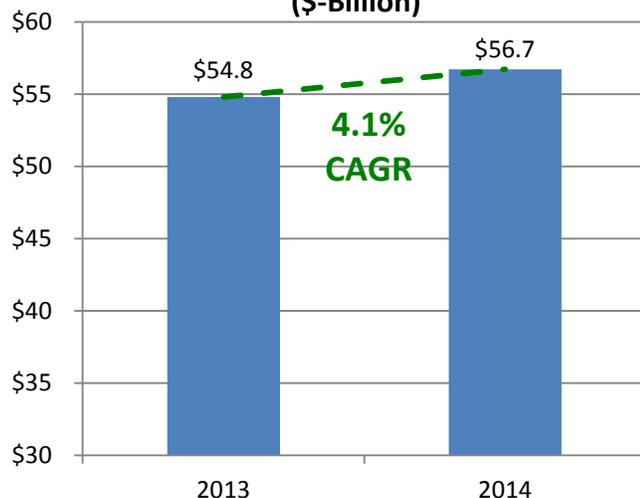


# 2014 In Vitro Diagnostics Industry Review

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On a global basis, 2014 was another difficult year for the IVD industry with sales increasing at 3.5% in Dollars or 4.1% at Constant Exchange Rates (CER).

**Figure 1**  
**IVD Industry Sales**  
 (\$-Billion)



Total IVD manufacturer sales increased year over year from \$54.8 billion to \$56.7 billion (Figure 1).

While total IVD industry growth in 2014 was comparable to that of 2013, it is worth noting that, excluding the whole blood glucose monitoring segment, the overall IVD industry growth was a more robust 5.3%.

Some of the key factors that placed a drag on market growth in 2014 included:

- The economic crisis in Europe, particularly Southern Europe, which led to cuts in national health care spending and reimbursement cuts for some tests and a concentration of testing

into fewer laboratories which left sales in this region flat to declining.

- 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 and the rise of Accountable Care Organizations has 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 higher:

- The emerging markets -- particularly China, India and Brazil -- 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 almost \$4.5 billion and continued to be a key driver of IVD sales, with growth of 7.5%.
- Anatomic Pathology, a \$2.8 billion market, continued to have healthy growth at a rate of 5.3%, driven by advanced staining products (IHC, ISH).

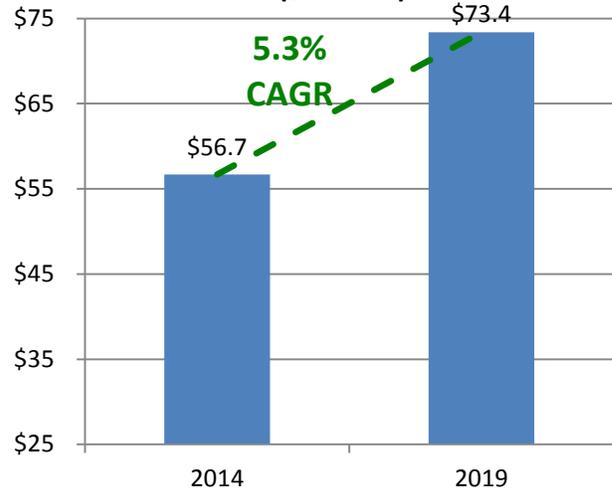
- Immunoassays, the largest IVD discipline, grew globally by 6.1%, reaching \$14.0 billion.
- The POC/POL segment grew 7.2%, to reach \$6.0 billion, driven by new product introductions and test menu expansion.
- Hematology, a \$2.7 billion market, saw a higher than expected 5.7% growth rate in 2014, driven by an overall 14.8% 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 (+29.4%) and in Asia-Pacific (+20.8%).

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 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 2015, almost 12 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.

Based on the above factors, EAC predicts 5.3% annual growth, with the IVD market reaching \$73.4 billion in 2019, assuming constant currency exchange rates (Figure 2).

**Figure 2**  
**IVD Industry Sales**  
 (\$-Billion)



The 5.3% CAGR during the next 5 years assumes a 4.4% growth in 2015, improving to 4.9% in 2016 and reaching 6.0% by 2019. The improvement in overall growth is due to continued double digit growth rates in Asia-Pacific and Latin America.

