, the BioRobot MDx DSP system, and the BioRobot EZ1 DSP system are intended for in-vitro diagnostic use in Europe. The PAXgene Blood RNA System is intended for in-vitro diagnostic use.

The QIAamp DNA Blood Mini Kit and the QIAamp Viral RNA Mini Kit are intended for general laboratory use. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of a disease.

The BioRobot MDx workstation is intended for laboratory use. No claim or representation is intended for its use to provide information for the diagnosis, prevention, or treatment of a disease.

BioRobot EZ1 workstation, QIAplex Panels, SBTextcellerator HLA Kits: For Research Use Only. Not for use in diagnostics procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of a disease.

SBTextcellerator HLA Kits are licensed from Genome Diagnostics BV.

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