2019 In Vitro Diagnostics Industry Review

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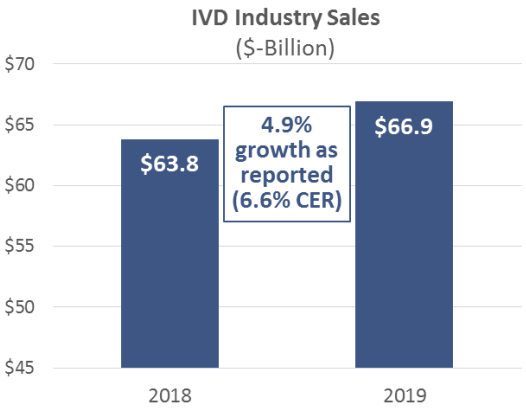
For the 9th year in a row, EAC is pleased to provide our snapshot of the global In Vitro Diagnostics (IVD) industry. Based on a deep dive analysis of 140 IVD companies, we have collected product information, revenue data, corporate announcements and other materials to build a model of industry size and growth by discipline, test location, and region.

Figure 1



In 2019, total IVD manufacturer sales increased 4.9% (as reported in dollars) to $66.9 billion (Figure 1). Due to continued strengthening of the US dollar, the IVD industry grew 6.6% at constant exchange rates (CER). This is higher than the 5.8% CER growth rate EAC projected last year and is attributable primarily to Whole Blood Glucose Monitoring (WBGM) which grew at a CER of 12.5% and contributed nearly $900 million in additional industry revenue.

Excluding WBGM, the overall IVD industry growth rate was 5.8%, a respectable and healthy growth rate given that many segments of the industry are relatively mature and reimbursement pressures continue to impact many countries.

IVD Market by Discipline

Looking at the market by discipline, we see a range of growth rates from 2.5% to 12.5% (Table 1).

Table 1
IVD Market by Discipline (2019)

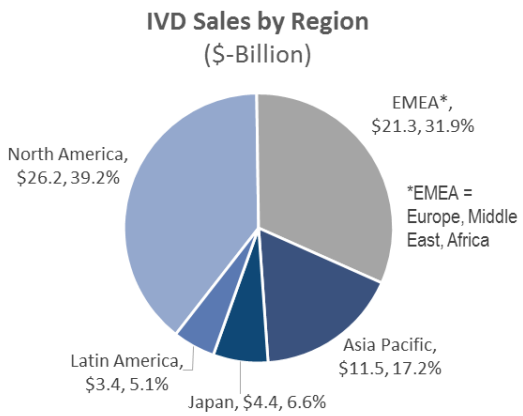
Test Discipline	Sales $-Million	% Growth 2018-2019 CER
Immunoassays	$16,619	6.2%
Whole Blood Glucose Monitoring	$9,217	12.5%
POC/POL	$7,166	6.1%
Clinical Molecular	$6,843	9.8%
Clinical Chemistry	$6,777	3.2%
Microbiology	$3,477	5.5%
Anatomic Pathology	$3,409	4.3%
Hematology	$3,374	6.4%
Coagulation	$2,168	4.4%
ImmunoHematology	$1,759	5.1%
Blood Screening Immunoassays	$1,675	4.9%
Central Lab Critical Care	$919	4.0%
Blood Screening Molecular	$880	3.1%
Clinical Flow Cytometry	$725	2.5%
Urinalysis	$673	5.5%
Other Products	$1,248	4.4%
TOTAL	$66,929	6.6%

- At 12.5% CER, WBGM was the fastest growing segment. Growth was driven once again by Continuous Glucose Monitoring (CGM) products, mainly from Dexcom with its G6 system and Abbott with its FreeStyle Libre system. The additional need for sensors and transmitters for CGM has driven up the cost of managing diabetes, thus translating to higher manufacturer revenues.
- Clinical Molecular continued to have one of the highest growth rates at 9.8%, due to rapid adoption of multiplex syndromic panels (e.g., BioFire's Respiratory/Blood Culture ID, GenMark's Respiratory Viral panel) as well as continuing growth in virology, tuberculosis, and other infectious disease tests.
- Point-of-Care (POC), comprising both hospital and physician office segments, showed modest growth of 6.1%, with growth mainly in the infectious disease area, driven by the increased adoption of higher priced CLIA waived molecular testing technologies for tests such as flu, strep and RSV.
- Central Lab Immunoassays, the largest IVD discipline at $16.6 billion, grew at a respectable 6.2% due to continuous expansion of test menus on automated platforms and further penetration into emerging markets.

