Automation Solutions

Automated testing is changing the laboratory landscape by streamlining workflows, ensuring faster and more reliable results while improving economic feasibility.

Laboratory automation is creating a new paradigm in diagnostics and other applications, fueling widespread uptake of making molecular technologies routine in healthcare and everyday life. Automation enables laboratories to keep pace with increasing sample volumes by significantly accelerating and simplifying the testing process, while rendering it more affordable and efficient. In addition, automation dramatically increases the reliability of molecular tests by increasing the reproducibility of results, eliminating the ‘human factor’ and the risks of sample mix-ups – further driving the dissemination of molecular technologies into a growing number of applications in diagnostics, research and applied settings such as forensics and food safety.

Changing the laboratory landscape

Research and commercial laboratories alike face unprecedented opportunities – and challenges – in this era of growing genomic knowledge. Labs face increasing economic, regulatory and time pressure. As the potential of molecular diagnostics expands exponentially, new genomic tests are constantly being developed and adopted in medical practice. The amount of data being generated by next-generation sequencing is vast. Alongside advances in knowledge and technological capabilities, there are an ever-growing number of regulations. Health and safety targets also are becoming more ambitious and require results more urgently. So the value of automation in molecular diagnostics is growing rapidly for wide range of reasons.

Automation helps labs cope with challenges

In the current economic environment, resources for research and commercial testing can be severely limited and must be used with optimum efficiency. Many research and development (R&D) programs have been restructured to align better with available resources and demands. Research facilities are under pressure to deliver results quickly, free up the time of highly qualified scientists and engage in more creative work. Commercial laboratories face stiff competition and are forced to continuously enhance efficiency, while improving their level of service to customers. In addition, there is a constant struggle to find additional ways to control healthcare costs. Payers require greater transparency and push for value-based reimbursement, instead of direct payments for procedural steps in a laboratory.

Increasing regulatory demands are particularly relevant in commercial labs. A wrong diagnosis or test result can be a matter of life and death. The accuracy of results in these situations is also
associated with serious liability risks, so laboratories need to establish, maintain and monitor high quality standards and compliant processes to ensure the reliability and reproducibility of test results. This includes tracking samples throughout the entire diagnostic process and ruling out cross-contamination. They also need to eliminate the chance of human error, as much as possible, because the technologies used are so sensitive.

Due to reduced costs of testing and a constant stream of new applications, the volumes of samples that laboratories process are increasing. In addition, effective patient management often requires results within a certain time frame – for example, in exploring donor and recipient matches in organ transplantation, or in monitoring the progress of a particular disease.

Laboratory automation eases the impact of these challenges, so the majority of laboratories are already employing a variety of instruments to automate at least part of their activities. It also helps laboratories record the progress of a sample through the entire laboratory process and feeding this data into the laboratory’s information system. Automation also accelerates the diagnostic process by reducing the time needed to perform tests and report results. This sometimes enables new application areas to be introduced, for example in food testing, where control procedures need to match the fast pace of production and distribution. Wider dissemination and further evolution of new molecular technologies is, in turn, driven by these and other developments.

**Automation options from Sample to Insight**

Recognizing the challenges clients face, QIAGEN offers instrumentation systems that automate entire laboratory workflows to provide efficient solutions for a broad range of applications. Platforms range from the complete QIAsymphony RGQ system, the world’s leading automation solution for medium-throughput molecular testing, to special-purpose instruments automating individual tasks in laboratory workflows. With a constantly expanding test menu the QIAsymphony addresses customers’ demands for robust automation systems and trends such as increasing test volumes and increasing IVD and laboratory-developed tests.

QIAGEN is also commercializing the GeneReader NGS System, the world’s first complete Sample to Insight next-generation sequencing (NGS) solution designed for research laboratories to deliver actionable insights. This automation solution enables customers to perform reliable and reproducible nucleic acid sample preparation, assay setup, target detection and other tasks, and to interpret and report actionable insights from those test in an integrated, “Sample to Insight” workflow. By continuing to broaden its content menu of innovative tests for this system, QIAGEN will be a ‘one-stop shop’ for customers seeking molecular Sample to Insight solutions – offering simplicity, precision, efficiency and affordability for customers. The pricing of the GeneReader NGS System and kits provides users with maximum flexibility and control because users pay per “insight.” QIAGEN’s goal for the GeneReader NGS System is to earn more than a 20-percent share of the oncology benchtop sequencing market. The company expects to expand its portfolio of tests for the GeneReader NGS System, enabling QIAGEN to reach other clinical and research
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areas. Universal NGS solutions that the company will introduce are expected to provide innovative new workflow solutions that will further support market growth and share gains.

QIAGEN’s key automation products include:

- **Sample technologies:** QIAGEN offers a broad portfolio of instruments for the automated processing of samples geared towards different throughput requirements. It includes the QIAcube, an award-winning robotic workstation for automated purification of DNA, RNA, or proteins, the EZ1 Advanced XL, which is frequently used in forensic applications, or the BioRobot Universal System tailored for high-throughput applications.

- **Assay technologies:** QIAGEN customers can select from a wide range of detection platforms. QIAGEN’s offering includes QIAgility, a user-friendly system for separation of nucleic acids with great sensitivity and time to results; PyroMark, a high-resolution detection platform for the real-time analysis and quantification of genetic mutations and DNA methylation patterns down to single base pair levels; and Rotor-Gene Q, the world's first rotary real-time PCR cycler system, using real-time PCR reactions to make specific sequences of DNA and RNA visible through amplification, and also quantifiable through real-time measurement.

- **Integrated solutions:** In addition to instruments for individual workflow steps in laboratories, QIAGEN also develops and commercializes integrated solutions that automate laboratory workflows from Sample to Insight. The QIAsymphony family of instruments is a highly flexible mid-throughput platform for the automation of tests based upon real-time PCR technology. It gives customers access to a broad menu of commercially available assays while allowing them to run their own laboratory-developed tests. In 2018, QIAGEN reached another important milestone with more than 2,500 cumulative placements of the QIAsymphony platform.

- **QIAstat-Dx:** The next generation in one-step multiplex molecular diagnostic systems that enable fast, cost-effective and flexible syndromic testing with novel Sample to Insight solutions based on PCR technology. Launched in 2018 in Europe, and planned for U.S. launch in 2019, QIAstat-Dx addresses the needs of clinical laboratories for near-patient testing for a range of conditions and helps reduce diagnostic uncertainty.

- **NeuMoDx:** The NeuMoDx automated PCR systems have the distinction of fully integrated operation, including performing every step from sample extraction through detection and results reporting. The NeuMoDx 96 and 288 platforms offer market-leading ease of use, true continuous random-access, and rapid turnaround time while achieving optimal operational and clinical performance for customers and the patients they serve.

- **The GeneReader NGS System:** is the world’s first complete NGS workflow, providing a seamlessly integrated workflow offering ease of use and efficiency for clinical research. The platform integrates extraction, purification and pretreatment of nucleic acids; automated NGS sample preparation; gene panel assays; the scalable GeneReader NGS System; and powerful bioinformatics for the interpretation and reporting of results. QIAGEN’s GeneReader NGS System can be seamlessly integrated with a customer’s laboratory information management systems (LIMS).