



WORLD GLUCOSE  
SELF-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 worldwide incidence of diabetes is dramatically increasing, and it is estimated that 592 million people will have developed the disease by 2035. As such, the global market for blood glucose self-testing is undergoing a significant transition driven by the advent of new analytical technologies and new recommendations for tight glucose control for monitoring diabetes. In addition, the proliferation of the middle class within developing nations, particularly China and India, has resulted in both a substantial rise in Type 2 diabetes and the financial means to manage the disease.

The purpose of this TriMark Publications report is to provide a comprehensive analysis of the specific segment of the over-the-counter diagnostics sector known as the glucose self-testing market. The term “self-testing” is used to distinguish it from *in vitro* diagnostics testing for blood glucose in hospitals, commercial labs and doctor’s offices, the so called “professional” component of the glucose testing market. This study reviews the viable technology drivers and assesses the market dynamics of the glucose self-testing market worldwide. This report also looks at the industry challenges and potential threats, and it makes strategic recommendations for boosting market share. Specifically, this study analyzes the market for glucose self-testing in the following product segments:

- Blood glucose testing devices (blood glucose test kits, blood glucose meter/monitors).
- Diabetes testing supplies (blood glucose test strips, lancet devices, reagent strips, blood glucose sensors, and control solutions).

In the current medical diagnostics market, glucose self-testing offers continued promise for growth and innovation, albeit at a lower growth rate than the “professional” market component. The development of this sector of the diagnostics industry has been driven by:

- Use of small, portable instruments for blood glucose determinations designed for the layman.
- Development of a wide variety of easy to use technology platforms.
- Increasing prevalence of diabetes.
- New developments in the effective diagnosis and treatment of diabetes.
- Need for screening for blood glucose in the near-patient setting.
- Improved detection levels and sensors.
- Use of computer-assisted data analysis.

This review analyzes the size and growth of the glucose self-testing market, including the factors that influence the various market segments within it and the dollar volume of sales, both in the U.S. and worldwide. Also examined are:

- Glucose detection technology platforms.
- Clinical applications of world glucose self-testing.
- The market for quantitative diagnostic glucose tests.
- Companies participating in this sector.
- New instrumentation.
- Trends in the industry.
- The internal structure of the world glucose self-testing sector.

### 1.2 About This Report

This report includes the following features:

- Examination of all generally-accepted clinical analytical activities in use today in the world glucose self-testing sector. It includes the prevalent clinical measurement devices and the accompanying reagents and supplies utilized in over-the-counter (OTC) glucose testing.

- Discussion on the potential benefits of the glucose self-testing market for various sectors of the medical and scientific communities worldwide, and it assesses the market drivers and bottlenecks from the perspective of these communities.
- Establishment of the current total market size and future growth of the world glucose self-testing market and analyzes the current size and growth of various segments.
- Assessment of various business models in glucose self-testing and provides strategic recommendations for near-term business opportunities globally.
- Examination of the products offered and roles played by companies that have invested significantly in this market, and it provides current and forecasted market shares by these companies.

The main objectives of this analysis are to:

- Identify viable technology drivers through a comprehensive look at platform technologies for world glucose self-testing, including new sensor technology, pain free testing, point of care systems, lancets, controls and reagents.
- Obtain a complete understanding of the chief glucose self-testing assays—*i.e.*, predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic—from their basic principles to their applications.
- Discover feasible market opportunities by identifying high-growth applications in different clinical diagnostic areas and by focusing on expanding markets, such as employee screening, emergency medicine, HbA1c testing, and satellite clinic testing.
- Focus on global industry development through an in-depth analysis of the major world markets for glucose self-testing, including growth forecasts.
- Assess the impact of glucose self-testing on laboratory growth plans globally.
- Identify laboratory tests that are the most likely candidates for migration to self-testing platforms.
- Analyze the business issues associated with glucose self-testing market around the worldwide.
- Present feasible market opportunities by identifying high-growth applications in different clinical diagnostic areas and by focusing on expanding markets, such as employee screening, emergency medicine, HbA1c testing, and satellite clinic testing.
- Assess the development of the global industry through an in-depth analysis of the major world markets for world glucose self-testing, including growth forecasts.
- Evaluate the impact of world glucose self-testing on clinical laboratory growth plans.

