New study finds:

- US demand for in vitro diagnostic (IVD) reagents and instrumentation is expected to reach $12.7 billion in 2005, reflecting average annual gains of 7.2 percent.

- Immunochemistry will remain the largest market, buoyed by advances in portable immunoassays and immunohistochemistry instrumentation.

- The US IVD market remains highly concentrated, with nearly 70 percent of products supplied by seven, large diversified -- Abbott Laboratories, Bayer, Beckman Coulter, Becton Dickinson, Dade Behring, Johnson & Johnson and Roche -- each of which is active in multiple technologies.
In Vitro Diagnostics, a new study from The Freedonia Group, provides you with an in-depth analysis of major trends in the industry and the outlook for product segments by type, condition and point-of-testing market -- critical information to help you with strategic planning.

This brochure gives you an indication of the scope, depth and value of Freedonia’s new study, In Vitro Diagnostics. Ordering information is included on the back page of the brochure.

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US demand for in vitro diagnostic (IVD) reagents and instrumentation is expected to reach $12.7 billion in 2005, reflecting average annual gains of 7.2 percent.

Immunochemistry will remain the largest market, buoyed by advances in portable immunoassays and immunohistochemistry instrumentation.

The strongest growth will be seen in the burgeoning nucleic acid testing market, as the proliferation of information derived from the human genome begins to yield commercial diagnostic protocols; cellular analysis will post robust gains as well due to rapid market penetration of and favorable reimbursements for automated Pap smear systems.

Large-scale clinical chemistry testing will decline modestly, as automation, broader test menus and keen competition continue to reduce unit prices and profit margins.

The US IVD market remains highly concentrated, with nearly 70 percent of products supplied by seven, large diversified -- Abbott Laboratories, Bayer, Beckman Coulter, Becton Dickinson, Dade Behring, Johnson & Johnson and Roche -- each of which is active in multiple technologies.

* Excluded from the scope of the study is coverage of standard biopsy and histology procedures, certain prenatal tests (e.g., amniocentesis, chorionic villus sampling) and diagnostic imaging.
### In Vitro Diagnostics Product Demand

(million dollars)

<table>
<thead>
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<th>Item</th>
<th>1990</th>
<th>2000</th>
<th>2005</th>
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<td></td>
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<td>1650</td>
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<td>Microbiology</td>
<td>480</td>
<td></td>
<td></td>
<td></td>
<td>2.3</td>
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<tr>
<td>Nucleic Acid-Based</td>
<td>137</td>
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<td>Other</td>
<td>454</td>
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Diagnostics Demand

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Sexually Transmitted Diseases

Hepatitis

Other

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Sexually Transmitted Diseases

Table - In Vitro Drug Testing Demand by Condition & Type

Hepatitis

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Company Profiles

Order form on last page
The Market Environment Sections discuss factors influencing in vitro diagnostics demand, including health expenditures, market trends and diagnostic methods.

This information provides you with an understanding and an analysis of the climate in which the in vitro diagnostics industry operates.

Acute & Chronic Medical Conditions

Clearly, the incidence and prevalence of medical conditions are the most direct determinants of IVD demand. As the US population grows, the overall incidence of acute and chronic conditions is exacerbated by the demographic trend toward elderly persons and the inability of medical science to develop effective cures for numerous chronic ailments. In light of these factors, the total number of acute and chronic medical conditions is projected to exceed 890 million in 2005, an increase of nearly 100 million from a decade earlier.

In contrast to acute conditions, the rate at which chronic conditions occur is more closely related to demographic trends among the elderly. Such conditions as arthritis and Alzheimer’s disease are generally not employed in the identification of chronic parasitic infections requiring immediate medical care (e.g., malaria).

