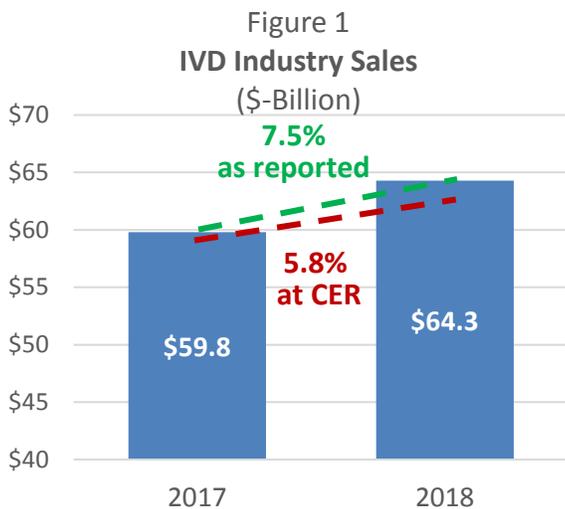


2018 In Vitro Diagnostics Industry Review

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Enterprise Analysis Corporation, EAC, has been tracking the in vitro diagnostics (IVD) industry since 2008, and this is the 8th publication of our In Vitro Diagnostics Industry Review.



In 2018, total IVD manufacturer sales increased 7.5% (as reported in dollars) to nearly \$64.3 billion. At constant exchange rates (CER), this translates to a 5.8% increase (Figure 1). This is somewhat higher than the 5.5% overall growth rate EAC projected last year.

A discipline that did better than expected is Whole Blood Glucose Monitoring (WBGGM), due to the very rapid market acceptance of Continuous Glucose Monitoring Systems. Excluding WBGGM, the overall IVD industry growth rate was 5.3%, slightly less than in the two previous years, mainly due to continued pricing pressures from reimbursement cuts, both in the U.S. and in Europe.

IVD Market by Discipline

By discipline, worldwide growth rates ranged from 2.6% to 9.2% (Table 1):

- WBGGM had been a drag on IVD growth in recent years despite seeing slight growth in the population of patients diagnosed with diabetes (3% CAGR since 2011¹). It had become a commoditized market, however, it has shown renewed growth starting in 2017. Sales have been driven by Continuous Glucose Monitoring (CGM) systems, mainly Dexcom, and more recently, Abbott, with its very successful new FreeStyle Libre system. The additional need for sensors and transmitters for CGM has driven up the cost of managing diabetes. WBGGM has become the fastest growing segment of the IVD market.
- Clinical Molecular continued to have one of the highest growth rates, 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 the hospital and physician office segments, showed particularly strong growth in the infectious disease area, driven by the increased adoption of new higher priced CLIA waived molecular testing technologies for tests such as flu, strep and RSV.

Table 1.
 IVD Market by Discipline (2018)

Test Discipline	Sales \$-Million	% Growth 2017-2018 CER
Immunoassays	\$15,900	5.0%
Whole Blood Glucose Monitoring	\$8,605	9.2%
Clinical Chemistry	\$6,839	4.1%
POC/POL	\$6,834	7.0%
Clinical Molecular	\$6,337	8.9%
Microbiology	\$3,360	5.9%
Anatomic Pathology	\$3,310	5.1%
Hematology	\$3,217	4.0%
Coagulation	\$2,195	5.2%
Immunochemistry	\$1,706	3.1%
Blood Screening Immunoassays	\$1,626	3.4%
Central Lab Critical Care	\$901	3.9%
Blood Screening Molecular	\$869	2.6%
Clinical Flow Cytometry	\$721	3.9%
Urinalysis	\$649	3.5%
Other Products	\$1,217	3.4%
TOTAL	\$64,286	5.8%