### 1.3 Scope of the Report

The goal of this study is to review the market for world glucose self-testing equipment and supplies, including reagents and instruments for analysis of glucose in body tissues and fluids (particularly whole blood and urine). Toward this goal, this review answers the following key questions:

- Which companies are utilizing cutting-edge technologies to develop, validate and promote glucose self-testing globally?
- What are the current impediments to incorporating promising glucose self-testing assays into clinical practice?

- Which new glucose self-tests show the most promise for approval?
- What are the economic challenges to gaining approval?
- How can regulatory oversight drive approval and adoption of new technologies?
- Which alliances show the greatest synergy in bringing world glucose self-testing to market?
- Which shared technologies are driving the most encouraging development?

The U.S., Europe and Japan—the world’s three largest glucose self-testing markets—are the focus of this report. Market size, growth rates and market components for instruments, reagents, controls and consumables used in this area are analyzed. This analysis emphasizes the companies that are actively developing and marketing glucose self-testing instrumentation, reagents and supplies for performing home testing across the globe. The reader should consult other TriMark Publications reports at [www.trimarkpublications.com](http://www.trimarkpublications.com) for detailed discussions of important individual market segments related to the blood glucose testing market, such as clinical chemistry testing and high-growth diagnostic tests markets. Diagnostics glucose tests marketed primarily as qualitative or quantitative reagents are generally included in this report, although there is inevitably some overlap. TriMark provides a separate market report called [Point of Care Diagnostic Testing World Markets](#) report, which discusses near-patient glucose professional testing in clinical settings.

#### 1.4 Objectives

One goal of this study is to review the market for world glucose self-testing equipment and supplies that utilize reagents and instruments for analysis of individual components in whole blood, serum, or plasma. The report also defines the dollar volume of sales, both worldwide and in the U.S., and analyzes the factors that influence the size and the growth of the market segments. The subsections of the world glucose self-testing market segment are examined in detail and include: clinical testing markets, trends, analysis, SWOT, challenges, government regulations, reimbursement and billing, and business decisions. Additionally, the factors that influence purchases are also discussed. On a more technical level, this report:

- Discusses the problems of using indirect methods for analyzing complex biological fluids when making diagnostic decisions and their replacement with other technology platforms.
- Reviews the strategies available for sample collection.
- Contrasts the optimal methods for quality control when employing portable glucose meters.
- Evaluates the applications of new technologies to the clinical laboratory assessment of world glucose.
- Reviews the dynamic regulatory environment (*e.g.*, FDA) and assesses how glucose self-testing may play a role in the clinical laboratory.

This review answers the following key questions:

- Which companies are utilizing cutting-edge technologies to develop, validate and implement glucose tests for near-patient use?
- What impediments still exist to incorporating glucose self-testing into clinical practice?
- Which new glucose self-tests show the most promise for approval?
- What are the economic challenges to approval?
- How can regulatory oversight drive approval and adoption of new technologies?
- Which alliances show the greatest synergy in bringing glucose self-testing tests to market in specific countries?
- Which shared technologies are driving the most encouraging development?
- How are businesses entering the clinical lab testing space by leveraging glucose self-testing?



## 1.5 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. 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. Some of the information in this report comes from direct interviews with senior decision makers and market experts from many of the leading IVD companies.

### **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.

## 1.6 Executive Summary

Worldwide, there are estimates of over [REDACTED] diabetics. This corresponds to approximately [REDACTED]% of the world's adult population. The global incidence of diabetes is expected by industry experts to increase dramatically, reaching an estimated [REDACTED] by [REDACTED]. The increase in Type 2 diabetes is predicted to occur because of factors such as population aging and growth, as well as from obesity, unhealthy diets and sedentary lifestyle. According to [REDACTED], there are currently an estimated [REDACTED] people in the U.S. afflicted with diabetes. Approximately [REDACTED]% to [REDACTED]% of this patient group has Type 2 diabetes, while the rest are patients of Type 1 diabetes. Other parts of the world are similarly impacted by this disease. In India and China alone, there are approximately [REDACTED] people afflicted with diabetes ([REDACTED] in India and [REDACTED] in China, according to [REDACTED]).

The comprehensive worldwide blood glucose testing market was valued at \$[REDACTED] in [REDACTED] and is projected to reach \$[REDACTED] by [REDACTED]. This includes both the professional testing segment (doctors, hospitals, etc.) and self-testing home-based markets (SMBG). Products included in this market are glucose monitoring meters and strips, insulin pumps, lancing devices, and clinical chemistry analyzers. One of the largest segments within this arena is the self-testing whole blood glucose monitoring market (SMBG). Sales of the self-testing glucose monitoring device market were greater than \$[REDACTED] in [REDACTED], and are projected to increase at approximately [REDACTED]% annually over the forecast period to over \$[REDACTED] by [REDACTED]. Products in this market include hand-held meters, disposable test strips, lancets, and other disposable items that are typically distributed OTC at retail pharmacies and mail order houses for use by patient's in their home. The four major competitors in the blood glucose self-testing market are LifeScan (a Johnson & Johnson subsidiary), Roche, Bayer and Abbott. These companies dominate the market, with a combined global market share of approximately [REDACTED]% and a combined U.S. market share of greater than [REDACTED].

The worldwide glucose home testing market shows the U.S. as the leader in sales with \$[REDACTED], followed closely by Europe (\$[REDACTED]), and to a lesser extent Asia (\$[REDACTED]) and ROW (\$[REDACTED]), with sales of disposable test strips being over [REDACTED]% of the market. The consumable aspect of the blood glucose test strips is the primary business driver of the world glucose self-testing market. 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. The Asian market, however, will exhibit the greatest growth rate of [REDACTED]% compounded annual growth rate (CAGR) from [REDACTED] to [REDACTED]. The European glucose self-testing market reached an estimated \$[REDACTED] in [REDACTED], with a projected CAGR of [REDACTED]% from [REDACTED] to [REDACTED]. In this regard, the European glucose self-testing market is estimated to be valued at \$[REDACTED] by [REDACTED]. Germany is the largest European market at \$[REDACTED]. The geographic market share is projected to decrease for the U.S. and Europe by [REDACTED], while Asia's share increases to north of [REDACTED]% of worldwide sales, with Japan still the largest, followed in order by China and India.

The high market growth forecasted for SMBG in the Asia-Pacific and South and Central American countries is primarily driven by the increasing diabetic population, increasing patient awareness through diabetes screening programs, and as yet very low penetration of the glucose self-monitoring systems in countries like India and China and the highly insured populations of Japan, Korea, Taiwan and Brazil.

As a follow on, the demand for blood glucose meters and strips is expected to increase dramatically in the Asia-Pacific market, at a projected CAGR of [REDACTED]% over the analysis period. Asian countries, specifically China, India,

the Taiwan, Pakistan, Malaysia, Thailand, Philippines, Indonesia, Hong Kong, South Korea and Singapore, have emerged to be major markets with a high diabetic population. The concept of self-monitoring of blood glucose (SMBG) is still not well known in India when compared with the West; only █% of Indians with diabetes use SMBG compared with almost █% of diabetes patients in developed countries.

Although Pan Asia is the smallest revenue contributor in the combined world markets, it is growing fast. Moreover, as Pan Asian countries have the highest diabetes incidence rate, the region offers potential in the underdeveloped markets. As in other parts of the world, the dominant players in the Asian markets are Johnson & Johnson's LifeScan, Roche Diagnostics, Abbott Diagnostics, and Bayer Diagnostics. Other major players in the Asian market include ARKRAY, Inc., DexCom, Inc., MediSense, Nipro Diagnostics, Inc., Nova Biomedical, Sanwa Kagaku Kenkyusho Co., Ltd., Sanofi-Aventis, Terumo Europe NV, among others. A serious competitor in Asia for the glucose meter market is Korean-based Allmedicus and i-Sens. These companies are expanding market share in Asia by increasing exports to China and the Southeast Asian countries.

