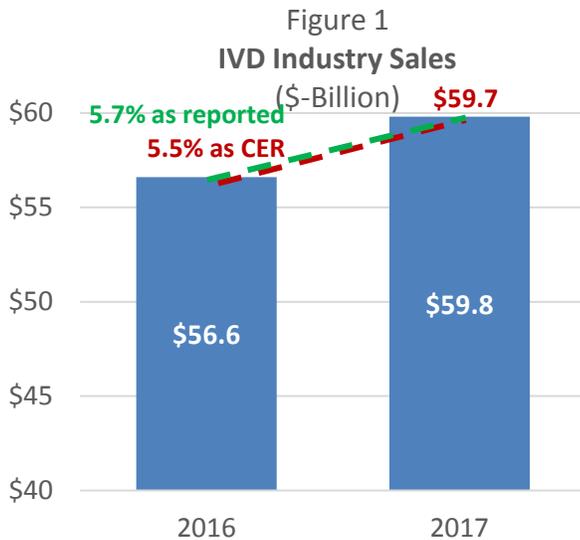


2017 In Vitro Diagnostics Industry Review

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In 2017, total IVD manufacturer sales increased 5.7%, (as reported in dollars) to nearly \$60 billion. At constant exchange rates (CER), this translates to a 5.5% increase (Figure 1). This is higher than the 5.1% growth rate EAC projected last year, driven by higher growth in Whole Blood Glucose Monitoring (WBGm), Microbiology, and Blood Screening Molecular.

Excluding WBGm, the overall IVD industry growth rate was 5.9%, compared to 5.7% in the previous year.

IVD Market by Discipline

The fastest growing disciplines in the worldwide IVD market in 2017 (Table 1) are described below:

- Clinical Molecular had the highest growth due to rapid adoption of multiplex syndromic panels as well as increased use of genetic disease and oncology tests.
- Microbiology showed strong growth, driven by rapid adoption of mass spectrometry platforms, growth in lab automation systems, and in blood culture systems, and rapid market penetration of new latent TB tests from Qiagen and Oxford Immunotec.
- Immunoassay, the largest IVD discipline, at nearly \$15 billion, had healthy growth due to continuous expansion of test menus on automated platforms and further penetration into emerging markets.
- Anatomic Pathology exhibited respectable growth, driven by advanced staining products from Roche Ventana, Agilent and Leica.
- Point-of-Care (POC), comprised of the hospital and physician office segments, showed particularly strong growth in the infectious disease area owing to the severe influenza season and the availability of new higher priced CLIA waived molecular testing technologies.
- WBGm has been a drag on IVD growth in recent years, but it showed renewed growth in 2017 driven by sales of Continuous Glucose Monitoring systems, mainly by Dexcom, and more recently, by Abbott with its FreeStyle Libre.

Despite better than expected IVD growth in 2017, regional economic factors prevented more robust growth:

- In Europe, signs of economic improvement continue but cuts to national health care budgets have led to reductions in IVD spending, price pressures and further laboratory consolidation.

Table 1
IVD Market by Discipline (2017)

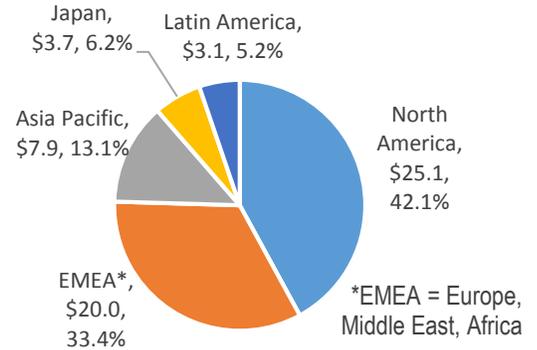
| Test Discipline | Sales \$-Million | % Growth 2016-2017 |
|--------------------------------|------------------|--------------------|
| Immunoassays | \$14,934 | 6.8% |
| Whole Blood Glucose Monitoring | \$7,727 | 4.0% |
| Clinical Chemistry | \$6,467 | 2.9% |
| POC/POL | \$6,344 | 6.3% |
| Clinical Molecular | \$5,683 | 8.5% |
| Microbiology | \$3,114 | 7.4% |
| Anatomic Pathology | \$3,110 | 6.4% |
| Hematology | \$3,048 | 4.7% |
| Coagulation | \$2,048 | 3.9% |
| Immunochemistry | \$1,624 | 4.2% |
| Blood Screening | \$1,545 | 5.3% |
| Immunoassays | | |
| Central Lab Critical Care | \$852 | 3.5% |
| Blood Screening Molecular | \$834 | 8.0% |
| Clinical Flow Cytometry | \$682 | 4.9% |
| Urinalysis | \$617 | 5.1% |
| Other Products | \$1,150 | 4.9% |
| TOTAL | \$59,779 | 5.7% |

