

OVER-THE-COUNTER  
DIAGNOSTIC PRODUCTS  
WORLD 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 purpose of this analysis is to describe the specific market segments of the over-the-counter (OTC) diagnostic products and home healthcare markets. It examines the diagnostic measurement devices and their reagents and supplies that are utilized in clinics and by patients directly in their homes to diagnose and monitor disease. This study also includes a review of home healthcare kits and devices that measure health-related conditions.

### 1.2 About This Report

Focus is on market dynamics and current market drivers of the OTC and home self-testing diagnostics market. This report also looks at the industry challenges and potential threats, and it makes strategic recommendations for boosting market share. The analysis covers healthcare-related devices that are designed for the home market in order to allow consumers to assess their health status through self-testing. In addition, this review examines some biowarfare detection systems.

The emphasis in this report is on those companies and products that are actively developing and marketing diagnostic reagents and supplies in market segments that are targeted for direct sale to the public. It is believed that this market segment has the potential for growth rates above 15% per year over the next five years in some of the less well-explored and well-developed areas. The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for OTC testing.
- Understanding the different sectors of OTC testing, such as home self-testing.
- Looking at a description of the instruments, reagents and supplies marketed by major companies in each segment of the OTC market segment.
- Discussing the market size, growth rates and market components for instruments and reagents, controls and consumables utilized.
- Obtaining a complete understanding of the individual OTC 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 the biggest and expanding markets.
- Examining global industry developments through an in-depth analysis of the major world markets for OTC measurement technologies, including growth forecasts for specific countries.
- Presenting market figures regarding the current value of OTC testing, market projections, market share, key players and sector growth rates.
- Providing a detailed analysis of each of the major device categories—blood OTC meters, blood OTC meter test strips, lancets and lancing devices, and urine OTC/metabolite monitoring strips.

By purchasing this report, the reader will have:

- An understanding of the most exciting OTC testing market segments, current and future.
- The latest information on leading products and R&D initiatives.
- Familiarity with recent developments and their effects on selected markets.
- Knowledge of the OTC testing market as an area of growth, research and investment.
- An extensive review of the market for clinical glucose testing equipment and supplies used in the clinical hospital market as well as testing in OTC settings.

Key questions answered in this report:

- How can OTC measuring tools and technologies facilitate improved patient care?
- What are the main types of OTC testing technologies that are currently available?
- Who are the current key players in this marketplace?
- Which OTC testing market areas have the greatest potential for growth?

- What is the current state of the OTC testing market?
- Which biotechnology and diagnostic companies are investing in new OTC testing technology platform solutions?
- What are the main OTC testing business strategies adopted by leading companies?
- What are the benefits of various OTC testing technology platforms?

Additionally, this report contains:

- Detailed analysis of recent trends in the OTC testing marketplace.
- In-depth profiles of the leading companies with OTC testing tools and technologies.
- A five-year forecast for the OTC testing market in the biotechnology and diagnostic industries.
- Views and principles on the OTC testing industry from leading industry experts.
- Analysis of potential new OTC testing applications in the clinical sector.
- Market predictions and trends analysis concerning U.S. expenditures on OTC testing solutions.
- Projections of OTC glucose testing market sizes for European and Asian markets.
- Analysis of commercial OTC testing business strategies such as co-branding.
- The latest news and M&A developments in the OTC testing marketplace.
- A comprehensive overview and insight into OTC testing business strategies for growth in foreign markets.

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 report will:

- Assess the OTC testing market drivers and bottlenecks, from medical and scientific community perspectives.
- Discuss the potential benefits of OTC testing for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the OTC testing market and analyze the current size and growth of individual segments.
- Analyze current and forecasted market shares by company.
- Review profit and business opportunities by segment.
- Provide strategic recommendations for near-term business opportunities.
- Examine current commercial uses of the OTC testing market.

The following questions will also be addressed in this report:

- What are the near-term business opportunities in the OTC testing market?
- What are the current and forecasted OTC glucose testing market sizes in the U.S., European Union (E.U.) and Japan, as well as in other key markets such as India and China?
- What are the business models currently used by companies in the OTC testing market?
- How will manufacturers, researchers, physicians and patients influence this market?
- What are the drivers and bottlenecks influencing the OTC testing market?
- How will new OTC testing technologies change diagnostic screening testing paradigms?
- What are the barriers to entry for the OTC testing market?
- How will new OTC testing technologies reduce diagnostic false negatives and decrease costs of patient care?
- What are the key technologies used in OTC testing?
- Who holds the proprietary rights to the OTC testing market technology platforms?
- How is this technology currently being applied and utilized?
- How will new OTC testing technologies reduce healthcare expenditures?
- In the U.S., Japan and the E.U., what regulatory processes apply to OTC testing technologies?
- How will new OTC testing technologies affect R&D spending?

