

POINT OF CARE
DIAGNOSTIC TESTING
SECTOR TRENDS
(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 segment of the diagnostic market aimed at point of care testing (POCT). It examines those measurement devices and their reagents and supplies that are utilized in hospitals, clinics, commercial clinical laboratories, doctor's offices and research institutions to detect cellular constituents and proteins for the purpose of diagnosis and monitoring of disease. Specifically, this study focuses on point of care sector trends. 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. The two most important areas where such tests are measured for immediate results in a point of care setting are in the hospital emergency room and the critical care clinics. The third place where these tests are frequently measured in what is characterized as a point of care setting is in physician's office labs (POLs). Newer areas of testing interest for these analytes are satellite labs and home testing locations.

This examination of POCT trends focuses on the point of care segments in important worldwide markets, such as the U.S., Japan and Europe. The focus is primarily on the hospital market segment and, separately, on a description of the instruments, reagents and supplies marketed by major companies in this segment. This review discusses the market size, growth rates and market components for instruments and reagents, controls and consumables used in testing, which is at the forefront of point of care testing.

There is a strong emphasis on the hospital segment of the point of care market, which because of its high testing volume potential, is generally where all of the innovations in point of care testing start out. The physician's office point of care devices are described throughout the report as well. Home testing is not directly covered, except where the products and companies in this market segment are also active in the hospital and physician's office point of care segments. Home testing is traditionally treated as a market separately from "point of care diagnostic testing," the latter which is sometimes referred to as "professional testing".

An extensive review of new trends in POCT in this report includes the market for clinical POCT equipment and supplies in the clinical hospital market, as well as the market for screening reagents and instruments for analysis of individual components in blood, serum or plasma. It defines the dollar volume of sales, both worldwide and in the U.S. market, and it analyzes the factors that influence the size and the growth of the market segments. Details on market sizes and growth rates for the U.S. and world market are provided.

Many of the companies known to be developing instruments and reagents for the clinical point of care market in the U.S. and worldwide have been surveyed. 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.

1.1 Statement of Report

The new analytical methods being developed to aid in diagnosis of diseases at the near-patient setting will be addressed. The emphasis is on those companies and products that are actively developing and marketing new laboratory technology platforms that bring clinical lab testing closer to the patient and provide more rapid results to the physician. The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for point of care testing.
- Obtaining a complete understanding of point of care tests from their basic principles to their applications.
- Discovering feasible market opportunities by identifying high growth applications in different analytical diagnostic areas, concentrating 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 diagnostic testing technology, including growth forecasts.
- Presenting market figures regarding the current value of the point of care market, projections and growth rates.

By purchasing this study, the reader will have:

- An understanding of the most exciting point of care 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 point of care market as an area of growth, research and investment.

Key questions addressed include:

- How can point of care tools and technologies facilitate other diagnostic tests?
- What are the main types of point of care technologies that are currently available?
- Who are the current key players in this marketplace?
- Which point of care market areas have the greatest potential for growth?
- Which biotechnology and diagnostic companies are investing in point of care solutions?
- What are the main point of care business strategies adopted by leading companies?
- What are the benefits of point of care technology platforms?

This document contains:

- 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.
- Analysis of potential point of care applications in the life science sector.
- 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 developments in the point of care marketplace.
- A comprehensive overview and insight into point of care business strategies.

Analysis includes charts and tables measuring product growth and trends within the marketplace. Company specific information—including sales figures, product pipeline status and R&D trends—is provided. In addition, this report will:

- 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:

- 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 technologies used in point of care?
- Who holds the proprietary rights to the point of care market technology platforms?
- How is this technology currently being applied and utilized?
- How will new point of care technologies change diagnostic screening and testing paradigms?

1.2 Scope of the Report

This analysis pertains to companies that are currently creating and marketing laboratory instrumentation, reagents and supplies for performing point of care tests in the so-called professional setting, which means hospitals and doctor's offices. There is also a small but growing market in satellite clinics and other outlying operations, which are under the direction of a professional healthcare organization.

The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the protein analysis market, such as clinical chemistry testing, high-growth diagnostic test markets, blood gas and electrolytes and over-the-counter (OTC) diagnostic testing markets. TriMark provides a separate market report called *DNA Sequencing and PCR Markets*, which emphasizes the analytical methods and PCR technology platforms used in clinical diagnostics.

An analysis of business and technology trends and developing areas of point of care and HPV testing is provided, along with a review of the market for point of care testing 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 examination 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 are examined, with projections (where sensible) for the U.S. and global markets. An overview of the current trends and market drivers in the point of care sector is evaluated:

- The global point of care marketplace.
- The shift from laboratory testing to point of care tests.
- The geographical split in the market.
- Emerging new technologies.
- The future of POCT.

Activity and trends in research markets—including the numbers of institutions that use POCT and the factors that influence purchasing—are addressed in this analysis. Also discussed are trends that have stimulated this market and patterns of information processing in array testing instruments. Leading companies are discussed in depth, with sections on the companies' histories, product lines, business and marketing analyses, and a subjective commentary on the companies' market positions.

1.3 Objectives

The goal of this study is to review the market for POCT, with special emphasis on emerging trends in 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 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. 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.