China has an estimated █ diabetic patients, compared with █ in Japan and about █ in the U.S. The incidence of diabetes in China is also rapidly rising due to the changes in lifestyle among the increasing mid- to high-income demographic. These numbers by themselves underscore the vast market potential for blood glucose testing in China. TriMark estimates that of the expected █ diabetic patients, perhaps █ have actually been diagnosed. Estimates of actual routine blood glucose monitoring are in the range of █ patients per year.

India has the second-largest population of diabetics in the world, with greater than █ diagnosed cases out of a projected █ total. By █, India is projected to have █ diabetics, which would account for █% of the world's total diabetic population. The glucose self-testing market in India is exhibiting strong growth, with sales of \$█ in █ forecasted to increase to \$█ in █, with a CAGR of █%. Currently, we estimate that greater than █% of the self-monitoring blood glucose market is untapped in this country.

More than half of the market share of the Korean domestic market of is occupied by Roche of Switzerland and Johnson & Johnson of the U.S. i-Sens is ranked in third place in the Korean domestic market, ahead of the Korean company Infopia in fourth place. The Southeast Asian self-testing blood glucose market reached an estimated \$█ in █ and is expected to increase at a CAGR of █% to \$█ by █. Thailand, Malaysia and Indonesia now account for █% of the Southeast Asian blood glucose testing market, and will exhibit the greatest rates of growth within the next five years.

From █ to █, the world glucose self-testing market grew at a CAGR approximately █% but has fallen to a projected █% CAGR from █ to █. Moreover, growth in the U.S. market has been nearly flat since █. Some components of the SMBG business, particularly the U.S., are changing from a high-growth market to a maturing, commodity type of business, where both consumers and insurance payers view all products essentially as interchangeable. Thus, while unit volume sales may continue strong growth, dollar growth is slowing. It seems likely that dollar growth approaching double-digits for SMBG products will be solely in the emerging markets like China, India and Brazil. The geographic market share is projected to continually decrease for the U.S. and Europe, while the Asian market share will increase to north of █% of worldwide sales, with China and India contributing the most to sales growth.

The diabetic test strip market is of course very large. Sales of blood glucose testing strips in the U.S. led the industry with manufacturers' sales of \$█ in █. Sales of blood glucose testing strips will continue to dominate this market segment, with sales growing to a projected \$█ in █.

Four major players dominate the global self-testing blood glucose monitoring market. Roche Diagnostics and Johnson and Johnson's LifeScan lead the pack with a █% and █% worldwide market share, respectively. The two other large players in the market are Bayer (█% market share) and Abbott (█% market share). While Roche Diagnostics and Johnson and Johnson's LifeScan both lead the world market, Roche's brand is strongest in its home territory of Europe. Several other companies, including ARKRAY and Nipro Diagnostics, form the remaining █% of the worldwide market share. LifeScan was first in the U.S. blood glucose self-testing market, with █% of market share, while Roche Diagnostics had a █% share of the U.S. self-testing market.

### ***Strategic Recommendations***

Given the increasingly competitive nature of the SMBG business and the inevitable unit declining prices, it will very likely be difficult for a new entrant to succeed in the SMBG market in the absence of a major technological innovation. With prices likely to decrease, yet another “me too” glucose meter/strip manufacturer has little chance to succeed.

For the existing players in the market, the key question becomes how to sustain strong growth while still maintaining adequate profit margins in the future. Recommendations include:

- 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.
- Research studies are needed to find newer and better ways of monitoring glucose levels *in vivo* with continuous monitoring techniques.
- Move to continuous glucose monitoring that may be partnered with insulin pumps to enable automated disease management using a closed loop system.
- Develop more accurate and reliable monitoring devices to take advantage of the increasing numbers of nursing home and other professional healthcare settings that are utilizing OTC blood glucose monitoring products.
- Greater emphasis should be placed on assays for tight glycemic control when educating patients about their disease management.