

2013 In Vitro Diagnostics Industry Review

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On a global basis, 2013 was another difficult year for the IVD industry with sales increasing at 4.1% in Constant Exchange Rates, the slowest rate in

Figure 1
IVD Industry Sales
 (\$-Billion)



over a decade (3.2% in dollars).

Total IVD manufacturer sales increased year over year from \$52.8 billion to \$54.5 billion (Figure 1).

While industry growth was even lower than 2012, it is worth noting that if the whole blood glucose segment is excluded, the overall IVD industry growth was a more robust 5.7%.

Some of the key factors that placed a drag on market growth in 2013 were:

- The economic crisis in Europe continues, particularly Southern Europe, which led to cuts in national health budgets and reimbursement cuts for some tests that left European sales essentially flat.

- The once high growth market for diabetic whole blood glucose testing continued to decline, as reimbursement cuts reduced volume and drove test strip prices lower. 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.
- In the U.S., continued pressure to contain health care costs has caused doctors and hospitals to be more cautious in their test ordering practices. This was compounded by nearly a 3% cut in the CMS Clinical Laboratory Fee Schedule for 2013.
- Japan continues to restructure the hospital sector by implementing reimbursement cuts with resulting suppression of test volume and prices.

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

- The emerging markets, particularly China, India and Brazil continued to grow at double digit growth rates, which compensated for the slow growth in the U.S. and in Europe.
- Clinical Molecular sales reached almost \$4.2 billion and continued to be a key driver of IVD sales, with growth of 7.9%. Anatomic Pathology, a \$2.7 billion market, continued to have healthy growth, driven by advanced staining products (IHC, ISH), contributing to a 6.2% growth rate.
- Immunoassays, the largest IVD discipline, grew globally by almost 6%, reaching \$13.2 billion.

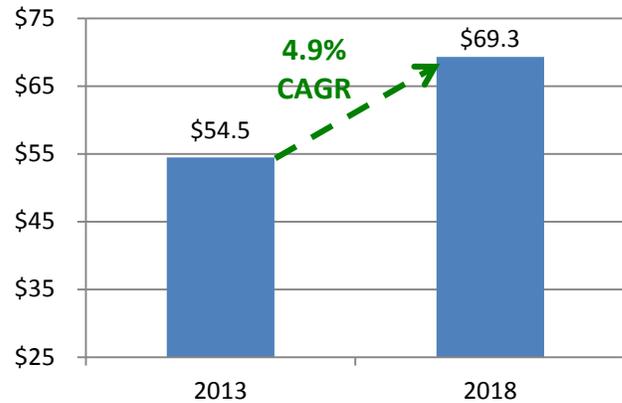
- The POC/POL segment grew 7.0%, to reach \$5.6 billion, driven by new product introductions and test menu expansion

Looking forward, the overall outlook for the IVD industry remains positive, though growth will be somewhat slower than the past decade. Factors favoring continued growth of the industry include:

- An eventual rebound in testing volumes and instrument purchases as the overall U.S. and European economic climate improves.
- The implementation of healthcare reform in the U.S. could provide an impetus for volume growth as 30-35 million Americans gain access to health insurance coverage. Latest statistics on the Affordable Care Act show that as of April 2014 at least 9.3 million more Americans have health insurance compared to September 2013.
- 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.

Based on the above factors, EAC predicts 4.9% annual growth with the IVD market reaching \$69.3 billion in 2018, assuming constant currency rates (Figure 2).

Figure2
IVD Industry Sales
 (\$-Billion)



The 4.9% CAGR during the next 5 years assumes a 4.0% growth in 2014, improving to 4.5% in 2015 and reaching 5.7% by 2018. The improvement in overall growth is due to continued double digit growth rates in Asia-Pacific and high single digit growth in Latin America.