Because human DNA molecules are long and contain 30,000 genes, detection of a particular gene or stretch of DNA was difficult prior to PCR, requiring unwieldy probes and tedious laboratory procedures. PCR circumvents these problems by allowing the one-billion fold amplification of a limited region of DNA. This is done in a PCR machine, which is essentially a variable temperature block. A PCR machine operates by first separating the two strands of DNA with heat, cooling

Polymerase Chain Reaction

Demand for polymerase chain reaction (PCR) instrumentation and reagents in IVD is expected to grow at an annual rate of 11.8 percent to $375 million in 2005. Gains will continue to be led by the development of diagnostic tests for a host of newly discovered genes as a result of the Human Genome Project. In addition to new genes, the use of single-nucleotide polymorphisms (SNPs) for use in research and in the burgeoning field of pharmacogenomics, whereby individual patients’ drug responses will be correlated with their genetic makeup. PCR will also benefit from cheaper, faster machines and from other expanding markets, including infectious disease diagnostics, paternity testing, forensic identity testing and transplantation testing. PCR is also used in conjunction with newer technologies, such as DNA microarrays. However, some markets for PCR -- life science research, for example -- have begun to exhibit signs of maturity.

Because human DNA molecules are long and contain 30,000 genes, detection of a particular gene or stretch of DNA was difficult prior to PCR, requiring unwieldy probes and tedious laboratory procedures. PCR circumvents these problems by allowing the one-billion fold amplification of a limited region of DNA. This is done in a PCR machine, which is essentially a variable temperature block. A PCR machine operates by first separating the two strands of DNA with heat, cooling
The Demand by Type Section provides demand for historical years and forecasts growth to 2005 and 2010.

This information helps you:

- Analyze your company’s growth potential in the industry.

- Outline your strategic plans for five and ten years out.

- Establish sales goals.

### Personal Monitoring - Blood Glucose

Demand for blood glucose monitors is forecast to increase at an annual rate of 12.3 percent, approaching $3 billion in 2005. Dynamic growth will be attributable to the commercial penetration of noninvasive monitors, the increasing number of recognized diabetics and educational initiatives promoting the beneficial effects of blood glucose monitoring. However, to the extent that noninvasive measurement devices fail to live up to their advertised advantages — that they are less painful, more convenient and nearly as accurate as finger stick devices — the glucose monitoring market could be dealt a severe setback.

**Growth Factors:** Blood glucose monitors will continue to account for the largest portion of the IVD device market devoted to a specific disease, and demand is expected to be fueled by several factors. Unlike large, expensive, conventional clinical chemistry analyzers, conventional blood glucose monitors usually sell for no more than $100 at retail outlets, while rapidly evolving technologies have enhanced consumer willingness to replace their monitors more frequently.

Since passage of the Balanced Budget Act of 1997, Medicare has provided coverage for up to 100 test strips and 100 lancets per month for all diabetics (regarding insulin use). Insulin users receive coverage for up to 100 test strips and 100 lancets per month, while noninsulin users receive coverage for half that; exceptions allow for additional test strip and lancet coverage subject to physician documentation of a need for more frequent testing.

Glucose monitor demand will be further stimulated for three other important reasons. First, despite increasing health consciousness, US diets remain high in fat and render the population susceptible to diabetes, a disease already affecting more...
This Section analyzes trends and considers the threats and opportunities for in vitro diagnostics by medical condition.

The information presented will help you:

- Focus your sales and marketing efforts on high growth areas.
- Propose new areas for development.

### IN VITRO DIAGNOSTICS DEMAND BY CONDITION

**Genetic Diseases - Diagnostics Demand**

Demand for reagents and instrumentation used in the in vitro diagnosis of genetic disease is forecast to rise at an annual rate of more than 21 percent. Robust growth will be attributable to the availability of the complete human DNA sequence, significant advances in disease gene expression and proteomics, and the advent of sophisticated, high-volume nucleic acid testing systems led by advances in DNA microarrays and nanotechnology. Potential obstacles to torrid growth in this segment include delays in FDA approval and drastic price reductions overwhelming volume growth; however, neither is anticipated.

