

CLINICAL
IMMUNOANALYZER
MARKETS

(SAMPLE COPY, NOT FOR RESALE)

TABLE OF CONTENTS

1.	Overview	6
1.1	Objectives	6
1.2	Methodology	6
1.3	TriMark Publications Report Research and Data Acquisition Structure	8
1.4	Scope of the Report	8
1.5	Executive Summary	9
2.	IVD Clinical Immunoanalyzer Market	11
2.1	Introduction	11
3.	IVD Clinical Immunoanalyzer Market Analysis	13
3.1	Markets	13
3.1.1	Global Markets	13
3.1.2	Global Drivers of Clinical Immunoanalyzer Testing	14
3.1.3	Global Outlook	15
3.1.4	U.S. Market	16
3.1.5	European IVD Market	18
3.1.5.1	German Clinical Immunoanalyzer Diagnostic Markets	21
3.1.5.2	U.K. Clinical Immunoanalyzer Testing Diagnostic Market	23
3.1.5.3	French Clinical Laboratory Diagnostic Testing Market	23
3.1.5.4	Italian Clinical Immunochemistry Diagnostic Market	24
3.1.5.5	Spanish Immunoanalyzer Market	25
3.1.5.6	Finnish Immunoanalyzer Market	25
3.1.5.7	Belgian Immunoanalyzer Market	26
3.1.5.8	Swiss Immunoanalyzer Market	26
3.1.5.9	Dutch Immunoanalyzer Market	26
3.1.5.10	Portuguese Immunoanalyzer Market	27
3.1.5.11	Austrian Immunoanalyzer Market	27
3.1.5.12	Greek Immunoanalyzer Market	28
3.1.5.13	Polish Immunoanalyzer Market	28
3.1.5.14	Romanian Immunoanalyzer Market	29
3.1.6	Indian Clinical Analyzer Diagnostic Market	29
3.1.6.1	India's in vitro Diagnostic Testing Industry	29
3.1.7	Japanese Clinical Immunoanalyzer Testing Market	34
3.1.8	Country Clinical Analyzer Smaller Markets	34
3.1.8.1	China Clinical Analyzer Market	34
3.1.8.2	Canada Clinical Analyzer Market	38
3.1.8.3	Brazil Clinical Analyzer Market	39
3.1.8.4	Turkey Clinical Immunoanalyzer Market	39
3.1.8.5	Australia Clinical Analyzer Market	40
3.1.8.6	Rest of the World Clinical Analyzer Testing Market	40
3.1.9	Overview of Asian Healthcare Market	40
3.1.9.1	Singapore	41
3.1.9.2	Malaysia	41
3.1.9.3	Thailand	41
3.1.9.4	Indonesia	41
3.1.9.5	Philippines	42
3.1.9.6	South Korea	42
3.1.9.7	India	42
3.1.9.8	Hong Kong	43
3.1.9.9	Taiwan	43
3.2	Clinical Immunoanalyzer Sector	44
3.2.1	Industry-Served Markets	45

3.2.2	Industry Players	45	
3.2.2.1	Manufacturing Companies	45	
3.2.3	Market Specialization	46	
3.2.4	Revenue and Reimbursement	48	
3.2.5	Companies	49	
3.3	Outlook for Clinical Immunoanalyzer Testing	50	
3.3.1	Long-Term Changes	50	
3.3.2	Market Drivers	51	
3.3.3	The Limits to Growth	51	
3.3.4	Hot Sectors in IVD Market	52	
3.3.5	Key Technologies	53	
3.3.6	Analyzer Integration Chemistry/Immunoassay	53	
3.3.7	Conclusion	54	
4.	Clinical Immunoanalyzer Instrument Market by Sector	55	
4.1	Market Analysis: Size, Growth, Share and Competitors	55	
4.1.1	Immunochemistry Analyzers	55	
4.1.2	Large-Volume Immunochemistry Analyzers	55	
4.1.2.1	Abbott Diagnostics	55	
4.1.2.2	Siemens Medical Solutions Diagnostics	56	
4.1.2.3	Beckman Coulter, Inc.	59	
4.1.2.4	Dade Behring (Acquired by Siemens)	60	
4.1.2.5	Diagnostics Products Corporation (Acquired by Siemens Healthcare Diagnostics)	61	
4.1.2.6	Olympus America, Inc.	62	
4.1.2.7	Ortho-Clinical Diagnostics	63	
4.1.2.8	Roche Diagnostics Corp.	65	
4.1.2.9	Tosoh Bioscience	67	
4.1.3	Batch-Type Immunoassay Analyzers	69	
4.1.3.1	Bio-Rad	69	
4.1.3.2	Dade Behring (Acquired by Siemens)	69	
4.1.3.3	Diamedix	69	
4.1.3.4	Tosoh	72	
4.1.4	Small-Volume to Mid-Volume Immunoassay Analyzers	72	
4.1.4.1	Awareness Technology, Inc.	72	
4.1.4.2	Siemens Healthcare Diagnostics, Inc.	72	
4.1.4.3	Beckman Coulter, Inc.	73	
4.1.4.4	bioMérieux SA	74	
4.1.4.5	Dade Behring (Acquired by Siemens)	74	
4.1.4.6	Randox Laboratories Ltd.	78	
4.1.4.7	Tosoh Corporation	79	
4.1.5	Other Immunoassay Analyzers	80	
4.1.5.1	Inverness Medical Professional Diagnostics	80	
4.1.5.2	Hycor BioMedical (A Part of Agilent Technologies)	80	
4.1.5.3	Phadia AB	80	
4.1.5.4	Trinity Biotech PLC.	81	
4.1.5.5	Diasorin	81	
4.1.5.6	Grifols U.S.A. Inc.	81	
4.1.5.7	Bio-Rad Laboratories, Inc.	82	
4.1.5.8	SFRI Diagnostics	82	
4.1.5.9	Qualigen Inc.	82	
4.1.5.10	PerkinElmer Inc.	82	
4.1.5.11	Innotrac Diagnostics Oy	83	
4.1.5.12	Tecan Group Ltd.	83	
5.	Important Technology Trends	85	
5.1	Technology Innovations in Immunoassay Testing	85	

