

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 over-the-counter (OTC) diagnostic products and home healthcare markets. It examines the diagnostic measurement devices and the device's 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 challenges and potential threats facing this industry, and makes strategic recommendations for boosting market share. The analysis covers healthcare-related devices designed for the home market that allow consumers to assess their health status through self-testing. In addition, this review examines some biowarfare detection systems. The emphasis of this report is on those companies and products that actively develop and market diagnostic reagents and supplies in market segments that are targeted for direct sale to the public. It is believed that this market segment has a potential growth rate of above █% 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 the 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 its basic principles to its 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.
- The latest information on leading products and R&D initiatives.
- Familiarity with recent developments and these development's 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 seven-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 United States 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.

Analyses include 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 the medical and scientific community perspectives.
- Discuss the potential benefits of OTC testing in 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 examination contains:

- A comprehensive overview of the several categories of OTC testing technology platforms that have or will revolutionize 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 responses to these products.
- Regulatory issues and legislation affecting the use and marketing of OTC testing products.

The study 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 to test for drugs of abuse.

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, point of care (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 for the device's 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 these are considered entirely different fields or markets.

The reader should consult other TriMark Publications reports at [www.trimarkpublications.com](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, 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, Blood Glucose Testing and Diabetes 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 these 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 author 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. The editor of this report is a Ph.D. in biochemistry from the University of Liverpool with many decades of experience in science writing and as a medical industry analyst.

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.

### ***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 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 databases, proprietary databases, direct meetings and personal interviews with key personnel.
- Formulating a study outline with the assigned writer, including important items:
  - 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.
- Launching a combination of primary research activities including two levels of questionnaires, executive-direct focused, company-specific, and region-specific communications to qualified and experienced senior executives worldwide.
- 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**

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 past several years. It increased from \$ [REDACTED] in [REDACTED] to over \$ [REDACTED] in [REDACTED]. It is predicted that the U.S. OTC market will increase in value to \$ [REDACTED] (CAGR [REDACTED]%) by the end of the forecast period of [REDACTED]. Market intelligence has determined that the global OTC market was estimated to be valued at \$ [REDACTED] in [REDACTED] with [REDACTED]% of the market in the U.S., [REDACTED]% in Europe, [REDACTED]% in Asia-Pacific and [REDACTED]% for the rest of the world. A worldwide growth rate of approximately [REDACTED]% is projected for OTC diagnostic products through between [REDACTED] and [REDACTED]. This is slightly higher than the projected growth rate of the U.S. OTC sector, reflecting the growth for this market in the emerging economies of China, India, Brazil and Russia.

Three basic factors have driven the market for OTC diagnostic testing products:

- Technical developments leading to easy-to-use, accurate assay kits.
- The cost to run a test on OTC kits is low.
- The Clinical Laboratory Improvement Act of 1988 (CLIA) and subsequent Healthcare Financing Administration (HCFA) regulations created a category of “waived” tests that are approved for use outside the traditional laboratory setting.

The OTC market comprises two general segments: home testing (where products are purchased at pharmacies and drug stores) and decentralized testing in non-institutional settings (insurance companies and law enforcement agencies). Home diagnostic testing is: accepted and growing; generally not an extension of the hospital’s central laboratory, and generally not instrument based.

Decentralized testing sites consist of nursing homes, pharmacies and other non-institutional, ambulatory settings in which non-physician healthcare providers perform diagnostic tests. This category does not usually include physician’s office laboratories (POL), which are considered a separate segment. The decentralized OTC market encompasses a large variety of *in vitro* diagnostic (IVD) products ranging from moderate-sized instrument-based diagnostic systems for use at large institutions to single-use, disposable tests that individuals can use at home.

### ***OTC Diagnostic Product Industry Trends***

TriMark believes that the trend in healthcare management to adopt OTC testing is increasing, and that demographic changes, reimbursement policies, manageable regulations, and the availability of clinically-valuable tests will increase the growth of this diagnostic category. More and more employers, health plans and payers recognize that OTC and home self-tests are a cost-effective means for improving the quality of care and patient satisfaction. Continuous improvements in technology have resulted in a growing number of new diagnostic tests that combine high levels of accuracy with rapid, easy-to-use product formats.

### ***Market Segments***

OTC diagnostic products and services are specifically targeted toward markets outside the traditional hospital or clinical laboratory. These include:

- Corporate and law enforcement areas.
- Pharmacy sites, including approximately [REDACTED] independent and retail chain pharmacies in the U.S., which have begun positioning themselves to respond to the consumer trend toward personal health management, although pharmacists face difficult reimbursement issues in a group of states with blocking state legislation.

