

The background of the cover is a solid blue color. Overlaid on this are several semi-transparent images of petri dishes, some containing a dark purple or blue substance. A pipette tip is also visible, pointing towards the center of the cover.

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CLINICAL LABORATORY
TESTING VOLUME 1:
REAGENTS AND
INSTRUMENTS
(SAMPLE COPY, NOT FOR RESALE)

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1. Overview

Clinical laboratory analysis for *in vitro* diagnostic (IVD) testing is one of the most important sectors of medical care. By all accounts, it is very mature, large and diverse—crossing the \$ [REDACTED] mark worldwide in [REDACTED]—and employing over [REDACTED] laboratory workers, and spawning an industry for reagents and instruments comprised of thousands of companies worldwide.

The term clinical laboratory analysis usually refers to determining the concentration or activity of a protein, carbohydrate, lipid, electrolyte, enzyme or small molecule in easily collected body 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 laboratory science. In fact, traditional specialization barriers such as microbiology, hematology, blood banking, immunology and even anatomical pathology are rapidly fading both operationally and instrumentally in the face of a more profound understanding of the genetic and molecular basis of disease.

But for the sake of limiting the subject to a reasonable size, we take the more traditional scope of clinical laboratory to be the subject of this report and thereby exclude the areas of anatomic pathology, blood banking, diagnostic imaging and microbiology.

1.1 Objectives of the Report

The purpose of this report is to describe the specific segments of the global clinical laboratory instrumentation and reagent market. Within this area, the report covers those segments that are highly active in terms of innovation and growth. Specifically, this global clinical laboratory markets report examines the markets for small lab equipment all the way up to highly-automated, large lab platforms, as well as accessory equipment such as reagents, supplies and manufacturers' original equipment manufacturer (OEM) additional equipment.

The emphasis in this analysis is on those companies and products that are actively developing and marketing laboratory analyzer products for the clinical setting, including hospitals, independent labs, physician's offices and miscellaneous clinics. This study concentrates on the clinical laboratory instrumentation industry market segment and the companion reagents sector in the U.S. and around the world. The regional markets and their differences are examined, including Europe, Asia (Japan, China and India) and the rest of the world (ROW). Particular attention is paid to those areas of the clinical laboratory instrumentation and reagents sector that are showing the greatest growth or the most innovation. This report attempts to answer the following questions:

- Which companies are the key players?
- What are the promising opportunities in clinical laboratory instrumentation and reagent markets?
- What is happening with the information revolution in lab instruments?
- What are the developing major trends?
- Where are the new clinical laboratory market growth areas?
- What are the most favored lab analysis technology platforms?
- Where is the laboratory analyzer instrument technology taking us?
- How is immunological technology blending with more established laboratory procedures?
- What are the key business trends in the IVD industry?

This analysis reviews the market for clinical laboratory instrumentation used in clinical practice. It defines the dollar volume of sales in each major regional market, as well as 25 individual European country markets, and it analyzes the factors that influence the size and the growth of the individual market segments. The report details market sizes and growth rates for the U.S. and world markets.

The study surveys some of the leading companies known to be marketing, manufacturing or developing products for the clinical laboratory instrumentation and reagent market for those sectors covered here. Each company is discussed in depth with a section on the history of the company, product lines, business and marketing analysis, and a subjective commentary of the position of the company in its market.

The unique benefits of this report are:

- In-depth analysis of the major sectors of the clinical laboratory instrumentation and reagent sectors, their size, growth rates and major drivers.
- Presentation of some of the emerging technology platforms, elucidating the potential areas that could gain traction in this 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.

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 National Institutes of Health (NIH), Food and Drug Administration (FDA) and the Centers of 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 chemical constituents of blood, plasma or serum of the patient. The two most important areas where such tests are measured are in the hospital and the independent clinical laboratories. Also, these tests are measured in physician office laboratories (POLs). Newer areas of testing interest for these analytes can be satellite labs and pharmacies and corporate clinics.

The emphasis in this analysis 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 <http://www.trimarkpublications.com> for a detailed discussion of the important individual market segments that are related to the IVD market, such as molecular diagnostic testing, high-growth diagnostic test markets, blood gas and electrolytes over-the-counter (OTC) diagnostic testing markets, point of care testing (POCT), clinical chemistry, hematology and immunochemistry. A companion report, *Clinical Laboratory Testing Volume 2: Business Strategies*, deals primarily with 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: 1) Hitachi and its relationship with Roche Diagnostics Corporation, 2) JEOL manufacturing products for Bayer, or 3) 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 laboratory diagnostics instrument and reagents marketing.