Although simple genetic disease such as cancer and diabetes, genetic disease diagnostics are likely to benefit immediately from the emergence of large scale screening technologies, such as DNA chips harboring thousands of genes. This is because single gene defects offer chip manufacturers simpler test cases on which to refine their technology, while offering hospital and reference labs the potential to increase their throughput even further. Other advances, such as labs-on-a-chip will allow further miniaturization of nucleic acid diagnostic assays for genetic disease.

In many cases, single gene defects may harbor a large number of mutations, thereby making comprehensive genetic screening labor intensive. Thus, for example, cystic fibrosis (CF) -- a relatively common genetic disease affecting one in 2,500 newborns -- may be caused by hundreds of distinct changes within the same gene. The advent of DNA microarrays makes it possible to create thumb-nail-sized chips containing short DNA molecules representing each of these mutations. Screening then becomes a matter of hybridizing patient DNA samples with the disease chip in order to determine which mutation (or mutations) is present in the patient. Similar chips can be designed for diseases determined by other genetic mechanisms.

### TABLE: Colorectal Cancer: In Vitro Diagnostics Demand

(million dollars)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
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<tbody>
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<td>New Colorectal Cases (000)</td>
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<td>132</td>
<td>130</td>
<td>125</td>
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<td>% colorectal</td>
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<td>438</td>
<td>618</td>
<td>888</td>
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</table>

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Industry Structure

Gain a better understanding of your competition and analyze your company’s position in the industry with information about:

- market share
- regulatory factors
  - FDA regulations
  - CLIA regulations
  - HCFA & medicare reimbursement
- research & development trends
- competitive strategies
- mergers & acquisitions
- licensing & related agreements

INdUSTRY STRUCTURE

HCFA & Medicare Reimbursement

The HCFA is the key decision maker regarding federal reimbursement monies for laboratory tests; it is the agency which establishes all Medicare reimbursement policies. Pursuant to the Balanced Budget Act of 1997, the HCFA is at liberty to adjust fees for medical IVD tests, if it deems the fees charged for those tests.

In 1996, the HCFA ruled that Medicare would pay only for those tests in an automated chemistry panel (typically comprised of 19 to 22 tests) which are medically necessary. In response, the American Medical Association, working with the HCFA, designed four new panels of four to twelve “clinically relevant” tests; HCFA sanctioned Medicare reimbursements for these panels in 1998. Manufacturers, in turn, have responded by configuring their instruments to carry out these testing panels.

Periodically, the IVD and/or other participants in the medical device industry may appeal to the HCFA for more favorable reimbursement policies. For example, in July 2000, the Advanced Medical Technology Association (AdvaMed, formerly the Health Industry Manufacturers Association) appealed to the HCFA for Medicare reimbursement for certain medical devices employed during clinical trials. Similarly, in April 2000, AdvaMed issued a policy position paper criticizing current HCFA policies for IVD tests used in outpatient settings as leading to inadequate reimbursement, thereby denying patients needed services and having a chilling effect on technological innovations. AdvaMed has advocated for open decision-making processes, opportunities for appeal and review, the use of principled methodologies in setting payment rates, reimbursement for CLIA-waived tests comparable to regulated tests, and use of market data in setting and adjusting payment levels.
Company Profiles

The Profiles Section analyzes 29 companies active in the U.S. in vitro diagnostics market. These profiles represent a sampling or cross-section of the types of companies involved in the industry.

Divisions, subsidiaries, joint ventures, etc., are discussed under appropriate parent companies.

Sources for profiles included:

- Information provided by key staff members in the respective companies
- Annual reports
- 10-K reports
- Security analysts reports
- Corporate product literature

COMPANY PROFILES

Cytyc Corporation
85 Swanson Road
Boxborough, MA 01719
978-263-8000

Cytyc Corporation designs, develops, manufactures and markets sample preparation systems for medical diagnostics. The Company’s premier product is the THINPREP system, designed as an improvement over conventional Pap smear products for cervical cancer screening. THINPREP systems can also be used for general cytology preparation for use in non-gynecological cancer screening applications. In 2000, Cytyc had US sales accounted for 92 percent, or a total of $130 million. The Company employed 460 in 2000.

