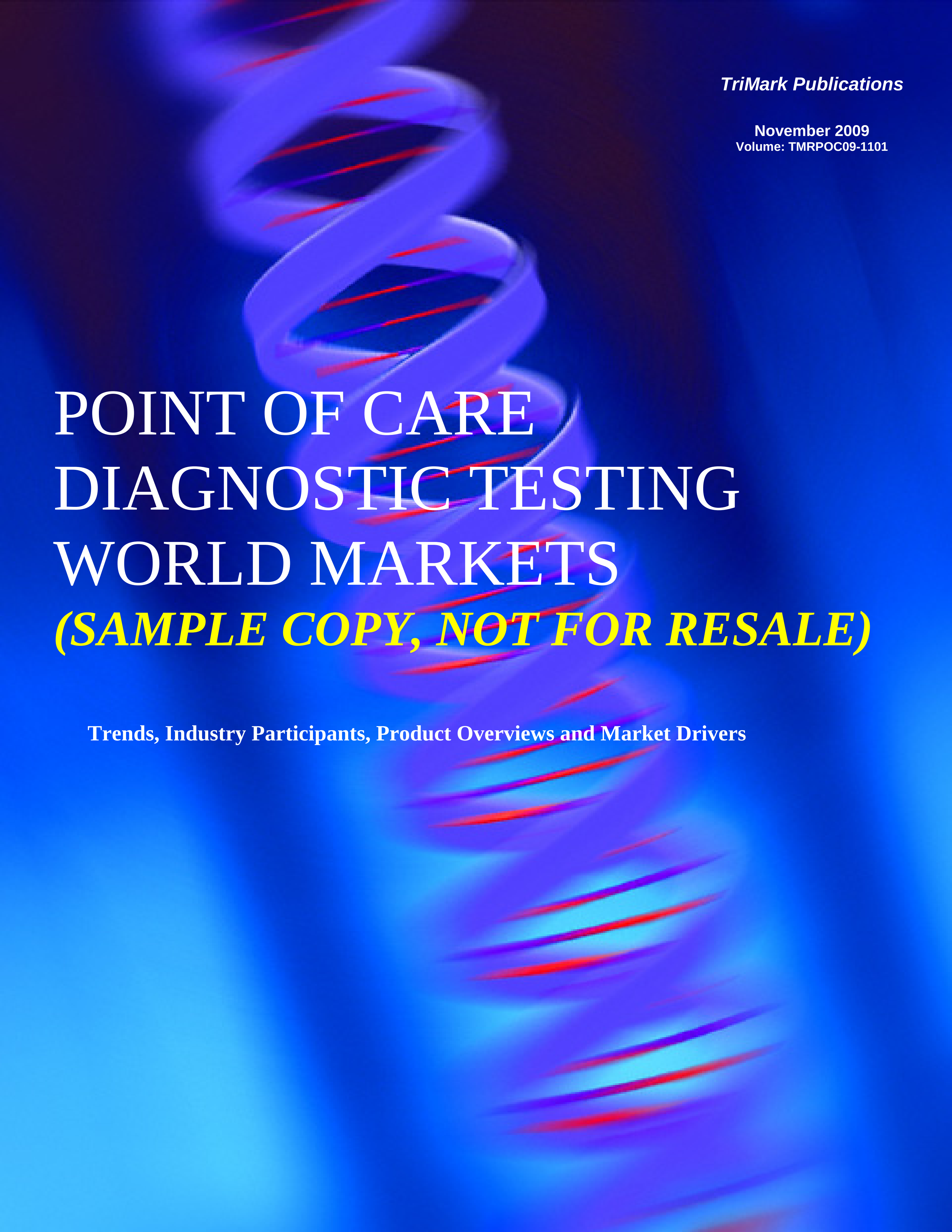

TriMark Publications

November 2009
Volume: TMRPOC09-1101

POINT OF CARE DIAGNOSTIC TESTING WORLD MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Overview

