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CARDIAC MARKER 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 (IVD) market devoted to cardiac marker testing. This study examines clinical measurement devices and their reagents and supplies as used in hospitals, clinics and doctor's offices and is arranged in such a manner to provide the reader with an overview of the outstanding diagnostic test market segments of cardiac care, with evidence that these segments are poised for high future growth. An overview of the diagnostic testing cardiac marker market is presented with the latest information regarding emerging new products and industry trends. It will not only quantify but also qualify the cardiac marker market segments as an area of research, product development and investment. Forecasts of the cardiac marker market and an analysis of products in the worldwide diagnostics market will provide a basis for understanding the significance of past developments and future possibilities within this diagnostic category.

1.2 Objectives of This Report

The principal objectives of this report are to:

- Identify viable technology drivers through a comprehensive look at various platform technologies for cardiac marker segments of the diagnostic testing market.
- Obtain a complete understanding of the chief cardiac markers and their diagnostic test predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic value, while also appreciating these elements from their basic principles to their applications.
- Discover feasible market opportunities via identification of high-growth applications in different cardiac marker 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 cardiac marker diagnostic testing, including forecasts for growth.
- Present market figures regarding the current value of the cardiac marker testing market, projections and growth rates. These are taken from the most recently available data of the global diagnostic industry.

By purchasing this study, the reader will gain:

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

This analysis will cover the following categories of the cardiac diagnostic testing segments:

- Acute myocardial infarction (AMI).
- Heart failure.
- Brain natriuretic peptide (BNP).
- Myoglobin.
- Homocysteine (Hcy).
- C-reactive protein (CRP).
- Pulmonary embolism (PE) (D-dimer test).
- Low-density lipoproteins (LDL) and high-density lipoproteins (HDL).
- Stroke.
- Creatine kinase-myocardial band (CK-MB) and cardiac enzymes.
- Albumin.
- Cardiac markers used in clinical decisions.

- Cardiac markers in renal failure.
- Troponins in non-ischemic heart disease.
- Cardiac panels.
- Point-of-care (POC) cardiac markers.

Analysis includes the use of charts and graphs measuring product growth and trends within the marketplace. In addition, a discussion of research into various illnesses provides the reader with a deeper understanding of the possibilities for future treatment and avenues for possible R&D budgets. Company-specific information, including sales figures, product pipeline status and R&D trends, is provided throughout the report. In addition, the study will:

- Assess the cardiac marker diagnostic testing market drivers and bottlenecks, from the perspective of the medical and scientific communities.
- Discuss the potential benefits of the cardiac marker diagnostic testing market for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the cardiac marker diagnostic testing 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 diagnostic testing segment.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the cardiac marker diagnostic testing market.

The following questions are answered in this analysis:

- What are the near-term business opportunities in the cardiac marker diagnostic testing market?
- What are the current and forecasted sizes of the cardiac marker diagnostic testing markets in the U.S., European Union (E.U.) and Japan, as well as other key country markets?
- What business models are currently used by companies in the cardiac marker diagnostic testing market?
- How will diagnostic manufacturers, researchers, physicians, patients and payers influence this market?
- What are the drivers and bottlenecks influencing the cardiac marker diagnostic testing market?
- What are the technologies used in cardiac marker diagnostic testing?
- Who holds the proprietary rights to the cardiac marker diagnostic testing market technology?
- What are current applications of this technology?
- What regulatory processes must the cardiac marker diagnostic testing technologies undergo in the U.S., Japan and the E.U.?
- How will new cardiac marker diagnostic testing technologies change treatment and payment paradigms?
- How will cardiac marker diagnostic testing technologies reduce adverse clinical reactions and decrease total patient care cost?
- How will cardiac marker diagnostic testing technologies reduce healthcare expenditures?

The examination contains:

- A comprehensive overview of the several categories of diagnostic tests that are, or will be, revolutionizing the treatment of cardiovascular diseases (CVDs).
- A chapter on each of the important cardiac-related categories: AMI, heart failure and stroke, and the diagnostic tests that are used in their treatment.
- Full descriptions of the technologies involved and how these differ from existing and emerging technologies.
- Analysis of the technological approaches undertaken by the various competitors, as well as industry and end-user responses to these products.
- Regulatory issues and legislation affecting use and marketing of products.
- Market forecasts for each category of product through 2010, including profiles of selected competitors in each category.

1.3 Scope of This Report

The emphasis in this analysis is on those companies that are actively developing and marketing cardiac marker diagnostic testing technologies. The reader should consult other TriMark Publications reports at http://www.trimarkpublications.com for a detailed discussion of the important individual market segments that are related to the cardiac marker diagnostic testing technologies market, such as hepatitis testing, clinical chemistry, cancer testing, infectious disease markers, and other new diagnostic methods.

This study reviews the market for cardiac marker diagnostic testing technologies in the clinical hospital market. It defines the dollar volume of sales, both in the U.S. and worldwide, and analyzes the factors that influence the size and the growth of the market segments. The report details market sizes and growth rates, with projections usually—if applicable—for the U.S. and world markets.

The examination discusses activity and trends in the hospital markets. The study goes on to describe in detail the trends that have developed that have stimulated this market. It also comments on the patterns of information processing in cardiac marker diagnostic testing technologies. The report surveys all of the companies known to be marketing, manufacturing, or developing cardiac marker diagnostic testing technologies in the U.S. and worldwide for the selected segments identified. Leading companies are discussed in depth with a section on the history of the company, the product line, business and marketing analysis, as well as a subjective commentary of the position of the company in its market.

1.4 Methodology

The information in this study is based upon interviews with sales and marketing professionals of companies in the cardiac marker 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, chief executive officers (CEOs), and vice presidents of some of the companies discussed in the report. The structure of the 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 the data reported. The main 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) and various health data from the United Nations (UN) and the Organization for Economic Co-operation and Development (OECD). Where possible and practical, the most recent data available have 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 that we believe to be reliable, but we do not guarantee the accuracy, adequacy, or completeness of any information, or results obtained by the use of such information.

1.5 Executive Summary

In [redacted], the combined worldwide market for cardiac markers was about $[redacted]. This market segment of the IVD testing area is expected to rise at an average compounded annual growth rate (CAGR) of about [redacted]% to over $[redacted] in [redacted]. This product category represents a diagnostic testing segment in which dramatic change is under way. Most of the areas within the cardiac marker segment such as troponin, BNP, and other markers will experience double-digit growth throughout the forecast period.

CVD comprises conditions that affect the proper functioning of the heart and blood vessels. Among the most prevalent of life-threatening diseases are sudden cardiac arrest (SCA), AMI, congestive heart failure (CHF) and atherosclerosis. Every year, an estimated [redacted] people worldwide die of CVD, particularly from AMIs and strokes.

CVD remains the leading cause of death in developed countries. In the U.S., one person dies every [redacted] from heart disease. This translates to more than [redacted] people a day. Each year in the U.S., deaths from CVD represent approximately [redacted]% of all deaths, or some one million deaths. Heart disease is the leading cause of death for all Americans, age [redacted] and older.

The world cardiac rapid assay market is expected to achieve an average annual growth rate of [redacted]% to [redacted]% for the near future, driven by a host of new markers (high-sensitive C-reactive protein (hs-CRP), Hcy, plasminogen-activator inhibitors, s100 protein, p-selectin, soluble fibrin, glycogen phosphorylase-BB (GPBB), thrombus precursor protein, and recently discovered genetic factors). In addition, the possible involvement of infectious agents in heart disease offers another opportunity for IVDs. The U.S. cardiac marker diagnostic testing market is projected to grow at annual rates north of [redacted]% for the next [redacted] years.

There will be a steady increase in demand for POC services, along with pressures to improve the quality of healthcare delivered in hospital emergency rooms (ERs) and to lower its cost. The cardiac marker diagnostic products segment is poised for a major new phase of growth fueled by the availability of new technology coming out of the POC segment. In the chronic cardiac marker segments such as cholesterol, CRP and Hcy testing, there is a higher interest level of individual patients and general healthcare consumers in taking charge of their own health status. Continuous improvements in technology are resulting in a growing number of new IVD tests that combine high levels of accuracy with rapid, easy-to-use product formats. New cardiac drugs are driving more screening programs for chronic heart disease like atherosclerosis and chronic heart failure.

Many acute cardiac marker IVD products and services are specifically targeted at markets outside of the traditional hospital or clinical laboratory, in particular, the hospital ER. Competition in the development and marketing of cardiac marker diagnostic products is intense, and diagnostic technologies have been subject to rapid change. We estimate that the competitive factors in the cardiac marker diagnostic market include convenience, privacy, price and product performance as well as the distribution, advertising, promotion and brand name recognition of the marketer.

The market for cardiac-related diagnostic tests in the U.S. increased from $[redacted] in [redacted] to over $[redacted] in [redacted], representing a [redacted]% CAGR. In [redacted], we projected an even larger growth, in the [redacted]% range, to [redacted], reaching over $[redacted] by that time. Two test categories, CK-MB ($[redacted]) and troponin ($[redacted]), dominated this market in [redacted] and accounted for approximately [redacted]% and [redacted]% of the total cardiac marker *in vitro* market, respectively. The approximate number of troponin tests in the U.S. was [redacted], and we estimate perhaps twice that number for CK-MB. The difference in market size reflects the considerably lower price per test for the much more mature CK-MB test.

We see significant opportunities to grow the cardiac marker diagnostic testing business outside the U.S. During [redacted], the total European cardiac marker-oriented diagnostic testing business increased [redacted]% over the prior year and accounted for [redacted]% of the total world market. Germany, Italy and France were the top three revenue contributors. For example, we expect that the European Union will play a critical role in the further commercialization of cardiac marker diagnostic tests like troponin for AMI and BNP for heart failure. Demand for cardiac marker testing in the E.U. is likely to escalate over the next [redacted] years, as its true value becomes more apparent to decision-makers. In terms of revenue, Germany represents the largest market for cardiac risk assessment markers in the E.U., followed by France and Italy. Variations in the cost of troponins across Europe are set to narrow in the next few years. Among key conclusions: point-of-care testing (POCT) is still at a nascent stage in rapid cardiac marker testing while the two novel natriuretic peptide (NP) markers are poised to make an immediate impact.

In addition to the traditional cardiac marker CK-MB, a trio of other useful markers has become available. Troponin T (TnT) became available in the U.S. in [redacted], and was followed by Troponin I (TnI) in the summer of [redacted]. Experts praised the superiority of these two markers for their specificity in diagnosing AMI. It has been found that both assays have approximately [redacted]% specificity, while TnI had [redacted]% sensitivity to AMI.

TriMark estimates that the market in the U.S. for rapid POC cardiac markers grew to $[redacted] in [redacted]. Rapid growth rates of [redacted]% to [redacted]% are expected in this segment. At the head of the diagnostic ranks are the troponins—proteins that reside on the heart's thin filament of striated muscle fibers, the myocardium, and are released following injury. These markers represent the latest advance in the treatment of cardiac patients, vastly increasing specificity and speed of diagnosis. Further, back in the ranks are the traditional markers CK, CK-MB, myoglobin, and other proteins traditionally associated with myocardial infarction (MI). On the diagnostic horizon are cardiac markers already known to the research community, but whose clinical significance has only just begun to be appreciated.

The world market size for troponin as a cardiac marker will grow from an estimated [redacted] value of $[redacted] to a projected $[redacted] in [redacted]. Overall, we expect a growth rate of [redacted]% to [redacted]% per year to hold until that time. We expect the growth rates of the U.S. troponin market to slow from the [redacted]% rate to somewhat less than [redacted]% as this segment approaches full market penetration. In [redacted], worldwide sales for BNP testing was approximately $[redacted]. TriMark predicts a CAGR of [redacted]% until [redacted]. However, the growth rate of the U.S. BNP market is expected to slow from the [redacted]% rate to somewhat above [redacted]% as this segment approaches full market penetration. The market penetration of myoglobin is approximately [redacted]% in the U.S., but in the E.U. it is much lower, at about [redacted]%, and is therefore not as abundant. The total market size was approximately $[redacted] in [redacted]. Following several years of positive growth in myoglobin market, TriMark projects a slight negative growth rate until [redacted].

The world market size for CK-MB as a cardiac marker will grow from the [redacted] value of $[redacted] to a projected $[redacted] in [redacted]. Overall, we expect the growth rate of [redacted]% per year to hold until that time. We expect the growth rates of the CK-MB market segment to remain steady in pricing, and grow in volume primarily as patient demand grows, since this marker is already very mature and this segment approaches full market penetration. The overall global rate of growth should continue to be flat for some time, however, as other parts of the world have very high market penetrations, which will allow for modest growth tracking patient demands as admissions for chest pain and AMI continue to rise.