

The background of the entire page is a light blue color. Overlaid on this background are several petri dishes, some containing a dark purple or blue liquid. A pipette tip is visible, positioned over one of the dishes in the center. The overall aesthetic is clean and scientific.

TriMark Publications

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CLINICAL CHEMISTRY ANALYZERS *(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Overview

Clinical chemistry analysis is one of the most important areas within the overall *in vitro* diagnostic testing sector. The term *clinical chemistry* usually refers to determining the concentration or activity of a protein, carbohydrate, lipid, electrolyte, enzyme or small molecule in easily-collected bodily fluids such as blood, serum, plasma or urine. However, it is not necessarily limited to these determinations. The analysis of virtually any biologically-active substance—any place in the body—can loosely be defined as clinical chemistry. In fact, traditional specialization barriers such as microbiology, hematology, blood banking, immunology and even anatomical pathology are rapidly fading, both operationally and instrumentally. But for the sake of defining the subject to a reasonable size, the more traditional scope of clinical chemistry will be the subject of this study.

1.1 Objectives of the Report

The purpose of this report is to describe the specific segments of the global clinical chemistry instrumentation market. Specifically, this study examines the markets for small lab and highly-automated, large lab platforms, as well as accessory equipment such as reagents, supplies and manufacturers' original equipment manufacturer (OEM) additional equipment. The emphasis is on those companies and products that are actively developing and marketing chemistry analyzer products for the clinical setting, including hospitals, independent labs, physician's offices and clinics. Concentration is on the clinical chemistry instrumentation industry market segment in the U.S. and around the world. Particular attention is paid to those areas of the clinical chemistry instrumentation sector that are showing the greatest growth or the most innovation. This study attempts to answer the questions:

- Which companies are the key players?
- What are the opportunities in clinical chemistry instrumentation?
- What is happening with the information revolution?
- What are the development trends?
- Where are the new market growth areas?
- What are the most favored technology platforms?
- How is immunological technology blending with chemistry?

This examination defines the dollar volume of sales in each major regional market and analyzes the factors that influence the size and the growth of the individual market segments. Additionally, this study surveys some of the primary companies known to be marketing, manufacturing or developing products for the clinical chemistry instrumentation market. Each company is discussed in depth with a section on the history of the company, the product line, business and marketing analysis, and a commentary of the position of the company in its market. Unique benefits of this report are:

- In-depth analysis of the major sectors of the clinical chemistry instrumentation sector, including their sizes, growth rates and major drivers.
- Presentation of some of the emerging technology platforms, while elucidating the potential areas that could gain traction in the market.
- Analysis of the partnerships and alliances the various key sector players have forged, as well as describing financings of these market participants.
- Examination of new technology platforms in the U.S., Japan and Europe that seek to dominate this mature market.

1.2 Methodology

The author of this report is a Ph.D. in biochemistry from the University of Minnesota, 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 healthcare laboratories. 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 in TriMark Publications 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 data and proprietary databases.
- 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.

- Completing a confirmatory primary research assessment of the report's findings with the assistance of expert panel partners from the industry being analyzed.

1.3 Scope of the Report

This report deals with the analysis of analytes that are related to the common chemical constituents of blood, plasma or serum of the patient. The two most important areas where such tests are measured are in hospitals and independent clinical laboratories. The third place these tests are measured is in physician office laboratories (POLs). Newer areas of testing interest for these analytes are in satellite labs, pharmacies and corporate clinics.

The emphasis here is on those companies and products that are actively developing and marketing clinical laboratory instrumentation, reagents and supplies for performing clinical chemistry tests in clinical diagnostics. The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for a detailed discussion of the important individual market segments that are related to the *in vitro* diagnostics (IVD) market, such as molecular diagnostic testing, high-growth diagnostic test markets, blood gas and electrolytes over-the-counter diagnostic testing markets and POC testing (POCT). The analysis touches on the specialty testing areas in clinical chemistry diagnostic testing, such as C-reactive protein (CRP), lipoprotein profiling and cardiac markers, since these segments are frequently a part of the overall analytical focus of companies marketing general laboratory automation equipment. However, no effort is made to quantify the size of this broader market.

