

In vitro diagnostics: Technologies and global markets

By Jon Evans

In vitro diagnostics (IVD) are the highest revenue segment of the medical device market. The global market for IVD products is estimated to be \$74.1 billion in 2020, and it is expected to grow at a compound annual growth rate of 6.7% to reach \$102.4 billion through 2025.

IVD includes analyzers, reagents, disposable and reusable products, and accessory software products used by both clinical and research laboratories around the world. IVDs range from simple self-use tests to state-of-the-art genomic tests performed in laboratories, which can be used in the diagnosis of infectious and chronic diseases, as well as for preventive care and drug therapy monitoring.

Factors influencing the global IVD market include

- **Need for disease detection before appearance of symptoms**—Rapid advances in human genome sequencing enable the identification of faulty genes, increasing the probability of diagnosing a disease before its symptoms appear and thus starting treatment much earlier.
- **Need to identify the right patients for drug therapy**—New tests, known as companion diagnostics, generate critical data on a patient’s rate of drug metabolism and efficacy, for example, thus enabling healthcare experts to identify the right patient for a specific drug.
- **Need for faster real-time tests that enable personalized treatment**—Faster tests provide real-time results and thus allow healthcare providers to make timely decisions, reduce chances of any adverse side effects of drugs, and educate and motivate patients to make lifestyle modifications for improving their health conditions.
- **Need to minimize dependence on lab testing**—Point-of-care tests pro-

Table 1. Different types of coronavirus tests, 2020

	Molecular test	Antigen test	Antibody test
How it works	Detects the virus’s genetic material	Detects specific proteins from the virus	Looks for antibodies that are made by the immune system in response to a threat
How the sample is taken	Nasopharyngeal (the part of the throat behind the nose), nasal or throat swab, saliva	Nasal or nasal pharyngeal swab	Finger stick or blood draw
What it shows	Diagnoses active coronavirus infection	Diagnoses active coronavirus infection	Shows if you’ve been infected by coronavirus in the past
What it can’t do	Shows if you ever had COVID-19 or were infected with the virus that causes COVID-19 in the past	Antigen tests are more likely to miss an active COVID-19 infection compared to molecular tests. A healthcare provider may order a molecular test if an antigen test shows a negative result, but the person has symptoms of COVID-19.	Diagnose COVID-19 at the time or show that you do not have COVID-19.

vide critical information at the point of healthcare delivery, thus enabling timely diagnoses and treatment commencement by the medical care personnel, which in turn results in improved patient compliance with physicians’ recommendations.

Challenges affecting the global IVD market include

- **Declining reimbursement for IVDs in Europe**—In European countries such as Germany and the U.K., reimbursements were significantly reduced for tests such as glucose monitoring, hampering the growth of the point-of-care test segment. Similar trends in the U.S., such as Medicare cuts, were introduced, which may negatively affect the growth of certain IVDs.
- **U.S. medical device tax reduces profits for manufacturers**—In 2013, the U.S. government mandated a 2.3% excise tax on the sales revenues of medical devices. This tax put a significant burden on companies, especially those that are in early stages and are yet to begin a positive cash flow.
- **Stringent regulatory framework**—Since the beginning of 2005, the U.S. Food and Drug Administration’s process of reviewing and approving medical devices became lengthy and difficult, delaying the commercial launch of new and innovative products to the market.
- **High R&D and marketing costs**—High research & development and

marketing costs may result in an increase in partnerships and acquisitions to cut expenditures and enhance productivity. The number of mergers and acquisitions since the early 2000s has increased, and since 2010, the trend intensified.

Because of its large population and position as a medical technology innovation hub, North America is the global leader in terms of IVD use, accounting for roughly 42.0% of the total market in 2020. The emerging markets of India, China, Russia, and Brazil are poised to grow at double-digit growth rates due to rising incomes, growing healthcare budgets, and heightened health awareness among the population.

About the author

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