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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

Point of care testing (POCT) enables rapid diagnostic tests to be performed while the patient is at the point of care (POC) facility where results can be obtained immediately rather than waiting hours or even days for outside lab results to arrive. POCT 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, hemoglobin diagnostics, infectious disease testing and cholesterol screening. This TriMark Publications report describes the professional POC testing segment of the diagnostic market (as opposed to at-home testing and other venues that are not in the hands of healthcare professionals).

The two most important areas where such tests are measured for immediate results in a POC setting are hospital emergency rooms and critical-care clinics. The third place where these tests are frequently measured in what is characterized as a near-patient setting is in physician's office labs (POLs). Other testing areas of interest for these analytes are satellite labs, critical-care units, neonatal intensive-care units (NICUs), intensive-care units (ICUs) and home testing locations. Home testing is not covered in this report.

This report also examines the subsections of each POC market segment, including: glucose, blood gases, coagulation, cardiac markers, drugs of abuse, infectious disease and many others. Additionally, rapid detection of infectious pathogens (methicillin-resistant *Staphylococcus aureus* [MRSA], herpes simplex, avian flu, West Nile virus [WNV] and typhoid) is discussed.

This examination of POCT focuses on the POC segments in important worldwide markets, such as the U.S., Japanese, European, Asian and Rest-of-the-World (ROW) markets. An extensive review of POCT in this report includes the market for diagnostic equipment and supplies as well as the market for screening reagents and instruments for analysis of individual components in blood, serum, urine and other body fluids. This report defines the dollar volume of sales, for both worldwide and U.S. markets, and it analyzes the factors that influence the size and the growth of the individual market segments. The market estimates have been factored to reflect the professional healthcare use, which is of most interest to diagnostic companies.

Most of the companies known to be developing instruments and reagents for the clinical POC market are examined in this study. Each company is discussed in depth with a section on the history of the company, the product line, a business and marketing analysis and a subjective commentary of the position of the company in its market.

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 emergency department and the critical-care section). Another important place where these tests are measured is in POLs. Newer testing areas of interest for these analytes are satellite labs, corporate facilities, law enforcement agencies and home testing locations. This report's emphasis is on companies 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:

- For the general point of care testing market:
  - The size of the market and distribution between different market segments.
  - The expected growth over the next five years within each market segment.
  - A comprehensive overview of the main POCT players. What kind of instruments do they have and what is range of analysis?
  - Which analysis in POCT is expected to experience exceptional growth going forward?
- 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 POC tests, from their basic principles to their clinical applications.

- Discovering feasible market opportunities by identifying high-growth applications in different analytical diagnostic areas, emphasizing the biggest and expanding markets.
- Focusing on global industry development through an in-depth analysis of the major world markets for POC technology, including growth forecasts.
- Presenting POCT market figures regarding the market's current value, market projections, market share, key players and sector growth rates. This information is the most currently available data derived from the global diagnostic industry.

This study contains:

- A detailed analysis of recent trends in the professional POC marketplace.
- In-depth profiles of the leading companies with POC tools and technologies.
- A forecast for the professional POC market and diagnostic segments thereof.
- Views and predictions on the POC industry from leading industry experts.
- An analysis of potential new POC applications in the clinical sector.
- Market predictions and trends analysis concerning U.S. expenditures on POC solutions.
- Projections of POC market sizes for European and Asian markets.
- Projections for future applications of molecular diagnostic tests in POC-related screening.
- Analysis of commercial POC business strategies.
- The latest news and mergers and acquisitions (M&As) developments in the POC marketplace.
- A comprehensive overview of and insight into POC 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 POC market drivers and bottlenecks from medical and scientific community perspectives.
- Discuss the potential benefits of POC for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the POC 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 POC market.

The following questions will also be addressed in this analysis:

- What are the near-term business opportunities in the POCT market?
- What are the current and forecasted POCT market sizes in the U.S., the European Union (E.U.), Japan and other key country markets?
- What are the business models currently used by companies in the POCT market?
- How will stakeholders like manufacturers, regulators, physicians and patients influence this market?
- What are the drivers and restraints influencing the POCT market?
- What are the important technologies used in POCT?
- Who holds the proprietary rights to the POCT market technology platforms?
- In the U.S., Japan and the E.U., what regulatory processes apply to POCT technologies?
- How will new POC technologies change diagnostic screening testing paradigms?
- How will new POC technologies reduce healthcare expenditures and affect R&D spending?
- What are the newest instruments introduced into the professional POC market.