IVD Market by Region

With 39.2% of the total market, North America remains the largest region. Asia Pacific (excluding Japan) continues the trend of showing the highest growth at 12.4% CAGR and now represents a higher percentage of the total industry pie (17.2% vs 16.1% in 2018) while EMEA is lower (31.9% vs 33.8% in 2018). As recently as five years ago, domestic IVD manufacturers in China were considered niche players focused only on the local market. Today, there are several China based companies with hundreds of millions in revenue and their reach extends to the global market through distributor relationships. Latin America had respectable overall IVD growth of 8.7% maintaining a 5.1% share of the market, despite the two largest countries, Brazil and Argentina, continuing with economic struggles and pressure on healthcare spending.

Figure 2



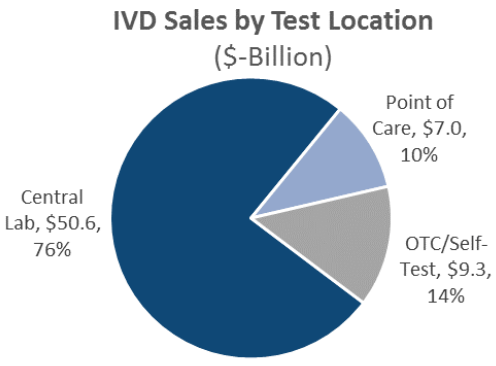
EAC notes the following economic factors impacting regional growth:

- In Europe, we see that the continued pressure on national healthcare budgets has led to further reductions in IVD spending, price pressures and laboratory consolidation.
- In Japan, growth continues in the low single digits as the government continues to exert strong pressure on healthcare spending through reimbursement cuts.
- In the US, continued pressure to contain healthcare costs, high insurance deductibles for patients, and further cuts to the laboratory reimbursement fee schedule have led to some softening of demand for routine IVD tests.

IVD Market by Test Location

The vast majority of IVD testing, 76%, is performed by central laboratories, defined as hospital labs, private reference labs, and blood bank labs (Figure 3). The POC market, representing 10%, has seen increased testing in urgent care centers, retail clinics and community clinics in the United States. Growth in the number of these testing locations has slowed recently but the number of visits to these sites continues to grow. These POC settings provide limited services but they do offer some on-site testing, predominantly urinalysis, glucose, pregnancy and acute respiratory infection tests for influenza virus, RSV and Group A Strep. Finally, consumer testing – either physician directed or over-the-counter (OTC) – represents a growing portion of the IVD market at 14%, with the bulk of this being self-testing for diabetes. Market dynamics for OTC/Self-Testing vary by country with some countries now pushing for broad adoption of HIV home test kits.

Figure 3

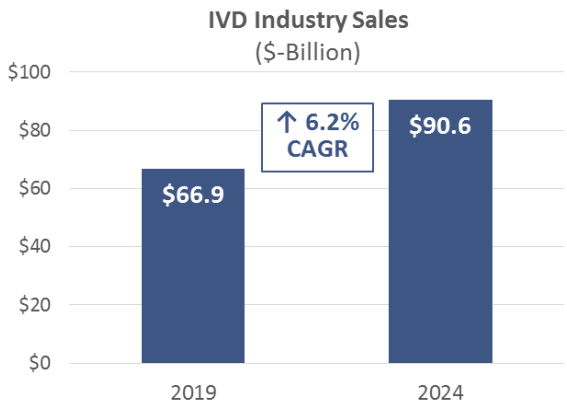


Some pregnancy testing shifted into the OTC category and some WBG shifted into Point of Care for bedside testing.

Industry Forecast

Overall, EAC predicts 6.2% CAGR during the next five-year period (assuming constant exchange rates), with the IVD market exceeding $90 billion in 2024 (Figure 4). WBGM, Clinical Molecular, Immunoassay and POC/POL will remain the key engines of growth in the industry.

