
photo: Roche Accu-Chek

In Vitro Diagnostics

Industry Study with Forecasts for **2016 & 2021**

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In Vitro Diagnostics

Industry Study with Forecasts for ***2016 & 2021***

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INDUSTRY STRUCTURE

An aging society, greater incidence of diseases and disorders, and the extension of health insurance coverage by the Affordable Care Act of 2010, will all spur US gains for IVD products.

US demand to approach $25 billion in 2016

US demand for in vitro (IVD) diagnostic products is forecast to rise 6.1 percent annually to $24.7 billion in 2016. A growing volume of patient care activity, spurred by aging demographic patterns, a heightened incidence of diseases and disorders, and the extension of health insurance coverage by the Affordable Care Act of 2010, will underlie gains. Advances in technology, along with the introduction of new and improved reagents and instruments, will drive up demand in most IVD product segments.

Molecular diagnostic IVD products to grow fastest

Demand for molecular diagnostic products will grow the fastest among all IVD products due to their throughput, accuracy, and speed advantages in the detection of infectious diseases, tumors, and genetic disorders. The US market for these products will benefit from the introduction of new, high value-added polymerase chain reaction (PCR) and related tests to post double-digit gains through 2016. Over the same period, demand for blood testing reagents and instruments will rise 3.4 percent per year to $2.6 billion. Competition from new immunoassay and molecular tests will moderate growth in demand.

Uses in patient health screening and diabetes self-monitoring, coupled with the widening availability of integrated and point-of-care systems offering greater productivity and operating ease, will boost demand for clinical chemistry products. The expansion of test menus for therapeutic drug monitoring, infectious disease detection, and cardiovascular and cancer testing, along with advances in chemiluminescent and other advanced systems, will promote gains for immunoassay products. Companion diagnostics used to determine the safety and effectiveness of drug therapies will provide especially strong growth for these products.

Cellular analysis reagents and instruments will continue to generate sizable demand from uses in ovarian and breast cancer screening and HIV monitoring. By contrast, demand for anatomical pathology reagents and instruments will expand well above the overall average growth pace of IVD products as clinical and forensic laboratories upgrade testing capabilities. The market for microbiology products will rise at a comparatively slow pace as molecular diagnostic and immunoassay technologies penetrate cancer and infectious disease testing procedures.

Hospital laboratories to remain dominant market

Hospital laboratories will continue to be the largest and most diverse market for IVD products based on extensive inpatient, emergency, and post-surgical testing activities. The home health care segment will expand at the fastest pace, with the vast majority of demand remaining concentrated in diabetes monitoring products. Through upgrading and broadening testing capabilities, independent clinical laboratories will continue to form the second largest overall and second fastest growing market served by the IVD industry.

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Sample Text, Table & Chart

TABLE IV-7

HEART DISEASE TESTING IVD PRODUCT DEMAND BY TYPE, TECHNOLOGY, & CONDITION (million dollars)

Item	2001	2006	2011	2016	2021
Cardiovascular Conditions (million)					
$ IVD products/condition					
Heart Disease Testing IVD Products					
By Type:					
Reagents & Consumables					
Instruments & Systems					
By Technology:					
Clinical Chemistry Products					
Immunoassay Products					
Blood Testing Products					
Anatomical Pathology Products					
By Condition:					
High Cholesterol					
Arterial Diseases					
Myocardial Infarction					
Other Heart Conditions					
% heart disease testing					
IVD Product Demand					

SAMPLE TABLE

PRODUCTS

Clinical Chemistry Products

Clinical chemistry procedures measure levels of natural
and externally consumed compounds (i.e., therapeutic and ill
and toxicants) in the body for the detection of potential disea
other medical conditions, the assessment of general health st
the selection and monitoring of therapies. Commonly tested
include carbohydrates, electrolytes, enzymes, lipids, mineral
proteins, as well as therapeutic medicines. A related field, to
involves the detection and analysis of toxic substances in the
cluding poisons and drugs-of-abuse. Spurred by increasing a
in diabetes self-monitoring, pre- and post-hospital admission
basic patient health screening, therapeutic drug monitoring, f
investigations, and other uses, such as pregnancy and drugs-c
l chemistry products is projected t
billion in 2016.

s usually do not provide definitiv
diseases or other conditions. Abnormally
compounds in the body, or the presence
ces, can result from one or more of several
health problems. For example, a deficiency in the protein albumin might be caused by ascites, Crohn's disease, cirrhosis, hepatitis, inflammation, liver cancer, lupus erythematosus, malnutrition, or pregnancy. The detection and quantifying of such a deficiency only represent a starting point for further testing.

