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# HIGH-GROWTH DIAGNOSTIC TESTS MARKETS

*(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

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## 1. Overview

### 1.1 Statement of Report

The purpose of this report is to describe the specific market segment of the *in vitro* diagnostics market called high-growth diagnostic testing. It examines these clinical measurement devices and their reagents and supplies as utilized in hospitals, clinics, and doctors' offices. We at TriMark Publications believe that each diagnostic segment described in this report offers an unusual outstanding opportunity for high market growth within the next five years. Our analysis is arranged to provide the reader with an overview of the outstanding diagnostic test market segments that are poised for high future growth. Each segment is accompanied by analysis and forecasts by product type and application.

Moreover, this report provides an overview of the diagnostic testing market, including the latest information regarding exciting new products and industry trends. It will not only quantify but also qualify the market high-growth segments as an area of research and investment. Forecasts of the market and analyses of products in the worldwide prescriptions market will provide a basis for understanding the significance of past developments and future possibilities within this therapeutic category.

### 1.2 Objectives of this Report

The principle objectives of this report are to:

- Identify viable technology drivers through a comprehensive look at various platform technologies for high-growth segments of the diagnostic testing markets.
- Obtain a complete understanding of the chief high-growth diagnostic test predictive, screening, prognostic, monitoring, pharmacogenomic, and theranostic value from their basic principles to their applications.
- Discover feasible market opportunities via an identification of high-growth applications in different diagnostic testing areas, with a focus on the biggest and expanding markets for diseases.
- Focus on global industry development through an in-depth analysis of the major world markets for high-growth diagnostic testing, including forecasts for growth.
- Market figures regarding the current value of the high-growth testing market are taken from the most recent available data of the global diagnostic industry. Projections and forecasts for the future of the diabetes market to 2010.

This report provides:

- An improved understanding of the current state and future of the most exciting high-growth diagnostic testing market segments.
- The latest information on the leading companies engaged in R&D and diagnostic testing products in the pipeline.
- The leading perspective of recent diagnostic test developments and revelations and how they will influence selected markets.
- Knowledge of the diagnostic testing market as an area of growth, research and investment.

This report will cover the following categories of diagnostic testing segments:

- Hepatitis testing.
- Cardiac monitoring.
- Cytogenetic testing.
- Fertility testing.
- Laboratory genomics.
- Glycosylated hemoglobin and glucose monitoring.
- Cancer marker testing.
- HPV.

- Biochips for clinical applications.
- HIV.
- Cellular imaging cytopathology and histopathology.
- Infectious disease testing.

Analyses include the use of charts and graphs measuring product growth and trends within the marketplace. In addition, a discussion of research in the illness provides the reader with a deeper understanding of possibilities for future treatment and avenues for possible research and development budgets. Company-specific information—including sales figures, product pipeline status, and research and development trends—is provided throughout the report. Additionally, our analysis will:

- Assess the high-growth diagnostic testing market drivers and bottlenecks, from the perspective of the medical and scientific communities.
- Discuss the potential benefits the high-growth diagnostic testing market for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the high-growth diagnostic testing market and analyze the current size and growth of individual segments.
- Provide current and forecasted market shares by company.
- Discuss business opportunities in the diagnostic testing segment.
- Provide strategic recommendations for near term business opportunities.
- Assess current commercial uses of the high-growth diagnostic testing market.

We answer the following questions in this report:

- What are the near term business opportunities in the high-growth diagnostic testing market?
- What are the current and forecasted sizes of the high-growth diagnostic testing market?
- What are the business models currently used by companies in the high-growth diagnostic testing market?
- How will diagnostic manufacturers, researchers, physicians, patients and payers influence the high-growth diagnostic testing market?
- What are the drivers and bottlenecks influencing the high-growth diagnostic testing market?
- What are the technologies used in high-growth diagnostic testing?
- Who holds proprietary rights to the high-growth diagnostic testing market technology?
- What are current applications of this technology?
- What regulatory processes must the high-growth diagnostic testing technologies undergo in the U.S., Japan and Europe?
- How will new high-growth diagnostic testing technologies change treatment and payment paradigms?
- How will high-growth diagnostic testing technologies reduce adverse drug reactions and decrease total patient care costs?
- How will high-growth diagnostic testing technologies reduce healthcare expenditures?
- How will high-growth diagnostic testing technologies decrease patient diagnostic testing costs?

### **1.3 Scope of this Report**

The emphasis in this report is on those companies that are actively developing and marketing high-growth diagnostic testing technologies. The reader should consult other TriMark Publication reports at <http://www.trimarkpublications.com> for a detailed discussion of the important individual market segments which are related to the high-growth diagnostic testing technologies market such as hepatitis testing, cardiac markers, cancer testing, infectious disease markers and other exciting new diagnostic methods.

