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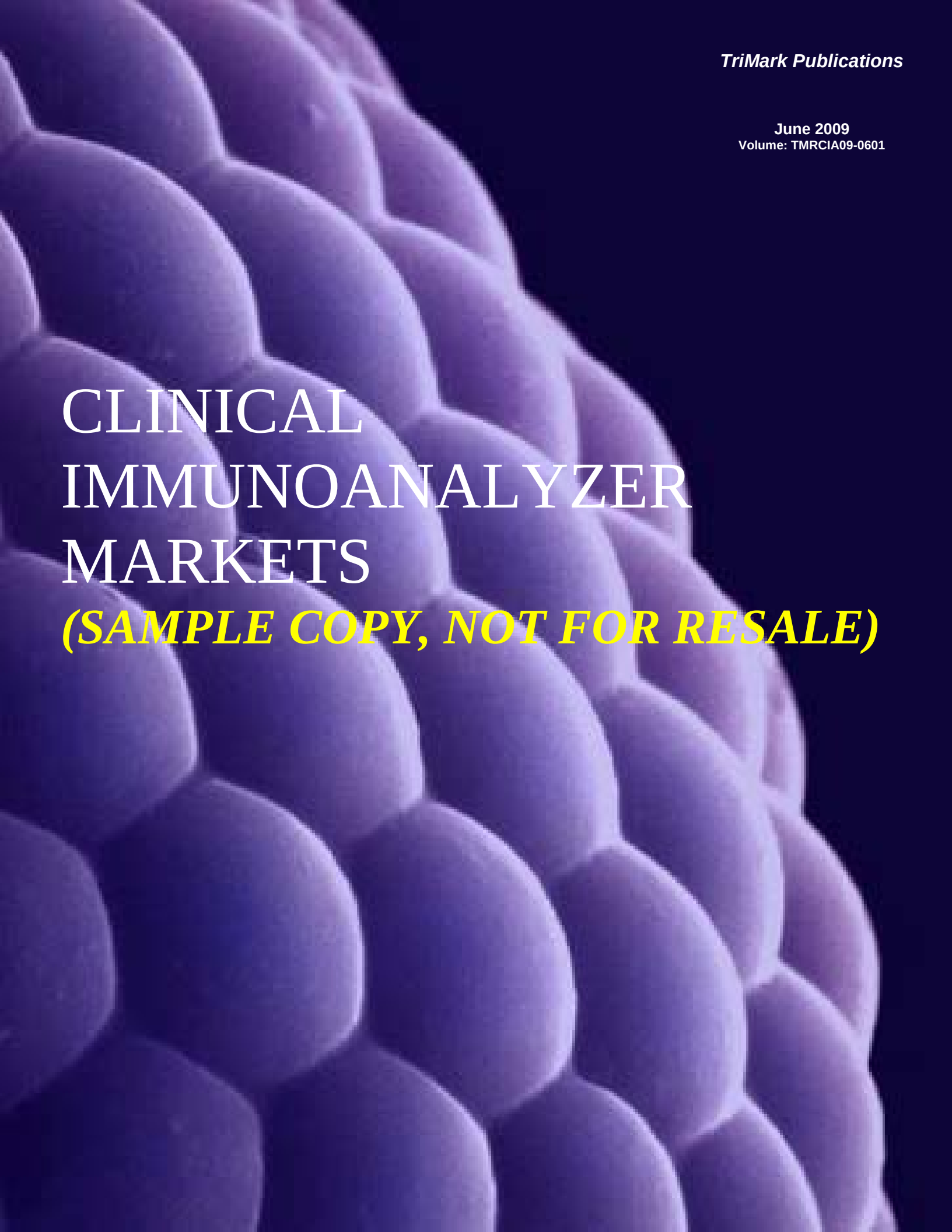

CLINICAL IMMUNOANALYZER MARKETS

(SAMPLE COPY, NOT FOR RESALE)

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1. Overview

Clinical immunoanalyzer analysis is one of the most important functions of clinical laboratory analysis. By all accounts, automated immunoassay testing is the most rapidly developing of the several traditional clinical laboratory sectors. Clinical immunoanalyzer analysis usually refers to determining the concentration or activity of protein, carbohydrate, lipid, enzyme or small molecule in easily collected body fluids, such as blood, serum, plasma or urine. However, it is not necessarily limited to these purposes. The analysis of virtually any biologically active substance in any place in the body can generally be defined as clinical immunoassay testing. In fact, traditional specialization barriers, such as microbiology, hematology, blood banking, immunology and even anatomical pathology are fading rapidly, both operationally and instrumentally. This report deals with the traditional scope of clinical immunoassay, while looking at the emerging technology trends in this sector.

1.1 Objectives

The purpose of this study is to describe the specific segments of the global clinical immunoanalyzer instrumentation market. Within this area, the highly-active segments in terms of innovation and growth are covered. Specifically, it examines the markets for small labs and highly-automated large lab platforms, as well as the market for accessory equipment, such as reagents and supplies. Emphasis is on those companies and products that are actively developing and marketing immunoanalyzer products for clinical setting, including hospitals, independent labs, physician's offices and clinics.

