

Infectious Diseases



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 their molecular mechanisms 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. 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 among the top ten leading cause of death worldwide, accounting for approximately 6 percent of deaths globally.¹ Each year, tuberculosis and other infectious diseases claim more than 3 million lives.¹ Even if they are not fatal, infectious diseases result in widespread suffering and a massive economic burden from treatment, disability and loss of function. In addition, infectious diseases evolve constantly and don't recognize geographic boundaries and with people traveling more, the spread of disease is now a global issue.

The role of diagnostics

Currently, laboratory testing comprises a small component of total healthcare spending, but has a disproportionately important influence on physicians' decisions. In the United States, about 5% of healthcare spending in 2016 was dedicated to medical devices and in-vitro diagnostics, which determined 70-80% of U.S. physicians' decisions.² 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 containment. Quick turnaround times are also important when dealing with immunocompromised patients after transplantation who need to be tested for the presence of widespread pathogens to prevent rejection of the transplanted organ.

Infectious disease testing accounts for 60% of the molecular diagnostics industry in the United States.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 like the human papillomavirus (HPV). 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 increasingly minute amounts of disease in small samples of tissue, blood, urine or other body materials.

QIAGEN and Infectious Diseases

QIAGEN is a global leader in profiling infectious diseases. Subject to regulatory approval in various countries, QIAGEN offers more than 130 tests for detecting various pathogens, including the SARS-CoV-2 Coronavirus, Influenza virus, HIV that causes AIDS, as well as the 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.



To further extend its leading position in Infectious Diseases, 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 FDA approvals of the QIAstat-Dx System and Respiratory Cartridge, the U.S. clearance of QIAGEN’s test to detect Influenza viruses in combination with the Rotor-Gene Q MDx[®] detection platform, or the recent menu expansion with FDA approvals and CE-IVD markings for the NeuMoDx Platform.

QIAGEN’s current portfolio includes:

- **Tests:** Subject to regulatory approval in different markets, QIAGEN markets a total of more than 130 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’s *digene* HC2 HPV Test, is the world’s most validated and

sensitive diagnostic test for detection of high-risk HPV and is recognized as the “gold standard” in HPV screening. QIAGEN is frequently the first company to provide testing solutions in outbreaks of infectious diseases that pose a public health threat, such as COVID-19, 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). In 2020, QIAGEN offered a rapid multiplex syndromic testing solution for SARS-CoV-2, and was able to detect the first COVID-19 positive case in Spain. The 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.³ In 2020, COVID-19 deaths in the US surpassed 150,000 by August.

- **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:** Infectious Diseases require 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. Additionally, QIAGEN offers the QIAstat-Dx and NeuMoDx systems. QIAGEN has also developed portable devices which bring molecular profiling into the field, near to patients and emergency medicine facilities, in partnerships as with Australian Ellume.



¹ <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>

² https://www.advamed.org/sites/default/files/resource/estimates_of_medical_device_spending_in_the_united_states_november_2018.pdf

³ WHO 2014: http://www.who.int/gpsc/country_work/gpsc_ccisc_fact_sheet_en.pdf