This report reviews the market for high-growth diagnostic testing technologies in the clinical hospital market. It defines the dollar volume of sales, both worldwide and in the U.S., of the market and analyzes the factors that influence the size and growth of market segments. The report goes on to discuss in detail trends that have developed which have stimulated this market, and also comments in detail patterns of information processing in the high-growth diagnostic testing technologies.

The report surveys all of the key companies known to be marketing, manufacturing or developing high-growth diagnostic testing technologies in the U.S. and worldwide for selected segments identified. Leading companies are discussed in depth with a section on the history of the company, product line, business and marketing analysis, and a subjective commentary of the position of the company in its market.

The emphasis in this report is on those companies and products actively developing and marketing clinical laboratory instrumentation and reagents and supplies for performing diagnostic tests specifically related to several specified. High-growth market segments such as hepatitis, cardiac markers, cytogenetic testing, certain parts of infectious disease testing, cancer testing, and cellular imaging cytopathology and histopathology.

This report concentrates on high-growth testing market segments in important worldwide markets such as the U.S., Japan and Europe, including Germany, the U.K., and other countries of the European Union. It focuses primarily on the hospital market and commercial laboratory segment, and, separately, on a description of the instruments, reagents and supplies marketed by major companies in this segment. The report discusses market size, growth rates, and market components, and five-year projections for each of the important high-growth tests.

The report surveys most of the companies known to be marketing, manufacturing or developing instruments and reagents for the clinical high-growth testing market in the U.S. and worldwide. Special effort was made to include mention of smaller companies, and companies located around the world. Each company is discussed in depth with a section on the history of the company, product line, business and marketing analysis, and a subjective commentary of the position of the company in its market.

#### **1.4 Methodology**

The information in this report is based upon interviews with sales and marketing professionals of companies in the high-growth testing market. People from virtually every company mentioned in this report were queried, some several times, about their companies' products and marketing strategies as well as their overall thoughts about their industry segment. Information was also obtained from interviews with founders, CEOs, and vice presidents of some of the companies discussed in this report. The structure of hospital laboratories and near patient facilities was derived from interviews with laboratory directors and medical technologists working in these areas.

Other sources of information for the report were trade association publications and meetings, product brochures and catalogs, and company literature. Where the companies under discussion were publicly held, an examination of the annual reports, 10k filings, and financial reports were used as the basis of data reported. The main data sources include the Health for All database (HFA-DB) of the World Health Organization (WHO), published by the statistical office of the European Communities (Euro stat), as well as various health data from the United Nations (UN) and the Organization for Economic Co-operation and Development (OECD). Where possible and practicable, the most recent data available has been used. Some of the information obtained for the report was taken from Biotechnology Associates' proprietary databases and from the private data stores of TriMark Publications.

The information set forth in this study was obtained from sources we believe to be reliable, but we do not guarantee its accuracy, adequacy or completeness of any information, omission or for the results obtained by the use of such information.

#### **1.5 Executive Summary**

There will be a steady increase in demand for new diagnostic testing services in the next [REDACTED]-year period, along with pressures to improve the quality of healthcare delivered in the clinic and also to lower its costs. Clinical labs experienced a substantial growth during the last decade. Spending on lab services, including anatomical pathology, grew at an annual rate of [REDACTED]% during [REDACTED] through [REDACTED] to \$[REDACTED] billion worldwide. The clinical lab diagnostic testing market (ex-anatomic pathology) is currently at \$[REDACTED] billion worldwide. The clinical lab market is projected to grow by [REDACTED]% over the next ten years, following the general healthcare trend of increasing expenditure as a percentage of GDP. While lab expenditures comprise only [REDACTED]% of all healthcare spending, lab testing is usually involved in some way with almost all of the diagnostic decisions made with regard to healthcare.

The high-growth diagnostic products segments are poised for a major new phase of growth fueled by the availability of new technology coming out of the point of care segment and human genome research; and also the higher interest of individual patients and general healthcare consumers to take charge of their own health status. Continuous improvements in technology are resulting in a growing number of new *in vitro* diagnostic tests that combine high levels of accuracy with rapid, easy-to-use product formats.

The combination of the new molecular diagnostic technology platforms and traditional PCR will provide customers with a highly sensitive, accurate and rapid solution that is even more robust than either of them alone. These innovative combinations will provide the rich environment for diagnostic tests that grow more than █% per year in net sales dollars.

Many high-growth *in vitro* diagnostic products and services are specifically targeted at markets outside of the traditional hospital or clinical laboratory such as the point of care setting or genetic screening. Competition in the development and marketing of high-growth diagnostic products is intense, and diagnostic technologies have been subject to rapid change. We estimate that the competitive factors determining success in the diagnostic market include convenience, privacy, price and product performance as well as the distribution, advertising, promotion and brand name recognition of the marketer.

