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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

Cardiac marker diagnostic testing measures the concentration of certain proteins, *i.e.*, biomarkers, which indicate the presence or severity of cardiovascular disease (CVD). Among the most prevalent CVDs are sudden cardiac arrest (SCA), acute myocardial infarction (AMI), congestive heart failure (CHF) and atherosclerosis. Every year according to WHO, an estimated [REDACTED] people worldwide die from a CVD. This TriMark Publications report describes the specific market segment of the *in vitro* diagnostics (IVD) market devoted to cardiac marker testing, including size; growth; industry trends; product development and investment; and clinical measurement devices, reagents and supplies. Highly-attractive cardiac marker areas covered in this review include:

- The cardiac rapid assay market, troponins.
- Creatine kinase-myocardial band (CK-MB).
- Brain natriuretic peptide (BNP) testing.
- N-terminal pro-B-type natriuretic peptide (NT-proBNP).
- Myoglobin.
- Homocysteine (Hcy).
- C-reactive protein (CRP).
- D-dimer test.
- Low-density and high-density lipoproteins (LDL and HDL).
- Glial fibrillary acidic protein (GFAP).
- Fatty acid binding protein.
- Ischemia modified albumin.
- Troponin I and Troponin T.

These markers are used in stroke and other cardiac diseases to make; clinical decisions for cardiovascular disease; and also cardiac markers are used in renal failure, cardiac panels and point of care (POC), congestive, hypertensive and peripheral arterial disease.

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 with SWOT analyses.
- The leading perspective of recent diagnostic test developments and revelations as well as how they will influence selected clinical 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 United States, 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?

- What impact is increased testing in developing country markets likely to have on the diagnostic cardiac biomarker testing reagents markets in these countries?
- What are the true drivers for ordering volumes of troponin tests?
- How do the major geographic markets differ in their diagnostic testing protocols for troponin?
- What is the uptake of other biomarker tests, such as creatine kinase-MB (CK-MB) and myoglobin, across the major geographic markets?
- How will troponin, CK-MB, and myoglobin tests fare once the pipeline biomarkers co-peptin and H-FABP gain uptake?
- What are the opinions of interviewed experts regarding the next-generation of high-sensitivity troponin assays?
- However, manufacturers are continuing to develop more sensitive POC troponin tests.
- What are the opinions of interviewed experts regarding POC testing?
- What do they perceive as the advantages of POC testing?
- What are the growth opportunities for POC testing in this market?
- Who are the current and future players in the cardiac marker market?
- What determines the choice of brand for a laboratory?

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.

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 author of this report holds a Ph.D. in biochemistry from the University of Minnesota, and has had post-doctoral studies at the University of Connecticut School of Medicine. He has taught at Quinnipiac University, the Tufts School of Medicine, and New York Institute of Technology. He has been a senior scientist at DuPont and Pfizer

Pharmaceutical Laboratories in drug development and diagnostic testing. He was a leader in the formation and development of Dianon Laboratories, now part of LabCorp. He also has many decades of experience in science writing and as a medical industry analyst and consultant. He has over 40 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 Ph.D. in biochemistry from the University of Liverpool and an MBA from Oxford Brookes University 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 in TriMark Publications 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 data and proprietary databases.
- 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.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of expert panel partners from the industry being analyzed.

1.5 Executive Summary

Cardiovascular disease (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), acute myocardial infarction (AMI), congestive heart failure (CHF) and atherosclerosis. Every year, an estimated [REDACTED] people worldwide die of CVD, particularly from AMIs (heart attacks) 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 approximately one million deaths. Heart disease is the leading cause of death for all Americans, age [REDACTED] and older.

There will be a steady increase in demand for point of care (POC) services, along with pressures to improve the quality of healthcare delivered in hospital emergency rooms (ERs) and to lower testing 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 using POC methodologies. 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 rapid turnaround of test results, immediate availability, data handling techniques, price, reimbursement and product performance as well as the distribution, advertising, promotion and brand name recognition of the marketer.

The market for *in vitro* diagnostic tests for cardiac biomarkers is part of the larger IVD test market. The global IVD market has been estimated to be valued at \$[REDACTED] in [REDACTED]. One of the largest sub-segment of the global IVD market is Central Lab Immunoassays, where much of cardiac marker lab work is done. This sub-segment has been estimated to be valued at \$[REDACTED] in [REDACTED]. The majority of cardiac biomarker tests are included in the Central Lab Immunoassays sub-segment but a growing proportion of cardiac biomarker tests are being carried out as point of care tests and are included in the POC sub-segment.