### IVD Market Segmentation

Table 1 shows the worldwide IVD market, by discipline, for 2014. The 5 largest segments, in rank order, are Central Lab Immunoassays, Whole Blood Glucose Monitoring, Central Lab Clinical Chemistry, POC/POL and Clinical Molecular. However, the fastest growing segments in the past year were Clinical Molecular (7.5%), POC/POL testing (7.2%), Immunoassays (6.1%), Hematology (5.7%) and Anatomic Pathology (5.3%).

In contrast, the slowest growing segments were Whole Blood Glucose (-2.5%), Immuno-Hematology (2.8%), Clinical Chemistry (3.0%) and Blood Screening Immunoassays (4.0%). Interestingly, this is the third consecutive year where none of the market segments had double digit growth. This is partially due to the strengthening of the

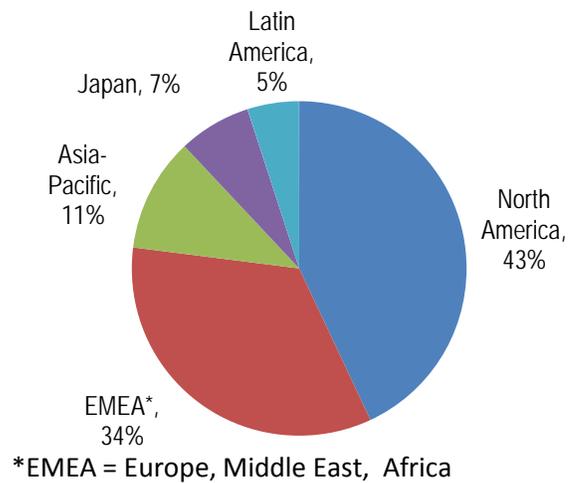
Dollar against the Euro which has the effect of reducing sales reported in U.S. Dollars.

**Table 1. IVD Market by Discipline-2014**

Test Discipline	Sales \$-Million	% Growth 2013-2014
Central Lab Immunoassays	\$13,947	6.1%
Whole Blood Glucose Monitoring	\$8,133	-2.5%
Central Lab Clinical Chemistry	\$6,823	3.0%
POC/POL	\$5,993	7.2%
Clinical Molecular	\$4,418	7.5%
Microbiology	\$2,989	4.3%
Anatomic Pathology	\$2,815	5.3%
Hematology	\$2,734	5.7%
Coagulation	\$1,752	4.5%
Immuno-Hematology	\$1,570	2.8%
Blood Screening Immunoassays	\$1,408	4.0%
Blood Screening Molecular	\$895	5.0%
Central Lab Critical Care	\$808	4.7%
Clinical Flow Cytometry	\$713	5.5%
Central Lab Urinalysis	\$523	5.0%
Other Products	\$1,193	4.0%
<b>TOTAL</b>	<b>\$56,714</b>	<b>4.1%</b>

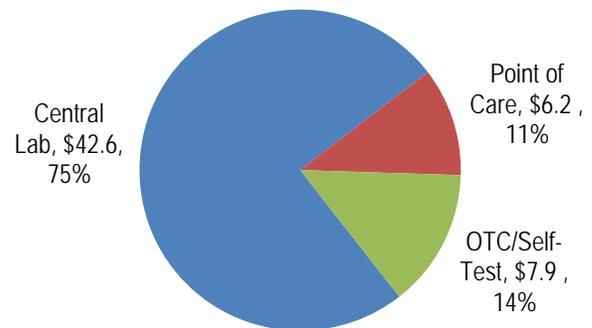
Looking at the IVD market by region (Figure 3), North America remains the largest market at \$24.4 billion (43%), followed by Europe/Middle East/Africa at \$19.4 billion (34%), Asia-Pacific at \$6.5 billion (11%), Japan at \$3.8 billion (7%) and Latin America at \$2.7 billion (5%).

**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**
- **Immuno-Hematology**
- **POC/POL**
- **Whole Blood Glucose Monitoring**

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