5.2	Immunoassay Detection Technology Platforms	85
5.2.1	Fluorescence Detection	85
5.2.2	Chemiluminescence Detection	85
5.3	The New Paradigm	86
5.4	Consolidated Workstations	86
5.5	Automation in the Laboratory in Response to Labor Shortages	88
5.6	Laboratory Information System (LIS)	89
5.7	Biosensor Technology	89
5.8	Data Management Issues	91
5.8.1	Wireless LANs	92
5.8.2	Data and Workflow Management Systems	93
5.8.3	Beckman Central Command	93
5.8.4	Advances in Information Management	95
5.8.5	Connectivity Platforms	98
5.8.6	DataLink Data Management System	100
5.8.8	Technical Problems of Connectivity	102
5.8.9	Web-Based Data Interface and Internet Connectivity	103
5.8.10	HIT Competition	104
5.8.11	FDA-Required Software Verification	104
5.8.12	Advantages of Connectivity	105
5.8.13	Technologies for Internet-based Remote Architecture	105
5.8.14	Abbott Multi Tiered Internet System	105
6.	Business Trends in Clinical Immunoanalyzer Sector	106
6.1	Key Developments	106
6.2	Sector Consolidation	106
6.3	Diagnostic Testing Growth Trends	107
6.4	Reagents and Hardware Business in Japan	107
6.5	New Products	108
6.6	Acquisitions, License Agreements, Internal Developments and Partnerships	108
6.7	Product Testing Depth in Clinical Immunoanalyzer Testing	109
6.8	Government Regulations	109
6.8.1	U.S. Government Regulations	109
6.8.1.1	Importing Medical Devices into the U.S.	111
6.8.1.2	Exporting Medical Devices from the U.S.	111
6.8.2	U.K. Regulations	112
6.8.3	E.U. Regulations	113
6.8.4	Japanese Regulations	115
6.8.5	Korean Regulations	115
6.9	Increased Market Penetration	115
6.10	Costs of Doing Business in Europe	117
6.11	Drivers of European Diagnostics Testing	117
6.12	European Reimbursement Practices	117
6.13	Cost Containment in Europe	118
6.14	Medicare Spending Trends/Medicare Part B Spending Trends	118
7.	Company Profiles	121
7.1	Abbott Diagnostics	121
7.3	Beckman Coulter, Inc.	125
7.4	bioMérieux	127
7.5	Dade Behring (Acquired by Siemens)	128
7.6	Bio-Rad Laboratories, Inc.	130
7.7	Olympus America, Inc.	130
7.8	Ortho-Clinical Diagnostics, Inc.	131
7.9	Phadia AB	132
7.10	Randox Laboratories Ltd.	133

7.11	Roche Diagnostics Corp.	133
7.12	Tosoh Corporation	135
7.13	Siemens AG	136
8.	Clinical Immunoanalyzer Testing Sector: Trends and Forecasts	137
8.1	Automated Instrument Platforms Evolution	137
8.2	Reagents and Supplies Market for Clinical Lab Instruments	137
8.3	Bar Code Reading	138
8.4	Measurement and Detection for Immunoassay Analyzers	138
8.5	Robotics Systems	139
8.6	Move Away from Central Laboratory	140
8.7	Modular Automation	140
8.8	Components of Immunoassay Analyzers	140
8.9	Drivers of Clinical Immunoanalyzer Testing	144
8.10	Confluence of New Technology	144
8.11	New Trends in Clinical Laboratory Testing	145
8.11.1	Trends in Reimbursement Practices	145
8.11.2	Managed Care	148
8.11.3	Changes in Patient Management	148
8.11.4	Focused Testing	148
8.11.5	Spending for Clinical Laboratory Testing	148
8.11.6	Reimbursement Pressure	149
9.	Product Launches	151
9.1	Immunoassay Analyzer Product Launches	151
9.2	Immunoassay Reagent Product Launches	152