The study does mention companies that market and sell a limited number of instruments and equipment as an OEM part of a much larger clinical laboratory product line by other companies; for example, Hitachi and its relationship with Roche Diagnostics Corporation, JEOL manufacturing products for Bayer or Furuno Electric Co. and Polymedco and their relationship with Randox. However, these companies are only reported *en passant*, since they are not a direct focus of the clinical chemistry diagnostics instrument market. Moreover, the report does not cover the following areas: 1) immunochemistry instruments and reagents, 2) hematology and coagulation market and 3) diagnostic device markets—although many of the instruments, reagents and techniques in the clinical chemistry diagnostics market segment are intimately associated with these broader areas. Furthermore, this examination does not cover disposable plastic supplies for the clinical laboratory or blood gases and electrolytes. All of these subjects are treated thoroughly in other TriMark Publications reports.

Although there is mention of recombinant proteins in passing—as well as techniques measuring the serum concentrations of therapeutic drugs and drugs of abuse—no extensive treatment of this subject is presented here. Such a discussion is outside the scope of this analysis. This report reviews the clinical POCT reagents and equipment market in the U.S. and worldwide. This market can be divided into four broad areas: 1) hospital market, 2) independent lab market, 3) doctor's office market and 4) the clinic market (to a much lesser extent).

1.4 Executive Summary

Clinical chemistry testing includes processes used to detect levels of enzyme, sugars, proteins and other substances in the blood in order to determine such clinical conditions as nutritional state, liver function, kidney function and others. Such testing is widely applied in identifying conditions like diabetes, hyperlipidemia and arteriosclerosis during clinical diagnoses and as a part of regular health checkups. During [REDACTED], approximately [REDACTED] clinical chemistry tests were carried out within hospitals in the U.S. This figure is forecast to grow to [REDACTED] tests per annum by [REDACTED]. Most of these tests were performed as screening, or multi-channel tests, performed on automated chemistry analyzers specifically designed for that purpose. Automated multi-channel testing addresses those tests that can be and are frequently done as groups and combinations on automated clinical chemistry equipment.

The global IVD market for all test types was estimated to be \$[REDACTED] in [REDACTED], up [REDACTED]% over the previous year (CAGR of [REDACTED]%, [REDACTED]% and [REDACTED]% for [REDACTED], [REDACTED] and [REDACTED] respectively), with the U.S., Europe and Asia (Japan, China and India) comprising approximately [REDACTED]%, [REDACTED]% and [REDACTED]%, respectively, of the market. [REDACTED] countries account for approximately [REDACTED]% of the IVD market worldwide. [REDACTED] country markets account for [REDACTED]% of total IVD sales.

Ten companies control approximately [REDACTED]% of the total \$[REDACTED] diagnostics industry. The worldwide IVD market is estimated to be growing at [REDACTED]% per year. Although more than [REDACTED] major companies are involved in the \$[REDACTED] global market for clinical diagnostics, only [REDACTED] have sales of over \$[REDACTED], creating an environment

that is still ripe for consolidation and partnering. Of the top seven companies, only Beckman Coulter is not part of a larger corporate structure that includes a pharmaceutical division. TriMark believes that the global IVD market will continue to grow due to a number of key favorable industry trends:

- Demographic shifts resulting from the aging of the population and socio-economic improvements are expected to increase the overall level of demand for diagnostic testing.
- Increased focus on lowering total healthcare expenditures will likely increase demand for diagnostic testing as an effective tool to improve patient outcomes and reduce the costs of misdiagnosis through earlier and more accurate diagnosis and patient monitoring.
- Emerging markets will provide additional demand as economic improvements in these countries lead to increases in healthcare expenditures.
- Technological improvements in new tests, pathogens and markers will result in the increased use of diagnostics to aid in the diagnosis of diseases.
- Improvements in lower-cost POC/near-patient testing capabilities are expected to expand the application of diagnostic testing capabilities into non-laboratory settings (*e.g.*, operating room, emergency room, acute care centers).
- Increased automation of diagnostic instruments is expected to lower the overall cost of diagnostic testing and thereby increase accessibility and demand.

In the U.S., approximately █% of clinical diagnostic testing is currently conducted in hospital-based and commercial laboratories. Clinical chemistry testing represented █% of the \$█ U.S. market for clinical diagnostic testing reagents, controls and equipment, or \$█ in █, and it is projected to grow at an annual rate of █% in the U.S. through █ to a total of \$█. Surveys show that █% of hospitals with more than █ beds have adopted some form of clinical chemistry testing, with over █% of the █ U.S. hospitals (█-bed size and larger) having installed some form of clinical chemistry instrumentation over the █ months to the end of █. Two key things one needs to be aware of concerning the clinical chemistry diagnostics market in Germany are:

- Reimbursement for diagnostic tests is under constant negative pressure.
- New technology platforms, particularly strip technology, are more accepted in Germany than in any other European country.