- In Latin America, several countries are just beginning to emerge from recession.
- Japan continues its efforts to control health care spending by decreasing reimbursement rates periodically, which leads to centralization of IVD testing and price pressure on IVD vendors.
- In the U.S. continued pressure to contain health care costs, the rise of Accountable Care Organizations along with high insurance deductibles for patients has led to a softening of demand for IVD tests.

IVD Market by Region

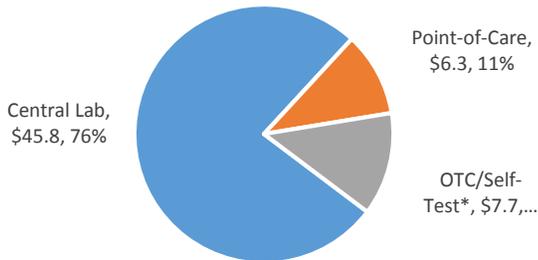
Looking at the IVD market by region (Figure 2), North America remains the largest market while the smaller but faster growing Asia-Pacific market is gradually gaining a larger share of the overall IVD market at the expense of other regions.

Figure 2
IVD Sales by Region



IVD Market by Test Location

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



* Some pregnancy testing shifted into the OTC category and some WBG shifted into Point-of-Care.

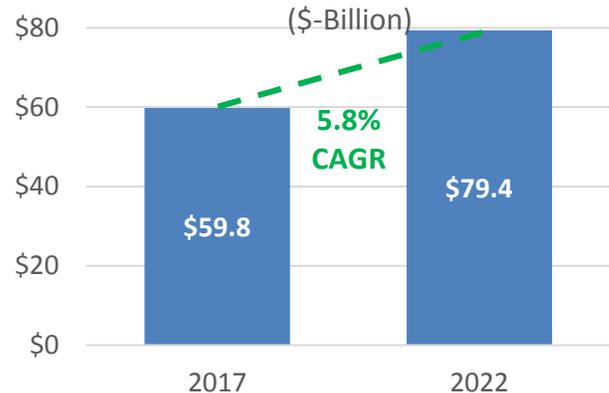
The vast majority of IVD testing (76%) is performed by central laboratories, defined as hospital labs, private reference labs, and blood bank labs. The POC market, representing 11%, has seen increased testing in urgent care centers, retail clinics and community clinics. Finally, consumer testing – either physician directed or over-the-counter (OTC) – represents 13% of the IVD market, down from 16% 5 years ago when WBG was in the midst of a steep sales decline.

IVD Projections 2017-2022

Looking forward, the overall outlook for the IVD industry remains positive; continuously improving through 2022. Macroeconomic factors favoring steady growth include longstanding trends such as an aging population, rising middle class in BRIC countries, and an improving global economic environment.

Two disciplines that are expected to drive growth in the future are Clinical Molecular (8.3% CAGR) and POC (6.5% CAGR). 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 recent growth of WBG will continue and significantly contribute to future growth.

Figure 4
IVD Industry Sales (\$-Billion)



On a negative note, the large U.S. market could be adversely impacted starting in 2018 by the new Protecting Access to Medicare Act's (PAMA) effect on the reimbursement fee schedule resulting in lower payments for almost 90% of laboratory tests just in 2018 and continuing through 2020.

Overall, EAC predicts 5.8% CAGR during the next five-year period, with the IVD market reaching over \$79 billion in 2022, assuming CER (Figure 4). CAGR assumptions: 5.4% (2018), 5.9% (2020), 6.3% (2022).

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 135 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.

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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