The purpose of this report is to describe the specific market segment of the *in vitro* diagnostics (IVD) market called point of care testing (POCT). It examines these clinical measurement devices and their reagents and supplies as utilized in near-patient environments like hospitals, clinics and doctor's offices. An analysis of analytes that are related to the common chemical constituents of blood, plasma or serum at the point of care of the patient is addressed. Moreover, the study 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. Also examined are the subsections of each market segment, including the research labs, hospital labs and commercial laboratories. This report analyzes in detail the important sections of the point of care diagnostics sector including: glucose, blood gases, coagulation, cardiac marker, drugs of abuse, infectious disease, and many others. Additionally, rapid detection of food pathogens and infectious pathogens (MRSA, herpes simplex, avian flu, West Nile virus [WNV] and typhoid) are discussed. The report surveys almost all of the companies known to be marketing, manufacturing or developing instruments and reagents for the point of care market in the U.S. Each company is discussed in extensive depth with a section on its history, product line, business and marketing analysis, and a subjective commentary of the company's market position.

1.1 About this Report

A review of analytes that are related to the chemical and cellular constituents of blood, plasma or serum at the point of care of the patient is addressed in this study. The two most important areas where such tests are measured are in the hospital and the clinic environments. The third place where these tests are measured is in physician's office labs (POLs). Newer areas of testing interest for these analytes are satellite labs, corporate facilities, law enforcement agencies, insurance and home testing locations. Emphasis is on those companies and products that are actively developing and marketing clinical laboratory instrumentation, reagents and supplies for performing clinical diagnostic tests in the near-patient environment. The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for POCT.
- Understanding the different sectors of POCT, looking at the hospital market segment and, separately, at a description of the instruments, reagents and supplies marketed by major companies in each segment.
- Obtaining a complete understanding of the individual point of care tests 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.
- Focusing on global industry development through an in-depth analysis of the major world markets for point of care technology, including growth forecasts.
- Presenting market figures regarding the current value of the POCT, market projections, market share, key players and sector growth rates. The source of this information is the most current data derived from the global diagnostic industry.

This study contains:

- A detailed analysis of recent trends in the point of care marketplace.
- In-depth profiles of the leading companies with point of care tools and technologies.
- A forecast for the point of care market in the biotechnology and diagnostic industries.
- Views and principles on the point of care industry from leading industry experts.
- An analysis of potential new point of care applications in the clinical sector.
- Market predictions and trends analysis concerning U.S. expenditures on point of care solutions.
- Projections of point of care market sizes for European and Asian markets.
- Projections for future applications of molecular diagnostic tests in point of care-related screening.
- Analysis of commercial point of care business strategies.
- The latest news and mergers and acquisitions (M&A) developments in the point of care marketplace.
- A comprehensive overview and insight into point of care business strategies.
- An in-depth examination of the subsections of each market segment, including the POLs and clinic testing.

Analysis includes charts and graphs measuring product growth and trends within the marketplace. Company-specific information, including sales figures, product pipeline status and research and development (R&D) trends, is provided. This review will also:

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

The following questions will also be addressed in this analysis:

- What are the near-term business opportunities in the point of care market?
- What are the current and forecasted point of care market sizes in the U.S., European Union (E.U.) and Japan, as well as in other key country markets?
- What are the business models currently used by companies in the point of care market?
- How will manufacturers, researchers, physicians and patients influence this market?
- What are the drivers and bottlenecks influencing the point of care market?
- What are the technologies used in point of care?
- Who holds the proprietary rights to the point of care market technology platforms?
- In the U.S., Japan and the E.U., what regulatory processes apply to point of care technologies?
- How will new point of care technologies change diagnostic screening testing paradigms?
- How will new point of care technologies reduce healthcare expenditures and affect R&D spending?

