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BIOMARKER TECHNOLOGY PLATFORMS FOR CANCER DIAGNOSES AND THERAPIES *(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 segment of the cancer diagnostics market which develops new biomarker technology platforms for diagnosing and treating cancer. Biomarkers are useful in following the course of cancer and evaluating which therapeutic regimes are most effective for a particular type of cancer, as well as determining long-term susceptibility to cancer or recurrence. This study examines those clinical measurement devices, and their reagents and supplies, which are meant to be used in hospitals, clinics, commercial laboratories and doctor's offices to diagnose and monitor cancer. The examination also provides an in-depth discussion of the application of biomarkers in developing novel targeted cancer therapeutics, their predication response and efficacy, as well as their use in diagnosis of cancer.

1.2 About This Report

The report describes new technology platforms developed for the analyses of constituents of blood, plasma, serum or tissue that are connected to the growth and progression of cancer. The emphasis is on those companies and products that are actively developing and marketing new clinical laboratory instrumentation, reagents and supplies for performing tumor marker tests, as opposed to the more routine and clinically accepted tumor markers that are manufactured and marketed by large diagnostic companies. This study focuses on smaller biotech companies who have new products and procedures in this sector. Research companies in the process of developing new ideas are not reviewed in any detail here.

The main objectives of this analysis are:

- Identifying viable technology drivers for cancer biomarkers and related companion diagnostics through a comprehensive look at platform technologies including, probe-based nucleic acid assays, microarrays and sequencing, and mass spectroscopy.
- Obtaining a complete understanding of the new cancer biomarker diagnostic tests—*i.e.*, predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic—from their basic principles to their applications.
- Discovering growing market opportunities by identifying high-growth applications in different cancer diagnostic areas, focusing on the biggest and expanding markets in oncology (*e.g.*, biomarkers for breast cancer and predictive biomarkers).
- Focusing on global industry development through an in-depth analysis of the major world markets for cancer diagnostics, including growth forecasts.

1.3 Scope of the Report

This analysis emphasizes companies that are actively developing and marketing new reagents and supplies for performing cancer biomarker diagnostics tests. It discusses the various market trends and opportunities using new biomarkers, while providing an in-depth analysis of market share, revenue forecasts, and market drivers and restraints. The comprehensive focus of the study, backed by strategic recommendations, enables companies to position their growth strategies to benefit from the changing market conditions and obtain maximum return on investment.

The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the cancer diagnostics market, such as clinical chemistry testing, high-growth diagnostic test markets, blood gas and electrolytes, over-the-counter (OTC) diagnostic testing markets, and point-of-care (POC) testing. TriMark publishes a separate report on routine clinical tumor markers in current use and their markets called *Cancer Diagnostic Testing World Markets*.

The development of new cancer biomarkers by the biotech sector is the focus of this report. But attention is paid to the hospital market segment, and separately, to the instruments, reagents and supplies marketed by 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.

Specialty cancer diagnostics testing such as pathology screening methods and special tissue stains to examine cancer cells *in situ* are mentioned, since they are often part of the overall analytical focus of companies that market cancer technology platforms. However, no effort is made to quantify this older and broader market. In addition, this report does not cover special stains for the cancer testing, except in the case of testing for BRAC in breast cancer. These subjects are discussed in other TriMark Publications reports.

An analysis of business trends, technology trends, and developing areas of cancer diagnostics testing using new biomarkers is provided, along with a brief review of the routine market for clinical cancer diagnostics testing equipment and supplies in the clinical hospital market, using screening reagents and instruments for analysis of individual components in blood, serum or plasma. This report defines U.S. and global market dollar sales volume and analyzes factors that influence the size and growth of market segments. Activity and trends in hospital markets, including the numbers of institutions that use cancer diagnostics testing and the factors that influence purchasing, are addressed in this report. Also discussed are trends that have stimulated this market and patterns of information processing in POC testing instruments.

Several subjects related to the major elements of cancer diagnostics testing, such as clinical chemical testing instruments, are discussed only briefly in this report because they are considered entirely different fields or markets. Fuller explorations of these areas of interest can be found in other TriMark Publications reports, such as *Clinical Chemistry Analyzers* and *Point of Care Diagnostic Testing World Markets*.

1.4 Objectives

The goal of this report is to review the market for new cancer biomarker testing equipment and supplies using reagents and instruments for analysis of individual components in blood, serum or plasma, which depend on the breaking developments in the genomic and proteomic spaces. The study 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: the physician office labs, hospital labs and commercial laboratories. Additionally, the numbers of institutions using this type of testing and the factors that influence purchases are discussed. The analysis examines:

- Opportunities and barriers for new cancer biomarkers using proteomics.
- Secreted proteins as biomarkers.
- Adaptive design using biomarkers.
- Pharmacodynamic biomarkers identified with broad-based phenotyping as companion diagnostics.
- Tools for improving measurement, safety and validation of biomarkers.
- Filling the gap between discovery and clinically validated biomarkers.
- Enabling technologies for oncology biomarker discovery.

This study answers the following questions:

- Which companies are utilizing cutting-edge technologies to develop, validate and implement cancer biomarkers for clinical use?
- What impediments still exist to incorporating promising research into clinical practice?
- Which cancer biomarkers 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 valid biomarkers to market?
- Which shared technologies are driving the most encouraging development?

