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**MOLECULAR
DIAGNOSTICS 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

This report describes the specific market segment of the *in vitro* diagnostics market known as molecular diagnostics and includes all of the generally-accepted clinical analytical activities in use today in the molecular diagnostics sector. It examines the prevalent clinical-measurement devices, as well as their reagents and supplies as utilized in hospitals, clinics, large reference laboratories and doctor's offices.

1.2 About This Report

The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for molecular diagnostics, including probe-based nucleic acid assays, microarrays and sequencing.
- Obtaining a complete understanding of the chief molecular diagnostics tests—*i.e.*, predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic—from their basic principles to their applications.
- Discovering feasible market opportunities by identifying high-growth applications in different clinical diagnostic areas and by focusing on expanding markets, such as communicable diseases, cardiology and oncology.
- Focusing on global industry development through an in-depth analysis of the major world markets for molecular diagnostics, including growth forecasts.

1.3 Scope of the Report

This analysis emphasizes the companies that are actively developing and marketing clinical laboratory instrumentation, reagents and supplies for performing molecular diagnostics tests. The emphasis in this report is on the clinical use of molecular diagnostics tests.

The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the molecular diagnostics market, such as clinical chemistry testing, high-growth diagnostic tests markets, blood gas and electrolytes, over-the-counter diagnostic testing markets, and point-of-care testing. Diagnostics tests marketed primarily as over-the-counter are generally not included in this report, although there is inevitably some overlap. TriMark provides a separate market report called *DNA Sequencing and PCR Markets*, which emphasizes the analytical methods and polymerase chain reaction (PCR) technology platforms used in molecular diagnostics.

1.4 Objectives

The goal of this study is to review the market for molecular diagnostics testing equipment and supplies using reagents and instruments for analysis of individual components in blood, serum or plasma. Many new techniques in this space depend on the breaking developments in the genomic and proteomic spaces. The report defines the dollar volume of sales, both worldwide and in the U.S., and analyzes the factors that influence the size and the growth of the market segments. Also examined are the subsections of each market segment, including: commercial, hospital and physician's office laboratories. Additionally, the numbers of institutions using this type of testing and the factors that influence purchases are also discussed.

This examination surveys most of the biotech companies known to be currently marketing, manufacturing or developing instruments and reagents for the molecular diagnostics market in the world. Each company is discussed in depth with a section on its history, product line, business and marketing analysis, and a subjective commentary of the company's market position.

In this report, we:

- Assess the molecular diagnostics market drivers and bottlenecks from the perspective of the medical and scientific communities.
- Discuss the potential benefits of the molecular diagnostics market for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the molecular diagnostics market and analyze the current size and growth of various segments.
- Provide current and forecasted market shares by the company.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the molecular diagnostics market.
- Review the molecular diagnostics business models.

The United States, Europe and Japan—the world’s three largest molecular diagnostics markets—are the focus of this report. Primary attention is paid to the hospital market segment and, separately, to the instruments, reagents and supplies marketed by the major companies in this segment. Market size, growth rates and market components for instruments, reagents, controls and consumables used in this area are also analyzed.

This review answers the following key questions:

- Which companies are utilizing cutting-edge technologies to develop, validate and implement molecular tests for clinical use?
- What impediments still exist to incorporating promising molecular tests into clinical practice?
- Which new molecular diagnostics tests show the most promise for approval?
- What are the economic challenges to approval?
- How can regulatory oversight drive approval and adoption of new technologies?
- Which alliances show the greatest synergy in bringing molecular diagnostics tests to market?
- Which shared technologies are driving the most encouraging development?

This examination surveys all companies known to be marketing, manufacturing, or developing instruments and reagents for the clinical molecular diagnostics market, in both the U.S. and the world. Leading companies are discussed in depth, with sections on the company’s history, product line, business and marketing analysis, and a subjective commentary on the company’s market position. Several subjects related to the major elements of molecular diagnostics testing, such as clinical chemical testing instruments, are discussed only briefly because they are considered entirely different fields or markets. Fuller explorations of these areas can be found in other TriMark Publications reports, such as *Clinical Chemistry Analyzers* and *Point of Care Diagnostic Testing World Markets*.

