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U.S. GLUCOSE 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

U.S. glucose testing is undergoing a significant transition, driven by new analytical technologies and developments in diabetes treatment. Although the blood glucose testing segment of the *in vitro* diagnostics (IVD) industry is mature, the home testing devices for diabetes management continues to be significant market force due to its large size. Direct access testing, or self-testing, is an important segment in the blood glucose testing market, and non-invasive and minimally-invasive testing now represent major new areas for the application of IVD testing. This TriMark Publications report describes the specific market segments for blood glucose testing for diabetes management in the U.S. market. It reviews all of the generally-accepted clinical analytical methods that are currently in use today for measuring serum, plasma or whole-blood glucose concentrations. Additionally, this study examines clinical measurement devices, reagents, and supplies as utilized in hospitals, clinics, doctor's offices, and at-home care locations. Moreover, it analyzes almost all of the companies known to be marketing, manufacturing or developing glucose testing products for the U.S. market.

1.2 About This Report

The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for glucose testing for diabetes management.
- Understanding the different sectors of glucose testing, such as the home self-testing and the professional glucose testing segments.
- Obtaining a complete understanding of the individual glucose 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 industry development through an in-depth analysis of the U.S. market for glucose measurement technology, including growth forecasts.
- Presenting U.S. market figures regarding the current value of blood glucose testing, market projections, market share, key players, and sector growth rates.
- Providing a detailed analysis of each of the major device categories, such as blood glucose meters (including non- and minimally-invasive), blood glucose meter test strips, lancets and lancing devices, and urine glucose/metabolite monitoring strips.

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

Additionally, this study contains:

- Detailed analysis of recent trends in the glucose testing marketplace.
- In-depth profiles of the leading companies with glucose testing tools and technologies.
- Perspectives of the glucose testing industry from leading industry experts.
- Analysis of potential new glucose testing applications in the clinical sector as they pertain to diabetes management.

- Market predictions and trends analysis concerning U.S. expenditures on glucose testing solutions.
- Projections of the U.S. glucose testing market size.
- Projections for future applications of non-invasive tests in glucose testing-related screening.
- Review of commercial glucose 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 R&D trends—is provided. Also, this review includes:

- Assessment of glucose testing market drivers and bottlenecks, from medical and scientific community perspectives.
- Discussions on the potential benefits of glucose 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 U.S. glucose testing market and analysis of the current size and growth of individual segments.
- 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 glucose testing for diabetes management.

The following questions will also be addressed in this report:

- What are the near-term business opportunities in the U.S. glucose testing market?
- What are the current and forecasted glucose testing market sizes in the U.S?
- What are the business models currently used by companies in the glucose testing market?
- How will manufacturers, researchers, physicians and patients influence diabetes management?
- What are the drivers and bottlenecks influencing the glucose testing market?
- What are the barriers to entry for the glucose testing market?
- What are the key technologies used in glucose testing?
- Who holds the proprietary rights to the glucose testing market technology platforms?
- How is this technology currently being applied and utilized?
- What regulatory processes apply to glucose testing technologies in the U.S.?

1.3 Scope of the Report

This analysis emphasizes companies that are actively developing and marketing instrumentation, reagents and supplies for performing glucose tests in the U.S. Specific attention is paid to the clinical market segment and, separately, to the instruments, reagents, and supplies marketed by major companies for the home self-testing market for diabetes management. Market size, growth rates and market components for instruments, reagents, controls, and consumables 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 and the numbers of institutions that use glucose testing and the factors that influence purchasing.

This report surveys all companies known to be marketing, manufacturing or developing instruments and reagents for the glucose testing market, and delineates the major market segments of professional glucose testing and self-monitoring of blood glucose in the U.S. There are also sections on the companies' histories, product lines, business and marketing analyses, and a subjective commentary on the key companies' market positions. Several subjects related to the major elements of glucose testing, disposable plastic supplies, needles, and lancets are discussed only briefly in this report because they are considered entirely different fields or markets. In-depth analysis of these areas of interest can be found in other TriMark reports at www.trimarkpublications.com, such as *Blood Glucose Testing and Diabetes Management*, *World Glucose Self-Testing Markets* and *Point of Care Diagnostic Testing World 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 investigating cancer immunotherapies 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. 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

Advances in diabetes treatment have revolutionized the blood glucose testing market. Direct access testing—which allows consumers to order tests themselves without visiting a doctor—has emerged as a strong force in the blood glucose testing segment. Indeed, there's an increasing range of test devices now available to consumers to perform self-testing. Moreover, automation is now a well-established trend in the central clinical laboratory, driven primarily by efforts to reduce costs, and a continuing shortage of qualified technologists and technicians. Information management, including Internet-based reporting and consultation—as well as remote data acquisition and result-reporting for POC glucose testing—is becoming a more important element of many suppliers' product offerings. The analysis and reporting of data from blood glucose tests is another area that will become increasingly important in the future.

The risk for the later development of microvascular disease makes it important to identify patients with Type 2 diabetes (sometimes referred to as adult onset diabetes). Demonstration of unequivocal hyperglycemia (plasma glucose >200 mg/dL [11.1 mmol/L]) two hours or more after a mixed meal is considered diagnostic for diabetes mellitus according to [redacted]. Moreover, HbA1c levels are now accepted as an indicator of diabetes. As such, frequent monitoring of blood glucose levels facilitates control of diabetes.