The report contains:

- A comprehensive overview of the several categories of point of care technology platforms that are, or will be, revolutionizing the use of diagnostic tests in hospitals.
- A chapter on each of the important point of care categories and applications.
- 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 use and marketing of point of care products.
- Market forecasts for each category of product, including profiles of selected competitors.

1.2 Scope of the Report

The POCT diagnostic products market in the U.S., Japan and Europe—the world's three largest analytical markets—are the focus of this study. A number of other smaller country markets are included for analysis of their diagnostic and point of care activity. Primary attention is paid to the clinical market segment, and, separately, to the instruments, reagents and supplies marketed by major companies in this segment. Market size, growth rates and market components for instruments, reagents, controls and consumables used in this area are also analyzed. In general, the non-professional (home care) market for self testing is considered an entirely different market than professional (hospital, clinic and doctor's office) testing, and is not considered in this report in any detailed way. Other related areas like infant jaundice evaluation, anthrax detection, homeland defense testing, BSE (mad cow disease), tuberculosis and food pathogens are discussed.

An analysis of business trends, technology trends, and developing areas of POCT is provided, along with a review of the market for POCT equipment and supplies in the clinical and research market segments, using screening reagents and instruments for analysis of individual components in blood, serum or plasma. This study defines U.S. and global market dollar sales volume and analyzes factors that influence the size and growth of market segments. Market size and growth rates, with projections (where sensible) for the U.S. and global markets, are examined. European market sizes are also expressed in euros. The reader should consult other TriMark Publications reports at http://www.trimarkpublications.com for detailed discussions of important individual market segments related to the POCT market.

1.3 Objectives

The goal of this study is to review the market for POCT equipment and supplies, using screening reagents and instruments for analysis of individual components in tissue samples, blood, serum or plasma. It 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. Also examined are the subsections of each market segment, including the research labs, hospital labs and commercial laboratories. Additionally, the numbers of institutions using this type of POCT and the factors that influence purchases are discussed.

1.4 Methodology

The author of this report has a Ph.D. in biochemistry with many decades of experience in scientific writing and as a medical industry analyst. He has been a senior director of several large regional and national cancer testing laboratories. He has over 30 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 editor of the report has a Ph.D. in anatomy and degrees in molecular biology and has worked as a research assistant professor.

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 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 we publish annually. We extract relevant data and analytics from TriMark's 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.

Market Forecasts and Modeling

The numerical data on market size, growth rates and sales forecasts are obtained from a well-examined model based upon quantitative market information obtained from the leading global companies in the sector, private seminar presentations by company experts and public SEC filings. Many industry experts are also consulted to confirm these market estimates. The numbers used are washed of discounts and returns, and represent the final sale numbers. In addition, global numbers are assessed by region components as well, taking into account differences in market conditions between the U.S., Europe and Asian markets in particular.

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 the key personnel.

- 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.

- 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.

1.5 Executive Summary

During [redacted], [redacted] point of care tests were carried out within hospitals in the U.S. This figure is expected to grow to [redacted] tests per *annum* by [redacted] with an estimated compounded annual growth rate (CAGR) of [redacted]%. In the U.S., there were an estimated [redacted] to [redacted] visits to emergency departments in both [redacted] and [redacted]. The overall worldwide *in vitro* medical diagnostic testing market was $[redacted] in [redacted]. Typically, the market is segmented by the underlying technology involved in performing the diagnostic test. For example, the largest market segments of the IVD testing industry are clinical chemistry, with approximately [redacted]% of the market, and immunodiagnostics, with approximately [redacted]% of the market size.