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 thirty years of experience in laboratory testing, and instrument and reagent development technology, as well as extensive experience in senior level positions in biotech and medical service companies. The 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

The global point of care market reached \$ [REDACTED] in [REDACTED], and is growing at approximately [REDACTED]% per year. In the U.S., approximately [REDACTED]% of clinical diagnostic testing is currently conducted in hospital based and commercial laboratories. POCT represents [REDACTED]% of the \$ [REDACTED] U.S. market for clinical diagnostic testing reagents. Overall, the U.S. hospital point of care market was estimated to total approximately \$ [REDACTED] in sales in [REDACTED]. The point of care market is composed of two general segments: hospital testing and decentralized testing. Hospital POCT is usually an extension of central lab testing. For example, immediate turnaround of blood gases and electrolytes are very helpful in the operating room (OR) or the emergency room (ER). Pregnancy tests or cardiac monitoring tests in the ER can be very helpful to manage critically ill patients.

A main component of this 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 was estimated to total \$ [REDACTED] in sales in the U.S. in [REDACTED]. There is a strong growth in rapid tests in Europe compared to the flat performance of central laboratory tests. Indeed, there appears to be a continuing strong demand all over Europe for diabetes (glucose) testing, where there is an estimated [REDACTED]% growth in reagent sales. The POCT market in Europe, including near testing and self-testing devices, is projected to grow dramatically from \$ [REDACTED] (€ [REDACTED]) in [REDACTED] to over \$ [REDACTED] (€ [REDACTED]) in [REDACTED].

Worldwide sales of blood glucose professional testing products reached over \$ [REDACTED] in [REDACTED], the global market is projected to grow to \$ [REDACTED] by [REDACTED], a CAGR of [REDACTED]%. The blood glucose monitoring segment is by far the largest of the point of care market segments, both self-testing and professional testing. Virtually all U.S. hospitals now perform point of care glucose monitoring. The market is very mature. U.S. sales were \$ [REDACTED] in [REDACTED]. The market is projected to grow to \$ [REDACTED] by [REDACTED]. POCT instruments in this segment are rapidly replacing stat labs (labs that turn out test results quickly after sample collection), which have been historically located next to the intensive care unit (ICU) or the operating room (OR) suites. These systems may be either handheld, such as the i-STAT instruments, or cart based, like the Roche instrument cluster. This is a relatively mature segment with a modest overall growth rate, but the point of care component is growing more rapidly as the instruments move steadily from the central lab to the bedside and the available technology improves.

2. Overview of Diagnostic Point of Care Testing

In recent years, there has been a definitive shift in the use of POCT with a predictive market growth expectancy annual rate of █% for the next █ years. TriMark Publications recognizes the importance of this expanding market and subsequently has interviewed leading experts from the pharmaceutical and diagnostics industry to evaluate the latest developments in this arena.

This report explores the rapid growth of POCT in terms of technology advancements and healthcare economics, with a specific focus on glucose, coagulation, infectious disease, drugs of abuse, and critical care testing, which TriMark believes are the sectors of POCT that offer the most promise for future growth. In addition, it will critically analyze the growth of the global market, assessing the drivers and shapers, and ascertain the significance for individual companies.

2.1 Key Issues in the Point of Care Diagnostic Testing Sector

- Locations of POCT and their development process.
- Hospital lab rapid tests: how to compete with near-patient testing in turn around and quality.
- Hospital non-laboratories: how to compete with central labs in quality and recording keeping.
- Doctor's office/laboratory: how to provide the same results as the hospital.
- Other non-hospital POCT: how to produce cost efficiencies and record keeping.
- Home monitoring and home diagnosis: search for quality results.
- Is technology development the key? Advances in small meters, IT and connectivity; test strips and particles; biosensors and eventually biochips.
- Regulatory changes, will they help create the opportunity?
- Expansion of test menus for the ER.

2.1.1 Current Market Trends and Drivers

The growth of diagnostic testing in the recent past is a clear indicator of the trends and market drivers in the point of care industry. The diagnostics industry has gone through the classic phases of the industry life cycle—technology driven emergence, fast growth, maturity and consolidation. The consolidation phase has seen mergers, bankruptcies, and a serious worsening of the return on capital employed. Although individual divisions of selected companies grew strongly, the overall amount of revenues in the industry has shrunk for the past ten years.

The IVD industry is grossly undervalued, both from a financial standpoint and in terms of the value patients and physicians place on the information that diagnostics provide. During the past few years, investment growth in the IVD segment has remained flat even though Medicare spending has increased. Although the healthcare sector accounts for approximately █% of the U.S. gross domestic product (GDP), and █% of that sector consists of healthcare products, only █% of those products are IVDs. This is an issue that must be addressed over time: better use of quality diagnostic tests results in more targeted treatments, improved patient care, and reduced costs to the healthcare continuum. This is the place where POCT can play a key role in revitalizing diagnostic testing.

With the immediate response that POCT offers and the demographics of the Baby Boom generation, there will be increasing demand for diagnostic testing over the next several decades. TriMark believes that the future of the IVD industry hinges on developing point of care decentralized laboratory testing. POCT technologies still need to improve to the point that performance is comparable to central lab test results. Until now, the objection to POCT by hospital labs has been difficult to overcome.

The diagnostics industry could be doomed to accept continued downsizing. However, TriMark predicts that it will re-emerge, but only those who change the industry will thrive in the future. Executives who come from incestuous work environments and like to hide out in this industry will need to change their ways of doing business before they regain financial health. Some strategies: