

## A WORLD OF OPPORTUNITY FOR IVD INNOVATION

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### FOREWARD

Around the globe, health care innovation remains a boom industry, consistently attracting the attention and imaginations of engineers and scientists who see unbridled opportunity in medtech.

Diagnostic tools, in particular, comprise a large share of the market and are omnipresent in hospitals, clinics and research facilities. Among these technologies, the in vitro diagnostic (IVD) market continues to be robust and still growing.

According to the U.S. Food and Drug Administration (FDA), IVDs are diagnostic tests performed on samples such as blood, urine or tissue to detect and diagnose disease.<sup>1</sup> They can also be used to monitor a person’s overall health and to help diagnose, treat or prevent diseases or other medical conditions.

For decades, conventional in vitro testing has been performed in large laboratory facilities, staffed with trained specialists using expensive equipment. However, the latest generation of IVD medical devices on the market are producing quicker, more accurate and earlier diagnoses, improved patient comfort, greater cost-effectiveness, easier accessibility and simplicity of use.<sup>2</sup>

Consumers are helping to drive this uptick in the IVD market, with the growing demand in point-of-care (POC) testing. As health care providers strive to make their business models more consumer-friendly, remote connectivity is an emerging medtech opportunity, according to a 2017 Forbes article.<sup>3</sup>

For example, real-time access to data and a simplified sample collection process through innovations in the IVD market are predicted to one day become a natural part of the telehealth evolution, taking it beyond simple video conferencing. All of these developments, combined with the promise of economic growth, have made the IVD market even more competitive, which is helping to further attract interest and participation from medical device manufacturers, testing labs, hospitals, health care providers and investors.

This study strives to provide an overview of the IVD market, explain key drivers and results, and offer a look into the future for innovation.

The global in vitro diagnostics market is, so far, unstoppable with analysts expecting a compounded annual growth rate (CAGR) of 4.6%, from \$69.43 billion to just under \$100 billion between 2018 and 2026.<sup>4</sup>

According to the U.S. National Library of Medicine, we have approached an era in which we can detect and predict disease at earlier stages and predetermine



1 <https://www.fda.gov/medical-devices/products-and-medical-procedures/in-vitro-diagnostics>  
 2 <https://link.springer.com/article/10.1007/s41664-019-00095-y>  
 3 <https://www.forbes.com/sites/reenitadas/2017/01/06/9-top-healthcare-predictions-for-2017/#4ab0b55b5e68>  
 4 <https://www.globenewswire.com/news-release/2019/05/15/1825449/0/en/In-Vitro-Diagnostics-IVD-Market-To-Reach-USD-99-46-Billion-By-2026-Reports-And-Data.html>  
 5 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3570996/>

the effectiveness of medication down to the individual patient, thanks to ongoing innovation around in vitro diagnostics.<sup>5</sup>

In fact, according to Deloitte, the single biggest driver behind the rise in medtech Series A investments in 2017 was \$118 million worth of deals in the IVD space.<sup>6</sup>

All of this activity has created a high level of volatility, as established players and agile startups jockey for position. Inorganic market growth is coming from mergers and acquisitions that expand portfolio offerings, enable procurement of the latest technologies and amplify reach into new markets.

These large mergers and acquisitions will persist, and consolidations will continue, as long as there is a healthy ecosystem for startups, according to a 2016 article by Mark Crawford in Medical Product Outsourcing magazine.<sup>7</sup>

He also notes that, “While there is pressure for cost containment, the fundamental value of IVD design still represents a bargain in the overall scheme of health care economics and expansion within the market will continue.”

With anticipated growth comes more competition—from both established players and nimble startups vying for market share. New product launches and technological developments enabling cost-effectiveness, accuracy and portability are proliferating.

## IVD MARKET DYNAMICS

### Four Factors Driving Growth

For end users, from hospitals and clinics to large lab systems and home consumers, the upward trajectory of the IVD market is in no small part due to societal expectations of smaller, faster, more accurate and accessible technology. These expectations intersect perfectly with a still growing need for cost-sensitive and easier-to-use diagnostics among large populations in Europe, North America and Asia Pacific.<sup>8</sup>

The burgeoning geriatric population and subsequent increase in chronic and infectious diseases, as well as growing adoption of point-of-care medical devices and fully automated instruments by testing laboratories, are the four key factors pushing the market.

