

Disease Profiling

Molecular testing of patients to more precisely profile their diseases is delivering better medical outcomes and more effective containment of infections.



Our ability to pinpoint diseases and characterize the molecular mechanisms responsible for them has advanced enormously in recent years. Pathogens such as viruses or bacteria, for example, can now be detected much faster than ever before and even in minute amounts – proving essential in disease management, precise protocols and treatment regimens. Therewith, molecular profiling of infections is an essential capability for improving public health.

Second-biggest worldwide killer

Infectious diseases, caused by pathogens such as bacteria or viruses, are the second-leading cause of death worldwide, accounting for approximately 16% of deaths.¹ Each year, tuberculosis, AIDS and diarrhea alone claim about 4.5 million victims.² Even if not fatal, infectious diseases result in widespread suffering and a massive burden economically from treatment, disability and loss of functionality. In addition, infectious diseases evolve constantly and don't recognize geographic boundaries and with people travelling more, the spread of disease is now a global issue.

The role of diagnostics

Currently, laboratory testing comprises a small component of total health care expenditure, but has a disproportionately important influence on physicians' decisions. In the United States, two to three percent of the healthcare expenditure in 2011 was dedicated to laboratory testing, which determined 70-80% of U.S. physicians' decisions.³ The situation in many developed countries is similar. Increased testing, more accurate diagnosis, early detection and monitoring using molecular technologies are believed to offer significant opportunities to reduce healthcare spending.

This is because molecular diagnostic technologies often offer faster, more reliable and increasingly sensitive tests compared to traditional methods, such as bacterial cultures. Results can be obtained within hours, as opposed to days or weeks, which is particularly important in catching infectious diseases earlier to enable effective treatment and their containment. Quick turnaround times are also important when dealing with immunocompromised patients, e.g. in transplantations, who need to be tested for the presence of widespread pathogens to prevent complications.

Infectious disease testing accounts for 60% of the molecular diagnostics industry in the U.S.³ The most commonly tested for infectious diseases include Human Immunodeficiency Virus (HIV), hepatitis viruses, healthcare-associated infections, respiratory viruses, tuberculosis and diseases

associated with women's health. Molecular technologies also play an important role in testing immunocompromised patients, for instance for the presence of the cytomegalovirus (CMV). The technologies continue to evolve and become increasingly sophisticated – recognizing even minute amounts of disease in small samples of tissue, blood, urine or other body materials.

QIAGEN and Profiling

QIAGEN is a global leader in profiling infectious diseases. Subject to regulatory approval in various countries, it offers approximately 120 tests for detecting various pathogens, including the Influenza virus, HIV that causes AIDS, as well as Hepatitis B and C viruses. In select markets, QIAGEN also commercializes multiplexing methods that can be used to detect more than 20 different pathogens in a single test run. Currently, QIAGEN's Profiling portfolio contributes more than \$200 million in annual sales.

To further extend its leading position in Profiling, QIAGEN is constantly introducing innovations that lead to progress in clinical practice. One of the main aspects is combining the advantages of molecular tests with the efficiency of automated systems. The success of this approach is demonstrated by a growing number of tests available for the company's automated platforms and regulatory clearances that have been granted following stringent approval procedures, such as the U.S. clearance of QIAGEN's test to detect Influenza viruses in combination with the Rotor-Gene Q MDx[®] detection platform.

QIAGEN's current portfolio includes:

- **Tests:** Subject to regulatory approval in different markets, QIAGEN markets a total of approximately 120 tests for various infectious agents and its range is continually growing. Currently, QIAGEN's portfolio includes tests for widespread infectious diseases such as HIV, Tuberculosis, Hepatitis and Influenza; multiplex tests to analyze several potential pathogens in a single test run; tests to detect potentially lethal infections in transplant patients; and also tests for exotic pathogens. QIAGEN is frequently the first company to provide testing solutions in outbreaks of infectious diseases that pose a public health threat, such as recent Avian and Swine Influenza epidemics. QIAGEN introduced the world's first, clinically-validated test for Avian Influenza (H5N1) in 2005 and Swine Influenza (H1N1) in 2009. In 2014, QIAGEN added to its portfolio various tests for detection of healthcare-associated infections, including vancomycin-resistant bacteria (VanR) and methicillin-susceptible *Staphylococcus aureus* (MRSA). QIAGEN plans to submit all of these tests for regulatory approval in Europe and the United States. The new tests address an urgent need in healthcare, as healthcare-associated infections are estimated to affect 5.8 million hospitalized patients a year in Europe and the United States, leading to more than 100,000 deaths.⁴
- **Sample preparation kits:** QIAGEN also produces a wide range of sample preparation kits that are essential to preserve and process patient samples for downstream testing. QIAGEN has developed a wide range of sample preparation technologies for processing of various sample types such as blood, saliva or tissue.



- **Instruments:** Disease profiling requires fast, reliable, specific testing methods. Handling infectious materials can pose an inherent danger to laboratory staff. And in addition, the cost-effectiveness of diagnostic tools is also important. QIAGEN thus also offers systems that automate laboratory workflows to provide efficient solutions for a broad range of testing needs. QIAGEN's portfolio includes the QIASymphony RGQ, a highly flexible modular platform that automates laboratory workflows from sample to result. The platform has been designed to address the requirements of mid-throughput laboratories to carry out a wide array of tests from different samples more efficiently. QIAGEN has also developed portable devices which bring molecular profiling into the field, near to patients and emergency medicine facilities. QIAGEN's ESEQuant Tube Scanner permits low-throughput molecular testing in physician practices, emergency rooms, remote field areas and other settings where a laboratory infrastructure is not accessible and fast turnaround is required.



¹ WHO: The Global Burden of Disease, 2004 Update.
² WHO 2014: <http://www.who.int/mediacentre/factsheets/fs310/en/index.html>
³ Cowen and Company 2013: Diagnostics kit.
⁴ WHO 2014: http://www.who.int/gpsc/country_work/gpsc_ccisc_fact_sheet_en.pdf