The upcoming expiration of basic PCR patents provides additional opportunities to move into new diagnostic test markets. Compared to traditional methods, molecular diagnostics offers better performance, shorter testing times, and objective results that do not require interpretation by highly trained technologists. Most of all, clinicians are now able to provide patients and the community with more consistent, affordable, and higher-quality healthcare. Expertise in nucleic acid testing (NAT) products and the associated technology platforms has enabled a number of companies to enter this high-growth segment and to obtain U.S. Food and Drug Administration (FDA) approvals for products that detect a wide variety of infectious microorganisms. According to industry consultants, the worldwide NAT market in █ for infectious diseases was approximately \$█ billion. While NAT currently represents only a small portion of the estimated \$█ billion worldwide market for human diagnostic clinical testing products, it is the segment with the highest recent growth rate – it reportedly grew at a compounded annual rate in excess of █% during the three years beginning in █.

This report's primary focus is on market products in high-growth segments of the estimated \$█ billion *in vitro* diagnostics (IVD) market, \$█ billion bio-defense market and \$█ billion genomic research market. There are a few (perhaps █) large dominant global players; these are matched by hundreds of small companies with a few or one product aiming at niche markets, for example, fetal development or early labor tests (Medix Biomedical). Last year, worldwide sales of glucose monitoring meters grew by █% to \$█ billion. And sales of other point-of-care tests grew by █% to an estimated \$█ million. Meanwhile, sales of nucleic acid tests are booming, driven by STDs, HIV viral load, and blood banking. Last year, this industry segment grew by more than █% to \$█ million. Flow cytometry, increasingly used in clinical monitoring, grew by an impressive █% to reach \$█ million in worldwide sales.

We see significant opportunities to grow the high-growth diagnostic testing business outside of the U.S. During █, the total European high-growth-oriented diagnostic testing business increased █% over the prior year. For example, we expect that the expanded organization will play a critical role in the further commercialization of high-growth diagnostic tests like HPV Tests for cervical cancer screening, urine strip testing in less developed regions, infectious disease testing, and hepatitis screening.

The high-growth *in vitro* diagnostic testing market segment is characterized by growth frequently above █% per year, and occasionally much more (at least for a while). More established testing market segments like hepatitis, HIV or glycohemoglobin are in the former range of growth. Newer segments like laboratory genomics and biochips are in the █% range of growth, but start from a low base in the \$█ million per year range, compared to the nearly \$█ billion estimate for more mature testing segments like hepatitis. The major players using the following strategies are pursuing growth in the high-growth sector:

- Improving profit margins through improved product pricing and operational efficiencies.
- Securing a stronger new product pipeline from internal research and development.
- Pursuing licensing and acquisitions opportunities, when financially and strategically attractive.

- Launching diagnostic test business under brand by leveraging marketing and distributing strength in the U.S., maximizing worldwide sales through current and newly identified sales channels in Europe and the rest of world.
- Launching a new and improved CLIA waived tests worldwide.
- Launching rapid diagnostic tests on a worldwide basis in conjunction with a development partner such as a pharmaceutical company.
- Expanding development and marketing collaborations with large pharmaceutical and other healthcare companies.
- Identifying business development opportunities in the form of product or company acquisitions to enhance product portfolio and further leverage distribution channels worldwide.
- Expanding international sales through external alliances, collaborations and sales focus.

TriMark believes that significant market potential exists for rapid diagnostics with novel applications that are capable of precise quantitative measurement of single or multiple analytes. Rapid, point-of-care testing is optimal to significantly improve patient care and reduce healthcare costs, especially for acute conditions. However, diagnostic needs and objectives vary from hospital to hospital. Therefore, most diagnostic reagent manufacturers have made their tests available on a centralized automated testing platform in addition to their own existing technology platforms.

Rapid identification of biological agents is critical to national defense, for example the application of technology to the detection of biological agents in the water supply. There is currently a need for optimizing a platform for specific use as a field-deployable system to enable bio-defense first responders, such as fire and police departments, to rapidly and more accurately detect signature nucleic acid sequences of known biological pathogens (*e.g.*, anthrax and plague). Public attention to agricultural biotechnology continues to grow. Several companies are developing a diagnostic tool to detect genetically modified organisms (GMOs) and address the need to rapidly identify biologic contamination. Approximately \$ billion was spent on genomic and proteomic research in , and this figure was projected to grow by at least % each year for the next years. The underlying technology must be applicable to both disease and population-driven genomics and are best developed through corporate partnerships.

The demand for the latest new tests and technology is expanding. More and more hospital labs are consolidating and seeking to expand their test menus and keep more tests on-site. At the same time, larger independent reference labs like Quest Diagnostics and LabCorp are seeking to stay on the cutting edge of esoteric testing and are making major investments in research & development to keep pace. We have selected 12 test categories, which we believe constitute most of the total high-growth *in vitro* diagnostic testing market:

- Hepatitis testing.
- Cardiac markers.
- Cytogenetic testing.
- Fertility testing.
- Genomics testing.
- Glycosylated hemoglobin.
- Cancer testing.
- HPV.
- Biochips for clinical apps.
- HIV.
- Cellular imaging.
- Infectious testing.