The report contains:

- A comprehensive overview of the several categories of POC technology platforms that are or will be revolutionizing the use of diagnostic tests in hospitals.
- A chapter on each of the important POC categories and applications (glucose, cardiac markers, HIV, respiratory diseases, and more…).
- Full descriptions of the technologies involved and how they 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 POC products.
- Market forecasts for each category of product, including profiles of selected competitors.

1.2 Scope of the Report

The POCT diagnostic product markets in the U.S., Japan and Europe—the world's three largest analytical markets—are the focus of this study. Analysis of the diagnostic and POC activity of a number of other smaller country markets is also included. 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 from professional (hospitals, clinics and doctor's offices) testing and is not considered in this report in any detailed way. Other related areas, *e.g.*, infant jaundice evaluation, anthrax detection, homeland defense testing, bovine spongiform encephalopathy (BSE, *i.e.*, Mad Cow Disease), tuberculosis and food pathogens, are also discussed.

This report focuses on the "point of care" market. In this context, this phrase means "professional" testing, which extends beyond the hospital ER to doctor's offices and other medical facilities where trained personnel perform the tests. In the context of this report, and by general agreement within the diagnostics sector, this will exclude so called "home testing". Over [redacted]% of this type of testing is used for glucose measurements. More information on self-testing markets is available in a TriMark report entitled *World Glucose Self-Testing Markets*.

The reader should consult other TriMark Publications reports at www.trimarkpublications.com for detailed discussions of important individual market segments related to the POCT market such as *POC Diagnostic Sector Testing Trends*, *Blood Glucose Testing and Diabetes Management*, and *Women's Health Diagnostic Testing*.

1.3 Objectives

The key objective of this study is to conduct a comprehensive 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's office labs, specialty labs (*e.g.*, NICUs) and critical-care laboratories. In addition, this report reviews a number of institutions using these forms of POCT and includes a discussion of 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 POC 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 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.

Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites as well as from 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 U.S. 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 the results obtained from 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 from 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 the following:

    - 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 and 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.

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.

Finally, before publication, each market report is reviewed by a fact checker, and editor and a proof reader. The final copy is ultimately released by the Editor-in-Chief and management.

1.5 Executive Summary

The professional POCT market sub-segment was valued at $[redacted] in [redacted]. It is estimated that the global POCT market will exhibit a compound annual growth rate (CAGR) of [redacted]% between [redacted] and [redacted] to $[redacted].

The report provides a summary of the global professional POCT market divided into individual major market sub-segments, with market values for [redacted] and market projections to [redacted]. With any growth rate estimate, glucose testing remains the leading point of care testing global segment, accounting for [redacted]% of global near patient testing by [redacted] Excluding glucose testing, only rapid cardiac markers rises to >$[redacted] in POC testing by [redacted], accounting for an estimated [redacted]% of total testing by [redacted].

Despite budget pressures on hospitals, point of care testing will continue to grow at a rate larger than central lab testing, powered by continuing trends for adoption and use of these platforms across disciplines, notably cardiac markers, coagulation and infectious disease. As such, several diagnostic companies have scheduled advanced multiplexing platforms in their development pipelines, including a broad range of immunoassays and molecular tests.

The U.S. is recognized as the largest single country market for POCT products by [redacted]. In [redacted], the U.S. POCT market was valued at $[redacted]. TriMark estimated that the U.S. POCT market would exhibit a CAGR of [redacted]% between [redacted] and [redacted] to $[redacted]. In the U.S. market, glucose testing remains the leading point of care testing segment used by hospital professionals, accounting for [redacted]% of near patient testing by [redacted], decreasing to [redacted]% in [redacted]. Excluding glucose testing, no rapid testing segments rise to the $[redacted] level in U.S. POC testing by [redacted]. Glucose testing is still king. U.S. Point of Care testing by professionals for infectious diseases is projected to grow at [redacted]% over the forecast period; accounting for an estimated [redacted]% of total testing by [redacted]; compared with its [redacted]% share of U.S. testing in [redacted]. Infectious disease testing at POCT will emerge as the third largest segment by [redacted], surpassing the blood gas & electrolytes sector. Infectious disease testing is rising fast.