This study focuses on the clinical immunoanalyzer instrumentation industry market segment in the United States and around the world. The regional markets and their differences are examined *vis-à-vis* Europe, Japan and the rest of

the world (ROW). Particular attention has been paid to those areas of the clinical immunoanalyzer instrumentation sector that are showing the greatest growth or innovation. Among other things, the report attempts to answer the following questions:

- Which companies are the key players?
- What are the opportunities in clinical immunoanalyzer instrumentation industry?
- What are the development trends?
- Where are the new market growth areas?
- What are the most favored technology platforms?
- Where is the immunoanalyzer instrumentation technology taking us?
- How is the immunological technology blending with the immunoanalyzer?

The study surveys some of the leading companies known to be marketing, manufacturing or developing products for the clinical immunoanalyzer instrumentation market. Each company is discussed thoroughly with a section on the history of the company, product lines, marketing analyses, and a subjective commentary of the position of the company in the market. Readers can gain the following insights from this report:

- Complete analysis of the major sectors of the clinical immunoanalyzer instrumentation market, 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 that various key sector players have forged, including the financing linkages of these market participants, apart from insights into potential market collaborations.
- 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 National Institutes of Health (NIH), 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 TriMark Publications Report Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly available databases, proprietary databases, direct meetings and personal interviews with key personnel.

- Formulating a study outline with the assigned writer, including important items:

    - Market and product segment grouping, and evaluating their relative significance.
    - Key competitors' evaluation, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
    - End-user research to evaluate analytical significance in market estimation.
    - Supply chain research and analysis to identify any factors affecting the market.
    - New technology platforms and cutting-edge applications.

- Identifying the key technology and market trends that drive or affect these markets. Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.

- Launching a combination of primary research activities including two levels of questionnaires, executive-direct focused, company-specific, and region-specific communications to qualified and experienced senior executives worldwide.

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

1.4 Scope of the Report

This study deals with the examination of analytes related to the constituents of blood, plasma or serum of patients that fall within the area of traditional immunoassay, as opposed to traditional clinical chemistry testing. Immunoassay tests are typically analytes like peptide, thyroid and steroid hormones, and biologically important proteins like immunoglobulins, alpha-1anti-trypsin, calcitonin, lipids, carbohydrates, and so on. Typical immunoassay tests are discussed in Section 2. The two most important places for conducting such tests are hospitals and independent clinical laboratories. Such tests are also measured in physician's office laboratories (POLs). Potential areas of testing interest for these analytes include satellite labs and corporate clinics.

The emphasis in this report is on those companies and products that are actively developing and marketing clinical laboratory instrumentation and reagents, and supplies for performing clinical immunoanalyzer 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 point of care testing (POCT). The analysis touches on the specialty testing areas in clinical immunoanalyzer diagnostic testing, such as C-reactive protein (CRP), lipoprotein profiling and cardiac markers as these segments are frequently a part of the overall analytical focus of companies marketing general laboratory automation equipment. However, no effort is made to quantitative the size of this broader market.

The study also mentions companies that market and sell a limited number of instruments and equipment as an OEM part of a much larger clinical laboratory product line of other companies; for example, Hitachi's 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* as they are not a direct focus of the clinical immunoanalyzer diagnostics instrument market.

This report does not cover what is generally characterized as chemistry instruments and reagents. What's more, it does not address hematology or coagulation markets—or other diagnostic device markets—although many of the instruments, reagents and techniques in the clinical immunoanalyzer diagnostics market segment are intimately associated with these broader areas. Moreover, this examination does not cover disposable plastic supplies for the clinical laboratory or blood gases and electrolytes. Although this analysis mentions recombinant proteins in passing—as well as techniques such as measuring the serum concentrations of therapeutic drugs and drugs of abuse—no extensive or complete treatment of this subject is presented. Such a discussion is outside the scope of this analysis.

1.5 Executive Summary

Clinical immunoanalyzer testing includes processes used to detect levels of enzyme, sugars, proteins and other substances in the blood in order to determine clinical conditions, such as nutritional state, liver function, kidney function and others. Immunoassay testing is widely applied in identifying conditions like arthritis, infectious diseases and thyroid diseases during clinical diagnoses and as a part of regular health checkups. During [redacted], approximately [redacted] clinical immunoanalyzer tests were carried out within hospitals in the U.S. Most of these tests were performed as screening or multi-channel tests using automated immunoanalyzers 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 immunoanalyzer 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 six 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 the demand for diagnostic testing as an effective tool to improve patient outcomes and to reduce the costs of misdiagnosis through earlier and more accurate diagnosis and patient monitoring.
- Emerging markets will provide additional demand as economic improvements in several 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 point-of-care (POC) and/or 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 [redacted]% of clinical diagnostic testing is currently conducted in hospital-based and commercial laboratories. Clinical immunoanalyzer testing now represents [redacted]% of the $[redacted] U.S. market for clinical diagnostic testing reagents, controls and equipment. This is projected to grow at an annual rate of [redacted]% in the U.S. through [redacted], to a total of $[redacted]. Surveys show that [redacted]% of hospitals with more than [redacted] beds have adopted some form of clinical immunoanalyzer testing, with over [redacted]% of the [redacted] U.S. hospitals ([redacted] beds and larger) have installed some form of clinical immunoanalyzer instrumentation..

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

The European immunoassay market increased significantly in [redacted] in most of the European countries (but not all) to €[redacted], and the average growth was around [redacted]% in [redacted]. Projections for the analysis period estimate the European immunoassay market in [redacted] at €[redacted]. Individual country markets for immunoassay analyzers and reagents are described.