#### 1. Growing aging population

Older populations tend to be at higher risk of age-related diseases that require more frequent testing.<sup>9</sup> Aging Baby Boomers in Western Europe and the U.S. comprise an exceptionally large group in this market. Further, as a society, people are living longer and are therefore creating a greater need for IVD medical devices.

#### 2. Rise in chronic and infectious diseases

The rise in incidence of chronic diseases in North America—including cancer, diabetes and cardiovascular disease—are another driver behind the IVD market growth as demand for fast, accurate diagnoses, and therefore timely, more personalized treatment plans grow.<sup>10</sup>

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6 <https://blogs.deloitte.com/centerforhealthsolutions/early-stage-medtech-venture-investment-is-up-driven-by-digitally-enabled-diagnostics-but-is-the-market-ready/>

7 from [https://www.mpo-mag.com/issues/2016-11-01/view\\_features/ivd-market-diagnosis](https://www.mpo-mag.com/issues/2016-11-01/view_features/ivd-market-diagnosis)

8 For the purposes of this report, the focus is on Europe and North America where growth continues unabated but is forecasted to be overshadowed within the next decade by even greater demand in the East and among developing nations. Interestingly, U.S. manufacturers are currently seeing opportunity in Asia, too, with sales of refurbished machines and redesigns of old product lines that were otherwise facing end-of-life.

9 <https://www.grandviewresearch.com/industry-analysis/in-vitro-diagnostics-ivd-market>

10 <https://www.reportsanddata.com/report-detail/global-in-vitro-diagnosticsivd-market>

According to the U.S. National Center for Health Statistics, 80% of Americans over 65 have at least one chronic health condition.<sup>11</sup> The increase in infectious diseases, whose treatment and containment are aided by early detection, currently account for the highest revenue in the IVD market.<sup>12</sup>

In 2016, the Centers for Disease Control reported that more than 3.9 million people visited hospital outpatient departments for infectious and parasitic diseases, such as tuberculosis, salmonella and meningococcal diseases. In addition, hospital-acquired infections are becoming increasingly drug-resistant, also resulting in greater focus and reliance on in vitro diagnostics.

### 3. Increasing adoption of point-of-care and in-home/personalized testing

As devices proliferate and technology improves, many health care providers are now able to provide in-office diagnostics that would not have been possible less than a decade ago.

Providers and patients are adopting point-of-care solutions for bloodwork, cardiac workup and HIV diagnostics in a doctor's office or local clinic, for instance, to reduce the time and stress it takes to travel to larger facilities with much more expensive equipment.

In-home self-testing is also a growing market opportunity. Although in vitro diagnostics have been around for a while, most notably glucose monitoring by diabetics and pregnancy tests, newer wearable technology is leading the drive for further innovation.<sup>13</sup>

Personalized care—in the form of blood glucose monitoring devices, cholesterol testing, hemoglobin sensors, pregnancy test kits, urine analyzers and hormone home tests—have become the norm for Western consumers who have a growing appetite for “sample-to-answer” diagnostics.

### 4. Growing use of automated instruments

A heavy emphasis on cost containment, driven by insurers, consumers and government entities, is further pushing innovation in the IVD market space. Automation is one way to address the call for budget cuts in the health care.

Applying this to the IVD market, fully automated instruments help hospitals and labs reduce overhead and control costs, especially labor expenditures, because there is less need for specialized technicians.<sup>14</sup> Further, with quicker on site tests and analyses, hospital stays and related costs are often reduced—a significant driver in health care innovation.

Not only is the focus on new, smaller POC instruments, but also on larger instruments with faster, higher throughput. If a lab sees each test as a revenue stream, it only stands to reason that it would prefer to use smaller sample sizes stretched across more tests.

In addition to supporting cost-sensitivity, automation also helps reduce testing errors, enhance efficiency and increase accuracy for improved outcomes.<sup>15</sup>

## MARKET SEGMENTATION: PRODUCTS AND TECHNOLOGY

### IVD Products

In the IVD market, products are divided into three major segments: reagents and kits, instruments and accessories.

- **Reagents and Kits**

Reagents are solutions of highly-specific biological or chemical substances that are able to react with target substances in the samples to produce an outcome that can be measured or seen. Chemical, biochemical and complex biological/biochemical reagents fill this large market segment.