According to [redacted], there are currently an estimated [redacted] people ([redacted] diagnosed and [redacted] undiagnosed) in the U.S. afflicted with diabetes. An estimated [redacted] new cases of diabetes are diagnosed each year in the U.S. Approximately [redacted]% to [redacted]% of diabetics have Type 2 diabetes, while the rest are patients of Type 1 diabetes. The total prevalence of diagnosed diabetes in the U.S. increased by [redacted]% from [redacted] to [redacted]. Demographic changes, population growth, and increasing prevalence rates are equally weighted contributors to this phenomenon. Ethnic groups such as Native Americans, African Americans, and Hispanics (the latter of which are the fastest growing minority in the nation) are experiencing particularly large increases in the diabetes epidemic. The ADA estimates that the prevalence diabetes during the past few years has been approximately [redacted]% of the U.S. population.

In addition, approximately one in four adults ([redacted]) are considered to be in a "pre-diabetic" state, in which symptoms such as impaired glucose tolerance or hyperglycemia are manifested. These pre-diabetic individuals are at a significantly greater risk for developing Type 2 diabetes, heart disease, and stroke. In light of this staggering 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.

There are two key market segments for glucose testing: self-testing and professional testing. In the U.S., self-testing glucose meters and strips were worth $[redacted] in [redacted] and are expected to grow to over $[redacted] by [redacted]. The U.S. professional glucose testing market (includes central laboratory glucose testing, hospital POC glucose testing, and POC glucose testing within physicians' offices but excludes self-testing) was worth $[redacted] in [redacted] and is expected to increase to $[redacted] by [redacted]. The glucose monitoring market is dominated by the four large international companies: Roche, Johnson & Johnson (LifeScan), Bayer, and Abbott.

The sector for glucose testing devices is lucrative, but very competitive and overpopulated. Greater than [redacted] models of hand-held blood glucose monitors are being marketed by more than [redacted] companies for blood glucose self-testing in the U.S. In addition, there are a number of large and fully diverse diagnostic products companies that specialize in marketing clinical chemistry analyzers for the professional testing of blood glucose.

The consumable aspect of the blood glucose test strips is the primary business driver of the world glucose self-testing market. The diabetic test strip market is very large. Although unit volume growth in the U.S. market will continue to be strong, pricing pressures will push the dollar value growth to a lower pace. Sales of blood glucose testing strips across both self-testing and professional POC markets led the U.S. industry, with manufacturers' sales of over $[redacted] in [redacted]. The market for blood glucose test strips, which comprise nearly [redacted]% of the total North American blood glucose testing market, is expected to grow to $[redacted] in [redacted], at a CAGR of [redacted]%.

Clinical chemistry analyzers are positioned in hospitals, reference labs, independent labs, regional labs, and doctor's offices. They range from the ultra-large to the small, based on their throughput (and price). Glucose testing occurs in virtually every chemistry profile put through these analyzers. The volume of glucose testing in these settings dwarfs the self-testing market in terms of numbers of tests. TriMark estimates more than [redacted] glucose tests are performed in the U.S. on these analyzers. However, the price per test is very low, on the order of ten or [redacted] per test, due to the efficiency of these highly engineered instruments.

The explosion of glucose monitoring devices on the market has given consumers an unprecedented choice of instruments and reagents to monitor blood glucose levels. It has also given manufacturers and developers of new technology a cohort of customers who are used to changing devices and are looking for new technologies. Underlying all of this is the classic "razor and razor blade" marketing model. Each manufacturer makes a different test strip, and they're not interchangeable from one monitor to another. Some even make a different strip for each individual monitor type. The reagents substantially drive sales, as costs and ease of use are large factors in customer choice.

Co-branding is one of the strategies that seem to offer smaller companies successful entry into the crowded glucose testing market and provides good market share. Co-branding is valuable to a device manufacturer in a number of ways:

- Manufacturers launch a co-branding program with a product line that represents the latest technology and the highest of quality standards.
- Co-branding sets the stage for a number of initiatives for other chronic disease products and services in the direct-to-consumer needs category.
- It raises the profile of smaller, less well-known companies. It leverages the marketing power of the pharmacy or retail co-brander for the small device manufacturer.

Additional recommendations include:

- Focusing diagnostic development on more effective, consumer-friendly, and affordable devices and tests for diabetes management.
- Developing better ways of monitoring glucose levels *in vivo* with continuous monitoring techniques.
- Moving to continuous glucose monitoring that may be partnered with insulin pumps to enable automated disease management using a closed loop system.
- Developing more accurate and reliable monitoring devices to take advantage of the increasing numbers of nursing home and other professional healthcare settings that are utilizing hand-held blood glucose monitoring products.
- Develop technologies (*i.e.*, mobile phone hardware and applications) that enable the increasingly tech savvy consumer base to monitor their disease.
- Focus diagnostic development on the significant and largely untapped global market that exists by creating more effective and affordable tests to manage diabetes.