The Company’s THINPREP system, which allows for the automated preparation of cervical cell specimens on microscope slides for use in cervical cancer screening, encompasses such components as the THINPREP PAP TEST, THINPREP 2000 Processor, THINPREP 3000 Processor, and related reagents and supplies. The THINPREP system is based on Cytyc’s THINPREP PAP TEST, a unique method for the automated preparation of microscopic slides for cervical cell samples. The Company claims the THINPREP systems tests is the first test recognized by the US Food and Drug Administration (FDA) as significantly more effective than traditional Pap smears for the detection of early signs of cervical abnormalities in a variety of patient populations. Cytyc also believes that the accuracy of the test is improved by making the slide more representative of the patient’s clinical condition; improving preservation of the sample; standardizing the presentation of cells on the slide; and reducing the presence of mucus, blood and other obscuring debris. As of early 2001, the THINPREP PAP TEST was reportedly used in...
Companies Profiled

Abbott Laboratories
MediSense Products
Affymetrix Incorporated
Akzo Nobel NV
Applera Corporation
Applied Biosystems
PE Corporation
Perkin-Elmer Corporation
Tropix
Bayer AG
Beckman Coulter Incorporated
Becton Dickinson and Company
bioMerieux-Pierre Fabre SA
Biosite Diagnostics Incorporated
Carter-Wallace Incorporated
Wampole Laboratories
Chronimed Incorporated
Cytyc Corporation
Dade Behring Incorporated
Chimera Research & Chemical
MICROSCAN Incorporated
Point-Of-Care Technologies
Syva Corporation
Diagnostic Products Corporation
Enzo Biochem Incorporated
i-STAT Corporation
Johnson & Johnson
LifeScan Incorporated
Ortho-Clinical Diagnostics
Medisys plc
Hypoguard USA Incorporated
MEDgenesis Incorporated
Myriad Genetics Incorporated
Nova Biomedical Corporation
Olympus Optical Company Limited
QIAGEN NV
Radiometer Medical A/S
Roche Holding Limited
TCPI Incorporated
Health-Mark Diagnostics LLC
Technical Chemicals & Products
Thermo Electron Corporation
BioStar Incorporated
Trinity Biotech plc
Ventana Medical Systems Incorporated
Vysis Incorporated

In Vitro Diagnostics #1424

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Freedonia does not just collect and reprint data; Freedonia develops data. Our analysts thoroughly investigate an industry by extensively interviewing key industry participants and analyzing information from sources such as associations, government and trade literature. Once this research is complete, Freedonia establishes one set of forecasts. All writing, editing and forecasting is done in-house to assure quality and consistency. In cases where data does not exist, Freedonia develops the data based on input/output ratios, bills of materials and flow charts. The following chart summarizes Freedonia’s methodology:
The Freedonia Group, Inc. is a leading international industry study/database company.

Since 1985, Freedonia has published over 1,600 titles covering areas such as chemicals, coatings and adhesives, building materials, plastics, industrial components and equipment, health care, packaging, household goods, security, and many other industries.

Freedonia has produced a wide variety of titles, including:

- *Biochips: Products & Services*
- *World Health Care I: Developed Countries*
- *Pharmaceutical Chemicals*
- *In Vitro Diagnostics - Private Companies Report*

Because Freedonia is a reliable information source, our forecasts are cited in numerous publications such as *The Wall Street Journal, Genetic Engineering News* and *Chemical Week*.

**In-house operations**
Because all of our staff work at the same location, interaction between analysts and departments provides a strong system of checks and balances.

**Consistency**
Our Economics Group develops indicators that are used by all analysts. Therefore, every Freedonia study is based on a consistent set of economic assumptions (GDP, resident population, number of medical conditions, etc.)

