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CANCER DIAGNOSTIC TESTING WORLD 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 segment of the cancer diagnostics market called tumor marker testing. This study reviews all of the generally accepted clinical and research methods that are currently available today for detection of cancer cells in patients. It examines the clinical measurement devices, including their reagents and supplies, utilized in hospitals, clinics, commercial laboratories and doctor's offices to diagnose and monitor cancer.

1.2 About This Report

This examination describes the analysis related to the common chemical constituents of blood, plasma or serum that are connected to the growth and progress of cancer. Emphasis is on those companies and products that are actively developing and marketing clinical laboratory instrumentation, reagents and supplies for performing tumor marker tests. The main objectives of this report are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for cancer diagnostics, including probe-based nucleic acid assays, microarrays and sequencing.
- Obtaining a complete understanding of the chief cancer 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, focusing on the biggest and expanding markets in oncology.
- Focusing on global industry development through an in-depth analysis of the major world markets for cancer diagnostics, including growth forecasts.

By purchasing this analysis, the reader will have:

- An understanding of the most exciting cancer marker market segments.
- The latest information on leading products and R&D initiatives.
- Familiarity with recent developments and their effects on selected markets.
- Knowledge of the cancer marker market as an area of growth, research and investment.

The report defines the dollar volume of sales, both worldwide and in the U.S. of the market, and it analyzes the factors that influence the size and the growth of the market segments. Key questions answered in this study:

- How can cancer marker measuring tools and technologies facilitate improved patient care?
- What are the main types of cancer marker technologies that are currently available?
- Who are the current key players in this marketplace?
- Which cancer marker market areas have the greatest potential for growth?
- What is the current state of the cancer marker market?
- Which biotechnology and diagnostic companies are investing in new cancer marker technology platform solutions?
- What are the main cancer marker business strategies adopted by leading companies?
- What are the benefits of various cancer marker technology platforms?

This review contains:

- Detailed analysis of recent trends in the cancer marker marketplace.
- In-depth profiles of the leading companies with cancer marker tools and technologies.
- Opinions on the cancer marker industry from leading industry experts.

- Analysis of potential new cancer marker applications in the clinical sector.
- Market predictions and trends analysis concerning U.S. expenditures on cancer markers.
- Projections of cancer marker market sizes for European and Asian markets.
- Projections for future applications of non-invasive tests in cancer marker screening.
- Analysis of commercial cancer marker business strategies such as co-branding.
- A comprehensive overview and insight into cancer marker business strategies for growth in foreign markets.
- An in-depth examination of the subsections of each cancer marker market segment is conducted.
- An industry structure analysis including companies in the field and their focus.

Analysis includes charts and graphs measuring product growth and trends within the marketplace. Company-specific information, including sales figures, product pipeline status and R&D trends, is provided. Also, this report will:

- Assess cancer marker market drivers and bottlenecks, from medical and scientific community perspectives.
- Discuss the potential benefits of cancer markers for various sectors of the oncology community.
- Establish the current total market size and future growth of the cancer marker market and analyze the current size and growth of individual segments.
- Provide current and forecasted market shares by company.
- Discuss profit and business opportunities by oncology segment.
- Provide strategic recommendations for near-term business opportunities.

The following questions will also be addressed in this study:

- What are the near-term business opportunities in the cancer marker market?
- What are the current and forecasted cell therapy market sizes in the U.S., European Union (E.U.) and Asia?
- What are the business models currently used by companies in the cancer marker market?
- How will manufacturers, researchers, physicians and patients influence this market?
- What are the drivers and bottlenecks influencing the cancer marker market?
- What are the barriers to entry for the cancer marker market?
- What are the key technologies used in cancer marker testing?
- Who holds the proprietary rights to the cancer marker technology platforms?
- How is this technology currently being applied and utilized?
- How will new cancer marker technologies reduce healthcare expenditures?
- How will new cell therapy technologies affect cancer therapy decisions?