The examination does not cover what is generally characterized as anatomic pathology, microbiology, blood banking or other diagnostic device markets, although many of the instruments, reagents and techniques in the clinical laboratory diagnostics market segment are intimately associated with these broader areas. Moreover, this review 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 this report mentions many common lab procedures and analytes, as well as techniques such as measuring the serum concentrations of therapeutic drugs, drugs of abuse, genetic testing and molecular diagnostics, no

extensive or in-depth treatment of this subject is presented. Such a discussion is outside the scope of this analysis. This report reviews the clinical lab 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 laboratory 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 laboratory 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 laboratory analyzers specifically designed for that purpose. Automated multi-channel testing addresses those tests that can be done as groups and combinations on automated clinical laboratory equipment.

The global IVD 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. [REDACTED] countries account for approximately [REDACTED]% of the IVD market worldwide. [REDACTED] country markets account for [REDACTED]% of total IVD sales.

The distribution of clinical laboratory testing worldwide shows a preponderance of this type in North America and Europe. The European Union, 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 market segments, such as chemistry/hematology workstations, hematology and routine microbiology. In addition, IVD markets in South America and South Asia are experiencing [REDACTED]% to [REDACTED]% annual growth rates, respectively. Japan 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 medical establishment is very slow to adapt to change.

[REDACTED] 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 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 [REDACTED] companies, only Beckman Coulter is not a part of a larger corporate structure that includes a pharmaceutical division. Among the largest IVD companies, Johnson & Johnson (J&J)—including Ortho-Clinical Diagnostics (OCD) and LifeScan—grew the fastest.

While clinical chemistry and immunoassays will remain the most profitable parts of the global IVD industry through [REDACTED], nucleic acid products—especially those that detect infectious disease and cancers—will generate the fastest gains, the report predicts. Sales of these products totaled \$ [REDACTED] in [REDACTED] and are expected to grow by [REDACTED]% per year until [REDACTED], when they will reach \$ [REDACTED]. Applications used for DNA-based forensic, genetic, and identity testing will sustain the strongest gains in demand.

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.
- Technology 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 (ER), acute care centers etc.).

- 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 U.S. clinical diagnostic testing is currently conducted in hospital-based and commercial laboratories. Clinical chemistry laboratory testing now represents █% of the \$█ U.S. market for clinical diagnostic testing reagents, controls and equipment, or \$█ in █, and 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 laboratory testing, with over █% of the █ U.S. hospitals (█-bed size and larger) having installed some form of clinical laboratory instrumentation over the █ months.

While clinical chemistry and immunoassays will remain the most profitable parts of the IVD industry through █, nucleic acid products—especially those that detect infectious disease and cancers—will generate the fastest gains. Sales of these products totaled \$█ in █ and are expected to grow by █% per year until █, when they will reach \$█. Applications used for DNA-based forensic, genetic, and identity testing will sustain the strongest gains in demand. Among other products, cellular analysis tests used in cervical cancer testing and anatomical pathology reagents and instruments used in specialized applications for cancer biopsies and detecting infectious disease will provide the best growth opportunity. The market for blood testing diagnostics will continue to post below average growth through █, but cardiac markers will provide niche opportunities.

In █, the European estimate of █ countries had a total IVD market of \$█. With an expected real growth at a compounded annual growth 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 products, with \$█ in sales. Overall European IVD market performance is inconsistent, with large differences from country to country and from product type to product type. For example, strong growth is seen in emerging countries of the former Eastern Bloc, such as Hungary, Poland and the Czech Republic, along countries with relatively low per-capita expenditure for *in vivo* testing like the Netherlands. In contrast, growth in the major markets like Germany remains somewhat lower. Central and Eastern Europe have large potential for a further increase in market based on spending as a percent of GDP. Growth sectors in the European IVD sector are:

- Molecular diagnostics.
- Microbiology.
- Immunoassay cardiac tests.
- Blood glucose testing.

In contrast, growth in the clinical chemistry sector has been slow because of pricing pressures and laggard implementation of diagnosis related groups (DRG). While the U.K. has been reducing hospital laboratory fees, private labs and POLs will continue to receive appropriate fees and reimbursement. The primary drivers of the shift toward more laboratory automation in Europe are:

- Pressures from labor unions.
- A shortage of qualified medical technicians.
- The availability of laboratory space.

