The Worldwide Market for In Vitro Diagnostic (IVD) Tests, 10th Edition

Description: The global IVD market is currently 60.5 billion dollars. The market for IVD reagents, kits, and instruments will grow, but in a complex pattern that involves challenges to growth in traditional categories and reliable large markets combined with opportunities in novel tests and growth nations. This is the finding of a comprehensive study on IVD, released every 2 years and analyzing every segment of IVD testing with trend analysis, market forecasts and company profiles. The 1,600-page study is used by the IVD industry for business planning efforts. A variety of factors are driving growth in IVD sales:

- Aging Population
- Disease Incidence, Notably Cancer and Infectious Disease
- New Biomarkers
- Increased Insurance and Spending in Emerging Nations

There are challenges to the IVD industry's growth. While the development of IVD product choices has been a boon for medical care, it also puts a great deal of pressure on physicians to make the right choices and for payers to pay for new technologies that may still be unproven. As an aging society begins to use more healthcare services, cost efficiency imperatives continue to put pressure on payers, providers and suppliers. As a result healthcare organizations have developed strict cost/performance and care guideline directives.

This report, The Worldwide Market for In Vitro Diagnostic Tests, has been updated for two decades in ten editions, keeping readers informed about developments in all areas of the IVD industry, around the world, in one volume. The 1,600-page report provides market size estimates and projections for the entirety of the clinical diagnostics testing market. It also tracks hundreds of competitors, notes significant partnerships, distribution deals and acquisitions and defines the market share situation for the in vitro diagnostic market and competitive analysis for many segments.

Important Segment Markets in the In Vitro Diagnostic Market

Published every two years, this report estimates the current in vitro diagnostics market size and forecasted market size to 2021 for defined segments of the IVD market and various sub-segments, including:

- Molecular Assays (Infectious Disease, Blood Screening, Inherited Diseases, Oncology, Pharmacodiagnostics, Tissue Typing, Prenatal)
- Clinical Chemistry and "Core Lab" Markets (including sub segment revenues for General Chemistries, Workstations, Analyzers Blood Gases, Urinalysis, Critical Care)
- Point-of-Care Testing (POC), (Professional and Self-Testing, Glucose Testing, Pregnancy Tests, drugs of abuse, HIV, H. pylori, Other, OTC/Self Total, Professional POC, Cardiac Markers, Drugs of Abuse, HbA1c, Pregnancy, Other)
- Microbiology and Virology by Test Type (Immunnoassays, ID/AST, Infectious Diseases - DNA; ID/AST: Panels and Reagents, automated; Panels and Reagents, manual; Blood Culture; Chromogenic Media; Rapid Micro; Supplies)
- Blood Banking (Grouping, Imunoassay Screens, NAT Screens)
- Tissue-Based Testing - Histology and Cytology (Pap, ISH, IHC, HPV)
- Infectious Disease Immunoassay Testing (Hepatitis, HIV, STDs, TORCH, Respiratory, Sepsis, Parasitology, Mycology, Others)
- Hematology
- Molecular Tests in Infectious Diseases (HAI, HIV, Hepatitis, GC/Chlamydia, Respiratory, Organism ID, Mycobacteria, TB, Others)
- Non-Infectious Disease Immunoassay Sales by Analyte Type (Cardiac markers, Tumor markers, Diabetes/HbA1c, Autoimmune, Allergy, Thyroid, Proteins, Anemia, Fertility, Therapeutic drugs, Tox/Drugs of abuse, Vitamin D)
- Coagulation Tests (Lab-Based, POC, Genetic Markers)
- Sequencing and Flow Cytometry

No other report provides similar understanding of the world diagnostics market. For each of the listed segments, 2016 market size, 2021 projection and compound annual growth rate is provided, as well as significant companies in the market and product innovations. The market data is put into a context with real
Regional and Country IVD Markets

In vitro diagnostics is a global market and the report reflects the global scope. Companies sell globally and think globally. Trends in one part of the world affect product decisions and company financial performance in others. Thus, this is a global report and the following regional and country overall IVD markets are included:

- US
- Europe
- Germany
- UK
- France
- Spain
- Italy
- Russia
- Netherlands
- Turkey
- Poland
- Canada
- China
- Japan
- Saudi Arabia
- Brazil
- Latin America
- Eastern Europe
- Emerging Markets
- Rest of World

The Worldwide Market for In Vitro Diagnostic Tests is a testament to the publisher's methodology. It is the result of months of painstaking work by an experienced IVD industry analyst, who has tracked hundreds of companies for developments, trends and financial results. This research is compiled along with the opinion, observations and insights of industry experts to produce an unparalleled vision of the industry as it is in 2016.

