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# BLOOD GLUCOSE TESTING AND DIABETES MANAGEMENT

***(SAMPLE COPY, NOT FOR RESALE)***

**Trends, Industry Participants, Product Overviews and Market Drivers**

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# 1. Overview

## 1.1 Statement of Report

There has been a dramatic increase in the incidence of diabetes worldwide, which 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, 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 blood glucose testing products is undergoing a significant transition driven by the advent of new analytical technologies and developments in diabetes treatment. Although the blood glucose testing segment of the *in vitro* diagnostics (IVD) industry is mature, certain segments of the market, such as home testing devices for diabetes management, will exhibit strong growth. What's more, non-invasive testing now represents a major new area for the application of IVD testing. Additionally, direct access testing—or over-the-counter testing, which allows consumers to order tests themselves without visiting a doctor—has emerged as a strong force in the blood glucose testing segment.

The purpose of this TriMark Publications report is to describe the specific market segments for blood glucose testing and diabetes management. This study reviews all of the generally-accepted clinical analytical methods that are currently in use today for measuring serum or plasma or whole-blood glucose concentrations. Moreover, it examines clinical measurement devices, reagents and supplies as utilized in hospitals, clinics, doctor's offices and at-home care locations.

## 1.2 About this Report

The emphasis in this examination is on those companies that are actively manufacturing clinical laboratory instrumentation, self-testing meters, point of care (POC) devices, reagents and supplies for performing blood glucose testing to facilitate effective diabetes detection and management. The reader should consult other TriMark Publications reports at http://www.trimarkpublications.com for a detailed discussion of the important individual market segments which are related to the POC testing (POCT) market, such as clinical chemistry, hematology and coagulation, blood gas and electrolytes, cancer tumor markers, cytology and immunochemistry.

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 home self-testing, and the professional glucose testing segment.
- 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 global industry development through an in-depth analysis of the major world markets for glucose measurement technology, including growth forecasts.
- Presenting 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, POC glycated hemoglobin testing products and urine glucose/metabolite monitoring strips.

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 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 glucose testing market sizes for U.S., European and Asian markets.
- 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 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 the glucose testing market by diabetes management.

The following questions will also be addressed in this report:

- What are the near-term business opportunities in the glucose testing market?
- What are the current and forecasted glucose testing market sizes in the U.S., E.U. and Japan, as well as in other emerging markets such as India and China?
- 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?
- In the U.S., Japan and the E.U., what regulatory processes apply to glucose testing technologies?
- How will new glucose testing technologies change diagnostic screening/testing paradigms and reduce diagnostic false negatives and decrease costs of patient care?
- How will new glucose 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, reagents and supplies for performing glucose tests. The world's three largest analytical markets, the U.S., Japan and Europe are the primary focus here. 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, 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. 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 Publications reports, such as *Disposable Medical Supplies Markets* and *Diabetes, Metabolic Syndrome and Cardiovascular Disease*.

## 1.4 Methodology

The author of this report is a Ph.D. in biochemistry from the University of Minnesota, with many decades of experience in science writing and as a medical industry analyst. He has over thirty 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. The senior editor is a Ph.D. in physiology from the University of Toronto and is a post doctoral research fellow in the Department of Cell and Systems Biology at the University of Toronto. The editor is a Ph.D. in life sciences from Jawaharlal Nehru University with an extensive background in molecular biology.

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) and 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 laboratory, driven primarily by 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. As such, frequent monitoring of blood glucose levels facilitates control of diabetes.

Worldwide, there are about [redacted] diabetics according to [redacted]. Due to rising rates of obesity and increased lifespan, the prevalence of diabetes is on the rise. By [redacted], the global incidence of diabetes is expected to increase [redacted]%, afflicting [redacted] people worldwide. Despite this large patient population, physician research reveals that, even now, only [redacted]% 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 [redacted] deaths are attributed to health complications arising from diabetes every year. The ten countries containing the largest population of diabetic patients are: India, China, the U.S., Russia, Germany, Japan, Pakistan, Brazil, Mexico and Egypt. There are currently an estimated [redacted] people in the U.S. afflicted with diabetes (men [redacted]%, women [redacted]%, non-



 

Hispanic black [redacted]%, non-Hispanic whites [redacted]%). An estimated [redacted] new cases of diabetes are diagnosed each year in the U.S.

The sector for glucose testing devices is lucrative, but very competitive and overpopulated. Worldwide, more than [redacted] companies market blood glucose monitors. 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. These dominate the glucose testing sector in all customer categories (POL, POCT, self-testing and central lab). Primarily, the increasing numbers of diagnosed diabetic patients who closely monitor their own blood glucose values drives this extraordinarily diverse market. This sector continues to attract more entrants to the industry and is heavily technology driven. The two major diabetes-related personal medical devices are glucose monitors and insulin pumps. The glucose monitor market is dominated by the four large international companies: Roche, Johnson & Johnson (LifeScan), Bayer and Abbott.

There are two key market segments for glucose testing: home self-testing and professional testing. Self-testing glucose monitors were worth $[redacted] worldwide in [redacted] and are expected to grow to over $[redacted] by [redacted]. The U.S. self-testing diabetes diagnostic market for glucose monitoring devices is a $[redacted] market. The global professional glucose testing market (excluding self-testing) was worth $[redacted] in [redacted]. The diabetic test strip market is very large and growing. Sales of blood glucose testing strips led the U.S. industry, with manufacturers' sales of over $[redacted] in [redacted].

There were more than [redacted] Europeans diagnosed with diabetes mellitus in [redacted] according to the [redacted]. Left untreated, the number of diabetics in Western Europe is expected to reach [redacted] by [redacted]. Of this, [redacted]% suffer from Type 1 diabetes. There are about [redacted]% of European diabetic patients practicing self-glucose monitoring. The European glucose monitoring market reached $[redacted] in [redacted], growing at a compounded annual growth rate (CAGR) of [redacted]%. The European glucose monitoring market is estimated to be valued at $[redacted] by [redacted].

The Southeast Asia and western Pacific region is believed to have had at least [redacted] diabetics in [redacted], and by [redacted] the number of diabetes patients is expected to reach [redacted]. Only about [redacted]% of diabetic patients are currently undergoing treatment. The rising incidence of diabetes has prompted a flourishing market, not only for the pharmaceutical manufacturers but also for companies producing diabetes monitoring devices and drug delivery systems. For example, this has created a huge market potential for the home care lancet market. Japan, with an aging population and declining birthrates, is the most advanced country for medical care and diagnostic testing in the Asian region. In addition, as the two most populous countries in the world, China and India are hot spots for manufacturers of glucose meters.

According to industry analysts, the market for blood glucose test strips, which comprise nearly [redacted]% of the total North American blood glucose testing market, was approximately $[redacted] in [redacted] in North America and is expected to grow to $[redacted] in [redacted], at a CAGR of [redacted]%. Estimates place the market outside of North America for blood glucose strips at approximately $[redacted], growing at [redacted]% per annum through [redacted]. The total home care lancet demand in the U.S. and E.U. was about [redacted] units and [redacted] units, respectively, in [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 out-sized 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. The price per test is very low, on the order of [redacted] or [redacted] cents 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.

 