

Molecular Diagnostics



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

Molecular biology has revolutionized the diagnosis of disease. Modern tests based on the detection of nucleic acids (DNA and RNA) offer considerable advantages over traditional methods of pathogen detection such as viruses, immune response monitoring and personalized healthcare. The global COVID-19 pandemic has highlighted the need and many advantages of molecular diagnostics. These molecular tests are more rapid with far greater sensitivity and specificity. If necessary, tests can even be done at the point of need without access to a laboratory. 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 prevention programs. In these ways, molecular diagnostics provides modern medicine with the necessary tools for developing new and more effective strategies in the battle against both acute and chronic diseases.

Hospitals and diagnostic laboratories using molecular technologies demand products that combine the highest levels of performance with speed and efficiency. Performance is essential, as an inaccurate or missed diagnosis can be a matter of life and death. Early detection is also important, as it may allow earlier treatment with patient-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 just 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 the Molecular Diagnostics sector and generated \$737 million of sales in this customer class in 2019.

- **Infectious Diseases:** QIAGEN offers several comprehensive test panels for detection of bacterial and viral pathogens such as SARS-CoV-2, including those running on the highly-versatile QIASymphony, QIAstat-Dx and NeuMoDx families of instruments that serve as the growing basis of the company's infectious disease expansion. QIASymphony is a highly flexible mid-throughput platform for the automation of tests is based upon real-time PCR technology. It gives customers access to a constantly growing menu of commercially available assays while allowing them to run their own laboratory-developed tests. The QIAGEN assays are CE-IVD marked, cleared/approved by the U.S. Food and Drug Administration or registered for in vitro diagnostic use in other countries. QIAGEN's portfolio encompasses assays for the detection of individual pathogens such as HIV, Hepatitis, and healthcare-associated infections, as well as tests for the detection of several different pathogens in a single run (known as multiplexing). In 2018, QIAGEN reached another important milestone with more than 2,500 cumulative placements of the QIASymphony. In 2020, the QIAstat-Dx SARS-CoV-2 Respiratory Cartridge was the FDA EUA and CE-IVD marked multiplex assay to detect the first COVID-19 case in Spain and has been used worldwide for the rapid detection of SARS-CoV-2 as well as 21 additional pathogens.

Across the full range of healthcare needs, QIAGEN offers proprietary platforms for the automation of workflows in molecular diagnostics and clinical research— 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 across broad technologies including PCR sequencing, NGS sample preparation and Pyrosequencing.

- **Oncology:** QIAGEN's oncology portfolio includes tests for a broad range of clinically relevant cancer biomarkers. QIAGEN's current product offering encompasses the *therascreen* line of companion diagnostics developed in collaboration with leading pharmaceutical companies such as Pfizer, AstraZeneca, Boehringer Ingelheim, Eli Lilly, and Amgen. These companion diagnostics are marketed in combination with specific drugs, helping to guide treatment decisions. Examples include the *therascreen* PIK3CA RGQ PCR Kit for the breast cancer treatment PIQRAY, the *therascreen* KRAS RGQ PCR Kit for the colon cancer drugs Erbitux (*cetuximab*) and Vectibix (*panitumumab*), the FGFR RGQ RT-PCR Kit for identifying metastatic urothelial cancer patients eligible for treatment with BALVERSA (erdafitinib), as well as the EGFR RGQ PCR Kit paired with the lung cancer drugs IRESSA (*gefitinib*) and Gilotrif (*afatinib*).

QIAGEN continues to expand its pipeline of Sample to Insight technologies for personalized healthcare applications.

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 are transforming the diagnosis and treatment of cancer. In Europe, QIAGEN markets a CE-IVD marked liquid biopsy-based companion diagnostic for the lung cancer drug IRESSA and for the breast cancer treatment PIQRAY.

- *Modulation of Immune Response*: QIAGEN's QuantiFERON-TB Gold Plus Test (QFT) is regarded worldwide as the standard for the detection of *latent Tuberculosis* infection. According to WHO estimates, this condition affects approximately 2.5 billion people worldwide. 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 is committed to expanding QuantiFERON's global reach through intensified commercial efforts in strategic markets, automation upgrades to improve the test's workflow and continued expansion of the company's immune response test menu in other indication areas.

Tuberculosis is a global disease that is having an impact in the United States as well, where up to 13 million people are infected and nearly 10,000 people are currently suffering with active disease. In mid-2017 the U.S. Food and Drug Administration approved QuantiFERON®-TB Gold Plus (QFT®-Plus), the company's fourth-generation TB blood test. It combines breakthrough CD4/CD8 design for comprehensive immune response detection with the most flexible blood collection workflow.