1.5 Methodology

The information in this report is based on interviews with sales and marketing professionals of companies in the molecular diagnostics market. Representatives from virtually every company mentioned were queried, some several times, about their companies’ products and marketing strategies, as well as their overall opinions about the industry segment in which they work. Information was also obtained from interviews with founders, CEOs and vice presidents of various companies discussed in this report. The structure of the hospital laboratories and patient facilities was derived from interviews with the laboratory directors and medical technologists working in these areas. Other information was gleaned from trade association publications and meetings, product brochures and catalogs, and company literature. Where the companies under discussion were publicly held, their annual reports, 10-K filings and financial reports were examined. Information available from the proprietary databases at Biotechnology Associates and from the private data stores of TriMark Publications was also used in preparing this report.

Important data sources include the Health for All Database of the World Health Organization, data published by the Statistical Office of the European Communities (Eurostat), as well as various health data from the United Nations and the Organization for Economic Co-operation and Development. Where possible and practicable, the most recent data available have been used.

The author of this report is a Ph.D. in biochemistry with many decades of experience in scientific writing and as a medical industry analyst. He has been a senior director of several large regional and national cancer testing laboratories. He has over thirty years of experience in laboratory testing, and instrument and reagent development technology, as well as extensive experience in senior level positions in biotech and medical service companies. The editor of the report has a Ph.D. in biophysics and has worked as a research assistant professor at the University of Missouri.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information set forth 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, any omission or the results obtained by the use of such information.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research in the past three years as part of this data collection. We also extract qualified data feeds from e-questionnaire responses and primary research responses for this compilation.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, Investment Research Reports, Trade & 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. The report conclusions are verified through intensive interviewing of the top ranking companies in the industry.

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 the key personnel.
- Formulating a study outline with the assigned writer, including important items, as follows:
 - 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.

1.6 Executive Summary

The technologies that constitute molecular diagnostics—first-generation amplification, DNA probes, fluorescent *in situ* hybridization (FISH), second-generation biochips and microfluidics, next-generation signal detection, biosensors and molecular labels—are influencing the discovery of therapeutic molecules, the screening and diagnosis of patients, and the optimization of drug therapy. In the past few years, this rapidly evolving field has seen several fascinating developments, including:

- Impact on pharmacogenomics and molecular epidemiology.
- Integration into central lab and point-of-care clinical practice.
- Impact on proteomics.
- Integration into therapeutics and diagnostics.
- Development of lab-on-a-chip devices.
- Novel relevant technologies, *e.g.*, new ways of labeling and signal detection.

In [REDACTED], an estimated [REDACTED] molecular diagnostics tests were performed at U.S. hospitals and laboratories, a figure that is predicted to grow to [REDACTED] tests per year by [REDACTED]. Driving the change from older technology to molecular testing are:

- Hospital requirements to streamline care and reduce testing costs.
- New technologies that permit the necessary quality control and data capture from tests.
- Broader menu of available tests.

More than [REDACTED] companies market products in this segment. Most of these are relatively small, with annual sales less than \$[REDACTED]. Many major diagnostics companies, such as Abbott Laboratories, Siemens and Roche Diagnostics, have substantial market shares in each category of the molecular diagnostics market. A major outlet for novel diagnostics tests is through original equipment manufacturer (OEM) agreements with global platform suppliers such as Abbott Laboratories, Siemens, Beckman Coulter and Roche. Small- and medium-size companies with innovative products have a great opportunity for success in the field of molecular diagnostics. The molecular diagnostics market segment is characterized by unprecedented growth rates, in contrast with the low or even negative growth rates of mature laboratory-testing segments such as hematology and microbiology.

