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HEMOGLOBIN A1c 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 global prevalence of diabetes mellitus continues to increase rapidly, with more than [REDACTED] diabetics worldwide. By [REDACTED], experts predict that the number of people with diabetes will soar to [REDACTED]. The dramatic increase in the incidence of diabetes worldwide has been exacerbated by the growing obesity problem across the globe. Once thought of as primarily a childhood disease—sometimes referred to as juvenile diabetes, now mostly Type 1 diabetes—the obesity crisis linked to the adoption of a high-fat, high-carbohydrate, and high calorie American diet has resulted in skyrocketing rates of diabetes, particularly Type 2 diabetes, among adults across the world.

As such, the global market for diabetes testing products is undergoing a significant transition driven by the advent of new analytical technologies and developments in diabetes treatment. Hemoglobin A1c (HbA1c) testing is the most recent major technology to have entered the diabetes testing market, and has made great strides in gaining acceptance over the past [REDACTED] years. It is now an essential assay in the diabetes testing repertoire. Its clinical utility and improvements in its accuracy and implementation of standardized protocols have translated into continued strong market growth.

The purpose of this TriMark Publications report is to describe the specific market segment that encompasses hemoglobin A1c testing for diagnosing and monitoring diabetes. This study reviews all of the generally-accepted clinical analytical methods that are currently in use today for measuring HbA1c levels. Moreover, it examines clinical measurement devices and reagents as utilized in hospitals, clinics, doctor's offices and at-home care locations. This report also provides an update on the new guidelines and parameters for the use of HbA1c.

1.2 About This Report

The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for HbA1c testing for diabetes management.
- Understanding the different sectors of the HbA1c testing space, such as the home self-testing and the professional glucose testing segments.
- Obtaining a complete understanding of the individual HbA1c testing platforms, from their basic principles to their clinical applications.
- Discovering feasible market opportunities by identifying high-growth applications in different analytical diagnostic areas.
- Focusing on global industry development through an in-depth analysis of the world market for HbA1c measurement technology, including growth forecasts.
- Presenting market figures regarding the current value of HbA1c testing, market projections, market share, key players and sector growth rates.
- Providing a detailed analysis of each of the major device categories.

This analysis defines the dollar volume of market sales, both worldwide and in the U.S., and analyzes the factors that influence the size and the growth of the market segments. Key questions answered in this examination include:

- How can HbA1c measuring tools and technologies facilitate improved diabetes patient care?
- What are the main types of HbA1c testing technologies that are currently available?
- Who are the current key players in this marketplace?
- Which HbA1c testing market areas have the greatest potential for growth?
- What is the current state of the HbA1c testing market?
- Which diagnostic companies are investing in new HbA1c testing technology platform solutions?
- What are the main business strategies adopted by leading HbA1c testing companies?
- What are the benefits of various HbA1c testing technology platforms?
- How does HbA1c testing compliment the existing diabetes testing platforms?

Additionally, this study contains:

- Detailed analysis of recent trends in the HbA1c testing marketplace.
- In-depth profiles of the leading companies with HbA1c testing tools and technologies.
- Perspectives of the HbA1c testing industry from leading industry experts.
- Analysis of potential new HbA1c testing applications in the clinical sector as they pertain to diabetes management.
- Market predictions and trends analysis concerning U.S. expenditures on HbA1c testing solutions.
- Projections of HbA1c testing market size for the global market.
- Review of commercial HbA1c testing business strategies such as co-branding.

Analysis includes charts and graphs measuring product growth and trends within the marketplace. Company-specific information—including sales figures, product pipeline status, and research and development (R&D) trends—is provided. Also, this review includes:

- Assessment of HbA1c testing market drivers and bottlenecks, from medical and scientific community perspectives.
- Discussions on the potential benefits of HbA1c testing for various sectors of the medical and scientific community, as they relate to diabetes management.
- The current total market size and future growth of the HbA1c testing market.
- Current and forecasted market shares by companies.
- Discussions on profit and business opportunities by segments.
- Strategic recommendations for near-term business opportunities.
- Analysis of the current commercial uses of HbA1c testing.

The following questions will also be addressed in this report:

- What are the near-term business opportunities in the HbA1c testing market?
- How will manufacturers, researchers, physicians and patients influence diabetes management?
- What are the drivers and bottlenecks influencing the HbA1c testing market?
- What are the barriers to entry for the HbA1c testing market?
- What are the key technologies used in HbA1c testing?
- Who holds the proprietary rights to the HbA1c testing market technology platforms?
- How is this technology currently being applied and utilized?
- In the U.S., what regulatory processes apply to HbA1c testing technologies?
- How will new HbA1c testing technologies change diagnostic screening/testing paradigms and decrease costs of patient care?
- How will new HbA1c testing technologies reduce healthcare expenditures and affect R&D spending?

1.3 Scope of the Report

This analysis emphasizes companies that are actively developing and marketing instrumentation and reagents for performing HbA1c tests. Specific attention is paid to the clinical market segment and, separately, to the instruments, reagents and supplies marketed by major companies for the point of care and home self-testing markets for diabetes management. Market size, growth rates and market components for instruments and reagents used in this area are also analyzed. Activity and trends in research, including patterns of information processing in array testing instruments, are addressed. Also discussed are trends that have stimulated this market, the numbers of institutions that use HbA1c testing and the factors that influence purchasing.

