



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

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1. Overview

Clinical chemistry analysis is one of the most important areas within the overall *in vitro* diagnostic (IVD) testing sector. The term clinical chemistry usually refers to determining the concentration or activity of a protein, carbohydrate, lipid, electrolyte, enzyme or a small molecule in easily-collected bodily fluids such as blood, serum, plasma, urine or saliva. 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. In fact, in the area of analytical instrumentation, analysis of traditional chemistry analytes and traditional immunochemistry substances are converging into a unified automated system. 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 and its growing importance in connectivity issues?
- What are the development trends?
- Where are the new market growth areas?
- What are the most favored technology platforms?
- Where is the laboratory analyzer instrument technology taking us?
- How is immunological technology blending with chemistry?
- What are the key business trends in the clinical analysis instrumentation industry?

This examination defines the dollar volume and unit 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 report surveys most 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, giving insight into potential market collaborations.
- Examination of new technology platforms in the U.S., Japan and Europe that seek to dominate this mature market, and to identify lead positions and potential future growth areas.
- Country market examinations of clinical chemistry sales volume, five year projections on sales and comments on local trends in the IVD markets.

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. 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. The editor has a Ph.D. in medicinal chemistry from Medical College of Virginia, Virginia Commonwealth University, with postdoctoral work in clinical assay development and validation combined with molecular biology, and has worked in small and large pharmaceutical companies in the department of drug safety evaluation to support efforts in drug discovery and for commercialization of new chemical entities as drugs for over 17 years.

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.

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.

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 in this study is on those companies and products that are actively developing and marketing clinical laboratory instrumentation and reagents and supplies for performing clinical laboratory tests in clinical diagnostics. The reader should consult other TriMark Publications reports at www.trimarkpublications.com for a detailed discussion of the other areas with the clinical laboratory market. Specifically, the *Clinical Laboratory Testing Volume 1: IVD Instruments and Reagents Markets* report deals primarily with the IVD industry and the instruments and reagents that are marketed to clinical laboratories. And the companion report, *Clinical Laboratory Testing Volume 2: Key Players for Laboratory Testing, Business Trends and Strategies*, focuses on the business aspects of running a clinical laboratory.

This 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 Siemens 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 does not review the clinical point of care reagents and equipment market in the U.S. and worldwide.

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 by physicians in identifying conditions like diabetes, hyperlipidemia and

arteriosclerosis during clinical diagnoses and as a part of regular health checkups. During [REDACTED], over [REDACTED] clinical chemistry tests were carried out within hospitals in the U.S. This figure is forecast to grow to over [REDACTED] tests per annum by [REDACTED], and projected to reach approximately a billion tests 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 reagent and instrument market for all test types was estimated to be \$ [REDACTED] in [REDACTED], up [REDACTED] % over the previous year, with the U.S., Europe and Asia (Japan, China and India) comprising approximately [REDACTED] %, [REDACTED] % and [REDACTED] %, respectively, of the market. Five countries account for approximately [REDACTED] % of the IVD market worldwide. Twelve country markets account for [REDACTED] % of total IVD sales.

Many manufacturers are planning to launch new versions of automated chemistry analyzers during the analysis period, and this has become an ongoing process and an important marketing tool in the IVD industry. 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 [REDACTED] methods simultaneously, and multiplexing are being introduced by manufacturers.

The top [REDACTED] companies control approximately [REDACTED] % of the total \$ [REDACTED] diagnostics industry. Roche ([REDACTED] %), Abbott ([REDACTED] %), Siemens ([REDACTED] %), J&J ([REDACTED] %), Beckman ([REDACTED] %), and bioMérieux ([REDACTED] %) continue to be top leaders. One company, Gen-Probe of San Diego, CA, has shown significant growth and has replaced the privately-held Instrumentation Laboratory in the top [REDACTED] largest IVD companies. 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, especially in Asia and more specifically in China, 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.

The worldwide clinical chemistry instrument, reagent and supply segment of the IVD market was estimated by TriMark to be over \$ [REDACTED] in [REDACTED]. The sales of this market segment are projected by TriMark to exceed \$ [REDACTED] by [REDACTED], and reach approximately \$ [REDACTED] by [REDACTED]. In addition to instrument sales and leasing, this includes consumable reagents for general chemistry, electrolytes, enzymes, blood gases, lipids and urinalysis, as well as disposable plastic products.