- Health promotion sites, which include a variety of locations such as corporate wellness programs, fitness centers, health promotion service providers, community health centers, public health programs, the U.S. military, and other independent screeners.
- Consumer events, including promotional sporting and social events and retail-venue events.
- eHealth, including Internet-enabled information requests, counseling and monitoring of cardiovascular disease and cholesterol.
- Patient home self-testing.

### ***Competitive Outlook***

Competition in the development and marketing of OTC diagnostic products is intense, and diagnostic technologies have been subject to rapid change. The competitive factors in the OTC and home self-testing diagnostic market are estimated to include convenience, price and product performance as well as the distribution, advertising, promotion, and brand-name recognition of the marketer.

Many of this market's current and prospective competitors include several large pharmaceutical and diversified healthcare companies that have substantial financial, marketing and other resources. These competitors, including Abbott Laboratories, Alere, Inc., Beckman Coulter Primary Care, BD, Bayer, Ortho-Clinical Diagnostics (a division of Johnson & Johnson), and Roche Holdings Ltd., have developed OTC and home self-monitoring tests designed for preventive care and maintenance testing. These competitors have substantially greater financial, technical and marketing resources than the small companies that offer diagnostic test kits in this market. In addition, such competitors offer broader product lines than the small companies, have greater name recognition than these companies and offer discounts as a competitive tactic. That said, it is believed that several smaller companies are currently making or developing products that will compete with those of the large players in this market segment. These competitors will actively compete to maintain and increase market share, and seek to develop multi-analyte tests that qualify for CLIA waiver. TriMark believes that the market opportunity for nationwide consumer cholesterol testing vastly exceeds that of all existing test services combined. This is still a largely untapped market.

### ***Market Strategies***

The OTC market segment is characterized by high growth and enhanced marketing opportunities. The major players are pursuing growth in the OTC sector using the following strategies:

- Improving profit margins through improved product pricing and operational efficiencies.
- Securing a stronger new product pipeline from internal R&D.
- Pursuing licensing and acquisitions opportunities when financially and strategically attractive.
- Launching a diagnostic test business under a brand by leveraging the marketing and distribution strength in the U.S. and maximizing worldwide sales through current and newly identified sales channels in Europe and the rest of the world.
- Launching new and improved CLIA-waived tests worldwide.
- Launching rapid diagnostic tests on a worldwide scale in conjunction with a development partner, such as a pharmaceutical company.
- Expanding development and marketing collaborations with large pharmaceutical and other healthcare companies.
- Identifying business development opportunities in the form of product or company acquisitions to enhance product portfolios and further leverage distribution channels worldwide.
- Expanding international sales through external alliances, collaborations and sales focus.

### ***Glucose Monitoring***

Diabetes management by blood glucose testing is the largest self-test market for medical diagnostic products in the world. According to industry sources, the worldwide market for personal glucose monitoring systems and related disposables, which include test strips and lancets, was valued at approximately \$ [REDACTED] in [REDACTED]. By the end of the forecast period to [REDACTED], it is predicted that the market will have increased in value to \$ [REDACTED] (CAGR [REDACTED]%). It is estimated that more than [REDACTED] people worldwide have diabetes. The six countries with the



largest number of people with diabetes in [REDACTED] included: India ([REDACTED]), China ([REDACTED]), the U.S. ([REDACTED]), Russia ([REDACTED]), Brazil ([REDACTED]) and Japan ([REDACTED]). The blood glucose monitoring segment is by far the largest of the OTC diagnostic testing market segments and still has a lot of room to grow. It is estimated that less than a third of the people diagnosed with diabetes are regular users of blood glucose monitors. The OTC market for blood glucose monitors will expand to include nursing homes and home care in the next years.

### ***Pregnancy Testing***

Women's health is the second largest self-test market for medical diagnostic products in the U.S., with \$ [REDACTED] in sales in [REDACTED]. Players in this segment market include OTC pregnancy and ovulation self-test kits under brand labels and a variety of private labels. Sales efforts in this segment are currently focused on: 1) large drug, food and mass merchandising retail chains; 2) wholesalers who service smaller accounts; and 3) Internet retailers. The products are currently contracted with broker agencies geographically distributed across the U.S.