The report contains:

- A comprehensive overview of the several categories of OTC testing technology platforms that are, or will be, revolutionizing the use of diagnostic tests in hospitals.
- A chapter on each of the important OTC testing categories and applications, including disposable supplies like lancets and reagent strips.
- Full descriptions of the technologies involved and how these differ from existing and emerging technologies.
- Analysis of the technological approaches undertaken by various competitors, as well as industry and end-user response to these products.
- Regulatory issues and legislation affecting use and marketing of OTC testing products.

The report will allow the reader to:

- Evaluate the effect of strategic factors such as technology driven change and industry consolidation.
- Investigate how cost-constraints and technological advances are driving change in the OTC testing diagnostics market.
- Examine the structure of the OTC testing industry and learn how to plan successful product placement in the seven largest markets of the U.S., Japan, Germany, France, the U.K., Italy and Spain.
- Assess future growth opportunities in all OTC testing sectors.
- Review the main products in each sector and plan a product entry strategy in line with the strengths and weaknesses of the competition.

### 1.3 Scope of the Report

The OTC and home self-testing diagnostic markets that are identified as candidates for exceptionally high annual growth rates over the next five years in the OTC marketplace are:

- Glucose monitoring.
- Pregnancy testing.
- Hepatitis testing.
- Drugs of abuse screening testing.
- Infectious disease testing.
- Cholesterol testing.
- Coagulation testing.
- Urine dipstick testing.

The home healthcare device categories that are emerging for direct consumer self-testing are:

- Home patient monitoring devices.
- Home patient alert systems.
- Home genetic testing kits.
- Home paternity testing.
- Home health hazards detection.
- Lead.
- Radon.
- Asbestos.
- Pesticides.
- Mold.
- Carbon monoxide.
- Water quality.
- Bacteria in water.
- Thyroid disease.
- Carpal tunnel.

- Allergy.
- Nutrition and wellness.
- Testosterone and male hormones.
- Antioxidants.
- Sleep apnea.
- Male check.
- Female check.
- Mineral check.
- Stress check.

Concentration is placed upon an overview of individual diagnostic testing markets that are believed to be the principal segments of the OTC diagnostic product segment. The report assesses the current status of each market, makes five-year projections for market size, discusses the market strategies of the leading companies in each market segment, and evaluates the forces that underlie the high growth of each segment. Also presented is a description of the instruments, reagents and supplies marketed by major companies in each market segment. In addition to the home care market, this report also touches upon the industrial screening market for drugs of abuse testing.

This analysis touches on the specialty testing areas in each high-growth market, since these segments are frequently a part of the overall analytical focus of companies marketing general laboratory automation equipment. However, no effort is made to quantify the size of this broader market. The total diagnostic market can be analyzed in general hospital and commercial clinical laboratory terms, POC technology, alternate site diagnostic testing and high-growth diagnostic testing. In some cases, there is very little distinction between home testing and doctor's office devices. This is particularly true for glucose testing, where the so-called professional devices are essentially the same technology platform as their home testing brethren, with the possible exception of containing more on-board data management capabilities. Perhaps the single most important difference is the source of supply, *e.g.*, distributors for physicians and pharmacies and the Internet for home patient testing devices.

There are a number of companies that market diagnostic testing devices—particularly urine test strips and occult blood test kits—that are primarily distributors of these products rather than the primary developer. These companies, necessary and important to the diagnostic testing industry, are covered here. Although this study mentions recombinant proteins in passing, as well as techniques such as measuring the serum concentrations of therapeutic drugs and drugs of abuse, no extensive or in-depth treatment of this subject is presented. Such a discussion is outside the scope of this analysis. Several subjects related to the major elements of OTC testing such as disposable plastic supplies, needles and lancets, are discussed only briefly in this report because they are considered entirely different fields or markets.