TriMark has determined that Europe represents the largest regional market for POCT products in [redacted], but falls to secnd place versus the U.S. in [redacted]. In [redacted], the European POCT market was valued at $[redacted]. TriMark estimated that the European POCT market would exhibit a CAGR of [redacted]% between [redacted] and [redacted] to $[redacted]. Germany is widely recognized as the largest single market for both IVD and POCT products within Europe. The German POCT market in [redacted] was valued at $[redacted]. The hospital and healthcare services structure in Germany makes it particularly suitable for the use of POCT products, leading to the higher percentage of POCT products as part of the IVD market.

In the European professional POCT market, glucose testing remains the leading point of care testing segment, accounting for [redacted]% of near patient testing by [redacted], decreasing to [redacted]% in [redacted]. Excluding glucose testing, no rapid testing segments rise to the $[redacted] level in Europe. Glucose testing is still king, even in Europe. In fact, this dominance for glucose testing is predominantly the result of weaker sales in all other segments of POCT, unlike the U.S. market where several segments are projected to grow by double digits (cardiac markers & infectious disease).

European Point of Care testing by professionals for infectious diseases is projected to grow at [redacted]% over the forecast period; accounting for an estimated [redacted]% of total testing by [redacted]. Infectious disease testing at POCT will emerge as the second largest segment in the European market by [redacted].

Asia (which includes Japan, China and India for the purposes of this report) represents a major market, but there are significant differences in growth rates for each of the individual countries. The POCT segment represented an estimated [redacted]% of the Asian IVD market in [redacted]. In [redacted], the POCT market for Japan, China and India (referred to as the Asian POCT market in this report) was $[redacted]. TriMark estimated that the Asian POCT market would exhibit a CAGR of [redacted]% between [redacted] and [redacted].

The Japanese POCT market has slowed recently and is expected to see a CAGR of [redacted]%; it is estimated to have been valued at $[redacted] in [redacted]. In contrast, the emerging markets of India and China are exhibiting higher CAGRs of [redacted]% and [redacted]%, respectively, between [redacted] and [redacted], and are valued at $[redacted] and $[redacted] in [redacted], respectively.

The report also provides a summary of the Asian POCT market segmented by individual major market sub-segment with market values for [redacted] and market projections to [redacted].

Although the ROW segment represents the geographic region with the smallest revenue, it is nevertheless a moderate growth opportunity (CAGR [redacted]%), and includes the emerging markets of Brazil and Russia. Included in this regional analysis are the Middle East, Africa, other Asian countries, Australia, Canada and other Latin American countries such as Mexico and Argentina.

As a result of the analysis carried out during the preparation of this report, TriMark has concluded that the professional handled POCT market for the ROW was valued at $[redacted] in [redacted]. It is predicted that the market for professional POCT products in the ROW will be valued at $[redacted] by [redacted] (a CAGR of [redacted]% between [redacted] and [redacted]). The underlying market fundamentals remain strong given the rising number of people with diabetes globally, especially in Asia and the ROW.

Roche, Alere [to be possibly acquired by Abbott] and Abbott Laboratories are the three largest suppliers of POCT devices throughout the world and collectively comprise an estimated [redacted]% of the global market. Although other companies, such as Nova, are becoming increasingly focused on POCT, increasing their product expansion and collaboration efforts to gain market share, the market remains extremely fragmented. Alere has sought to improve its market position through its acquisitions of companies like Biosite, Axis-Shield and its collaborations with SureStat and Chembio. Alere's HIV market share, on the other hand, could erode with the entry of Roche and Orasure and the advent of oral HIV tests. Nova Biomedical is becoming a reliable player with its new POCT platform. POCT dynamics are changing rapidly, and smaller players are poised to deliver value with their innovative platforms and growing test menus. The market has been driven by a transition to fully-automated systems, real-time amplification, connectivity platforms and growing test development for POC platforms.