### ***Drugs of Abuse Screening Testing***

The U.S. market for drugs of abuse testing is over \$ [REDACTED] annually, with over [REDACTED] tests performed in [REDACTED]. In [REDACTED], the U.S. OTC drug of abuse testing market was \$ [REDACTED]. Approximately \$ [REDACTED] annually is spent worldwide for drugs of abuse. Testing is concentrated on a set of commonly abused drugs called the NIDA (National Institute of Drug Abuse)-5, consisting of cocaine, methamphetamines, opiates, marijuana, and PCP. This market segment is highly fragmented with a large number of specialized players. The market segment can be said to be at a critical juncture because the future of this market segment depends critically on the assumption of leadership by some of the large players in the field like Siemens Healthcare Diagnostics, Abbott, Roche, and Inverness Medical Innovations. The U.S. market can be divided into four major categories:

- *Medical Testing*: The medical testing segment represents testing typically performed in a hospital laboratory.
- *Non-Medical Testing*: The non-medical testing market consists of testing performed for the workplace, the criminal justice setting and drug rehabilitation centers. It is estimated that approximately [REDACTED]% of the drugs of abuse testing in the U.S. occurs in this segment. Roche dominates this segment of the marketplace.
- *Reference Laboratory Testing*: The reference laboratory testing market accounts for a significant percentage of the total drug testing market. Approximately [REDACTED]% of testing for drugs of abuse occurs in this segment.
- *Hospital/Emergency Department Testing*: Drug abuse plays a significant role in emergency medicine cases annually in the U.S., either as a primary cause, such as an overdose, or as a contributing factor, such as in the case of an accident. Approximately [REDACTED]% of the testing for drugs of abuse in the U.S. occurs in this segment.

Workplace screening is becoming important in the U.S. Among adults [REDACTED] years of age or older, [REDACTED]% reported using illicit drugs in a National Survey on Drug Abuse and Health in [REDACTED]. In industry, there is still a need for rapid results since many employment decisions hinge on a potential employee's ability to pass physical and other examinations that include a test for illegal drugs. Despite a need for rapid results, there is a [REDACTED]- to [REDACTED]-hour wait based on the sample transportation and testing process used by major reference laboratories. In [REDACTED], over [REDACTED] tests for drugs of abuse were run in the workplace. Approximately [REDACTED] of these tests were mandated by the workplace testing acts for employees in the transportation and in other industries regulated by the Federal Transit Administration and the Department of Transportation (DOT). An estimated [REDACTED] to [REDACTED] drug tests are performed each year in the criminal justice, uniformed services, U.S. Postal Service, school-based student testing, and non-federal public and private sectors.

There are two kinds of drug tests. The first kind is the drug "screen". Drug screens are simple and inexpensive methods to determine if there is a drug in the urine above or below a certain level. If the drug is present below the level, the screen result is "negative". If the drug is present above the level, the screen result is "positive". Drug screens do not show the level of the drug, but only show if the drugs are present above the specified level for that

drug. The QuickScreen 10 Minute Urine Drug Tests are drug screens. Other drug screens include the Emit<sup>®</sup>, the Roche OnTrak<sup>®</sup> and OnTrak Testcup<sup>®</sup>, and the Biosite Triage<sup>®</sup>. The second kinds of drug tests are “confirmation tests”. Confirmation tests include gas chromatography and mass spectrometry (GC/MS). These tests require expensive laboratory equipment and trained laboratory personnel. The confirmation test reports exactly the amount of drugs found in the urine sample. The report is indicated in nanograms per milliliter (ng/ml).

### *Infectious Disease Testing*

#### *Hepatitis Testing*

According to an article in Liver International in September [REDACTED], it has been estimated that the total number of individuals infected with Hepatitis C in the U.S. is between [REDACTED] to [REDACTED]. Currently, hepatitis C is responsible for an estimated [REDACTED] to [REDACTED] deaths annually from chronic liver disease. Without effective intervention, that number is believed to triple in the next [REDACTED] years. Hepatitis C is the leading cause for liver transplant and the tenth leading cause of death in the U.S. Comparatively, hepatitis C is five times more prevalent than human immunodeficiency virus (HIV). Hepatitis C statistics are enumerated in the full text of the report.

The Home Access<sup>®</sup> Hepatitis C at-home test was approved by the U.S. FDA on [REDACTED] and was available in [REDACTED] through the company’s website or by calling (888) 888-HEPC. By [REDACTED], it was available in over [REDACTED] drugstores in the U.S. Home Access Hepatitis C Check test service is also available online from CVS pharmacies in the U.S.

