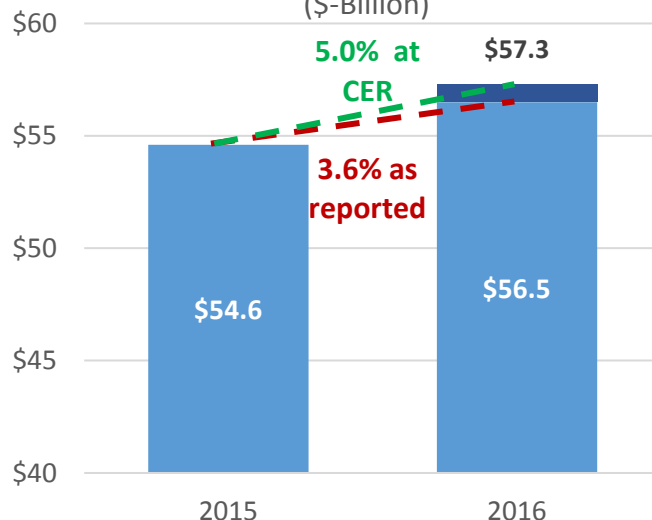


# 2016 In Vitro Diagnostics Industry Review

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In 2016, total IVD manufacturer sales increased 3.6%, from \$54.6 billion in 2015 to \$56.5 billion, as reported, in dollars. Due to the continuous strengthening of the U.S. Dollar versus other currencies, especially the Euro, this translates to a 5.0% increase to \$57.3 billion dollars, at constant exchange rates (CER). This is almost identical to the 4.9% growth rate EAC projected last year for 2016 using its **IVDMARKETREACH** modeling tool.

Figure 1  
 IVD Industry Sales  
 (\$-Billion)



Excluding the whole blood glucose monitoring segment (WBGGM), the overall IVD industry growth rate was 5.7%, compared to 5.0% in the previous year.

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 slower growth rates in the U.S. and in Europe.

- Clinical Molecular sales showed a 9.4% growth rate, the highest growth of any segment, having reached about \$5.1 billion. Clinical molecular testing continues to be a key driver of IVD sales.
- The POC/POL segment grew 6.6%, to reach \$6.1 billion, driven by new product introductions and test menu expansion.
- Immunoassays, the largest IVD discipline, grew globally by 6.3%, reaching \$14.0 billion.
- Microbiology, a \$2.9 billion market, continued to develop above market average at 6.3%, driven by rapid expansion of mass spectrometry utilization and increased automation.
- Anatomic Pathology, a \$2.9 billion market, continued to have healthy growth at a rate of 5.8%, driven by advanced staining products.

Among the factors contributing to a drag on IVD growth are:

- Many European countries continue to face pressure in health care spending, with cuts to national health care budgets, which leads to less money available for IVD spending.
- The ongoing recession in Brazil has slowed growth for IVD spending overall for Latin America.
- Diabetic WBGGM continues to be a drag on overall IVD growth, with sales nearly flat from 2015 to 2016. The major WBGGM vendors have had several consecutive years of declining sales. The only positive note in the WBGGM

segment is the rapidly growing market for Continuous Glucose Monitoring, especially in the U.S.

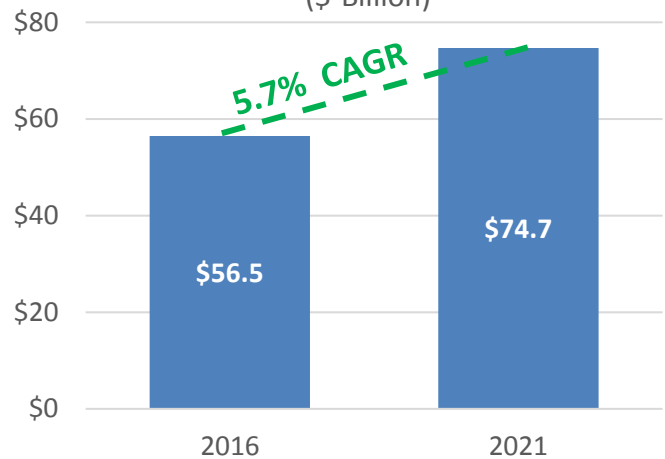
- Continued pressure to contain health care costs and the rise of Accountable Care Organizations in the U.S. have caused doctors and hospitals to be more cautious in their test ordering practices.
- Japan continues its efforts to control health care spending by decreasing reimbursement rates leading to an increase in centralization and rationalization of IVD testing.

Looking forward, the overall outlook for the IVD industry remains positive, with growth improving slightly for the 2016 – 2021 period. Factors favoring continued growth of the industry include:

- A gradually improving economic environment in Europe leading to increased testing volumes even as pricing pressure continues.
- 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 leading to increased demand for diagnostic tests.
- The emergence of Next Generation Sequencing as a clinical tool with significant potential in the oncology, prenatal and genetic testing fields.