In addition, in several countries such as Germany and France, microbiology testing must be completed within █ hours in order to be reimbursed, resulting in an increased shift to automation and adoption of point of care testing (POCT). IVD product manufacturers in Europe are responding to several major trends. These include automation and standardization, adoption of POCT, and hospital consolidation. Japanese companies manufacturing medical instruments for the U.S. market have experienced a competitive advantage by the nearly █% fall in the yen. Ironically, the global economic forces that depressed the value of the yen relative to the dollar have played directly to the overall strategy of Japanese industry, which is to commoditize industrial products while leveraging their advantage in process control, operational costs and market dominance.

The much higher growth rates for medical and diagnostic products that were being achieved in Latin America and the Pacific Rim countries during the last decade are now in serious jeopardy. The worldwide economic collapse has all but guaranteed negative growth rates for this region. These relatively new areas of medical instrumentation are

home to over [REDACTED] people, who are beginning to demand modern medical services on a level seen in the industrialized countries of North America, Europe and Japan. Emerging economies of countries like China, Taiwan, Thailand and South Korea were showing growth rates [REDACTED] to [REDACTED] times larger than the industrialized countries. This market segment reached over \$ [REDACTED] in sales by [REDACTED]. If world economic recovery is slow, IVD industry growth rates could be negative in these countries for some time.

Ultra-Large Throughput Laboratory Analyzers

The ultra-large clinical laboratory analyzer market is identified by the use of instruments with throughputs of substantial size, usually over [REDACTED] tests per hour. These large-capacity instruments are used primarily in large university teaching and research hospitals and medical centers and, of course, the large commercial or reference labs. The laboratories with annual volumes of over [REDACTED] tests per year would encompass this market. Instruments that are fully-automated, including accessibility to robotic lines, characterize the analyzers at this top end of the market. This category of analyzers consists of instrument systems marketed by Olympus, Beckman Coulter, JOEL, Roche Diagnostics and Bayer Diagnostics. These very large and expensive instruments are sold only to the very limited number of large medical centers and big commercial labs. These customers are generally very price-savvy and demand substantial discount arrangements for hardware and reagents. However, these difficulties are often offset for the manufacturers of large-capacity products by the very high-volume usage of reagents and other consumables.

Large-Throughput Analyzers

The high-volume clinical laboratory market segment, with testing greater than [REDACTED] tests per day, accounts for [REDACTED]% of the U.S. market, or about \$ [REDACTED] per year. Others have estimated the worldwide high test-volume clinical laboratory market segments to be \$ [REDACTED]. These large-throughput analyzers are used primarily in large hospitals and second-level reference labs. The laboratories with annual volumes of between [REDACTED] and [REDACTED] tests per year would encompass this market. The analyzers at this top end of the market are characterized by instruments capable of performing [REDACTED] to [REDACTED] tests per hour and are fully-automated. This category of automated clinical laboratory analyzer constitutes the heart of the laboratory analyzer market. These instruments are marketed to the broad category of large hospitals, clinics, and medium-sized private commercial laboratories. These users comprise the largest market segment in terms of use of reagents and other consumable items available for repeat sale.

Mid-Size Clinical Laboratory Analyzers

This market segment is the next large part of the automated clinical laboratory analyzer market and encompasses both hospitals and commercial laboratories. The broadest market for automated laboratory analyzers has always been the traditional mid-size community hospital. The number of these hospitals has decreased by [REDACTED]% in the last [REDACTED] years due to restructuring; however, the actual number of institutions in the [REDACTED]- to [REDACTED]-bed range remains the highest of any segment of the laboratory analyzer market. Remember—regardless of size—all hospitals need some type of laboratory analyzer for continued patient care. The mid-size market segment laboratories usually perform between [REDACTED] and [REDACTED] patient profiles per day. Based on an average of [REDACTED] chemistries per profile, this equals about [REDACTED] to [REDACTED] tests/day. This equates to an analyzer throughput of [REDACTED] to [REDACTED] tests/hour. Currently, this throughput can be achieved by a relatively large number of available automated laboratory instruments.

Automated laboratory instruments in this class have a throughput capacity of about [REDACTED] to [REDACTED] tests/hour. They are marketed to the large number of mid-sized hospitals with between [REDACTED] to [REDACTED] beds. Also, some large group practice labs have enough profiling to use these instruments effectively. Beckman Coulter sells several general laboratory systems for use in the clinical laboratory laboratories of medium to large hospitals and to reference laboratories. The company's line of Synchron automated general laboratory analyzers is a family of modular diagnostic instruments and reagents, standards and other consumable products required to perform commonly requested diagnostic tests.