Companies in the IVD Market

The report contains hundreds of profiles. Top-tier companies such as Roche Diagnostics, Abbott, Siemens, Beckman Coulter, bioMérieux, Qiagen and Ortho Clinical Diagnostics are discussed at great length and hundreds of smaller companies are detailed. Modest IVD growth in developed countries, stronger growth in developing countries with a simultaneous shift from a preoccupation with infectious diseases to chronic conditions, is expected. Increased privatization of healthcare services throughout the world, developed and emerging economies included and thus increased pricing pressure on all devices including IVDs.

The report concentrates over a thousand pages on detailed and tiered profiles of companies in the in vitro diagnostics markets. The experience that this publisher has in this market is evident in its tiering and segmentation of companies.

Top Tier Companies: These are the dominant companies in IVD. For each company, extensive, discussion of recent financial performance is provided. Their main products are detailed and any significant company strategies, partnerships and acquisitions are considered:

- Abbott Diagnostics
- Alere Inc
- Beckman Coulter, Inc. / Danaher
- Becton, Dickinson and Company (BD)
- bioMérieux Inc.
- Bio-Rad Laboratories
Next Tier IVD Companies: growth-oriented companies that have significant presence in one or several areas are profiled and their new products and strategies discussed in the report. Among these:

Affymetrix Inc.
Cepheid
ERBA Diagnostics, Inc
DiaSorin S.p.A
Illumina
Luminex Corporation
Menarini Diagnostics.
Mindray Medical International Limited
Myriad Genetics
Perkin Elmer, Inc. (PE)
Quidel Corporation
Randox Laboratories Ltd
Royal Philips
TOSOH Corporation
Trinity Biotech
Wako Pure Chemical Industries

Specialist Companies: While these companies focus on one segment of the IVD market, they can often be dominant in the They are important to watch because they can often develop products in new areas of testing and move categories.

Molecular Specialists
Blood Banking Specialists
Point of Care Specialists
Prenatal Test Service Providers
Quality Control and Pretreatment Specialists
Coagulation Specialists
Histology and Cytology Specialists
Microbiology Specialists
IT Solutions Companies
CTC and Liquid Biopsy Specialists

Deep Understanding of IVD Market Trends

Published continuously for two decades, the report reflects the experience this publisher has in watching events in IVD and the emergence and reemergence of industry, technological and clinical trends. For instance:

- The revolution in bioinformatics is allowing clinical and traditional medical engineering to blend with components derived from the telecommunications, information and computer sciences industries. This opens new niche markets for POC test devices, which will have a positive impact on diagnostic testing.
- Getting information to care givers and patients is now not an added plus, it is a prerequisite of all lab operations. Thus the next 3-5 years will see an intensification of the healthcare industry’s emphasis on informatics, wireless communications, data networking and cost/effective healthcare delivery.
- In the area of test economics, outcomes based disease management establishes guidelines and directives for patient care. This is having a significant effect on the use of new tests, which have to prove their added value to patient care. It also affects how many and which tests are recommended and thus reimbursed for a specific disease group.

None of the above would be happening without significant forces in the market driving them. This updated
report presents the trends, technologies, customer needs and major suppliers with an eye on how they are shaping the IVD industry, including the following trends:

- Top 20 Companies and Niche Players 2012-2016
- Acquisitions in the IVD Market
- NGS, LC-MS and Other Novel Testing
- Lab Market Segmentation (Hospital, Independent, POLs)
- Emerging Markets
- Digital Technology, IT and Big Data
- Gene Editing
- Wearables
- Europe and Austerity
- Status of LDTs
- State of Biomarker Discovery
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- New Product Launches
- Near-Patient Testing
- DTC Testing
- New Testing Venues

Shifts in the Industry from 20 Years of Studying IVD

In addition to providing superior business planning tools, the following are among the many topics that the report tackles:

- The report contains a summary of the IVD industry from 1995 to the present. Amazingly a lot has changed - new tests and technologies have come to market but the very same major companies generate about 90% of product sales.
- Demographics: A number of world events bode well for the future of medical devices: an aging worldwide population and demand for new hospitals in developing countries. Increasing numbers of people between the ages of 45 and 75 years in the industrialized world consume more healthcare services such as heart and cancer tests. IVD companies are casting their nets in developing countries, where rising incomes and standards of living have sparked a new health consciousness and growing demands for quality medical care. The next five to ten years or so will see moderate and gradual change in IVD product markets.
- Changing Core Lab: Not 10-15 years ago most microbiology and anatomic pathology labs were tucked away somewhere in the basement. The major test areas similarly were separated by impenetrable walls. Those days are gone: imagine a centralized hospital lab where clinical chemistry, immunoassays, hematology, coagulation, urinalysis, some microbiology, some cytology tests are all performed in one room and often on instrumentation that are linked by an automated track line and all in the same room. More importantly by a lab information system that consolidates test results to an electronic patient record.
- Emerging Markets: High growth countries, primarily Saudi Arabia, Brazil, China and India experience market growth of double digits. This is fueled by privatization and health insurance initiatives by governments and employers. However this growth has a negligible effect to compensate for the lack of significant growth in major markets of Europe, Japan and the U.S.
- IVD-Focused Government Initiatives: New healthcare disease screening and health insurance initiatives proposed by the new U.S. administration under the guidance of President Barack Obama further bolster the use of IVDs, but continued economic difficulties has U.S. citizens forgo elective procedures because the co-payments may be somewhat unaffordable.
- Automation: There is also a lack of trained lab technologists, so there is a decreasing availability of human resources needed to run the more complex new set of molecular and histological tests and immunoassays. Therefore there has been a proliferation of test and lab automation tools launched that remove precious human resources from mundane pre-analytical and sample-tracking tasks to make time for more sophisticated ones. This phenomenon was once thought to be the purview of core lab biochemistry and immunoassays but automation is becoming a common feature in hematology, blood banking, microbiology, and histology. Demand for healthcare and thus diagnostic tests in all the major markets is driven by aging populations and increased incidence of conditions such as: cancer, diabetes, cardiovascular disease, arthritis and obesity. In light of the demand for these tests, they have been reformulated for automated analyzers where the cost per test is traditionally low.
- New Sampling: No more blood sampling: be prepared for an IVD world of breath tests for conditions that
includes respiratory infections, gastrointestinal disorders, cancer and even chronic diseases. Wearable patch sensors have been commercialized for glucose and vital signs monitoring; more and more applications are in development.

- Sequencing Enters the Clinic: In the 21st century, understanding a patient's personal genomic profile equips physicians with valuable information to better diagnose, predict, treat and prevent disease. Personalized medicine using genomic information improves patient outcomes and reduces healthcare costs and adverse drug reactions. The NGS data analysis market includes the market by product (software and services) and by applications such as whole genome sequencing, exome sequencing, targeted re-sequencing, de novo sequencing, RNA-Seq, ChIP-Seq and Methyl-Seq. As experience with sequencing intensifies, researchers are beginning to discover some of the ways in which the technology can be used. It is generally anticipated that whole genome sequencing is most appropriate for broad research looking for linkages between gene mutations and disease development.

Several market trends will have a significant impact on the evolution of diagnostics for diseases:

- Demand for healthcare and thus diagnostic tests in all the major markets is driven by aging populations and increased incidence of conditions such as: cancer, diabetes, cardiovascular disease, arthritis and obesity. In light of the demand for these tests, they have been reformulated for automated analyzers where the cost per test is traditionally low.
- The development of IVD product choices has been a boon for medical care. But it also puts a great deal of pressure on physicians to make the right choices and for payers to pay for new technologies that may still be unproven. As an aging society begins to use more healthcare services, cost efficiency imperatives continue to put pressure on payers, providers and suppliers. As a result healthcare organizations have developed strict cost/performance and care guideline directives. One of the ways to achieve these directives is to use medical and financial data to evaluate and prescribe the use of medical devices.
- What does all this mean for IVD marketers? Data, data and more data accompanied by the inevitable use of data to evaluate the medical usefulness and necessity of using a specific device. Medical device usage will be based on performance data, peer review research articles, contribution to patient outcome and a cost/benefit analysis. Wide dissemination of medical information in the media and on the Internet has spawned a more informed population that is prepared to seek out new technologies.
- There is also a lack of trained lab technologists, so there is a decreasing availability of human resources needed to run the more complex new set of molecular and histological tests and immunoassays. Therefore there has been a proliferation of test and lab automation tools launched that remove precious human resources from mundane pre-analytical and sample-tracking tasks to make time for more sophisticated ones. This phenomenon was once thought to be the purview of core lab biochemistry and immunoassays but automation is becoming a common feature hematology, blood banking, microbiology, and histology.
- These and many more topics are covered in The World Market for In Vitro Diagnostic Tests, 10th Edition. We publish other specific reports in molecular diagnostics, U.S. IVD, companion diagnostics and next generation sequencing and many others. Our entire library of reports are available via our Knowledge Center service at considerable savings and convenience for your company. Order your copy today.

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