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# *In Vitro* Diagnostics

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US Industry Study with Forecasts for **2013 & 2018**

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Study #2455 | March 2009 | \$4800 | 373 pages

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*Clinical chemistry and immunoassay will remain the top two IVD methodologies, while nucleic acid testing products will generate the fastest demand gains among IVD products.*

## US demand to grow 5.4% annually through 2013

US demand for *in vitro* diagnostic (IVD) products is forecast to increase 5.4 percent annually to \$23 billion in 2013. Clinical chemistry and immunoassay will remain the top two IVD methodologies, the former based on sales of personal blood glucose monitors and test strips and the latter due to the penetration of high value-added chemiluminescent products into infectious disease and drug testing markets. Nucleic acid testing products will generate the fastest demand gains among IVD products based on throughput, accuracy and speed advantages, especially in the detection of infectious diseases and cancer markers. Because of increasing blood glucose monitoring among diabetic patients, endocrine condition testing will remain the largest IVD application through 2013 and beyond.

## Evolving trends, care approaches to benefit most IVD products

Evolving epidemiological trends and patient care approaches will impact favorably on growth opportunities for most types of IVD products. The market for clinical chemistry reagents and instruments will benefit from an increasing number of diabetic patients engaging in self-blood glucose monitoring and the expanding use of general health screening in routine patient examinations. The



widening availability of chemiluminescent tests with inherent sensitivity and selectivity advantages will broaden applications for immunoassays in therapeutic drug monitoring, drugs of abuse detection and infectious disease testing.

Due to their ability to quantify heart attack and embolism risk prior to occurrence, hemostasis tests for D-dimer and other cardiac parameters will provide the best growth opportunities among IVD blood testing products. Demand for nucleic acid diagnostics will expand at a strong pace as next-generation PCR (polymerase chain reaction) and microarray technologies penetrate applications involving the analysis and charac-

terization of complex infections and tumors. DNA-based forensic, genetic and identity testing will comprise the fastest growing IVD application through 2013 as the vast potential of law enforcement and genetic screening markets begins to produce significant revenues. Among other IVD products, cellular analysis and anatomical pathology reagents and instruments will post favorable gains. Cellular analysis techniques will continue to dominate cervical cancer testing and penetrate additional cancer diagnostic applications. Anatomical pathology will remain the leading IVD technique for biopsy-based cancer and infectious disease detection.

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## Sample Text, Table & Chart

### IVD PRODUCTS

#### Instruments & Systems

Nucleic acid instruments and systems are used to create reagents, amplify patient samples, test for reagent-sample reactivity, and analyze results. Demand for these products is forecast to increase to \$1.5 billion in 2013. Technological advances are driving the development of upgraded equipment and convenience capabilities. The impact of a maturing market for PCR has created a large percentage of available laboratory markets. New biochip systems are expected to grow, but will serve more limited IVD applications due to competition from lower cost technologies.

**PCR Systems** -- One of the most advanced and versatile nucleic acid preparation systems is Roche Diagnostics' LIGHTCYCLER. The LIGHTCYCLER is a modified variable temperature block that separates and amplifies minute DNA particles from patient samples up to a million times to create probes detectable through laser-based or other imaging technologies. This system allows for real-time analysis of the amplification process to assure that enhanced probes match the structures of the starting DNA particles.

bioMerieux makes nucleic acid testing systems for detecting DNA or RNA gene sequences associated with various pathogens. Included in this line are NUCLISENS EASYQ automated systems for nucleic acid amplification and real-time molecular beacon detection; and NUCLISENS EASYMAG automated nucleic acid extraction equipment.

PCR analyzers utilize lasers to detect hybridization between amplified sample probes and enzyme-labeled reagent probes associated with a specific condition. Reagents are mixed with samples in the reaction chamber through the use of robotic arms. PCR has given rise to several

145

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**SAMPLE  
TEXT**

TABLE III-12

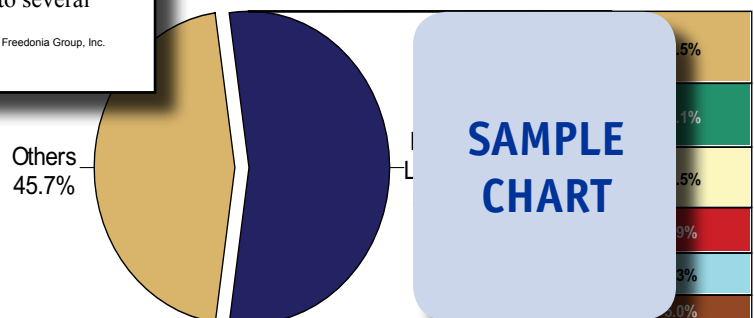
IMMUNOASSAY PRODUCT DEMAND BY APPLICATION  
(million dollars)

Item	1998	2003	2008	2013	2018
Immunoassay Product Demand					
Drug Testing:					
Therapeutic Drugs					
Illicit Drugs					
Infectious Disease Testing:					
Sexually Transmitted Diseases					
Other Infectious Diseases					
Endocrine Conditions					
Cancer					
Heart Disease					
Other					

**SAMPLE  
TABLE**

CHART VI-1

US IVD PRODUCT SALES,  
MARKET SHARE BY COMPANY, 2008  
(\$17.6 billion)

