

POINT OF CARE
DIAGNOSTIC TESTING
FORECASTS AND SECTOR
TRENDS
(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Overview

Point of care testing enables rapid diagnostic tests to be performed while the patient is at the point of care facility where results can be obtained immediately, rather than waiting hours or even days for outside lab results to arrive. Point of care testing covers: blood glucose testing, blood gas and electrolytes analysis, rapid coagulation testing, rapid cardiac markers diagnostics, drugs of abuse screening, urine strips testing, pregnancy testing, fecal occult blood analysis, food pathogens screening, hemoglobin diagnostics, infectious disease testing and cholesterol screening. This TriMark Publications report describes the segment of the diagnostic market aimed at point of care testing (POCT). 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. The physician's office point of care devices is 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.

This examination of POCT trends focuses on the point of care segments in important worldwide markets, such as the U.S., Japan and Europe. 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. Most of the companies known to be developing instruments and reagents for the clinical point of care market are examined 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.

1.1 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 research and development (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 has the greatest potential for growth?
- Which biotechnology and diagnostic companies are investing in point of care solutions?
- What are the main points 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 points 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 This 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. The reader should consult other TriMark reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the POCT market. An analysis of business and technology trends and developing areas of point of care 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. 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.

1.3 Objectives

The key objective of this study has been to conduct a review of the POCT market, with particular 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. Also examined are the sub segments of each market segment, including physician office labs, hospital labs and commercial laboratories. In addition, this report reviews the number of institutions using these forms of POCT, together with a discussion on the factors that influence their purchasing decisions. The report surveys almost all of the companies known to be marketing, manufacturing or developing instruments and reagents for the point of care market.

1.4 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 ■ 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.

1.5 Executive Summary

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 physician office labs (POLs), nursing homes, pharmacies and other non-institutional settings in which healthcare providers perform diagnostic tests.

POCT is not new and has been emerging now since the mid-1980s. The technology, however, has not changed significantly and there are numerous issues regarding lack of agreement between POCT and Central Laboratory testing. Since 2000, new technologies are being presented to the global marketplaces that show improved accuracy and precision plus agreement to central lab methods. This issue of improved accuracy and precision plus improved total error to achieve better agreement with central lab methods will continue to evolve and play a significant role in the further development of POCT from several perspectives: patients providers (lab plus clinicians), regulators, and manufacturers.

The IVD point of care market segment was estimated to total \$ [REDACTED] in sales in [REDACTED]. By the end of the forecast period in [REDACTED], it is predicted that the market will have increased in value to \$ [REDACTED] (CAGR [REDACTED]%). The value of the U.S. market in [REDACTED] was \$ [REDACTED]. By the end of the forecast period in [REDACTED], it is predicted that the U.S. market will have increased in value to \$ [REDACTED] (CAGR [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 from \$ [REDACTED] in [REDACTED] to over \$ [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 products such as 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.

A sea change is now occurring in the delivery of healthcare services, in which POCT will play a major role. This undercurrent involves improved communication technologies, connectivity, portability of data, and evolution of nano-technologies, *i.e.*, Lab on A Chip. Primary Care will require more diagnostic services at the point of care. Consequently, POCT will not be limited to the bedside and hospital. This shift in power to primary care will put the major IVD companies at risk, similar to the current digital revolution with respect to movies and music and what has occurred with computers and telecom, *i.e.*, smartphones. Areas of great change in development of POCT with new paradigms are occurring in Europe where the demand to reduce costs and improve outcomes is a major driver in this emerging market trend. POLs and home diagnostics will continue to play a larger role in the evolution of POCT.

As self-monitoring of blood glucose (SMBG) has added value to the management of diabetes mellitus and use of insulin, physicians will use the SMBG model to manage other chronic diseases with novel, simple, and easy to use POC devices in both the office and at home. The regulatory climate in Europe and outside the U.S. is more open to facilitate these changes and permit adoption of these new management and treatment regimens using POCT. POCT transformation will begin to evolve and new market participants will emerge. These include the following major companies:

- Alere.
- Procter and Gamble.
- Philips.
- Siemens (non-laboratory).
- SONY—DADC (Caliper).
- Panasonic.
- Baxter.
- GE.

The areas of disease management that will evolve resulting in expansion of POCT in POLs, skilled nursing facility (SNFs), and the home include:

- Renal dialysis.
- Renal transplant.
- Oncology.
- Bleeding disorders.
- Drug therapy.

An example of this transformation is occurring in two settings in the Netherlands for oncology patient management and renal transplant management post-transplantation. This transplant model is simple and enabled by digital devices and connectivity where the patient is linked from the home to the hospital, physician, or care provider. The goals are also simple—better outcomes, \geq 10% reduction of visits to the clinic, and significant cost savings for both the patient and the provider.

Other models will develop, and probably rapidly, as physicians gain more confidence in POCT. The quality of POCT is an area for improvement, but some advances in methods and devices have improved and it may turn out that “fresh whole blood” without collection in a tube containing an anticoagulant will produce higher quality results. This is a development that will become readily apparent over the next few years as standards and methods to assess accuracy and precision such as when total error are prepared, evaluated and accepted by the laboratory medicine and clinical medicine stakeholders. The desire for better standards such as POCT device performance is now openly discussed, as evidenced by the FDA Public Meeting, [REDACTED], on the quality and performance of glucose testing methods, specifically SMBG and POCTG.

An additional market that will develop is in the area of clinical trials where Big Pharma often gets confounding results and pays enormous amounts of money for the clinical trials to physicians and reference laboratories. With the development of organ and disease specific POCT platforms, *i.e.*, liver function, renal function, arthritis, COPD, etc. the major pharmaceutical companies can place the POCT devices in the participating clinician offices and control the information almost real-time and very quickly determine the efficacy of the clinical trial and/or the new drug. A new company, Blinded Diagnostics, was just recently launched to provide this service to Big Pharma where they place POCT devices in physician offices participating in the clinical trial, train the staff in the use of these devices, and then manage the collection and assessment of quality control of these devices plus the patient data generated at each physician office. In addition to Blinded Diagnostics, Carematix has developed a device hub that integrates data from digital blood pressure, digital weight scale, and POCT IVD devices from remote locations. This type of technology advancement is going to play an integral role in the paradigm shift to the empowerment of primary care diagnostics and the use of POCT IVD devices. These communication/connectivity platforms including the use of tablets and smartphones will facilitate the outmigration of testing in the central laboratory to the bedside and beyond.