The analysis contains:

- A comprehensive overview of the several categories of cancer marker technology platforms that are of use as diagnostic tests in hospitals and doctor's offices.
- A chapter on each of the important cancer categories and applications of cancer marker tests to diagnosis and treatment.
- Full descriptions of the technologies involved and how these differ from existing and emerging technologies.
- Analysis of the technological approaches undertaken by various competitors, as well as industry and end-user response to these products.
- Regulatory issues and legislation affecting use and marketing of cancer marker products.
- Complete review of the clinical uses of cancer marker tests.

1.3 Scope of the Report

This study emphasizes companies that are actively developing and marketing clinical laboratory instrumentation, reagents and supplies for performing cancer 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 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.

The U.S., Japan and Europe—the world's three largest cancer 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 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 is examined, since it is often part of the overall analytical focus of companies that market general laboratory automation equipment. However, no effort is made to quantify this broader market. In addition, this report does not cover disposable plastic supplies for the clinical laboratory. These subjects are discussed in other TriMark Publications reports.

1.4 Objectives

The goal of this survey is to review the market for tumor marker testing equipment and supplies using screening reagents and instruments for analysis of individual components in blood, serum or plasma. It 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 study surveys almost all of the companies known to be marketing, manufacturing or developing instruments and reagents for the clinical oncology market in the U.S. 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.

1.5 Methodology

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

Other sources of information included trade association publications and meetings, product brochures and catalogs, and company literature. We have also gathered statistical information from the U.S. government, the World Health Organization (WHO), and private foundations. Annual reports, 10k filings, and financial reports were used as the basis for data reported on publicly held companies. The author of this report is a PhD in biochemistry with years 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 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.

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 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 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 a 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 competitor's 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

Cancer testing is one of the most important growth opportunities for the next three to five years in the diagnostics segment. The National Cancer Institute (NCI) estimates that about ██████ Americans have or have had some form of cancer. The National Institutes of Health (NIH) estimates that the overall costs of cancer in ██████ was approximately \$██████. Pharmaceutical companies are developing more than ██████ new medicines for cancer, some of which are in development for more than one type of the disease, for a total of more than ██████ ongoing R&D projects. The number of Americans diagnosed annually with cancer will ██████ over the next ██████ years, from ██████ to ██████. The four major killer cancers—lung, colorectal, breast and prostate—accounted for ██████% of all cancer deaths in the U.S. from ██████ to ██████.

The American Cancer Society estimates that approximately ██████ new cancer cases will be diagnosed in ██████. Since ██████, approximately ██████ new cancer cases have been diagnosed. In ██████, about ██████ Americans are expected to die of cancer. This number equates to more than ██████ deaths each day. More than ██████ cases of basal and squamous cell skin cancer, approximately ██████ cases of breast carcinoma *in situ*, and

cases of *in situ* melanoma will be diagnosed in . In the U.S., of every deaths is from cancer. Cancer in all forms is the leading cause of death behind . New technology in the diagnosis and treatment of these diseases, and conditions should lead to attractive commercial opportunities. For example, the worldwide cancer treatment market currently is \$ and growing at a rate of % annually. The size and growth of the diagnostic tumor marker markets are influenced by a number of factors, including:

- Financing for biotech companies.
- Technological innovation in diagnostic practice.
- Government funding for basic and disease-related research (for example, heart disease, AIDS and cancer).
- R&D spending by biotechnology and pharmaceutical companies.
- Healthcare spending.

The specific products in this segment include:

- Immunoassays for serum cancer markers, receptor assays and hormone assays.
- Mammography equipment.
- Clinical chemistry reagents (occult blood reagents, enzymes and serum proteins).
- Deoxyribonucleic acid (DNA) reagents.
- Cytological products.
- Histological reagents.
- Immunocytochemistry products.
- Immunohistochemistry reagents.

Biotechnology Associates estimates the global product market for *in vitro* cancer detection products—including clinical chemistry reagents (occult blood reagents, enzymes, serum proteins), DNA reagents, cytological products, histological reagents, immunocytochemistry products, and immunohistochemistry reagents—is estimated to grow to \$ in . The U.S. market for all *in vitro* cancer detection products, including the tumor marker category, is estimated to be \$, or about % of the total worldwide market.