This report surveys all companies known to be marketing, manufacturing or developing instruments and reagents for the HbA1c testing market, for each of the major market segments of professional glucose testing, and self-monitoring of blood glucose. There are also sections on the companies' histories, product lines, business and marketing analyses, and a subjective commentary on the key companies' market positions. In-depth analysis of

diabetes management and glucose self-testing can be found in other TriMark Publications reports at www.trimarkpublications.com, such as TriMark's *Diabetes, Metabolic Syndrome and Cardiovascular Disease, U.S. Glucose Testing Markets, Point of Care World Testing Markets* and *World Glucose Self-Testing Markets*.

1.4 Methodology

The author of this report holds a Master's in immunology and has substantial experience in science writing and as a medical industry analyst. She also has many years of laboratory experience and has conducted laboratory testing and instrument and reagent development for biotech companies. The senior editor of this report holds a Ph.D. in biochemistry from the University of Minnesota and has had post-doctoral experience at the University of Connecticut School of Medicine. He has taught at Quinnipiac University and the Tufts School of Medicine, and has been a senior scientist at Pfizer Pharmaceutical Laboratories in drug development and diagnostic testing. He also has many decades 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 a licensed clinical laboratory director, as well as extensive experience in senior level management positions in biotech and medical service companies. He holds several patents on *in vitro* glucose testing.

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. Additionally, sources of information include the non-governmental organizations (NGOs) such as the World Health Organization (WHO), governmental entities like the U.S. Department of Health and Human Services (HHS), and U.S. federal agencies such as National Institutes of Health (NIH), Food and Drug Administration (FDA) and the Centers of 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

Hemoglobin A1c (HbA1c) assays have been on the market for over █ years, and it has become the primary test for monitoring long-term glycemic control. HbA1c is also consistently used to adjust therapy, assess quality of care, and predict risk for the development of complications. Moreover, HbA1c levels are now accepted as a diagnostic indicator of diabetes. The value of diabetes diagnostic and disease management tools, including the HbA1c assay, increases as the global incidence of diabetes increases.

Worldwide, there are about █ diabetics according to █. Due to rising rates of obesity and increased lifespan, the prevalence of diabetes is on the rise. By █, the global incidence of diabetes is expected to increase more than █%, afflicting █ people worldwide. Despite this large patient population, the IDF estimates that, even now, only █% of Type 2 diabetics have been diagnosed in the worldwide population. In light of this staggering worldwide prevalence of diabetes mellitus, there is increasing demand for effective monitoring of blood glucose and tight glucose control to delay disease progression, prevent diabetic complications and improve the quality of life for patients. Around █ deaths are attributed to health complications arising from diabetes every year. The World Health Organization predicts that diabetes will become the seventh leading cause of death in the world by █. The ten countries containing the largest population of diabetic patients are: China, India, the U.S., Brazil, Russia, Mexico, Indonesia, Germany, Egypt and Japan. There are currently an estimated █ people in the U.S. afflicted with diabetes (men █%, women █%, non-Hispanic black █%, non-Hispanic whites █%). An estimated █ new cases of diabetes are diagnosed each year in the U.S.

The results of the landmark Diabetes Control and Complications Trial (DCCT) and its continuation as the Epidemiology of Diabetes Interventions and Complications (EDIC) Trial, as well as the United Kingdom Prospective Diabetes Study (UKPDS), conclusively demonstrated that intensive glycemic control significantly reduces the risk of long-term diabetes complications. Researchers were then able to use the data collected from these studies to establish HbA1c goals based on observed increases in diabetes-related complications. For example, the American Diabetes Association (ADA) recommends that HbA1c levels be routinely obtained in all patients with diabetes at least two to four times per year and that non-pregnant adults should aim for HbA1c levels █%. More recently, the ADA recommended using HbA1c levels at █% to diagnose diabetes and at █% to █% as an indication of increased risk for diabetes.

These new recommendations, along with the steadily growing point of care (POC) HbA1c market segment, are key factors contributing to the solid performance of HbA1c market. The total worldwide HbA1c testing market was valued at approximately \$█ in █ and is projected to reach over \$█ by █, with a compound annual growth rate (CAGR) of █%. This includes both the point of care (POC) testing in doctors' offices and hospitals and testing within central laboratories. The POC segment occupies approximately █% of the total HbA1c market and is one of the fastest growing areas, with a CAGR of █% between █ and █. Laboratory based HbA1c testing continues to exhibit strong growth and is expected to increase from \$█ in █ to \$█ by █, with a CAGR of █%. The total U.S. HbA1c testing market was valued at \$█ in █ and is projected to reach \$█ by █, with a CAGR of █%.

The recent attention on setting optimal HbA1c thresholds for diabetes treatment and diagnosis has highlighted the need for clinical labs to have accurate and reliable methods to measure the HbA1c levels. Advances in global harmonization of the HbA1c assay and increased standards of quality have revolutionized the HbA1c testing market within the past decade. HbA1c assays should have acceptable performance, standardization to the national reference (National Glycohemoglobin Standardization Program, NGSP), and NGSP certification. Further improvements in POC HbA1c assays will enable them to be used to quickly and accurately diagnose diabetes. The ability to repeatedly produce accurate results is the key to the widespread adoption of HbA1c tests as screening assays in the future.

Additional recommendations include:

- Focusing diagnostic development on the significant and largely untapped global market that exists by creating more effective and affordable tests to manage diabetes.
- Developing more accurate and reliable HbA1c monitoring devices to take advantage of the increasing numbers of nursing home and other professional healthcare settings that are utilizing POC products.

SAMPLE