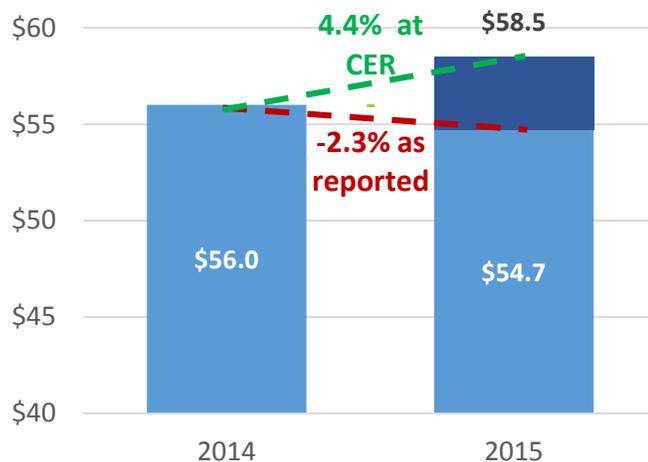


2015 In Vitro Diagnostics Industry Review

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In 2015, total IVD manufacturer sales decreased 2.3%, from \$56 billion in 2014 to \$54.7 billion, as reported in dollars. Due to the significant strengthening of the U.S. Dollar versus other currencies, especially the Euro and the Yen, this translates to a 4.4% increase to \$58.5 billion dollars, at constant exchange rates (CER).

Figure 1
IVD Industry Sales
(\$-Billion)



At 4.4% CAGR, world IVD industry growth in 2015 was identical to the growth rate that EAC had projected a year ago, in the 2014 IVD Industry Review. Excluding the whole blood glucose monitoring segment (WBGGM), the overall IVD industry growth rate was 5.0%, compared to 5.3% in the previous year. Some of the key factors that continued to slow down market growth in 2015 included:

- The relatively bleak economic situation in Europe continued to translate to pressure in health care spending with cuts in national

health care budgets and reimbursement cuts, for some tests, as well as a concentration of testing into fewer laboratories.

- The recession in Brazil and slowing economic growth in Asia had a negative impact on IVD spending as well.
- Diabetic WBGGM continued to disappoint with sales almost flat in 2015 vs. 2014. Private label and generic brands continued to displace more expensive name brands and new improved diabetes drugs have reduced the need for frequent monitoring in some patients. The only positive note in the WBGGM segment was the rapidly growing market for Continuous Glucose Monitoring, especially in the U.S.
- Continued pressure to contain health care costs and the rise of Accountable Care Organizations in the U.S. have caused doctors and hospitals to be more cautious in their test ordering practices.
- Japan continued to restructure the hospital sector by implementing reimbursement cuts resulting in a leveling off of test volumes and increased price pressures.

Despite these negative forces, there were several positive factors pushing IVD growth:

- The emerging markets -- particularly China, India and other Asia Pacific countries -- continued to expand at double digit growth rates, which compensated for the slow growth in the U.S. and in Europe.
- Clinical Molecular sales reached about \$4.7 billion and continued to be a key driver of IVD sales, with growth of 8.0%.

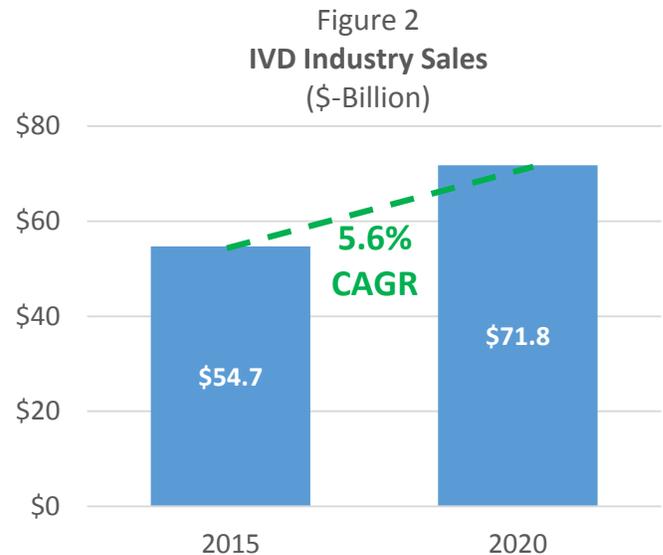
- The POC/POL segment grew 7.0%, to reach \$5.9 billion, driven by new product introductions and test menu expansion.
- Immunoassays, the largest IVD discipline, grew globally by 6.0%, reaching \$13.5 billion.
- Hematology, a \$2.8 billion market, saw a higher than expected 6.0% growth rate in 2015, driven by a 12.6% growth rate from Sysmex, the leader in this segment. Sysmex continues to gain market share in the U.S. and in Europe and is rapidly expanding its market presence in China (+25.8%) and in Asia-Pacific (+20.1%).
- Anatomic Pathology, another \$2.8 billion market, continued to have healthy growth at a rate of 4.8%, driven by advanced staining products (IHC, ISH).

Looking forward, the overall outlook for the IVD industry remains positive, although annual growth remains stuck in the 4-6% range. Factors favoring continued growth of the industry include:

- An eventual rebound in testing volumes and instrument purchases as the overall European and Latin American economic climates improve.
- The implementation of the Affordable Care Act (ACA) in the U.S. has increased access to health insurance for many Americans. As of February 2016, almost 13 million people had obtained health care through the Health Insurance Marketplace. EAC expects that the larger insured pool will result in more diagnostic tests being performed.
- An aging population in the major developed countries which will require more health care resources.
- A rising middle class in the BRIC countries that can afford access to health care.