The global point of care market has reached $[redacted] in [redacted] and is growing at approximately [redacted]% per year. In the U.S., POCT from all sources (hospitals, clinics, doctor's offices, but not home testing) now represents [redacted]% of the $[redacted] U.S. market for clinical diagnostic testing reagents, controls and equipment, or $[redacted] in [redacted]. It is projected to grow at an annual rate of [redacted]% in the U.S. through [redacted] to a total of $[redacted]. The professional point of care diagnostic testing market is composed of two general segments: hospital testing and decentralized testing. Hospital POCT is usually an extension of the central lab testing, and performed under the laboratory license. For example, immediate turnaround of blood gases and electrolytes is very helpful in the operating room or the emergency room (ER). Pregnancy tests or cardiac monitoring tests in the ER can be very helpful to manage critically-ill patients. This market segment in the U.S. was estimated at $[redacted] in sales in the U.S. in [redacted]. The second component of the decentralized market testing segment consists of POLs, nursing homes, pharmacies and other non-institutional settings in which healthcare providers perform diagnostic tests. This market segment in the U.S. was estimated at $[redacted] in sales in the U.S. in [redacted].

In the IVD industry, the European segment accounted for [redacted]% of the world market for IVD products in [redacted], or approximately $[redacted] for the European estimate of [redacted] surveyed. With an expected real growth at a CAGR of [redacted]% to [redacted]% through [redacted], estimates suggest that the market for IVDs in the E.U. will reach $[redacted] by [redacted]. The E.U. ([redacted]%) is second only to North America's ([redacted]%) market share of IVD products. The major segments of the point of care diagnostic testing market highlighted in this study are:

- Blood glucose monitoring.
- Blood gas and electrolytes (critical care testing).
- Rapid coagulation tests.
- Rapid cardiac markers.
- Rapid drugs of abuse.
- Urine strips.
- Urine pregnancy tests.
- Fecal occult blood.
- Hemoglobin testing.
- Miscellaneous rapid tests.
- Human immunodeficiency virus (HIV).
- Cholesterol.
- Infectious disease.
- Infant Jaundice.
- Anthrax.
- Fetal membranes.
- Food pathogens.

The professional POCT blood glucose monitoring segment is by far the largest of the point of care market segments. Virtually all U.S. hospitals now do point of care glucose monitoring. The market is very mature, with annual global sales at $[redacted] in [redacted]. The global market is projected to grow to $[redacted] by [redacted], a CAGR of [redacted]%. U.S. sales in [redacted] reached $[redacted] and are growing at a rate of [redacted]% per year. The market is projected to grow to $[redacted] by [redacted], with a CAGR of [redacted]%. Roche is still the market leader in point of care glucose testing.

Critical care diagnostic testing includes routine and time-sensitive testing for critically-ill patients in a variety of areas including pH/blood gases, electrolytes, metabolites and CO-oximetry. TriMark estimates the total worldwide sales in this segment in [redacted] was $[redacted], growing at a rate of about [redacted]% per year. The total U.S. market for critical care blood gas supplies in [redacted], for POCT, was $[redacted]. The electrolyte segment was a $[redacted] market in the U.S. in [redacted] and growing at a rate of about [redacted]% per year.

The market for rapid, point of care-type coagulation tests in the U.S. was approximately $[redacted] in [redacted], and growing at a rate of [redacted]% per year, attaining sales of $[redacted] by [redacted]. This is the highest growth rate of all of the segments in the rapid test area—save cardiac tests—but moves from a much higher base of sales than the latter. In [redacted], the global market for rapid cardiac markers was $[redacted]. This market is projected to grow to $[redacted] in [redacted]. The global market for handheld rapid cardiac markers was $[redacted]. This market is projected to grow to $[redacted] in [redacted]. Rapid growth rates of [redacted]% to [redacted]% are expected in this segment.

In [redacted], the market in the U.S. for rapid cardiac markers was $[redacted]. This market is projected to grow to $[redacted] in [redacted]. Rapid growth rates of [redacted]% to [redacted]% are expected in this segment. Most of the cardiac marker tests are still performed in the hospital central lab rather than in the ER. This trend is expected by TriMark to continue. In [redacted], the market for all cardiac markers was $[redacted]. In this total, TriMark projects that approximately [redacted]% of these tests, or $[redacted], will be performed at the point of care, in this case, the ER.