Based on these factors, EAC predicts 5.7% CAGR during the next five-year period, with the IVD market reaching \$74.7 billion in 2021, assuming Constant Exchange Rates (Figure 2).

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



The 5.7% CAGR during the next 5 years assumes a 5.2% growth in 2017, improving to 5.4% in 2018 and reaching 6.3% by 2021. The improvements in overall growth rates are due to continued growth rates in Clinical Molecular (+8.6%) and POC/POL (+7.3%) 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 2016. The 5 largest segments, in rank order, are Immunoassays, Whole Blood Glucose Monitoring (WBGGM), Clinical Chemistry, POC/POL and Clinical Molecular. However, the fastest growing segments in the past year were Clinical Molecular (9.4%), POC/POL testing (6.6%), Immunoassays (6.3%), Microbiology (6.3%) and Anatomic Pathology (5.8%).

In contrast, the slowest growing segments were Blood Screening Molecular (0%), Whole Blood Glucose (0.5%) and ImmunoHematology (2.7%).

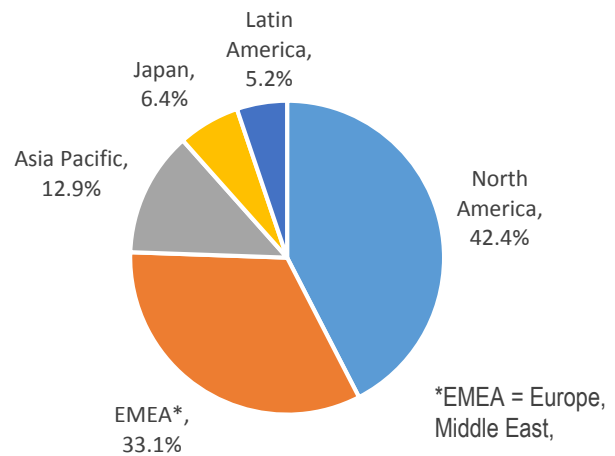
Interestingly, this is the fifth consecutive year where none of the market segments had double digit growth at CER.

**Table 1.  
IVD Market by Discipline (2016)**

Test Discipline	Sales \$-Million	% Growth 2015-2016 CER
Immunoassays	\$13,984	6.3%
Whole Blood Glucose Monitoring	\$7,430	0.5%
Clinical Chemistry	\$6,207	3.7%
POC/POL	\$6,078	6.6%
Clinical Molecular	\$5,118	9.4%
Anatomic Pathology	\$2,923	5.8%
Hematology	\$2,901	4.5%
Microbiology	\$2,899	6.3%
Coagulation	\$1,957	5.4%
ImmunoHematology	\$1,520	2.7%
Blood Screening Immunoassays	\$1,467	4.2%
Blood Screening Molecular	\$872	0.0%
Critical Care	\$823	4.5%
Clinical Flow Cytometry	\$650	4.0%
Urinalysis	\$567	3.5%
Other Products	\$1,097	3.9%
<b>TOTAL</b>	<b>\$56,493</b>	<b>5.0%</b>

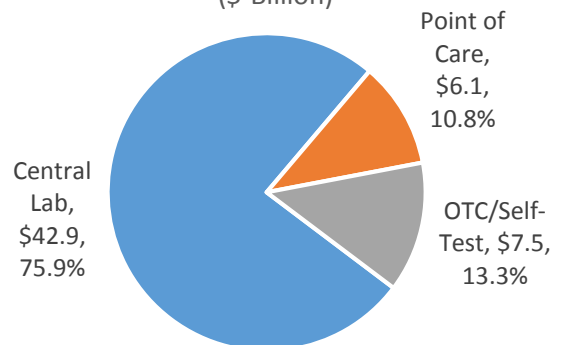
Looking at the IVD market by region (Figure 3), North America remains the largest market at \$24.0 billion (42.4%), followed by Europe/Middle East/Africa at \$18.7 billion (33.1%), Asia-Pacific at \$7.3 billion (12.9%), Japan at \$3.6 billion (6.4%) and Latin America at \$2.9 billion (5.2%).

**Figure 3  
IVD Sales by Region**



Relative to the location of testing (Figure 4), the vast majority of IVD testing (76%) 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 13% 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 120 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 analyze and assess scenarios of interest.

### 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**
- **ImmunoHematology**
- **Microbiology**
- **POC/POL\***

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

The summary data contained in this newsletter is just the tip of the iceberg. EAC's **IVDMARKETREACH** is available as an annual subscription. It provides valuable insights 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

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

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