At approximately [REDACTED] genes for the human genome, and with an estimated diagnostic significance of about [REDACTED]%, the commercialization of [REDACTED] or more gene-based tests will soon be a reality. Infectious disease testing and blood-banking applications are currently paving the way, but there will also be applications in pharmacogenetics, predisposition diagnostics and molecular cancer diagnostics. The molecular diagnostics industry is built around four competing technology platforms:

- DNA polymerization.
- RNA polymerization.
- Ligation.
- DNA repair.

In [REDACTED], the global molecular diagnostics market was approximately \$[REDACTED]. The molecular diagnostics market is projected to expand to \$[REDACTED] by [REDACTED]. The use of molecular diagnostics in oncology is predicted to be the second fastest growth application sector, expected to grow at a rate of over [REDACTED]% per year, reaching \$[REDACTED] by [REDACTED].

The molecular diagnostics testing market in the U.S. is the largest and most highly developed in the world. The molecular diagnostics segments will significantly outperform the overall *in vitro* diagnostic market in the U.S., with sales of the latter growing from \$[REDACTED] billion in [REDACTED] to \$[REDACTED] billion in [REDACTED] (a compound annual growth rate (CAGR)) of [REDACTED]%). U.S. molecular diagnostics market revenues are forecast to soar from \$[REDACTED] billion in [REDACTED] to \$[REDACTED] billion in [REDACTED].

billions in 2011. European molecular diagnostics market revenues are forecast to increase from \$ [REDACTED] in [REDACTED] to \$ [REDACTED] in [REDACTED], with a growth rate of [REDACTED]%. The Japanese molecular diagnostics market is at \$ [REDACTED]. The projected growth rate is [REDACTED]% per year through [REDACTED] to \$ [REDACTED].

The global nucleic acid-based amplification test (NAT) market for infectious diseases represents only a small portion of the world's estimated \$ [REDACTED] market for human diagnostics products; however, it is the segment with the highest recent growth rate. From [REDACTED] to [REDACTED], the global NAT market grew at a compounded annual rate of better than [REDACTED]%. Substantial market opportunities exist in two of the NAT market's principal segments: clinical diagnostics and blood screening. The global NAT market was estimated to be approximately \$ [REDACTED] at the end of [REDACTED]. TriMark estimates that by [REDACTED] the global market will reach \$ [REDACTED], with a CAGR of [REDACTED]%. In comparison, the U.S. market for DNA probe diagnostics generated \$ [REDACTED] in [REDACTED], and is forecast to grow to over \$ [REDACTED] by [REDACTED].

The largest segment of the PCR probe market for detection of infectious disease is Human Immunodeficiency Virus (HIV) testing. For [REDACTED], the annual HIV testing market is approximately \$ [REDACTED] per year in the U.S., and about \$ [REDACTED] worldwide. As a supplement to the HIV testing market, the viral load market is beginning to grow as physicians are using the quantity of HIV virus in the blood as a marker for the effectiveness of antiviral therapy for AIDS. Another significant area of infectious disease probe-based testing is sexually transmitted disease (STD) assessment. This U.S. segment was \$ [REDACTED] in [REDACTED], growing at [REDACTED]% per year, with gonorrhea and chlamydia testing generating \$ [REDACTED] per year.

Other segments of the PCR infectious disease category for diagnostics include mycobacteria and human papilloma virus, or HPV. In addition to infectious disease testing, the DNA probe market has other interesting but small-dollar-volume segments. For instance, the molecular diagnostics PCR segment is divided into four areas of customer interest:

- Academic ([REDACTED]%).
- Pharmaceutical ([REDACTED]%).
- Biotechnology ([REDACTED]%).
- Clinical ([REDACTED]%).

Principal factors driving market growth are:

- Conversion from low-priced manual methods to higher-priced automated systems.
- Introduction of new diagnostic marker assays.
- Recent U.S. Food and Drug Administration (FDA) ruling that pre-market applications are not required for tumor markers now in commercial distribution when they are used only for monitoring, which could speed the market introduction of some tests.