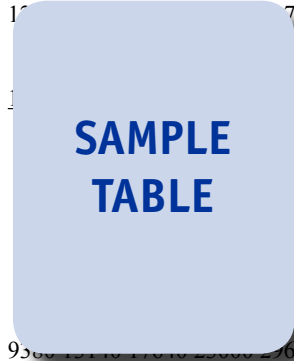


**SAMPLE  
CHART**

## Sample Profile, Table & Forecast

**TABLE IV-7**  
**CANCER TESTING --**  
**IVD PRODUCT DEMAND BY METHODOLOGY**  
**(million dollars)**

Item	1998	2003	2008	2013	2018
New Cancer Cases (000)	1,770				
000\$ IVD products/case					2.7
Cancer Testing - IVD Demand					4,600
Cellular Analysis					1,700
Microbiology					1,350
Immunoassays					1,000
Blood Testing					505
Nucleic Acid Testing					100
Other					80
% cancer testing IVD Product Demand	95				600



### COMPANY PROFILES

#### Meridian Bioscience Incorporated

3471 River Hills Drive  
 Cincinnati, OH 45244  
 513-271-3700  
<http://www.meridianbioscience.com>

Revenues: \$ (FY 2008)  
 Research and Development: \$ (FY 2008)  
 Employment: (FY 2008)

Key Products: (FY 2008) products, bulk antigens, anti...



Meridian Bioscience is a fully integrated life science company. The Company operates through three segments: US Diagnostics, European Diagnostics and Life Science.

Meridian Bioscience participates in the US *in vitro* diagnostic market via the US Diagnostics and Life Science segments. In FY 2008, the US Diagnostics segment generated revenues of \$88 million and employed 265. Through this segment, the Company develops and produces a broad range of rapid diagnostic test kits and related products at a plant in Cincinnati, Ohio. These products are mainly used in reference laboratories, hospitals and physicians' offices in the US and Canada.

Meridian Bioscience's rapid diagnostic test kits utilize various immunodiagnostic technologies -- such as enzyme immunoassay, immunofluorescence, particle agglutination and aggregation, immunodiffusion, complement fixation, and chemical stains -- to test samples of blood, urine, stool and other bodily fluids and tissues for markers of respiratory, gastrointestinal, viral, parasitic and other infectious diseases.

"IVD product demand in prostate cancer applications is projected to expand 4.3 percent annually to \$215 million in 2013. The condition's high survival rate, especially when detected in early stages, will promote growth by encouraging at-risk males to undergo periodic tumor screening procedures. Since the mid-1990s, the number of new prostate cancer cases has been declining due to the impact of healthier lifestyles and slow increases in the 65 years and older male population. Demand for IVD products in prostate cancer applications will benefit from ..."  
 --Section IV, pg. 233



**OTHER STUDIES**

**Home Medical Equipment**

US demand for home medical equipment will grow 5.5% annually through 2012. Cost-saving products such as CPAP machines, peritoneal dialysis equipment, IV pumps, ventilators and BP monitors will lead gains. Mobility devices, medical furniture and home safety equipment will continue to form sizeable markets. This study analyzes the \$7.7 billion US home medical equipment industry, with forecasts for 2012 and 2017 by equipment type. It also evaluates market share and profiles industry players.

#2447 ..... 01/2009..... \$4600

**Biochips**

US demand for biochip products and services will grow nearly 10% annually through 2012. Growth will be led by uses in drug discovery and epidemiological research, with protein characterization and analysis providing the fastest expanding technologies. Contract research and outsourcing will post the strongest gains among biochip services. This study analyzes the \$1.6 billion US biochips industry, with forecasts for 2012 and 2017 by product, service, application and market. It also evaluates market share and profiles industry players.

#2418 ..... 11/2008..... \$4600

**Cosmeceuticals**

Demand for cosmeceuticals in the US will increase 7.4% annually through 2012, driven by an aging population seeking to maintain the appearance of youth. Antioxidants will remain the largest chemical category while botanicals and enzymes stay among the best opportunities. Injectables and skin care products will register the fastest growth. This study analyzes the \$5.8 billion US cosmeceutical industry, with forecasts for 2012 and 2017 by product and chemical. It also evaluates market share and profiles major players.

#2413 ..... 10/2008..... \$4700

**Patient Monitoring Systems**

US demand for patient monitoring systems will grow 5.9% annually through 2012. Accessories will be the fastest growing segment, driven by blood glucose testing strips. Growth in the equipment sector will be based on strength in remote monitors that transmit data via the Internet or telephone, and in home use devices. This study analyzes the \$9 billion US patient monitoring system industry, with forecasts for 2012 and 2017 by product and market. It also details company market share and profiles major players.

#2323 ..... 04/2008..... \$4600

**Food Safety Products**

US demand for food safety products will grow 6.5% annually through 2012, driven by rising food safety concerns and new rules and regulations. Disinfection products will remain the largest segment and benefit from relatively new technologies such as ultraviolet and ozone equipment. Smart labels and tags will be the fastest growing products. This study analyzes the \$2.3 billion US food safety product industry, with forecasts for 2012 and 2017 by product and market. It also details market share and profiles major firms.

#2314 ..... 04/2008..... \$4500

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