The distribution of clinical laboratory testing worldwide shows a preponderance of this type in North America and Europe. The European Union (E.U.), Japan and the U.S. currently make up about [REDACTED] % of the IVD market. This portion is expected to decrease to [REDACTED] % by [REDACTED] due to erosion of mature country market segments, and the expanding IVD markets in Asia, particularly China. In addition, IVD markets in South America and South Asia are experiencing [REDACTED] % to [REDACTED] % annual growth rates. Japan, a very traditional country, has been slow to adapt clinical laboratory testing for point of care, considering its size as the second-largest economy in the world, and its position

as manufacturer of many OEM laboratory instruments. The Japanese IVD market is forecast to growth by somewhat less than █% during the forecast period.

In the U.S., █% of clinical diagnostic testing is currently conducted in hospital-based and commercial laboratories. U.S. Clinical chemistry testing represented █% of the \$█ global 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 \$█.

In the IVD industry, the E.U. accounted for █% of the world market for IVD clinical chemistry products and had a total IVD market of \$█. 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 E.U. is second only to North America's █% market share of IVD clinical chemistry products. TriMark finds that the IVD clinical chemistry overall growth is projected to remain in the █% to █% range for the forecast period to █.

European clinical chemistry testing market has five country market leaders: Germany, Italy, France, Spain and the U.K. These markets had approximately █% of the E.U.'s IVD sales in █. Specific country markets are enumerated in the report. Key trends one needs to be aware of concerning the individual clinical chemistry diagnostics country markets are:

- Reimbursement for diagnostic tests is under constant negative pressure in Germany and most of the E.U.
- New technology platforms, particularly strip technology, are more accepted in Germany than in any other European country.
- Given the dominance of the German IVD industry in Europe, the German market accounts for █% of the European market.
- In the U.K., the slow growth of clinical chemistry testing is expected to continue, and continues providing limited opportunities for manufacturers of automated chemistry diagnostic tests, especially HIV and cardiac tests.
- After dismal numbers, France recently showed a slight recovery, and modest growth has started to resume for the total IVD market. However, the picture is no brighter in the clinical chemistry segment.
- The Scandinavian clinical chemistry market is a vital and growing one. The countries of Scandinavia, particularly Sweden and Finland, have a number of important diagnostic companies.
- Brazil's IVD market is set to pass that of the U.K.'s, becoming the world's eighth-largest IVD market.
- Mexico's IVD market is now the █ largest worldwide and will break into the top ten within three years.
- Asia is becoming increasingly important as a major IVD market and manufacturing center for automated chemistry equipment.
- The Japanese clinical chemistry market exceeded \$█ in █.
- China's clinical laboratory market accounts for just █% of the total worldwide market. China is the second largest clinical laboratory market in Asia and one of the world's fastest growing. China's IVD market is growing at an estimated rate of █%, more than double the overall growth rate of the world clinical laboratory sector. The total Chinese IVD market was estimated to be over \$█ in █, growing to an estimated \$█ by █ and is projected to reach approximately \$█ by █.
- India's IVD market is growing at an estimated rate of █%, more than double the overall growth rate of the world IVD sector.
- The newest trend in the Indian IVD sector is the arrival of the Chinese medical equipment companies.

The trend to consolidation of companies, which is so vigorous in the rest of the diagnostic market because of its maturity, is exactly reflected in the clinical chemistry segment. Here, the direction of product development is in, not out. The products of this market segment move naturally to the centralized instruments. The central laboratory, with its old position of static dominant player, is still the king. The new mobile, quick, easy-to-use systems are challenging this position and will eventually be the dominant method of most chemistry analyses. But for now, clinical chemistry, performed in the large central lab by automated analyzers with a wide range of testing menus and dedicated data information processing, are still where the action is in this segment.

Eyeing the current size of the blood glucose-monitoring segment (roughly \$██████), for instance, nearly all analysts agree that it has the potential to remain a major factor in market growth for the foreseeable future. Increased consumer attention to, and reimbursement for, diabetes monitoring will be one of the biggest driver of growth in the IVD industry. Another force shaping the IVD market is the ongoing pressure for cost containment. For companies whose products are focused on automating big laboratories, it is good news if cost-containment pressures bring about further lab consolidation. Although analysts have high hopes for some segments of the automated chemistry market, other segments are expected to show little or no growth in the foreseeable future.

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