The industry is dominated by large multinationals that market automated systems. Critical to a company's success is the size of its installed base, as this not only drives profitable reagent sales but also serves as a barrier to competition. In this extremely competitive industry, prospects are not encouraging for new entrants or small players, such as those found in Canada, that lack a unique product. Even with an innovative product, commercial success will depend on a firm's ability either to market low-volume niche products (which do not interest multinationals) or to form alliances with these major producers for products that can work on automated systems. The fundamental restructuring of healthcare delivery, such as price pressures and reimbursement cuts, occurring on an international level is impeding the entire diagnostics market. To be successful, tests must be novel, cost-competitive, clinically relevant, reimbursable and capable of being conducted by lower-skilled technicians.

The use of molecular-based diagnostic solutions continues to expand to other diseases. For example, the viral load monitoring and genotyping techniques that have increased the life expectancy of HIV-infected patients have emerged as valuable tools for managing those patients infected with Hepatitis C Virus (HCV). The molecular diagnostics market includes an extensive list of innovative products and tests. New developments such as gene sequencing and nucleic acid amplification have revolutionized the *in vitro* diagnostics (IVD) industry in general. The future success of these companies depends on the speed at which they can find expanded applications for

assays. Increasing insight into the ways in which genes influence a pathogen's response to therapy is ensuring tremendous growth in pharmacogenomics. Collaborations between diagnostics and pharmaceutical companies are expected to drive sales of both products. The dynamic U.S. molecular diagnostics market is highlighted by the growth of the cancer diagnostics and pharmacogenomics sectors.

A shift in life sciences spending is occurring as the National Institutes of Health (NIH) emphasizes specific research areas. PCR-based technologies will greatly reduce costs, particularly as labor-saving measures. The largest market opportunities for PCR-based products will be in:

- Molecular clinical diagnostics.
- Genomics.
- Drug discovery.
- Gene therapy.

More tests will be available for infectious disease, oncology, genetic testing, human leukocyte antigen (HLA) testing and identity testing. A critical need exists for standardizing pre-analytical solutions, such as sample collection, stabilization, purification and handling. The clinical diagnostics segment is the fastest-growing part of PCR and molecular detection, at more than 20% per year in reagent sales.

As an example of the important trends in molecular diagnostics, TriMark believes the field of pharmacogenomics will become increasingly important in clinical trials and patient care. Through resequencing and genotyping technologies, DNA probe arrays could significantly reduce the cost and time required for high-volume polymorphism analysis, which is now performed through more labor-intensive techniques. The ability to predict which therapies are most likely to be effective for certain patients would constitute a powerful advance in diagnostic areas such as oncology.

Many drug companies without large diagnostic laboratories are concerned that genetic testing might upset the business models behind many of their most successful products. Even as they have begun experimenting with pharmacogenomics, these drug companies fear that the FDA might use the data they gather to limit the target patient population for potential blockbuster drugs. In view of this, major drug companies are likely to welcome a firm signal from the FDA that will reduce the questions surrounding this new field.

In another major trend, DNA microarrays have become indispensable tools in pharmacogenomics, toxicogenomics, developmental biology, cancer research and many other areas. TriMark believes that NAT diagnostic assays will be used in the field of pharmacogenomics to screen patients prior to administering new drugs.

The molecular diagnostics industry can be divided into four market opportunities:

- *Infectious Diseases.* This is the oldest, largest market opportunity, which still maintains good projected growth of up to 20% CAG. The actual growth rate may be higher if diagnostics-prescription applications emerge and drive incremental growth. It remains an exciting market, and anyone who wants to be a player in nucleic acid testing needs to be involved here at some level.
- *Genetics.* The standard applications being followed in this area today are cardiovascular, which is being pursued almost universally, factor-5, factor-2, etc. Also, there are several new applications, such as to cystic fibrosis.
- *Pharmacogenomics.* This is a separate market opportunity because it is technically more difficult to genotype a specific drug-metabolizing enzyme. Tests in this market may be a single test or a collection of perhaps a dozen different tests. Furthermore, the market relies on both nucleic acid technology and good bioinformatics.
- *Cytology.* Although all current cytology applications use FISH, new technologies may emerge offering alternatives that may examine, for instance, molecular oncology.