The worldwide tumor marker product segment, comprising proteins detected with immunological technologies in serum or plasma, is expected to grow worldwide at about % per year through , from \$ in . This market sector is primarily driven by the increasing number of people in the population who fall within the higher risk demographics of cancer and the increased marketing of new tests to doctors. The worldwide serum based tumor marker segment is expected to reach almost \$ by .

The tumor marker product segment in the U.S. is expected to grow at about % per year through , reflecting increasing demand for tumor markers, especially prostate specific antigen (PSA). It will be primarily driven by the increasing number of people in the population who fall within the higher risk demographics of cancer. The U.S. market is still constrained by the cost pressures from third-party payers who are reluctant to reimburse for new procedures, and the conservative stance of the Food and Drug Administration (FDA), which is slow to approve new diagnostic tests for cancer. The U.S. cancer serum based tumor marker segment is expected to reach \$ by .

The Japanese cancer marker market is expected to grow by % per year through , reaching a total of \$. Continued growth for tumor marker products is expected for Germany and France in the European market. In fact, the European market uses a wider variety of cancer tumor markers, although the dollar volume is still third to the U.S. and Japan. Primarily because of marketing forces, the tumor marker nuclear matrix protein (NMP)-22 sells very well in Germany. It is estimated that the serum based tumor marker business in Europe will reach \$ by . The rest of the world accounts for about \$.

The existing FDA-approved assays which comprise the main tumor marker assay segment in the U.S. are:

- DTA and NMP22, which were approved for monitoring bladder cancer.
- Carcinoembryonic antigen (CEA), which is used primarily for monitoring colorectal and breast cancers.
- PSA, which is used primarily for monitoring and screening prostate cancer.

- Truquant BR RIA, which is used for monitoring breast cancer.

Serum PSA testing has revolutionized the diagnosis and management of prostate cancer and several [REDACTED] tests are performed every year in the U.S. to screen for malignancy. It is estimated that over \$ [REDACTED] is now spent on PSA testing.

The market for cancer detection products generally encompasses diagnostic products companies like Abbott Diagnostics, Johnson & Johnson, Diagnostic Products, Roche Diagnostics, Bayer Diagnostics, Dade, Tosoh and bioMérieux, which all market instruments and reagents for measuring serum protein tumor markers in the clinical lab. Another subsection of the cancer detection market consists of companies like General Electric, Siemens, Philips, Toshiba and Hitachi that market *in vivo* detection products. In addition, there are radionuclides (DuPont, Mallinckrodt and Bristol-Myers Squibb), X-ray contrast media (Schering-Plough, Mallinckrodt and Bristol-Myers Squibb) and X-ray film (DuPont, Agfa, Eastman Kodak, Fuji and 3M).

Tumor markers used and approved in the U.S. by the FDA include:

- PSA.
- Prostatic acid phosphatase (PAP).
- CA-125 for ovarian cancer (but only to follow the course of the disease).
- CEA in colon cancer.
- Alpha-fetoprotein (AFP) in liver cancer and combined with the beta sub-unit of chorionic gonadotropin in germ cell tumors.
- Terminal transferase used in T-cell leukemia, tissue estrogen and progesterone receptors in breast cancer.
- CA-15-3 and CA-27.29 are the markers currently used for breast cancer.

In other parts of the world, a wider variety of tumor markers are used:

- CA-547, M26, M29, MCA for breast cancer.
- CA-19-9, CA-195, TAG72, CA-245, M43 for gastrointestinal cancers.
- CYFRA-21 in non-small cell lung cancer (NSCLC), neuron specific enolase (NSE) and calcitonin in neuroendocrine tumors.
- Squamous cell carcinoma antigen in squamous cell tumors of the cervix-uterus or head and neck.
- Non-specific markers like TPS, LSA and sialic acid.

The clinical value of serum tumor markers CEA, CA-50 and CA-242 in the distinction between malignant versus benign diseases causing jaundice and cholestasis is also being examined.