The specific category of IVD devices, which encompasses the sales of automated clinical chemistry analyzers, had sales of approximately \$█ in the U.S. in █, and that market was expected to increase to \$█ in █. By █, this portion of the market including sales in North America, Western Europe and Japan was expected to increase to \$█ if economic conditions remain relatively stable. The worldwide clinical chemistry instrument, reagent and supply segment of the IVD market was estimated by TriMark to be approximately \$█ in █. The sales of this market segment are projected by TriMark to \$█ by █. This includes general chemistry, electrolytes, enzymes, blood gases, lipids and urinalysis. In the U.S., this total market is almost \$█.

In the *in vitro* diagnostic (IVD) industry, the European segment accounted for █% of the world market for IVD products in █, or approximately \$█ for the European estimate of █ European countries surveyed. With an expected real growth at a compound annual rate (CAGR) of █% to █% through █, estimates suggest that the market for IVDs in the E.U. will reach \$█ by █. The European Union (█%) is second only to North America's (█%) market share of IVD products. The European clinical chemistry market has increased significantly in most of the European countries (but not all) to approximately €█ in █.

2. IVD Clinical Chemistry Market

2.1 Introduction

The most common *in vitro* diagnostic (IVD) tests performed by automated instruments in the clinical laboratory are traditional routine clinical chemistry tests such as glucose, cholesterol or sodium as part of routine blood checks or serum profiles. Other IVD tests measure bodily functions such as blood-clotting ability and cardiac function or measure the presence of infections or drugs. The wide range and important nature of these tests have established IVD testing as an integral part of the healthcare setting, providing for accurate and timely patient diagnosis and guides for treatment. Increasingly, IVD testing is being recognized as making a significant contribution to improving patient care and lowering total patient costs. IVD tests are performed in a number of different clinical settings, including hospitals, reference laboratories, physician's offices/ambulatory care centers and consumers' homes. IVD is used in virtually every part of the health delivery system and end users generally fall into one of following categories:

- Reference laboratories that conduct batteries of tests for physicians and hospitals.
- Hospital operating rooms, emergency rooms, laboratories, near-patient and patient bedside.
- Physician's offices and walk-in clinics.
- Pharmacies and supermarkets that offer in-store testing.
- Individuals who purchase kits for self-testing.

The number of clinical chemistry tests carried out within hospitals in the U.S. is forecast to grow from [REDACTED] annually to [REDACTED] tests per annum by [REDACTED]. Most of these tests are performed as screening, or multi-channel, tests, performed on automated chemistry analyzers specifically designed for that purpose. Automated multi-channel testing addresses those tests that can be and are frequently done as groups and combinations on automated clinical chemistry equipment. These groupings enable physicians to more accurately diagnose their patients' medical problems. The chemistry testing volume is being driven by:

- Hospital requirements to streamline care and reduce patients' length of stay, resulting in the need for accurate and rapid diagnosis.
- New technologies that permit the necessary quality control (QC) and data capture from tests performed by automated instruments.
- An expansion of the breadth of menu for tests available.

The main tests undertaken in these areas include blood gases and electrolytes, cardiac markers, infectious diseases, whole-blood glucose, drugs-of-abuse testing (DAT), urinalysis, coagulation and cardiac monitoring. In the diagnostic medical testing market, the clinical chemistry sector offers the prospect for low to moderate growth and considerable new innovation.

Many manufacturers are planning to launch new versions of automated chemistry analyzers during the analysis period. To meet the demand for increased onboard testing capacity, more types of clinical chemistry tests have been added, automation for quicker turnaround of results has been enhanced, user interfaces have been improved, and high-volume throughput has been underscored by design and marketing. Advanced concepts like modular analysis, consolidation of chemistry and immunoassay, ultra-integration, which combines four technologies that allow the user to process up to 100 methods simultaneously, and multiplexing are being introduced by manufacturers. The main diagnostic instrument manufacturers discussed in this report are:

- Abbott Diagnostics.
- Awareness Technology.
- Beckman Coulter.
- Clinical Data.
- Dade Behring (Acquired by Siemens).
- Olympus America.
- Ortho-Clinical Diagnostics.
- Randox Laboratories.