SAMPLE TEXT

The value of clinical chemistry to medical providers lie
pability of measuring several substances simultaneously. Co
cal chemistry panels contain reagents for testing a group of c
all of which are known to play a role in the onset of specific
conditions. For example, a typical liver function panel meas
of the protein albumin; the enzymes alanine aminotransferas

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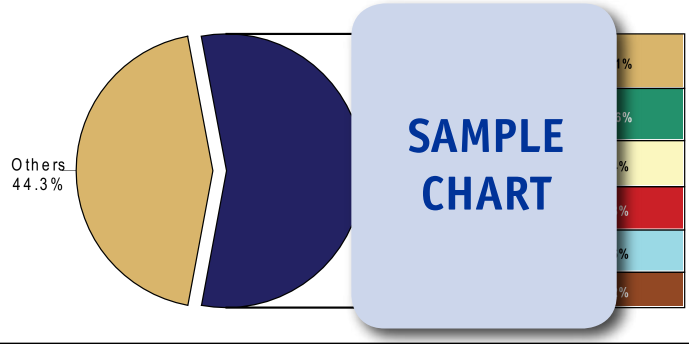
CHART VI-1

US IVD PRODUCT MARKET SHARE ($18.4 billion, 2011)



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Sample Profile, Table & Forecast

TABLE V-1

IVD PRODUCT DEMAND BY MARKET
(million dollars)

Item	2001	2006	2011	2016	2021
Number of IVD Testing Sites (000)					
000$ IVD products/site					
IVD Product Demand					
Hospitals					
Independent Clinical Laboratories					
Outpatient Facilities					
Home Health Care					
Physicians' Offices					
Other Markets					

SAMPLE TABLE

COMPANY PROFILES

Illumina Incorporated
5200 Illumina Way
San Diego, CA 92122
858-202-450
http://www.il

Revenues: $
US Revenues
Research and ... n (2011)
Employment

Key Products

SAMPLE PROFILE

Illumina is involved in the development and production of tools for the large scale analysis of genetic variation and function. The Company operates in two segments: Life Sciences and Diagnostics.

Illumina participates in the US in vitro diagnostic product industry through the Diagnostics segment, which is involved in developing, producing, and supplying molecular tests, systems, and services that facilitate earlier disease diagnosis, selection of appropriate therapies, and disease progression monitoring. The segment's in vitro diagnostic products include the BEADXPRESS molecular diagnostic system and general purpose reagents.

The BEADXPRESS system, which received FDA clearance in May 2010, consists of the BEADXPRESS Reader and VERASCAN software. The BEADXPRESS Reader provides simultaneous detection of several hundred analytes and is especially suitable for small, high throughput clinical laboratories. This instrument is a two color laser detection system that identifies the unique holographic codes inscribed in Illumina's VERACODE software. The BEADXPRESS Reader

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"IVD product demand in outpatient facilities is forecast to expand 6.0 percent annually to $2.7 billion in 2016. Growth will reflect advances in diagnostic technology, which will increase the performance capabilities and ease-of-use features of benchtop testing systems adaptable to point-of-care applications. Moderating influences on demand in this market will evolve from increased pressure on facilities to refer more complex diagnostic procedures to hospital and/or independent laboratories affiliated with their managed care networks."
--Section V, pg. 235-6

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Other Studies

World Home Medical Equipment

World demand for home medical equipment will rise 7.0 percent yearly to $28 billion in 2016. The US will remain the largest market while Brazil, China, India, and Russia will be among the fastest growing. Portable oxygen concentrators, remote patient monitors and home dialysis machines will offer some of the best opportunities. This study analyzes the $20 billion world home medical equipment industry, with forecasts for 2016 and 2021 by product, world region and for 15 major countries. The study also evaluates company market share and profiles industry players.

#2964 ....January 2013 .... $6300

World Wound Management Products

World demand for wound management products will increase 5.3 percent annually to $39.3 billion in 2016. China will be the fastest growing market. Developed countries, led by the US, will remain a much larger market than developing countries. Wound healing agents and wound dressings will be among the fastest growing products. This study analyzes the $30.3 billion world wound management product industry, with forecasts for 2016 and 2021 by type, world region and for 10 countries. The study also evaluates company market share and profiles industry players.

#2893 .... May 2012 .... $6100

Implantable Medical Devices

US demand for implantable medical devices is forecast to increase 7.7 percent annually to $52 billion in 2015. Orthopedic implants will remain the largest segment and be one of the fastest growing. Pacing devices will lead gains among cardiovascular implants. Other implants expected to do well include neurostimulators and drug implants. This study analyzes the $36 billion US implantable medical device industry, with forecasts for 2015 and 2020 by implant procedure, material and type. The study also evaluates company market share and profiles industry players.

#2852 .... March 2012................... $5100

Drug Delivery Products

US drug delivery product demand will rise 7.4 percent yearly to $134 billion in 2015. Parenteral products will grow the fastest, led by monoclonal antibodies and polymer-encapsulated medicines. Other types expected to do well include prefilled dry powder and metered dose brachytherapy implants, and implantable drug delivery products. This study analyzes the $93.8 billion US drug delivery system industry, with forecasts for 2015 and 2020 by material, product and application. The study also evaluates company market share and profiles industry players.

#2829 ....January 2012 .... $4800

Biologics

US demand for biologics is expected to grow 6.5 percent annually through 2015, driven by dramatic shifts in production technology and more targeted diseases such as cancer, diabetes and other serious medical conditions. Monoclonal antibodies will remain the largest category and be one of the fastest growing segments, outpaced only by hormones. This study analyzes the $74.3 billion US biologics industry, with forecasts for 2015 and 2020 by product and application. The study also evaluates company market share and profiles industry competitors.

#2792 .... September 2011................ $4900

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