¹ CDC, National Diabetes Statistics Report, 2011, 2014 and 2017

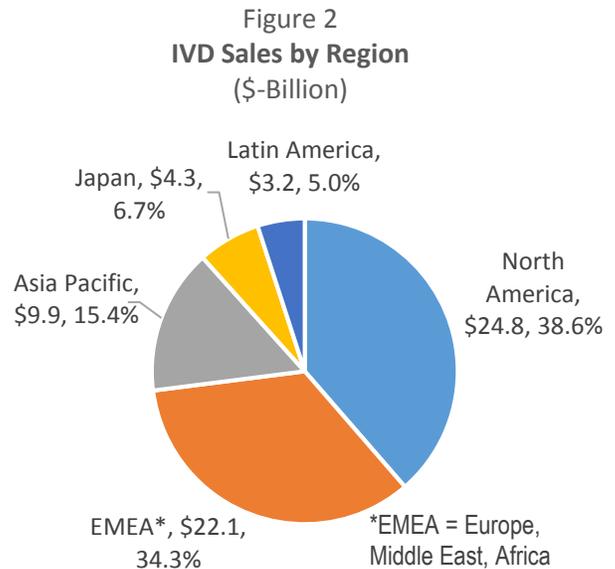
- Microbiology continued to show moderate growth, driven by increased adoption of mass spectrometry platforms, growth in microbiology lab automation systems, and rapid market penetration of latent TB tests from Qiagen and Oxford Immunotec.
- Immunoassays, by far the largest IVD discipline at nearly \$16 billion, had healthy growth due to continuous expansion of test menus on automated platforms and further penetration into emerging markets.

IVD Market by Region

Looking at the IVD market by region (Figure 2), North America remains the largest market while the smaller, but faster growing, Asia Pacific market is gradually gaining a larger share of the overall IVD market. Asia Pacific, followed by Latin American markets, are showing the highest growth at 10% CAGR, both of which have nearly doubled their share of the market over the past 10 years. As recently as five years ago, strong sales in just one region was enough for a company to be considered a market leader. Today, as consumer demand and competition from new market entrants (e.g., Mindray, Wondfo) increase strength across multiple markets is becoming almost necessary.

Despite better than expected IVD growth in 2018 in several disciplines, regional economic factors continue to suppress growth:

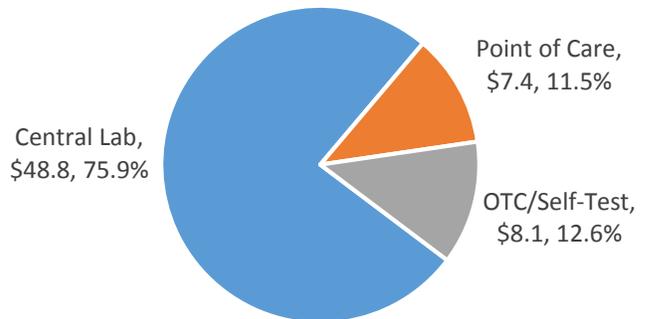
- In Europe, signs of economic improvement continue but cuts to national healthcare budgets have led to reductions in IVD spending, price pressures and further laboratory consolidation.
- In Latin America, several countries are just beginning to emerge from recession and GDP growth is only slowly improving.
- In Japan, reimbursement is reviewed regularly with the focus of reducing costs which leads to continued price pressure on IVD vendors.
- In the U.S., continued pressure to contain healthcare costs and high insurance deductibles for patients have led to some softening of demand for 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. The POC market, representing 11.5%, has seen increased testing in urgent care centers, retail clinics and community clinics. Growth in the number of 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, but also acute respiratory infection tests (flu and RSV) and strep. Finally, consumer testing – either physician directed or over-the-counter (OTC) – represents 12.6% of the IVD market with the bulk of this being self testing for diabetes.

Figure 3
IVD Sales by Test Location
 (\$-Billion)



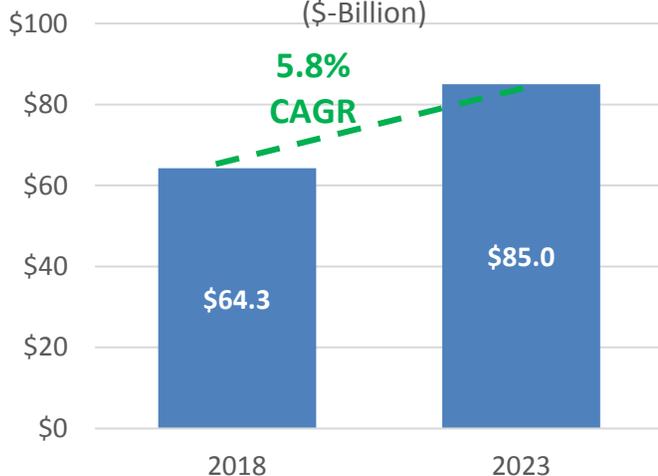
Some pregnancy testing shifted into the OTC category and some WBG shifted into Point of Care for bedside testing.