TriMark estimates that future growth will stem from emerging applications like genotyping for identifying drug-resistant strains; bioterrorism; testing applications within infectious disease like Influenza and HIV; and disease diagnostics and prognostic assays for disease applications like sepsis, cardiovascular disease (CHF) and coagulation testing. The industry consolidation is significant, as larger players like Abbott, with the acquisition of Alere, want to move into faster-growing markets to expand their product offerings and/or geographical reach. Larger, established diagnostic players like Roche are eager to build out and extend their molecular diagnostic franchises for point of care technology and are willing to pay premium prices for good technology.

Market growth will be paced by substantial gains in the cardiac markers market (primarily beta-natriuretic-peptide (BNP) testing), coagulation, infectious disease testing and continued moderate growth in the clinical chemistry sub-segment—the largest in the POCT market. The later constellation of routine tests, now dominated by central lab testing (ALT, AST, BUN, creatinine, etc.), will eventually migrate completely to near patient testing.

- The value of the global professional POC blood glucose analysis systems market in [redacted] was $[redacted]. By the end of the forecast period in [redacted], it is predicted that this market will have increased in value to $[redacted] (with an average CAGR of [redacted]% from [redacted] to [redacted]). Industry experts expect that the U.S. and Europe POC blood glucose testing market revenues will continue to be negatively impacted by pricing pressure and weak volume growth. In addition, the U.S. market may be affected by a proposed tightening of performance standards to address the limitations of some current blood glucose meters. However, the

underlying market fundamentals remain strong given the rising number of people with diabetes globally, especially in Asia and the ROW.

- The value of the global POC blood gas and electrolyte analysis systems market in [redacted] was $[redacted]. By the end of the forecast period in [redacted], it is predicted that this market will have increased in value to $[redacted] with an average CAGR of [redacted]% from [redacted] to [redacted]).

- The value of the global POC rapid coagulation analyzers systems market increased to an estimated $[redacted] by [redacted]. By the end of the forecast period in [redacted], it is predicted that the market will have increased in value to $[redacted] (with an average CAGR of [redacted]% from [redacted] to [redacted]).

- The value of the global POC cardiac marker analysis device market increased to an estimated $[redacted] by [redacted]. By the end of the forecast period in [redacted], it is predicted that the market will have increased in value to $[redacted] (with an average CAGR of [redacted]% from [redacted] to [redacted]).

- The value of the global POC substance/drug abuse testing devices market increased to an estimated $[redacted] by [redacted]. By the end of the forecast period in [redacted], it is predicted that the market will have increased in value to $[redacted] (with an average CAGR of [redacted]% from [redacted] to [redacted]).

- The global POC infectious disease testing devices market increased to an estimated $[redacted] by [redacted]. By the end of the forecast period in [redacted], it is predicted that the market will have increased in value to $[redacted] (with an average CAGR of [redacted]% from [redacted] to [redacted]).

- The value of the global POC urine strip testing products market increased to an estimated $[redacted] by [redacted]. By the end of the forecast period in [redacted], it is predicted that the market will have increased in value to $[redacted] (with an average CAGR of [redacted]% from [redacted] to [redacted]).

- The value of the global POC pregnancy testing devices market increased to an estimated $[redacted] by [redacted]. By the end of the forecast period in [redacted], it is predicted that the market will have increased in value to $[redacted] (with an average CAGR of [redacted]% from [redacted] to [redacted]).

- The value of the global POC fecal occult products market increased to an estimated $[redacted] by [redacted]. By the end of the forecast period in [redacted], it is predicted that the market will have increased in value to $[redacted] (with an average CAGR of [redacted]% from [redacted] to [redacted]).

- The value of the global POC cholesterol testing products market increased to an estimated $[redacted] by [redacted]. By the end of the forecast period in [redacted], it is predicted that the market will have increased in value to $[redacted] (with an average CAGR of [redacted]% from [redacted] to [redacted]).

- The value of the global POC HIV testing products market increased to an estimated $[redacted] by [redacted]. By the end of the forecast period in [redacted], it is predicted that the market will have increased in value to $[redacted] (with an average CAGR of [redacted]% from [redacted] to [redacted]).