As a result of the analysis conducted, TriMark has determined that the global market for *in vitro* diagnostic tests for cardiac biomarkers was estimated to be \$[REDACTED] by [REDACTED], and by the end of the forecast period ([REDACTED]), it is predicted that the market will be valued at \$[REDACTED] (CAGR [REDACTED]%).

In vitro diagnostic tests used for the detection of Troponin and BNP and NT-proBNP cardiac biomarkers are the largest single cardiac biomarkers representing revenues of \$[REDACTED] and \$[REDACTED] in [REDACTED], accounting for [REDACTED]% and [REDACTED]% of the global market value, respectively. The *in vitro* diagnostic tests used for the detection of Troponin and BNP and NT-proBNP cardiac biomarkers also represent the biomarkers with the highest growth rates with CAHRs of [REDACTED]% and [REDACTED]%, respectively.

Although there are a wide variety of established products and services with the cardiac marker testing market, the growth and further development of the market is expected to be driven by a host of new biomarkers—high-sensitive C-reactive protein (hs-CRP), homocysteine (Hcy), plasminogen-activator inhibitors (PAIs), S100 protein, p-selectin,

soluble fibrin, glycogen phosphorylase-BB (GPBB), thrombus precursor protein, and recently discovered genetic factors.

TriMark has determined that the U.S. market for *in vitro* diagnostic tests for cardiac biomarkers is the largest in the world representing an estimated █% of the global market. The U.S. market for *in vitro* diagnostic tests for cardiac biomarkers was estimated to be valued at \$█ in █. By █, it has been estimated that the U.S. market for *in vitro* diagnostic tests for cardiac biomarkers had increased in value to \$█ (CAGR █%), and by the end of the forecast period (█), it is predicted that the market will be valued at \$█ (CAGR █%).

The approximate number of troponin tests in the U.S. was █, and we estimate perhaps that same number for CK-MB. The difference in market size reflects the considerably lower price per test for the much more mature CK-MB test.

TriMark sees significant opportunities to grow the cardiac marker diagnostic testing business outside the U.S. The European market represents a large established market estimated to be valued at \$█ in █. By █, it has been estimated that the European market for *in vitro* diagnostic tests for cardiac biomarkers had increased in value to \$█, and by the end of the forecast period, it is predicted that the market will be valued at \$█ (CAGR █%). Germany, Italy and France were the top three revenue contributors. For example, we expect that the E.U. 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 five years, as its true value becomes more apparent to decision-makers. In terms of revenue, Germany represents the largest market for cardiac risk assessment biomarkers 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) biomarkers are poised to make an immediate impact. In addition to the traditional cardiac marker CK-MB, a trio of other useful biomarkers has become available. Troponin T (TnT) became available in the U.S. in █, and was followed by Troponin I (TnI) in the summer of █. Experts praised the superiority of these two biomarkers for their specificity in diagnosing AMI. It has been found that both assays have approximately █% specificity, while TnI had █% sensitivity to AMI.

China is recognized as the country with highest growth rate with a cardiac marker market value estimated at \$█ in █. By █, it has been estimated that the Chinese market for *in vitro* diagnostic tests for cardiac biomarkers had increased in value to \$█, and by the end of the forecast period, it is predicted that the market will be valued at \$█ (CAGR █%).

Whilst the other Asia-Pacific countries are exhibiting dramatic market growth rates the Japanese market has been shown to exhibit relatively slow market growth rates. The Japanese market value has been estimated at \$█ in █. By █, it has been estimated that the Japanese market for *in vitro* diagnostic tests for cardiac biomarkers had increased in value to \$█, and by the end of the forecast period, it is predicted that the market will be valued at \$█ (CAGR █%). The Japanese market is beset with cost constraints and subject to a variety of austerity measures as a method of reducing the overall cost of providing a highly sophisticated healthcare system to an aging population.

The Latin American market is also recognized as being a major opportunity and has market growth rates between █% and █% depending on the individual country and the individual types of cardiac marker being used.

The market penetration of myoglobin is approximately █% in the U.S., but in the E.U. it is much lower, at about █%, and is therefore not as abundant. The total market size was approximately \$█ in █. Following several years of positive growth in myoglobin market, TriMark projects a slight positive growth rate after █, as this biomarker has not been readily accepted by the clinical community.

The world market size for CK-MB as a cardiac marker will grow \$█ in █. Overall, we expect the growth rate of █% per year during the forecast period. 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