IVD Projections 2018-2023

Looking forward, the overall outlook for the IVD industry remains positive with continued growth expected through 2023. Macroeconomic factors favoring steady growth include longstanding trends such as an aging population, rising middle class in China and India, and improved laboratory productivity from new, innovative products and automated systems.

Two disciplines that are expected to drive growth in the future are Clinical Molecular (8.6% CAGR) and WBG (6.9% CAGR). In the molecular space, the emergence of Next Generation Sequencing (NGS) as a clinical tool will also make a significant impact in oncology, prenatal and genetic testing over the next five years. EAC also expects the POC/POL and the microbiology disciplines to significantly contribute to future growth of the total market.

Figure 4
IVD Industry Sales
 (\$-Billion)



On a negative note, EAC believes the large U.S. market will continue to be adversely impacted by the effect of the Protecting Access to Medicare Act (PAMA) on the reimbursement fee schedule, resulting in lower payments for almost 90% of laboratory tests in 2018, with many tests set for further cuts in 2019 and 2020. As an example, the reimbursement for a rapid molecular flu test intended for use at the point of care (e.g., Abbott IDNOW, Roche cobas Liat, Sekisui Silaris, Cepheid GeneXpert Xpress) has decreased from \$117 in 2017 to \$96 in 2019, an 18% decrease.

Overall, EAC predicts 5.8% CAGR during the next five-year period (assuming constant exchange rates), with the IVD market reaching over \$85 billion in 2023 (Figure 4).

EAC also closely follows companies and trends that we expect to have an impact on the industry. Some of the current trends we are watching include:

- Seamless connectivity and data management using tablets and telephone solutions that may alleviate the need for expensive implementation of middleware solutions
- Artificial Intelligence systems
- Potential assays such as those for:
 - Rapid antibiotic susceptibility testing (AST) and detection of resistant pathogens
 - Brain injury and mental health
 - Liquid biopsies
 - Companion diagnostics and personalized medicine to support expensive gene therapies
 - Immune system “host” response testing
- Utilization of smartphones for reading test results
- Clinical applications for sequencing technology
- Lastly, the microbiome is an area that holds a great deal of promise especially for the role it plays with infectious diseases



About EAC

EAC is a strategic consulting company serving diagnostic technology developers in the in vitro and in vivo domains, life science enterprises and pharma companies.

EAC has built a proprietary forecasting tool that is driven by a database of close to 140 of the largest in vitro diagnostics companies in the market today. EAC's **IVDMARKETREACH** is an interactive, customizable modeling tool that provides in-depth analysis of these companies. The tool uses historical revenue data and available corporate announcements to forecast public and private IVD company changes. It spans a broad range of disciplines reported by region, by segment and in summary. The tool also drills down into the POC/POL market, into the different disciplines covered, and the Molecular Diagnostics based infectious disease space.

Disciplines covered include:

- **Anatomic Pathology**
- **Blood Screening – Immunoassays**
- **Blood Screening – Molecular**
- **Critical Care**
- **Immunoassay**
- **Urinalysis**
- **Clinical Chemistry**
- **Clinical Flow Cytometry**
- **Whole Blood Glucose Monitoring**
- **Clinical Molecular**
- **Coagulation**
- **Hematology**
- **Immunochemistry**
- **Immunoematology**
- **Microbiology**
- **POC/POL**

*POC/POL includes cardiac markers, HbA1c, coagulation, hematology, chemistry, rapid immunoassay, critical care, urinalysis, and rapid molecular testing

EAC's clients who subscribe to the tool use it to:

- Identify market size and market shares in their served markets
- Project growth rates up to 10 years into the future (EAC provides projections for 5 years)
- Identify the primary and secondary players in each discipline
- Identify potential candidates for mergers, acquisitions or joint ventures
- View real time effects on market shares and revenues from changes in assumptions

EAC's IVDMARKETREACH is available as an annual subscription.

For pricing information or questions on the IVDMARKETREACH tool please contact:

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