11 <https://www.ncoa.org/news/resources-for-reporters/get-the-facts/healthy-aging-facts/>

12 <https://www.coherentmarketinsights.com/market-insight/in-vitro-diagnostics-ivd-market-195>

13 <https://www.ncbi.nlm.nih.gov/books/NBK447315/>

14 <https://www.ncbi.nlm.nih.gov/books/NBK447315/>

15 <https://www.cognex.com/industries/life-sciences/in-vitro-lab-automation>

- **Instruments**

**Analytical** instruments are the various machines and equipment that automate the diagnostic process and are used to bring samples and reagents together. **Automated** instruments may or may not be connected to a laboratory information system (LIS), hospital information system (HIS) and/or laboratory automation system (LAS), which performs measurements on a patient’s sample. They may also include specific hardware and/or software development that allows interface with a laboratory automation system.

- **Accessories**

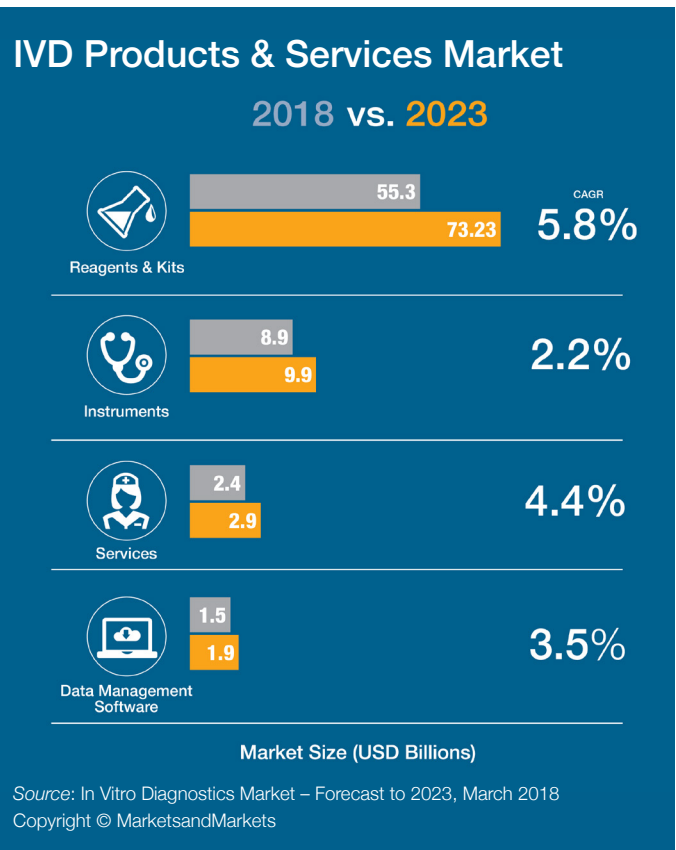
The software and hardware developed to support, supplement and augment the performance of IVD devices are by products but essential elements within IVD innovation.

Reagents and kits account for the greatest piece of the IVD pie—more than 80% in 2017—and these products are projected to grow the market by nearly 6% within the next five years, thanks to the popularity of self-test kits and POC devices. Not far behind, however, is the prevalence of analytic and automated instruments that determine the value, or other qualities and parameters, in test samples. This segment is forecasted to hold a market share of 35% by 2026, owing to the rise in automated instruments that simplify the job and provide accurate results.<sup>16</sup>

### IVD Technology

The top IVD testing technologies are immunoassay, clinical chemistry, molecular diagnostics, hematology, microbiology, coagulation and hemostasis and urinalysis. The immense value of these technologies lies in their ability to reveal accurate, time-sensitive information about a patient’s health—even in mid-procedure, when a patient is unconscious or otherwise unable to speak to the health care provider. This enables critical decisions to be made regarding treatment options in the moment.

Of these technologies, immunoassay is the most popular, being used in diagnosing a wide range of diseases and conditions from cancer to cardiovascular and autoimmune diseases. However, molecular diagnostics is forecasted to be the fastest-growing among all IVD testing techniques, with an 18% market share in 2018 and much more to come.<sup>17</sup> In particular, with infections becoming increasingly drug-resistant, molecular diagnostics shows promise in helping health care professionals detect early signs of onset so timely treatment can begin—or to confine and limit its transmission.<sup>18</sup> Additionally, molecular diagnostics are now widely used to diagnose genetic disorders and fetal abnormalities in utero.<sup>19</sup>



16 <https://www.grandviewresearch.com/industry-analysis/in-vitro-diagnostics-ivd-market>

17 <https://www.ncbi.nlm.nih.gov/books/NBK447315/>

18 <https://www.businesswire.com/news/home/20190204005418/en/Worldwide-In-Vitro-DiagnosticsIVD-Market-Product-Technique-Application>

19 <https://www.grandviewresearch.com/industry-analysis/in-vitro-diagnostics-ivd-market>

## POTENTIAL CHALLENGES TO THE IVD MARKET

There is no getting around the highly regulatory environment for medical device innovation in the U.S. and Europe. It is, simply, part of the landscape. But technology can sometimes outpace governmental organizations' oversight and may occasionally restrain market growth to an extent.<sup>20</sup> The specter of cumbersome reimbursement processes for health care providers can also inhibit growth. The current potential for trade wars, with tariffs and other obstacles to reaching the market, may also challenge the IVD market but those effects are as yet unknown.