Figure 4



This forecast comes amid considerable uncertainty with the recent arrival of the COVID-19 pandemic. At this time, it is difficult to predict the long term 5 year impact of COVID-19 on the entire IVD market. In the near term, especially 2020, COVID-19 has resulted in tens of millions of molecular PCR tests, and to a lesser extent serologic COVID antibody tests. Dozens of IVD manufacturers have quickly developed new COVID-19 tests to take advantage of this opportunity. At the same time, the COVID-19 pandemic has led to a temporary sharp decline in many routine IVD tests as elective medical procedures and routine doctor visits are delayed. The time frame for a return to normal IVD testing patterns is unknowable at this time. It seems more likely than not, that routine IVD testing will rebound in the 2nd half of 2020, at least partially. EAC has made the assumption that COVID-19 vaccines and anti-viral therapies will be available by Q2, 2021, thus enabling more normal IVD testing patterns. Also, in EAC's view, the need for COVID-19 tests, both molecular and serologic, is likely to continue through the forecast period, but at much lower levels once the pandemic is well contained.

In the Clinical Molecular testing space, COVID-19 testing should provide a significant boost, at least in the near term, as millions of COVID-19 PCR tests continue to be performed globally. Also, in the Clinical Molecular segment, the emergence of Next Generation Sequencing (NGS) as a clinical tool will have a significant impact in oncology, prenatal and genetic disease testing over the next five years. In the Immunoassay sector, there may be a significant near term boost from new COVID-19 serology tests. However, the clinical value of these serology tests remains uncertain at this time, thus making a test forecast difficult. In the WBGM segment, there appears to be ample opportunity for additional market penetration of CGM systems that will drive segment revenues. Finally, EAC also expects the POC/POL discipline to contribute to future growth given that POC molecular testing is experiencing rapid growth in volumes as well as the addition of new assays (e.g., COVID-19).

EAC believes the large US market will continue to be adversely impacted by the effect of the Protecting Access to Medicare Act (PAMA) on the reimbursement fee schedule. In 2019, there were lower payments for almost 65% of laboratory tests and many tests are set for further cuts in 2020. As an example, the reimbursement for a rapid molecular flu test for use at the point of care (e.g., Abbott ID NOW, Roche cobas Liat, Sekisui Silaris, Cepheid GeneXpert Xpress) decreased from $117 in 2017 to $96 in 2019, an 18% decrease.

Overall, despite a likely downturn in total testing volume in 2020 in response to the COVID-19 pandemic, EAC expects that there will be continued introduction of innovative tests and products and that demand for IVD testing will remain strong through the 5 year forecast period.

About Enterprise Analysis Corporation (EAC) and the IVD Industry Review

EAC's mission is helping diagnostic companies commercialize tests and technologies that positively impact healthcare and healthcare delivery. Our strategic consulting and market research services are designed to provide the data and insights that companies need to understand opportunities, navigate through resource decisions, and successfully commercialize new solutions.

Our tools include:

- Market audit and sizing
- Competitive landscape analysis
- Conjoint analyses for pricing and product design requirements/trade-offs
- Retrospective and prospective outcomes research
- Usability and workflow studies
- Voice of customer

We use these tools, along with deep IVD industry knowledge, to help companies answer critical questions:

- What is the clinical value of a new technology and what outcomes can be expected?
- What is the user acceptance of my solution in a laboratory and/or near patient setting?
- How competitive is my solution?
- What are the key product requirements, features, and trade-offs?
- What is my optimal pricing strategy?
- What is my market and/or growth opportunity?

As part of our contribution to the IVD industry, EAC annually conducts a deep dive analysis of the industry, collecting revenue data, product information, corporate announcements and other information to build a detailed model of industry size and growth for the prior calendar year. We also closely follow key segments and technologies, including (but not limited to): molecular testing, POC market, industry innovations, and advances in sepsis.

If you are interested in exploring how EAC can assist you with a "drill down" analysis into a market of interest, or to learn more about any of our tools and capabilities, please email Michelle Keane at mkeane@eacorp.com or call us at +1 (203) 348-7001.