

Molecular Diagnostics

Genomic technologies are transforming medicine by creating new opportunities for prevention and profiling diseases and enabling safer, more effective personalized therapies.



Molecular biology has revolutionized the diagnosis of diseases. Modern tests based on the detection of nucleic acids (DNA and RNA) offer considerable advantages over traditional methods of pathogen detection, discerning viruses and bacteria more rapidly and with far greater sensitivity and specificity. If necessary, tests can even be done at the point of need without access to laboratory infrastructure. Furthermore, the specific genetic makeup of individual patients can now be determined more precisely, enabling doctors to choose the most suitable therapy. Molecular technologies also enable the early identification of certain disease risks, improving the efficiency of existing prevention programs. In these ways, molecular diagnostics provides modern medicine with the necessary tools for developing new strategies in the battle against both acute and chronic diseases.

Hospitals and diagnostic laboratories using molecular diagnostic technologies demand products that combine the highest levels of reliability with speed and efficiency. Reliability is essential, as an inaccurate or missed diagnosis can be a matter of life and death. Early detection is also key, as it may allow earlier treatment with the appropriate therapy, in some cases even before the manifestation of symptoms. In emerging point of need testing applications such as emergency medicine, users require highly portable solutions with an ultra-fast time to result. Efficiency also is a basic requirement of all customers – not only for commercial laboratories – given the increasing cost pressures in healthcare systems.

QIAGEN and Molecular Diagnostics

QIAGEN offers one of the broadest portfolios of Sample to Insight solutions in Molecular Diagnostics.

- **Oncology:** QIAGEN's portfolio in oncology includes tests for a broad range of clinically relevant biomarkers, particularly in cancer. QIAGEN's current product offering encompasses the *therascreen* line of companion diagnostics developed in collaboration with leading pharmaceutical companies such as AstraZeneca, Boehringer Ingelheim, Eli Lilly, and Amgen. These companion diagnostics are marketed in combination with certain drugs, helping to guide treatment decisions. Examples include the *therascreen* KRAS RGQ PCR Kit for the colon cancer drugs Erbitux (*cetuximab*) and Vectibix (*panitumumab*), as well as the EGFR RGQ PCR Kit paired with the lung cancer drugs IRESSA (*gefitinib*) and Gilotrif (*afatinib*).

In addition, QIAGEN markets a range of gene panels for research applications in next-generation sequencing, covering dozens of genes associated with various cancers, such as the Actionable Insights Tumor Panel launched in 2015. This gene panel targets 12 clinically important genes that are often analyzed in most prevalent types of cancer, including breast, ovarian, colorectal, lung and melanoma. The panel can detect up to 1,250 different genetic mutations in a tumor sample. Finally, QIAGEN offers the broadest range of technologies for the extraction and enrichment of molecular biomarkers from body fluids, supporting the development of liquid biopsies. Minimally invasive liquid biopsies hold promise to transform the diagnosis and treatment of cancer. In Europe, QIAGEN already markets a CE-IVD marked liquid biopsy-based companion diagnostic for the lung cancer drug IRESSA.

- **Modulation of Immune Response:** QIAGEN's [QuantiFERON-TB Gold In-Tube Test \(QFT\)](#) is regarded worldwide as the modern standard for detection of latent tuberculosis infection. According to WHO estimates, this condition affects about one-third of the world's population. Up to 10% of people with latent TB infection will develop the active disease in the course of their lives. Therefore, the identification and treatment of at-risk groups with latent TB is important for sustainable control of this potentially life-threatening infectious disease.

QIAGEN also leverages the QuantiFERON technology into other indication areas. The CE-marked QuantiFERON-CMV test in Europe allows monitoring changes in cell-mediated immunity to cytomegalovirus (CMV), the most common and problematic viral infection in solid organ transplant recipients. In addition, QuantiFERON Monitor (QFM), also CE-marked for Europe, can provide valuable insights into the status of the immune system in immunosuppressed solid organ transplant patients. The test thereby targets an important medical need for physicians to assess patients' risk for both organ rejection and infections, in order to determine the right dosage of immunosuppressive drugs.

- **Infectious Diseases:** QIAGEN offers several comprehensive test panels for detection of bacterial and viral pathogens. These are CE-marked in accordance with the European IVD Directive, cleared by the FDA in the USA or registered for in vitro diagnostic use in other countries. QIAGEN's portfolio encompasses assays for the detection of individual pathogens such as Influenza, HIV, Hepatitis, and healthcare-associated infections, as well as tests for the detection of several different pathogens in a single run (known as multiplexing).

QIAGEN also has a global leadership position in screening for high-risk types of human papillomavirus (HPV), the primary cause of cervical cancer. Here too, QIAGEN sets the "gold standard" with its *digene* HPV Test and offers a screening assay specifically designed for use in low-resource settings, the *careHPV* Test.

Across the full range of healthcare needs, QIAGEN offers proprietary platforms for the automation of workflows in molecular diagnostics – from Sample to Insight. These flexible workflows support widely diverse needs for throughput and integrate seamlessly with bioinformatics for interpretation and reporting of actionable insights. QIAGEN is uniquely positioned with automation systems in all technologies for molecular diagnostics, including PCR sequencing, next-generation sequencing, multimodal approaches and Pyrosequencing.

With a [run rate over \\$680 million in sales](#) and continuous growth in this customer class, QIAGEN is a global leader in molecular diagnostics.