**Reliable forecasts**
Because all of our forecasts consider the environment in which a product or industry is operating, as well as threats and opportunities to the market, Freedonia forecasts are reliable indicators of future performance.

**One-on-one interviews**
All studies are produced by conducting interviews with key industry participants and end-users.

**Proprietary electronic database**
Freedonia’s analysts can tap into an extensive in-house electronic database containing corporate literature (including private company information), trade publications, government reports and many other sources of information.

*In Vitro Diagnostics #1424*

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About Our Customers

Freedonia’s clients include major US and international companies in the manufacturing, services, consulting and financial sectors.

Typical purchasers of Freedonia studies:

- Key Executives
- Corporate Planners
- Market Researchers
- Financial Analysts
- Information Centers
- New Product Developers
- Merger & Acquisition Specialists

Since 1985 we have provided research to customers ranging in size from global conglomerates to one person consulting firms. More than 90% of the industrial companies in the Fortune 500 use Freedonia research to help with their strategic planning.

Some of Freedonia’s customers in the in vitro diagnostics market include: Abbott Laboratories, Akzo Nobel NV, Bayer AG and Johnson & Johnson.
Plant-Derived Chemicals
Demand for plant-derived chemicals in the US will grow over 7% annually. Growth will be driven by new plant-based pharmaceuticals and gains in the beverage market, where consumers are preferring higher natural flavor loadings. Botanical extracts will be the fastest growing segment, surpassing essential oils as the top product by 2010. This study analyzes the $2 billion US plant-derived chemical industry to 2005 and 2010 by product and market. It also presents market share data and profiles key companies.

World Health Care I: Developed Countries
Developed world health spending will grow 5.7% annually to US$3.3 trillion in 2004. Prescription drugs will lead gains based on treatment strategies favoring medication over primary health care. Hospital care will remain the largest market due to rising inpatient admissions and the more intensive and expensive nature of inpatient care. This study analyses health care spending to 2004 and 2009 by type in over 20 developed countries. It also profiles key pharmaceutical and medical product companies.

Amino Acids
The US market for amino acids will exceed 1.1 billion pounds in 2004. Methionine will remain the leading product as it continues to benefit from expanding poultry demand. Lysine will grow even faster as more of it is used in chicken and pig diets. Tryptophan will experience stellar growth as it continues to emerge as an animal feed additive on an industrial scale. This study analyzes the $1.2 billion US amino acids industry to 2004 and 2009 by type and market. It also evaluates market share and profiles key firms.

Biochips: Products & Services
Demand for biochips in the US will grow 43% annually, propelled by a range of uses including gene expression profiling, single-nucleotide polymorphism (SNP) identification and typing, and burgeoning proteomic applications. Technology trends will include higher density arrays as well as further penetration by protein and laboratory chips. This study analyzes the $268 million US biochip industry to 2004 and 2009 by type, application and market. It also evaluates market share and profiles key companies.

Pharmaceutical Chemicals
US demand for pharmaceutical chemicals will increase 7% annually. Bulk hormones and related agents will see the fastest growth based on new bioengineered compounds for cancer, diabetes and infertility. Respiratory chemicals will also do well spurred by improved asthma and allergy therapies. This study analyzes the $14.6 billion US pharmaceutical chemicals industry to 2004 and 2009 by therapeutic class, regulatory status, and production source. It also presents market share data and profiles key industry players.

World Agricultural Biotechnology: GMOs
Global demand for transgenic seeds (genetically modified organisms or GMOs) will grow 13% annually to nearly $3 billion in 2004, mainly in the US, Canada and Argentina. New entrants in the GMO market will include China and Brazil. Corn will remain the dominant transgenic crop, with cotton growing the fastest. This study analyzes the world market for GMOs with historical data for 1996 and 1999 and forecasts to 2004 and 2009 by function, crop and key country. It also evaluates market share and profiles key firms.
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