The principal markets for rapid drugs of abuse testing are law enforcement, medical emergency, drug courts and the industrial workplace. The U.S. hospital market alone is estimated to total $[redacted] for drugs of abuse screening products. The on-site point of care (non-laboratory) testing/screening was at $[redacted] in [redacted] and scheduled to grow at annual rates in excess of [redacted]% through [redacted] to reach $[redacted]. The U.S. market for abused drug testing from all sources is approximately $[redacted] annually, including hospital, central lab, corporate, criminal justice and POCT.

The worldwide market for routine urinary analysis performed in laboratories is approximately $[redacted] per year, with [redacted]% of that business ($[redacted] in [redacted]) represented by test strip sales. More than $[redacted] in testing is generated in the U.S. alone. TriMark estimates the total worldwide sales in this segment for POCT in [redacted] of $[redacted], growing at a rate of about [redacted]% per year.

Over [redacted] tests for human chorionic gonadotropin (hCG), or pregnancy testing, are performed each year in U.S. doctor's offices, with clinics and ERs generating a market estimated at $[redacted] annually in [redacted]. The world market for point of care pregnancy testing is estimated to be $[redacted]. Quidel is the leader in the U.S. professional market; rapid, non-instrument-based pregnancy testing in doctor's offices holds a [redacted]% share of the $[redacted] market with [redacted] generic competitors. Abbott dominates the U.S. hospital lab market for pregnancy tests.

TriMark estimates the total worldwide sales in the fecal occult blood testing (FOBT) segment in [redacted] of $[redacted], growing at a rate of about [redacted]% per year. The U.S. hospital market for FOBT was $[redacted] in [redacted]. The market for doctor's offices was approximately $[redacted] in [redacted]. The market leader, Beckman Coulter, has been the dominant company with its Hemoccult product. There are a number of miscellaneous products in the POCT area for analytes, such as HIV, estriol, fetal fibronectin and *Helicobacter pylori*, which are covered in this report. The area of infectious disease is growing rapidly in the point of care segment. This report discusses rapid testing for giardia, salmonella, mononucleosis, chlamydia and other infectious diseases.

The global market for the point of care HIV/AIDS tests is substantially more than $[redacted] and predicted to grow at a rapid rate for the next decade. TriMark estimates that this market niche will grow worldwide to over $[redacted] within the next [redacted] years, particularly as rapid urine-based tests become available to the large third world markets, and cheaper therapeutic agents become available to poor populations. The latter, of course, would make HIV/AIDS testing much more relevant.

In the U.S., the estimate for [redacted] was $[redacted], growing [redacted]% per year. TriMark estimates that this market niche will grow worldwide to over $[redacted] within the next [redacted] years, particularly as rapid urine-based tests become available to the large third world markets, and cheaper therapeutic agents become available to poor populations. Infectious disease is the largest illness category in the world. In the U.S., over [redacted] cases of infectious diseases are diagnosed by physicians annually. This segment is projected to increase at a growth rate of over [redacted]% for the next [redacted] years. Testing needs range from routine, pre-conception immune status screening to the progressive battle against opportunistic pathogens associated with the AIDS virus.

The following are some key concepts to consider:

- The diagnostic POCT segment still has good growth potential, with multiple opportunities for entry and growth, as well as competition and change. Several segments such as cardiac testing, coagulation, and infectious disease testing are exhibiting double-digit growth.

- Advances in technology are propelling both new and old companies forward with fresh capabilities.

- The glucose and pregnancy segments account for the bulk of sales, at >[redacted]%. Growth from these segments, however, is expected to slow due to market saturation. Although the other segments are small today, it is an extremely fast-growing component of the market.

- Geographically, the U.S. constitutes almost [redacted]% of sales. Significant opportunities exist in the rest of the world, especially in the BRICs countries, such as India and China, with burgeoning population and increasing healthcare awareness.