IVD Market Segmentation

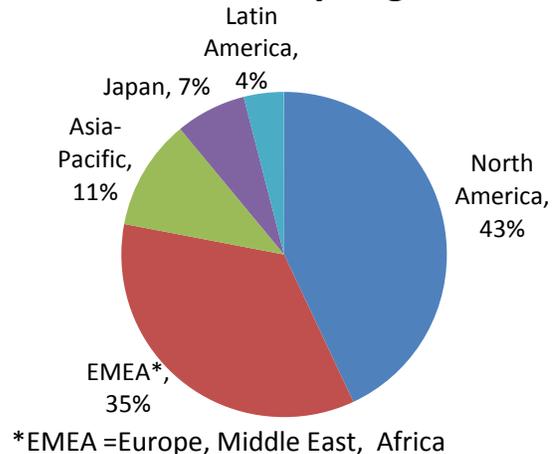
Table 1 shows the worldwide IVD market, by discipline, for 2013. The 5 largest segments, in rank order, are Immunoassays, Whole Blood Glucose, Central Lab Clinical Chemistry, POC/POL and Clinical Molecular. However, the fastest growing segments in the past year were Clinical Molecular (7.9%), POC/POL testing (7.0%), Hematology (6.3%), Anatomic Pathology (6.2%) and Immunoassay (5.9%)

In contrast, the slowest growing segments are Whole Blood Glucose (-3.9%), Immunohematology (3.0%), Molecular Blood Screen (3.9%) and Clinical Chemistry (4.2%). Interestingly, this is the second 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 which has the effect of reducing sales reported in U.S. dollars.

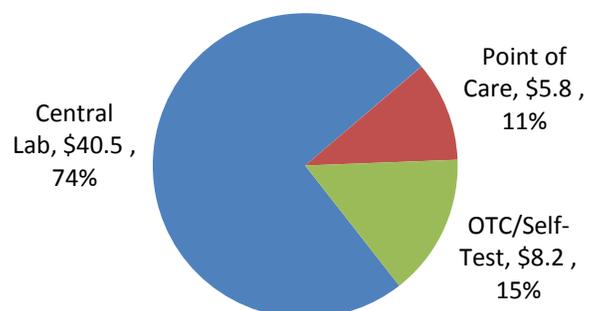
Table 1. IVD Market by Discipline-2013

Test Discipline	Sales \$-million	% growth 2012-2013
Central Lab Immunoassays	\$13,188	5.9%
Whole Blood Glucose Monitoring	\$8,424	-3.9%
Central Lab Clinical Chemistry	\$6,691	4.2%
POC/POL	\$5,600	7.0%
Clinical Molecular	\$4,161	7.9%
Microbiology	\$2,836	4.8%
Anatomic Pathology	\$2,676	6.2%
Hematology	\$2,602	6.3%
Coagulation	\$1,625	4.9%
Immuno-Hematology	\$1,510	3.0%
Blood Screening Immunoassays	\$1,359	4.3%
Blood Screening Molecular	\$785	3.9%
Central Lab Critical Care	\$737	4.3%
Clinical Flow Cytometry	\$678	5.3%
Central Lab Urinalysis	\$500	5.4%
Other Products	\$1,130	5.0%
TOTAL	\$54,502	4.1%

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 \$18.8 billion (35%), Asia-Pacific at \$5.9 billion (11%), Japan at \$3.9 billion (7%) and Latin America at \$2.5 billion (4%).

Figure 3
IVD Sales by Region


Relative to the location of testing, (Figure 4) the vast majority of IVD testing (74%) 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 15% 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 US, Europe, and Japan, and conducts research in the major markets of the world.

The company specializes in diagnostics, in: (1) human clinical medicine and life sciences to assist in the development and delivery of new technologies, (2) the intersection with pharmaceuticals for companion diagnostics, and (3) the health of production animals to improve productivity in the food chain.

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 data and educated projections for about 100 public and private IVD companies world-wide. 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**
- **Immuno-Hematology**
- **POC/POL**
- **Whole Blood Glucose Monitoring**

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