- **Complex regulatory environment**

New or modified devices must go through rigorous FDA review to ensure patient safety at the individual and public health levels. Devices meant to support or sustain human life would, therefore, have the highest level of review.<sup>21</sup> Think blood analysis for organ transplants or testing for contagious infections that can have a devastating impact on certain populations such as the young, elderly or immunocompromised.

According to the World Health Organization, this has led to the use of a risk-based approach to assessment, in which IVDs are classified according to the risk they pose to public and individual health, and take into account the potential outcomes and impact if the test does not perform properly or is not available.<sup>22</sup> These classifications are:

**Class I:** Low-to-moderate risk testing in which inaccurate results would not cause harm to the patient or general public (e.g., cholesterol testing);

**Class II:** Moderate-to-high risk necessitating pre-market review (e.g., pregnancy tests);

**Class III:** High-risk testing requiring pre-market review and post-market oversight (e.g., genetic testing for cancer treatment).

This classification leads to extra controls around a device's country of origin.

As the regulatory landscape evolves within the IVD market, companies interested in entering foreign markets will have to stay abreast of compliance developments in each country.

In the EU, Restriction of Hazardous Substances (RoHS and Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) are now common requirements in the design and development of IVD products and technologies.

Classifying a device correctly is imperative in order to avoid delays in market entry.<sup>23</sup> Research and product development teams must be mindful of this to avoid "going back to the drawing board." This is especially true in the U.S., where the FDA unintentionally discourages further innovation on already approved devices if the documentation is not sufficiently forward-looking.

As previously noted here, some companies are extending the lifespan of legacy devices by reengineering them for sale in developing nations where compliance is less of a barrier to the marketplace.

While there's certainly value in regulating IVDs, no one wants to be trapped in a web of policies that hyper-regulate to the point of hindering innovative IVD product development that could represent breakthroughs, particularly in devices classified as higher-risk. Documentation is critical in illustrating how a device meets all regulatory requirements.

- **Cumbersome reimbursement**

While a device may meet FDA and/or EU regulatory requirements, it shouldn't be assumed that it will automatically meet insurance reimbursement criteria. Compliance may be just one factor of many that payers will consider. Other considerations include competitor coverage policies, clinical guidelines and physician support, employer or advocacy group demands, cost/benefit analyses and the results of health technology assessments (HTAs).

20 <https://www.marketsandmarkets.com/Market-Reports/ivd-in-vitro-diagnostics-market-703.html>

21 <https://medcitynews.com/2017/12/risk-based-ivd-regulations/>

22 [https://www.who.int/diagnostics\\_laboratory/evaluations/140513\\_risk\\_based\\_assessment\\_approach\\_buffet.pdf](https://www.who.int/diagnostics_laboratory/evaluations/140513_risk_based_assessment_approach_buffet.pdf)

23 <https://medcitynews.com/2017/12/risk-based-ivd-regulations/>

Of these factors, cost/benefit analyses and HTAs are where IVD and digital health companies have the greatest ability to influence payers.<sup>24</sup>

Insurers are basing payment on a values-based approach—measurable outcomes—that demonstrate an IVD’s worthiness. Notes one analyst in a 2017 article in Medcitynews.com:

“Whether your company’s IVD is a predictive test, one used for diagnosis or screening or is designed to monitor a patient’s condition, it is critical to have the right data to satisfy regulatory requirements. As health care moves toward value-based reimbursement models and away from fee-for-service schemes, the data generated by clinical studies can further be used to support coverage determination policies and reimbursement levels set by insurers. IVD manufacturers should be aware of this and plan their clinical studies accordingly.”<sup>25</sup>

Unfortunately, a lack of peer-reviewed studies and real-world evidence of the efficacy of specific IVD devices has contributed to decisions by insurers not to cover testing.