#### *HIV*

The United Nations Organization (UNO) spearheading the global battle against HIV/AIDS reported that by the end of [REDACTED], [REDACTED] people worldwide were living with HIV/AIDS and [REDACTED] were newly infected. The global statistics also indicate that HIV/AIDS is increasingly becoming a disease affecting women. The number of annual AIDS-related deaths worldwide is steadily decreasing from the peak of [REDACTED] ([REDACTED] to [REDACTED]) in [REDACTED] to an estimated [REDACTED] ([REDACTED] to [REDACTED]) in [REDACTED].

AIDS has killed [REDACTED] people worldwide since the start of the epidemic more than [REDACTED] years ago. Sub-Saharan Africa is most affected by the epidemic, with [REDACTED]% of the adult population infected. At the end of [REDACTED], roughly [REDACTED] of the world’s HIV carriers lived in sub-Saharan Africa. It is estimated that [REDACTED] adults and children died of HIV/AIDS during [REDACTED].

Most HIV antibody screening tests are enzyme immunoassays (EIAs). These tests operate on the principle that antibodies will react with a known antigen; this reaction is detected by using enzymes as indicators. Outside of blood bank screening, physicians, the life insurance industry, the military, the criminal justice system, and the U.S. Citizenship and Immigration Services (formally known as the Immigration and Naturalization Service) generate the largest domestic demand for HIV testing.

The urine screen can be used to cost-effectively test for many other diseases and health concerns in addition to HIV. Also, its non-invasive nature is a positive to both healthcare professionals and to potential policyholders. In addition, urine can be collected in the absence of a paramedic. Even in cases where paramedics collect the urine, less is usually charged than when blood is collected because no venipuncture is required.

TriMark believes that there is a market for a rapid test for HIV in response to the reports by the CDC on the value of immediate HIV antibody test results. The high number of individuals who do not return for test results and counseling constitutes a threat to public health. In addition, in emergency rooms, delivery rooms and other settings, there is an urgent need to know the HIV status of the patient. The OTC market for HIV testing is currently served by only one FDA-approved product, the Home Access Express HIV-1 Test System manufactured by Home Access Health Corporation, which uses a dried blood spot to provide the patient’s sample. This sample is then sent to a laboratory for testing and test results are communicated to the customer via an 800 number. This is the only FDA-approved at-home test even though other at-home tests are being marketed.

### ***Coagulation Testing***

Evaluation of hemostasis is an integral part of patient diagnosis and treatment for a wide variety of medical conditions. Hemostatic test results must be provided quickly because a majority of the drugs used to regulate clotting are cleared rapidly from the body, and these drugs must be closely monitored to maintain drug levels within an effective treatment range. Most of the future high growth in coagulation will come with small devices at the level of the individual patient. Right now, diagnostic companies are introducing coagulation testing to the home patient in order to monitor post myocardial infarct Coumadin<sup>®</sup> levels. Several facts are apparent in coagulation testing:

- There is a large (> [REDACTED] worldwide) and growing (approximately [REDACTED]% per year) patient population on oral anti-coagulation therapy of the coumarin family (warfarin/coumadin).
- Warfarin has a narrow therapeutic index, meaning that the drug requires precise dosing and monitoring.
- More frequent testing enables a dramatically reduced incidence of life-threatening events.

### ***Fertility Testing***

Ovulation prediction test kits, marketed as brand names and under private label by various drugstore chains and mass merchandisers, are used by women to test for ovulation in their own home as an aid to family planning and to provide [REDACTED]- to [REDACTED]-hour notice of when ovulation is likely to occur. The early ovulation predictor has an easy-to-use and easily read self-test cassette that is used by applying a urine sample to the sample well with a supplied dropper. Clinically accurate results are available in approximately three minutes. Tests in this category are targeted toward women who are infertile or who want to control the timing of their pregnancies. These tests predict or confirm that ovulation has occurred and are used by primary care physicians, fertility specialists and consumers. Ovulation prediction test sales, including tests sold OTC, to physicians and to other healthcare organizations, represented approximately [REDACTED]% of the OTC diagnostic products market in the U.S.

This report weaves these analytical strands into a lucid assessment of the industry that is richly qualitative and quantitative. While focusing on new technologies, new markets for diagnostic products, and changing attitudes of patients and healthcare providers, this study is a sourcebook of data and analysis about a complex and quickly evolving industry whose products are transforming the practice of medicine.