1.5 Methodology

This report is based upon interviews with sales and marketing professionals of companies in the cancer biomarker market. They 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 the report. Descriptions of the hospital laboratories and nearby patient facilities were derived from interviews with laboratory directors and medical technologists in these areas.

Sources of information for the study 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 the data reported. Important data sources include the Health for All Database of the World Health Organization (WHO), data published by the statistical office of the European Communities (Eurostat), as well as various health data from the United Nations (UN) and the Organization for Economic Cooperation and Development (OECD). 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 science writing and as a medical industry analyst. He has been a senior director of several large regional and national cancer testing laboratories. The senior editor is a doctoral level clinical scientist. He has over 30 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.

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, 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 with regard to commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

The information in this study is also based upon direct experience with sales and marketing professionals of companies in the instruments and reagents market. People from many companies mentioned in this report were considered thoughtfully about their companies' products and marketing strategies as well as their overall thoughts about their industry segment. The structure of the laboratory facilities was derived from familiarity with scientists and technologists working in these areas.

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 of 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 and industry association reports, government affiliated trade releases, and other published information as part of our 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 study's conclusions are verified through intensive interviewing of 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 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.

1.6 Executive Summary

Until superior therapeutic treatments are developed to prevent, treat and cure cancer, the best means of reducing mortality and morbidity in a disease this complex is early detection and diagnosis. In the major solid cancer types such as lung, breast, colon and prostate, long-term survival rates drop precipitously once metastasis has occurred. The case is clear for development of biomarkers for early detection and screening tests for diseases such as breast, colon, ovarian and lung cancer. In addition, diagnostic measurement of cancer disease progression is essential to successful disease management. For these reasons, development of new and effective biomarkers for cancer detection and diagnosis is central to the cancer problem. The use of both nucleic acid and protein biomarker diagnostics has begun to answer these questions.

As the pharmaceutical and diagnostic industries increase the availability of biomarkers, their importance and influence in all aspects of drug discovery and the development process will continue to grow. Co-development of molecular diagnostics and targeted therapeutics has already been proven to be a successful strategy in the development of novel anti-cancer drugs such as Gleevec®. With the biomarker industry projected to become a \$ [REDACTED] industry by [REDACTED], an increased number of pharmaceutical companies have entered the market.

Unmet patient need is the major driver of innovation in both cancer therapeutics and diagnostics. There is significant need for high-sensitivity diagnostic methods to detect the presence of early-stage disease. Competitive pressures and reimbursement issues will increase the demand for better diagnostic testing information in order to satisfy the need for a diagnostic component to the clinical decision-making process.

The enormous developments in analytical instrumentation in the last [REDACTED] years have helped fuel the worldwide biotechnology instrumentation market. It is estimated that in [REDACTED], this market accounted for over \$ [REDACTED] in revenue. Conservative estimates of a [REDACTED]% to [REDACTED]% increase in the biotechnology instrumentation market for [REDACTED] would place the value of this market in the range of \$ [REDACTED] to \$ [REDACTED] dollars. The U.S. biotechnology

instrumentation market was estimated to be \$ [REDACTED] in [REDACTED]. With an estimated increase of just [REDACTED]% for [REDACTED], the market would have a current value of over \$ [REDACTED]. Of course, the deoxyribonucleic acid (DNA) revolution has brought an entire new class of analytical instruments on board in the last [REDACTED] years. DNA structure and function has lead to new classes of cancer markers.

Oncologic drug sales reached \$ [REDACTED] in sales in [REDACTED], up [REDACTED]%. The exact increase for [REDACTED] is still being calculated, but with even a low estimate of [REDACTED]% to [REDACTED]% growth for [REDACTED] the oncologic drug sales market would have a value between \$ [REDACTED] to \$ [REDACTED] dollars. If oncologic drug sales increased in excess of [REDACTED]%, then the current market would be in excess of \$ [REDACTED] dollars. This significant growth, the highest among the top ten therapeutic classes, has been fueled by strong acceptance of innovative and effective therapies that are reshaping the approach to cancer treatments and outcomes.

Targeted therapies have revolutionized the way cancer is being treated—opening up the possibility that many forms of the disease can be fought through long-term maintenance therapy. These therapies are helping to win individual battles against cancer, enabling us to think of it as a chronic illness, rather than a life-ending one. With the industry's innovation and ongoing scientific advances, growth in targeted therapies will continue to be very strong and the outcomes even more impressive, and this will drive the development of companion diagnostic tests. Cancer testing is one of the most important growth opportunities in the diagnostics segment for the next [REDACTED] to [REDACTED] years.

The efforts to diagnose cancer and other complex diseases have failed in large part because the disease is heterogeneous at the causative level (*i.e.*, most diseases can be traced to multiple potential etiologies) and at the human response level (*i.e.*, each individual afflicted with a given disease can respond to that ailment in a specific manner). Consequently, measuring a single protein biomarker when multiple protein biomarkers may be altered in a complex disease is unlikely to provide meaningful information about the disease state. The market for advanced cancer diagnostic testing will increase from an estimated \$ [REDACTED] today to over \$ [REDACTED] by [REDACTED]. This increase is attributable to multiple factors including increasing incidences of cancer in an aging population, new therapies and expanded testing panels. The patient market for breast cancer exceeds \$ [REDACTED] per year (although most of this is associated with mammography screening) and the patient market for cervical cancer testing exceeds \$ [REDACTED] per year.