Companies anticipating insurance reimbursement for IVD tests can improve their odds of payment by publishing their own data. While it might sound counterintuitive—as if showing your hand to the competition—it could actually highlight a strength, vis-a-vis competitors in the same space whose product development may not be as robust or deliver as compelling results.

Consider, too, that insurers value testing that contributes to saving lives, not to mention health care expenses, through earlier and more accurate diagnoses. Published results that demonstrate this can

greatly influence reimbursement decisions. This goes a long way toward achieving U.S. FDA approval as well.

## OPPORTUNITY FOR IVD INNOVATION

Medical device innovation in the IVD market will continue to be influenced by the need for cost-effective, accurate, rapid and continuous health monitoring. Instrument and equipment designers are seeking to become part of the next generation of products that are essentially “plug and play,” reducing the time and expense of medical diagnoses. Health care professionals also want to be able to perform more tests faster in both every day and emergency situations.

Personal care products and preventative medicine have expanded the need for simple-to-use, but accurate, medical devices and single-use diagnostic materials are in high demand.<sup>26</sup>

Most recent advancements in the IVD market encompass assay technologies. Assays have been developed that can detect more indicators using lower levels of reagents, enabling earlier detection of diseases and increasing

the ability of patients or caregivers to manage home care. This is particularly relevant in the oncology industry, where early stage cancer detection has dramatically decreased mortality rates. For advanced cartridge-based systems, cartridges are becoming smaller and more sophisticated, which has generated a critical need for design experts with deep knowledge of material science.

As writer Mark Crawford explains in his 2016 MPO magazine article, “As equipment gets smaller and lighter in weight, so must components such as microfluidic chips, biochips and biosensors, in both polymers and glass. As the sample and reagent volumes decrease, the feature sizes of the devices also decrease, opening up new opportunities for laser micro manufacturing.”<sup>27</sup>

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24 <https://medcitynews.com/2017/12/many-ivd-companies-face-uphill-battle-payers-reimbursement/?rf=1>

25 <https://medcitynews.com/2017/09/ivds-data-requirements-value-based-reimbursement-landscape/?rf=1>

26 [https://www.mpo-mag.com/issues/2016-11-01/view\\_features/ivd-market-diagnosis](https://www.mpo-mag.com/issues/2016-11-01/view_features/ivd-market-diagnosis)

27 [https://www.mpo-mag.com/issues/2016-11-01/view\\_features/ivd-market-diagnosis](https://www.mpo-mag.com/issues/2016-11-01/view_features/ivd-market-diagnosis)

3-D printing is an emerging technology that enterprising medtech entrepreneurs are considering today and preparing for the future. While not yet “ready for prime time” in the clinical or laboratory environment, it’s become an essential tool for prototyping and testing new design concepts with lightning speed.

### **Necessity Is the Mother of Invention**

The need for further innovation in this growing market is still very strong. New design and development will continue to be pushed by cost-control initiatives that result in faster approaches to disease detection and management, drug therapy monitoring and even wellness management. Innovation will also continue to transform large, expensive instruments into tabletop and handheld units—especially in next-gen sequencing, molecular diagnostics and point of care—taking IVDs from hospital, to physician, to home.

While the IVD market offers some wide ranging opportunities, there are still many unknowns when it comes to medical device innovation. Too little market intelligence, few case studies, inadequate definitions of product specifications—and as much as an 18 to 24-month lead time for development, regulatory approval and commercial scale-up—could thwart some of the best ideas from breaking into the marketplace. Startups and growth-focused companies seeking to establish a foothold may find an easier route to by partnering with more established industry players.

## **DRIVING INNOVATION TO MARKET FASTER**

Benchmark is fully engaged in the IVD market in both North America and Europe and has helped numerous customers design and develop new or reengineered devices through a customer-focused approach that produces real results.

Through a range of [Medical Creative Workshop](#) sessions, Benchmark offers a means to help IVD companies capitalize on medical device innovation in a more compressed time frame than conventional approaches.

Focused on key inflection points along the product life cycle, these unique workshops bring together engineering, science, medicine, industrial design, supply chain professionals and other subject matter experts to help companies realize their next great IVD concepts.

For growth-focused firms, particularly those new to the IVD market, these workshops supplement in-house knowledge with critical expertise and sound business leadership, as well as the experience to clear the path toward regulatory approval.

Partnering with Benchmark helps companies navigate the landscape more effectively and keeps cutting-edge IVD development on track to meet this exciting and still evolving market.

To find out more about Benchmark’s unique approach to Creative Workshops, schedule your no-obligation scoping session, [Contact Us Today](#).

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