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 these high-growth markets such as clinical chemistry testing, hematology and coagulation, blood gas and electrolytes, and immunochemistry as used in hospital, point-of-care (POC) and doctor's office settings. Fuller explorations of these areas of interest can be found in other TriMark Publications reports, such as *Clinical Chemistry Analyzers*, *Glucose Blood Testing Markets* and *Diabetes, Metabolic Syndrome and Cardiovascular Disease*.

#### **1.4 Objectives**

Reviews of the products for diagnostic testing, equipment and supplies using screening reagents and instruments for analysis of individual components in blood, serum, plasma or urine in the OTC, public market are presented here. This analysis defines the dollar volume of sales, both worldwide and in the U.S., of the OTC markets and analyzes the factors that influence the size and the growth of the market segments. Further examination is given to the subsections of each market segment, including the home testing and industrial sectors, including the numbers and types of customers using this type of testing and the factors that influence purchasing activity. The analysis goes on to discuss the trends that have developed and stimulated this market. There is also commentary on the patterns of information processing in home testing instruments.

A survey of almost all of the companies known to be marketing, manufacturing or developing instruments and reagents in the areas selected as leading OTC diagnostic markets in the U.S. is included in this study. Each company is discussed in depth with a section on the history of the company, the product line, business and marketing analysis, and a subjective commentary of the position of the company in its market.

## 1.5 Methodology

The information here is based upon interviews with sales and marketing professionals of companies in the OTC diagnostic product market. Personnel from virtually every company mentioned were queried, some several times, about their companies' products and marketing strategies as well as their overall thoughts about their industry segment. Information was also obtained from interviews with founders, CEOs and vice presidents of some of the companies discussed in the report. The structure of the hospital laboratories and near-patient facilities was derived from interviews with laboratory directors and medical technologists working in these areas.

Other sources of information were trade association publications and meetings, product brochures and catalogs, and company literature. Where the companies under discussion were publicly held, annual reports, 10k filings and financial reports were used as the basis of the data reported. Some of the information obtained for the report was taken from TriMark Publications' databases, Biotechnology Associates' files and the private data stores of the author. Guidelines for measuring glucose were adapted from recommendations of the National Academy of Clinical Biochemistry of the American Association for Clinical Chemistry. The information set forth in this study was obtained from sources that are believed to be reliable, but the accuracy, adequacy or completeness of any information, omission or results obtained by the use of such information are not guaranteed.

The study will include market segment size, growth rates, five-year projections, major players and competitive strategies for the OTC diagnostic products market segments. An analysis of technology platforms, descriptions of companies in the field, market drivers and trends in technology and business impacting this market segment is included. Moreover, there will be an examination of products in development, perceived medical and market needs, the market outlook, economic considerations and pricing for the OTC diagnostic market segment. This report is designed as an update of the current status and future potential of the market for OTC *in vitro* diagnostics worldwide.

## 1.6 Executive Summary

OTC diagnostic products and home self-testing segments are poised for a major new phase of growth fueled by the availability of new technology coming out of the POC segment and the higher interest of individual patients and general healthcare consumers in taking charge of their own health status.

### *Global OTC Diagnostic Products Industry*

Preventive healthcare is emerging as a primary focus of medical intervention, and consumer self-testing is becoming an important part of preventive healthcare as individuals become increasingly aware of and involved with their own health. Several self-tests—including those for blood glucose, pregnancy, ovulation, fecal occult blood and various urine components—are used as physicians and patients realize their potential for promoting improved healthcare.

### *The Structure and Size of the OTC Diagnostics Industry*

The OTC market for home health tests in the U.S. has grown substantially in the last [REDACTED] years. It increased from \$[REDACTED] in [REDACTED] to over \$[REDACTED] in [REDACTED], representing a [REDACTED]% compounded annual growth rate (CAGR) in that earlier period. More recently, in [REDACTED], the U.S. OTC market and home self-testing segment rose to \$[REDACTED]. The growth rate for the U.S. market is estimated to be [REDACTED]% per year through [REDACTED], reaching almost \$[REDACTED] by that time.

Overall, the OTC market worldwide was estimated to be about \$[REDACTED] in [REDACTED], with [REDACTED]% of the market in the U.S., [REDACTED]% in Europe and [REDACTED]% in the rest of the world including Asia and Japan. The rapid non-instrument-based OTC market is estimated to have manufacturer-realized revenue of approximately \$[REDACTED] worldwide in [REDACTED].