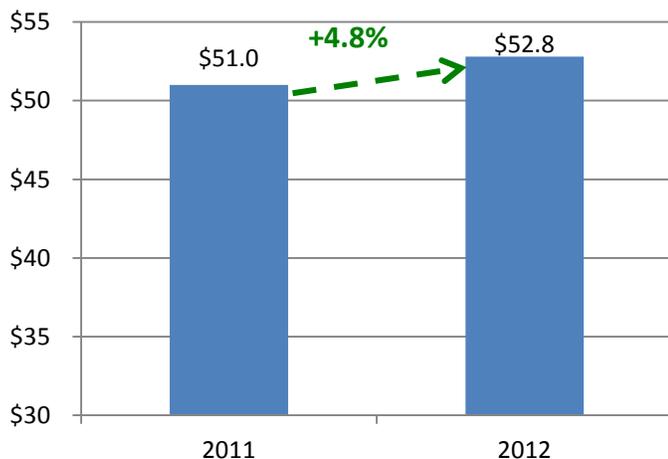


2012 In Vitro Diagnostics Industry Review

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On a global basis, 2012 was a difficult year for the IVD industry with sales increasing at 4.8% in Constant Exchange Rates, the slowest rate in over a decade (3.5% in dollars). Total IVD

Figure 1
IVD Industry Sales
 (\$-Billion)



manufacturer sales increased year over year from \$51.0 billion to \$52.8 billion (Figure 1).

While industry growth was somewhat lower than prior years, it is worthwhile noting that the IVD industry was valued at only \$20 billion in 2000. Thus, the annual growth rate in the succeeding 12 years has been 8.4% (excluding currency effects).

Some of the key factors that placed a drag on market growth in 2012 were:

- The economic crisis in Europe, 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 was completely flat as reimbursement cuts reduced volume and drove test strip prices lower and lower. Private label brands continued to displace more expensive name brands.
- In the U.S., continued pressure to contain health care costs is causing doctors and hospitals to be more cautious in their test ordering practices.
- Japan continues its practices of regular reimbursement cuts with resulting suppression of test volume and prices.

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

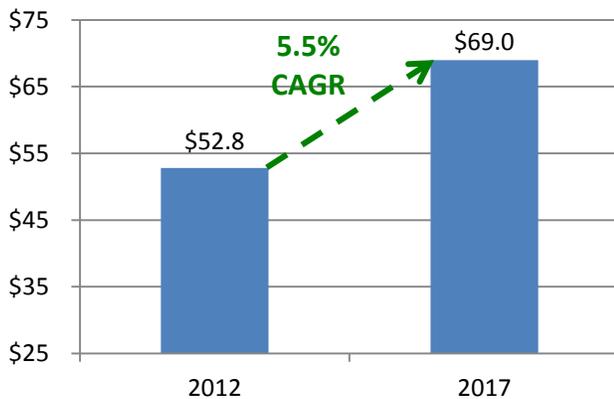
- The emerging markets, particularly China and India, continued with their double digit growth rates, which compensated for the slow growth in developed countries
- Clinical Molecular sales reached \$3.9 billion and continued to be a key driver of IVD sales with growth of 7.2% in 2012.
- Anatomic Pathology continued to show healthy growth with advanced staining products and digital pathology contributing to the 8.3% growth. Sales reached \$2.6 billion in 2012.
- Immunoassay, the largest IVD discipline, grew 6.7% to \$12.6 billion

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.
- 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 5.5% annual growth with the IVD market reaching \$69.0 billion in 2017, assuming constant currency rates (Figure 2).

Figure2
IVD Industry Sales
 (\$-Billion)



The 5.5% CAGR during the next 5 years assumes a 4.8% growth in 2013, improving to 5.1% in 2014 and reaching 6.2% by 2017. 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 2012. The 5 largest segments, in

rank order, are Immunoassay, Whole Blood Glucose, Clinical Chemistry, POC/POL testing, and Clinical Molecular Diagnostics. However, the fastest growing segments are Anatomic Pathology (8.3%), Clinical Molecular (7.2%), Point-of-Care (7.0%) and Immunoassay (6.7%).