INDEX OF TABLES

Table 2.1:	Common Immunoassay Tests	11
Table 3.1:	Worldwide IVD Testing Market, 2008	13
Table 3.2:	Worldwide Distribution of IVD Testing, 2008	13
Table 3.3:	Global Clinical Immunoassay Revenues, 2000-2012	14
Table 3.4:	Worldwide Distribution of Clinical Immunoassay Testing, 2006	14
Table 3.5:	U.S. Clinical Laboratory Testing Market, 2003-2012	17
Table 3.6:	U.S. Clinical Laboratory Diagnostic Test Market Segments, 2008	17
Table 3.7:	U.S. Individual Clinical Chemistry Laboratory Diagnostic Test Markets, 2007	17
Table 3.8:	U.S. Clinical Immunoanalyzer Testing Market, 2000-2012	18
Table 3.9:	European Clinical Laboratory Testing IVD Reagents and Instruments Market, 2000-2012	18
Table 3.10:	European Clinical Laboratory Testing IVD Reagents and Instruments Market, 2000-2012	19
Table 3.11:	European Clinical Laboratory Diagnostic Reagents and Instruments Markets by Analyte, 2008	19
Table 3.12:	European Clinical Laboratory Testing Diagnostics by Country Market Estimates, 2007	20
Table 3.13:	The European Immunochemistry Market, 2001-2012	20
Table 3.14:	European Immunochemical Reagents and Instruments Markets by Country, 2006	21
Table 3.15:	German Clinical Laboratory Testing Diagnostics Products Market Sales, 2003-2012	22
Table 3.16:	German Clinical Immunochemistry Testing Diagnostics Products Market Sales, 2006-2012	22
Table 3.17:	UK Clinical Immunochemistry Testing Diagnostics Products Market Sales, 2006-2012	23
Table 3.18:	French Clinical Immunochemistry Testing Diagnostics Products Market Sales, 2006-2012	24
Table 3.19:	Italian Immunochemistry Diagnostics Products Market Sales, 2006-2012	24
Table 3.20:	Spanish Clinical Laboratory Diagnostics Products Market Sales, 2006-2012	25
Table 3.21:	Finnish Clinical Immunoassay Products Market Sales, 2006-2012	25
Table 3.22:	Belgium Clinical Immunoassay Products Market Sales, 2006-2012	26
Table 3.23:	Swiss Clinical Immunoassay Products Market Sales, 2006-2012	26
Table 3.24:	Dutch Clinical Immunoassay Products Market Sales, 2006-2012	27
Table 3.25:	Portuguese Clinical Immunoassay Products Market Sales, 2006-2012	27

Table 3.26: Austrian Clinical Immunoassay Products Market Sales, 2006-2012	27
Table 3.27: Greek Clinical Immunoassay Products Market Sales, 2006-2012	28
Table 3.28: Polish Clinical Immunoassay Products Market Sales, 2006-2012	28
Table 3.29: Romanian Clinical Immunoassay Products Market Sales, 2006-2012	29
Table 3.30: Indian IVD Market, 2006-2012	29
Table 3.31: Number of Automated Clinical Labs in India, 2004-2012	30
Table 3.32: Indian IVD Market, 2008	30
Table 3.34: Japanese Clinical Immunoanalyzer Testing Market, 2000-2008	34
Table 3.35: Chinese Clinical Diagnostic Products Market, 2000-2008	35
Table 3.36: Canadian Clinical Analyzer Testing Market, 2000-2008	38
Table 3.37: Brazilian Clinical Immunoanalyzer Testing Market, 2000-2008	39
Table 3.38: Turkish Clinical Analyzer Testing Market, 2000-2008	39
Table 3.39: Australian Clinical Immunoanalyzer Testing Market, 2000-2008	40
Table 3.40: ROW Clinical Immunoanalyzer Testing Market, 2000-2008	40
Table 3.41: Estimated Number of Clinical Laboratories in Latin America	43
Table 3.42: Principal Marketers of Automated Clinical Immunoanalyzer Instruments	45
Table 4.1: Samples and Sample Handling Features of Centaur CP	58
Table 4.2: Large Immunochemistry Analyzers	68
Table 4.3: Small- to Mid-Volume Immunoassay Analyzers	83
Table 5.1: Wireless LAN Technology Companies	92
Table 5.2: Applications for Wireless LAN Technology	93
Table 5.3: CAP and JCAHO Requirements for Customized Reporting	101
Table 6.1: Hospital Laboratory Share of Part B Medicare Spending, 1996-2006	119
Table 6.2: Medicare Part B Spending Per Medicare Enrollee, 1998-2009	119
Table 6.3: Allowed Charges for Top 25 Clinical Laboratory Procedures, 2009	120
Table 8.1: Technology Platforms for Analyzer Detection Systems	138
Table 8.2: Medicare Billing Guidelines for Multi-Channel Immunoanalyzer Tests	146

LIST OF FIGURES

Figure 6.1: Part B Spending on Clinical Lab Services, 1991 to 2007	118
--	-----

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-1 anti-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.