Laboratory Analyzers for the Small Volume Market

The VITROS® 5600 is the next generation system is uniquely designed to integrate clinical chemistry and immunoassay testing to increase laboratory productivity and will be able to perform more than [REDACTED] different

chemistry, immunoassay and infectious disease assays on a single, high-quality system. In addition to its current broad menu including user-defined applications, the VITROS® 5600 Integrated System will have the capability to run future tests for earlier detection of diseases. “There are fewer steps for each test specimen going through the VITROS® 5600 Integrated System,” said Dr. John Chapman, Director of Core/Clinical Chemistry Laboratories and Point-of-Care Testing at University of North Carolina Hospitals. “It builds on the cost savings, quality and efficiency of its predecessors and adds enhanced immunoassay capability, one of the fastest growing diagnostic areas. The timing is perfect for the introduction of this innovation to meet current and future needs of high volume labs.” Dr. Chapman is a principal investigator for the VITROS® 5600 Integrated System and a paid consultant retained by Ortho Clinical Diagnostics.

“The VITROS® 5600 Integrated System will consolidate and simplify testing and proves you do not have to compromise quality to gain efficiency,” said Ortho Clinical Diagnostics Worldwide Commercial President Mark Straley. “By incorporating the flexibility to accommodate novel clinical diagnostic tests, this world-class system has the potential to help doctors diagnose disease earlier and make better informed treatment decisions for patients.”

The lower end of the market for automated clinical laboratory analyzers is for throughput capacities of less than ■■■ tests per hour. These instruments are marketed to small hospitals, satellite labs and doctor’s offices. Ortho-Clinical previously made the Vitros 250™ Analyzer, which was first sold in the U.S. in ■■■. This instrument has been replaced with the Vitros 350, which has up to ■■■ on-board chemistries and has a throughput of up to ■■■ results per hour. Time to first result is ■■■% faster than the Vitros 250 and with its enhanced software throughput is improved ■■■% to ■■■% over the Vitros 250. The Vitros 350 analyzer targets mostly relatively low-volume users like doctor’s group practices and small community hospitals. The instrument is particularly suited to smaller institutions, which have limited staffing, because the dry laboratory reagents which the system uses offer distinct advantages over liquid-based systems.

Immunochemistry Analyzers

Some of the clinical chemistry analyzers already discussed includes methods to quantitate proteins and metabolites utilizing latex immunoassay methods and turbidimetric immunoassays. These instruments generally do not have the capability of measuring low levels of fertility hormones, tumor markers and cardiac markers. The type of instrument that falls in the category of immunochemistry analyzer; however are designed to measure low levels of hormones, cancer markers, infectious disease antigens and antibodies. These analytes used to be measured utilizing radio immunoassay (RIA) techniques. Today’s instruments use chemiluminescence, fluorometric enzyme immunoassays (EIA) methods, among others to quantitate these hormones and markers.

One of the most important features that immunochemistry analyzers need today is the ability to measure B-type natriuretic peptides (BNP) and NT-proBNP. The instruments that have this ability today are the following, for BNP: Abbott Architect, Abbott AxSYM, Siemens ADVIA Centaur (and the older ACS: 180), Beckman Coulter Synchron, as well as the manual Biosite Triage; and for NT-proBNP: Dade Behring (a part of Siemens) Dimension Vista and Stratus CS, Roche E170, and Roche Elecsys Systems.

Lab Company Consolidation

The top-heavy independent lab sector, with many competing regional labs, continues to consolidate. Two deals, Clinical Pathology Laboratories’ (CPL) purchase of Cognoscenti and American Esoteric Laboratories’ (AEL) Texas acquisition, focused on big players in the Southeastern U.S. More acquisitions are predicted for the next few years, especially given the deep pockets behind some recent purchases, money coming from venture firms. The number of sizable independent labs up for sale is dwindling fast, asking each new deal richer than the last.

On the clinical lab side, ■■■ was also a banner year for lab acquisitions. Sonic Healthcare announced that it would be purchasing Clinical Laboratories of Hawaii, LLP for an estimated \$■■■■. Rosetta Genomics completed its acquisition of Parkway Clinical Laboratories Inc. The largest ■■■ U.S. acquisition was Quest Diagnostics’ purchase of AmeriPath, Inc. for \$■■■■.