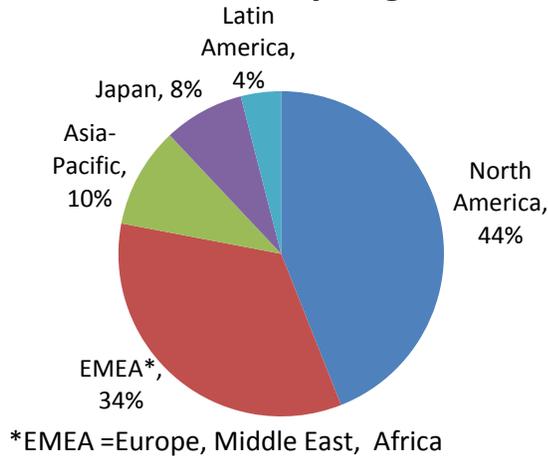
In contrast, the slowest growing segments are Urinalysis (4.1%), Whole Blood Glucose (0%), Clinical Chemistry (3.6%), Immuno-hematology (3.6%) and Blood Screen Immunoassay (3.5%). Interestingly, this is the first year in the past decade where none of the market segments had double digit growth. This 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-2012

Test Discipline	Sales \$-million	% growth 2011-2012
Whole Blood Glucose	\$8,816	0.0%
Central Lab Immunoassay	\$12,597	6.7%
Central Lab Clinical Chemistry	\$6,545	3.6%
POC/POL	\$5,346	7.0%
Clinical Molecular	\$3,855	7.2%
Microbiology	\$2,742	5.3%
Hematology	\$2,489	6.0%
Anatomic Pathology	\$2,551	8.3%
Coagulation	\$1,532	4.7%
Central Lab Critical care	\$697	4.5%
Blood Screen Immunoassay	\$1,324	3.5%
Blood Screen Molecular	\$767	3.9%
Immuno-Hematology	\$1,480	3.6%
Central Lab Urinalysis	\$470	4.1%
Flow Cytometry	\$641	5.4%
Other Products	\$962	4.0%
TOTAL	\$52,814	4.8%

Looking at the IVD market by region (Figure 3), North America remains the largest market at \$22.9 billion (43%), followed by Europe/Middle East/Africa at \$18.1 billion (34%), Asia-Pacific at \$5.4 billion (10%), Japan at \$4.3 billion (8%) and Latin America at \$2.1 billion (4%).

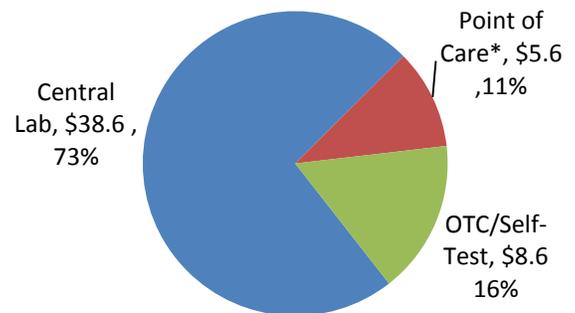
Figure 3
IVD Sales by Region



Relative to the location of testing, (Figure 4) the vast majority of IVD testing (73%) 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 16% 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 25 year old strategic consulting firm based in Stamford, Connecticut. 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 – Immunoassay**
- **Blood Screening – Molecular**
- **Central Lab Critical Care**
- **Central Lab Immunology**
- **Central Lab Urinalysis**
- **Clinical Chemistry**
- **Clinical Flow Cytometry**
- **Clinical Microbiology**
- **Clinical Molecular**
- **Coagulation**
- **Hematology**
- **Immunochemistry**
- **Immunoematology**
- **POC/POL**
- **Whole Blood Glucose Monitoring**

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