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HIGH-GROWTH DIAGNOSTIC TESTING 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 the clinical measurement devices and their reagents and supplies as utilized in hospitals, clinics and doctor's offices. Each diagnostic segment described in this report offers an outstanding opportunity for strong market growth over the next five years. Our analysis is arranged to provide the reader with an overview of the outstanding diagnostic test growth market segments that are poised for unusual advances in sales and earnings as the diagnostic market becomes an increasingly important segment of the health delivery system. Each high-growth market segment is accompanied by analysis and forecasts by product type and application.

This analysis provides an overview of the newest growth areas of the diagnostic testing market, including the latest information regarding new products and important industry trends. Forecasts of the market and analyses of products in the worldwide diagnostics market will provide a basis for understanding the significance of new developments and future possibilities within the diagnostic testing segment.

The principal objectives of this review are to:

- Identify key 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 fastest 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.
- Project and forecast the future of the IVD market. 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.

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 analyst's perspective of recent diagnostic test developments, and revelations on how these influence selected markets.
- Knowledge of the diagnostic testing market as an area of growth, research and investment.

The following categories of diagnostic testing segments are covered herein:

- Hepatitis testing.
- Cardiac monitoring.
- Cytogenetic testing.
- Fertility testing.
- Laboratory genomics.
- Glycosylated hemoglobin and glucose monitoring.
- Cancer marker testing.
- Human papillomavirus (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 diagnosis and avenues for possible research and development budgets. Company-specific information—including product pipeline status, and research and development trends—is provided throughout the report. Additionally, this analysis will:

- Assess the high-growth diagnostic testing market drivers and bottlenecks, from the perspective of the diagnostics industry, as well as medical and scientific communities.
- Discuss the potential benefits provided by the high-growth diagnostic testing market to 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 high-growth diagnostic testing segment.
- Provide strategic recommendations for exceptional 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 technologies undergo in the United States, Japan, China 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?

1.2 Scope of This Report

The emphasis in this review is on those companies that are actively developing and marketing high-growth diagnostic testing technologies. The reader should consult other TriMark Publications reports at 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 new diagnostic methods.

This analysis concentrates on high-growth testing market segments in important worldwide markets, such as the U.S., Japan, China and Europe, including Germany, the United Kingdom, and other countries of the European Union (E.U.). 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.

1.3 Methodology

The author of this report holds a Ph.D. in biochemistry from the University of Minnesota and has had post-doctoral experience at the University of Connecticut School of Medicine. He has taught at Quinnipiac University and the Tufts School of Medicine, and has been a senior scientist at Pfizer Pharmaceutical Laboratories in drug development. He also has many decades of experience in science writing and as a medical industry analyst. He has over 30 years of experience in laboratory testing and instrument and reagent development technology as a licensed clinical laboratory director, as well as extensive experience in senior level management positions in biotech and medical service companies. The editor of this report is a woman with many decades of experience in science writing and as a medical industry analyst.

Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites, as well as annual reports for publicly-held firms. Additional sources of information include non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities such as the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information or omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects, as well as Sector Snapshots that it publishes annually. TriMark extracts relevant data and analytics from its research as part of this data collection.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations.

TriMark Publications Report Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly available databases, proprietary databases, direct meetings and personal interviews with key personnel.
- Formulating a study outline with the assigned writer, including important items:
 - Market and product segment grouping and evaluating their relative significance.
 - Key competitors' evaluations including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
 - End-user research to evaluate analytical significance in market estimation.

- Supply chain research and analysis to identify any factors affecting the market.
- New technology platforms and cutting edge applications.
- Identifying the key technology and market trends that drive or affect these markets. Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.
- Launching a combination of primary research activities including two levels of questionnaires, executive-direct focused, company-specific, and region-specific communications to qualified and experienced senior executives worldwide.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of Expert Panel Partners from the industry being analyzed.

1.4 Executive Summary

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, molecular diagnostics and human genome research. There is also a higher awareness 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 of the new 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.

Table 1.1: Emerging Technology Platforms Driving High-Growth Diagnostics Market Segments

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- Polymerase Chain Reaction (PCR).
 - SYBR Green (Non-probe System).
 - MultiCode-RTx System.
 - TaqMan™ (Probe System).
 - HybProbe (Probe System).
 - Molecular Beacons (Probe System).
 - Branched DNA (bDNA).
 - Transcription Mediated Amplification (TMA).
 - Invader.
 - Signature™.
 - Other Real-time PCR Instruments.
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Source: Biotechnology Associates

Expiration of basic PCR patents in [REDACTED] opened additional opportunities for 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.

TriMark believes that markets will continue to develop for new applications for NAT technology, both in clinical and non-clinical fields. Among clinical fields, we believe NAT technology will be used in new applications, such as genetic predisposition testing and pharmacogenomics, which involves the study of the relationship between nucleic acid sequence variations in an individual's genome and the individual's response to a particular drug. We expect that nucleic acid assays will be used in the field of pharmacogenomics to screen patients prior to administering new drugs. Genetic testing to identify individuals at risk of certain diseases and pathological syndromes is emerging as an additional market for NAT technology. Nucleic acid-based testing for SNPs and other genetic anomalies can be used to determine an individual's predisposition to such conditions as thrombosis or blood clotting.

We see significant opportunities to grow the high-growth diagnostic testing business outside of the U.S. For example, we expect that the enhanced 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 [REDACTED] % per year, and occasionally much more. 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 [REDACTED] % range of growth, but start from a low base in the \$ [REDACTED] per year range, compared to the nearly \$ [REDACTED] estimate for more mature testing segments like hepatitis. Other new segments include forensic testing and paternity testing. 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 test 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.

Table 1.2: Market Trends in the High-Growth Diagnostics Space

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- Tests based upon molecular diagnostic (nucleic acid) technology platforms.
 - Move toward marketing rapid point of care test kits.
 - Tests developed as CLIA-waived tests.
 - Cost per test less of an issue with high demand diagnostic tests.
 - Coupling the diagnostic test with high profile diseases, *e.g.*, ovarian or breast cancer.
 - Move toward bringing complicated tests into a single expert lab.
 - Move for CLIA regulatory oversight using expert labs, rather than FDA using diagnostic kits.
 - Move away from central lab “big iron” chemistry analyzers.
 - Focus on improving patient outcomes with diagnostic tests.
 - Move to reduce expertise needed to run tests because of shortage of trained personnel.
 - More diagnostic start-ups to develop tests with high growth potential.
 - Increased M&As as larger players acquire exciting new test technology.
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Source: Biotechnology Associates

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 biodefense 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 \$[REDACTED] was spent on genomic and proteomic research in [REDACTED], and this figure is projected to grow by at least [REDACTED]% each year for the next five 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 tests and technology is expanding. More and more hospital labs are consolidating and seeking to expand their test menus, and to 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 and development to keep pace. We have selected [REDACTED] test categories that 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 and glucose monitoring.
- Cancer testing.
- HPV.
- Biochips for clinical applications.
- HIV.
- Cellular imaging.
- Infectious disease testing.