- The emergence of Next Generation Sequencing as a clinical tool with significant potential in the oncology field.

Based on these factors, EAC predicts 5.6% CAGR during the next five-year period, with the IVD market reaching \$71.8 billion in 2020, assuming Constant Exchange Rates (Figure 2).



The 5.6% CAGR during the next 5 years assumes a 4.9% growth in 2016, improving to 5.3% in 2017 and reaching 6.2% by 2020. The improvements in overall growth rates are due to continued growth rates in Clinical Molecular (+8.0%) and POC/POL (+7.0%) as well as continued double digit growth rates in Asia-Pacific and Latin America.

IVD Market Segmentation

Table 1 shows the worldwide IVD market, by discipline, for 2015. The 5 largest segments, in rank order, are Central Lab Immunoassays, Whole Blood Glucose Monitoring (WBGGM), Central Lab Clinical Chemistry, POC/POL and Clinical Molecular. However, the fastest growing segments in the past year were Clinical Molecular (8.0%), POC/POL testing (7.0%), Central Lab Immunoassays (6.0%), Hematology (6.0%) and Anatomic Pathology (4.8%).

In contrast, the slowest growing segments were Blood Screening Molecular (0%), Whole Blood Glucose (0.8%) and Central Lab Clinical Chemistry (2.0%).

Interestingly, this is the fourth consecutive year where none of the market segments had double digit growth. This is partially due to the strengthening of the Dollar against the Euro and the Yen, which had the effect of reducing sales reported in U.S. Dollars.

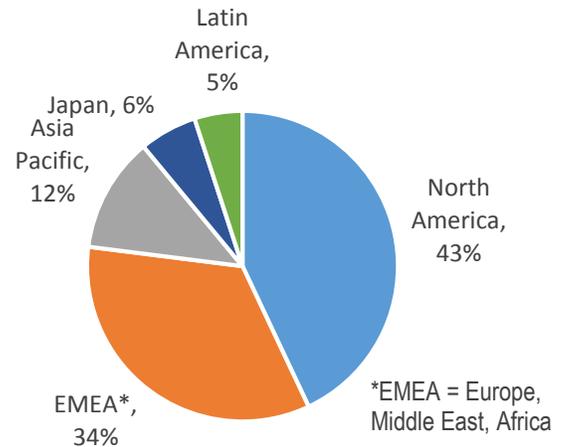
Table 1. IVD Market by Discipline (2015)

Test Discipline	Sales \$-Million	% Growth 2014-2015
Central Lab Immunoassays	\$13,546	6.0%
Whole Blood Glucose Monitoring	\$7,444	0.8%
Central Lab Clinical Chemistry	\$6,168	2.0%
POC/POL	\$5,924	7.0%
Clinical Molecular	\$4,718	8.0%
Anatomic Pathology	\$2,784	4.8%
Hematology	\$2,777	6.0%
Microbiology	\$2,763	4.0%
Coagulation	\$1,833	4.1%
ImmunoHematology	\$1,495	2.8%
Blood Screening Immunoassays	\$1,335	4.0%
Blood Screening Molecular	\$918	0.0%
Central Lab Critical Care	\$798	4.6%
Clinical Flow Cytometry	\$643	3.0%
Central Lab Urinalysis	\$515	4.6%
Other Products	\$1,036	4.0%
TOTAL	\$54,697	4.4%

Looking at the IVD market by region (Figure 3), North America remains the largest market at \$23.4 billion (43%), followed by Europe/Middle East/Africa at \$18.4 billion (34%), Asia-Pacific at

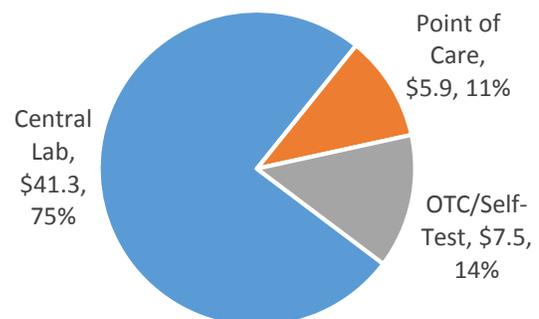
\$6.6 billion (12%), Japan at \$3.6 billion (6%) and Latin America at \$2.7 billion (5%).

**Figure 3
IVD Sales by Region**



Relative to the location of testing (Figure 4), the vast majority of IVD testing (75%) is still performed in central laboratories, defined as hospital labs, private reference labs, and blood bank labs. An increasing proportion is being performed at point-of-care locations in hospitals as well as physician offices and other decentralized sites such as retail and community clinics (11%). Finally, consumer testing – either physician directed or Over-the-Counter (OTC) – represents 14% of the IVD market.

**Figure 4
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.

About EAC

Enterprise Analysis (EAC) is a strategic consulting firm operating in Stamford, Connecticut since 1987. EAC serves clients in the U.S., Europe, and Japan, and conducts research in the major markets of the world. The company specializes in diagnostics, within: (1) clinical medicine, (2) pharma, for companion diagnostics, and (3) animal health.

EAC's **IVDMARKETREACH** is an interactive, customizable modeling tool that provides in-depth analysis of the top 100 in-vitro diagnostics companies in the market today. The tool is built using historical revenue data and educated projections for public and private IVD companies worldwide. It spans a broad range of disciplines across the diagnostics industry, organized by region, by segment or in summary. The tool can be customized by the user to change forecast assumptions, allowing companies to:

- Identify market size and market shares in any given discipline
- 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 and acquisitions
- View real time effects on market shares and revenues from changes in assumptions

Disciplines covered include:

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

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