

HIGH-GROWTH DIAGNOSTIC TESTING MARKETS *(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

TABLE OF CONTENTS

1.	Overview	8
1.1	Statement of Report	8
1.2	Scope of this Report	9
1.3	Methodology	9
1.4	Executive Summary	11
2.	Sector Overview	15
2.1	Global Diagnostic Products Industry	15
3.	High-Growth Testing Markets: Market Segment Analysis: Size, Growth and Share	20
3.1	Global High-Growth Diagnostic Testing Markets	20
3.1.1	Market Drivers in the High-Growth Diagnostics Testing Sector	22
3.1.2	Market Segments for High-Growth Testing	22
3.1.3	Key Players in the High-Growth Diagnostics Testing Segment	23
3.1.4	High-Growth Testing Sector Analysis	24
3.2	U.S. High-Growth Testing Market	25
3.2.1	Market Overview	25
3.2.2	Diagnostic Test Categories	26
3.3	European High-Growth Diagnostic Test Market	27
3.3.1	German Diagnostic Markets	29
3.3.2	U.K. Testing Diagnostic Market	31
3.3.2.1	U.K. Market Statistics	32
3.3.2.2	U.K. Competitive Analysis	36
3.3.2.3	U.K. Market Access	38
3.4	Japanese Diagnostic Testing Market	38
3.5	Chinese Diagnostic Testing Market	41
4.	High-Growth Testing Individual Markets	45
4.1	Hepatitis Serologic Markers and Nucleic Acid Testing	45
4.1.1	Hepatitis B Virus (HBV)	45
4.1.2	Hepatitis C Virus (HCV) Testing	54
4.1.3	Hepatitis B Virus/Hepatitis C Virus Viral Load and Drug Resistance	61
5.	Cardiac Markers	64
5.1	Market Overview	64
5.1.1	American Market	69
5.1.2	European Market	72
5.2	Acute Myocardial Infarction	74
5.3	Heart Failure (BNP)	75
5.3.1	Market Overview	75
5.3.2	Commercial Assays for BNP and NT-proBNP	77
5.3.3	Market Share	78
5.4	CRP	82
5.5	Pulmonary Embolism (D-dimer Test)	83
5.6	Key Players	84
6.	Cytogenetic Testing	93
6.1	Cancer Testing	93
6.2	Prenatal Testing and Cytogenetics	95
6.2.1	Cystic Fibrosis Testing	98
6.2.1.1	CF Testing Methodology	99
6.2.1.2	CF Screening Technology Summary	101
6.3	Key Players in Segment	101
7.	Fertility Testing	103
8.	Clinical Laboratory Genomics	106
8.1	Introduction	106
8.2	Clinical Laboratory Genomics Testing	107
8.3	Developments in Clinical Laboratory Genomics	108
8.3.1	Nucleic Acid Amplification Techniques	108

8.3.2	Chromosome Imaging	109	
8.3.3	Genomics Technologies	109	
8.3.4	Proteomics Technology	110	
8.3.5	Current Pharmacogenomic Tests	110	
8.3.6	Future Pharmacogenomic Testing	111	
9.	Glucose Monitoring	113	
9.1	Overview of Market Segment	117	
9.2	Competitive Strategies	118	
9.3	Analyses of the Current Market Conditions, Competition and Product Mix		118
9.3.1	First-Generation Monitors	119	
9.3.2	Second-Generation Monitors	119	
9.3.3	Third-Generation SMBG Technologies	120	
9.3.4	Other Monitoring Device Advancements	123	
10.	Cancer Biomarker Testing	124	
10.1	Segment Overview	124	
10.2	The Cancer Testing Market	125	
10.3	Competition	126	
10.4	Individual Markets	127	
10.4.1	Cancer Pathology: Testing	127	
10.4.1.1	Rare Cell/Micro Metastasis Detection	127	
10.4.1.2	Cancer Pathology: High-Throughput Screening	128	
10.4.1.3	Competition	130	
10.4.1.4	Drivers	130	
10.4.2	Breast Cancer	131	
10.4.2.1	CA 15-3	132	
10.4.2.2	CA 27-29	132	
10.4.2.3	BRCA1 and BRCA2 Breast and Ovarian Cancer Genes		132
10.4.2.4	Estrogen and Progesterone Receptor (ER and PR)	134	
10.4.2.5	HER-2	135	
10.4.2.6	Herceptin	135	
10.4.2.7	p53	135	
10.4.2.8	NMP66	136	
10.4.2.9	Mammastatin	136	
10.4.2.10	Drivers for Breast Cancer Test Development	136	
10.4.3	Ovarian Cancer	137	
10.4.3.1	CA 125 II™	137	
10.4.3.2	BRCA1 and BRCA2	138	
10.4.3.3	Steroid Hormone Receptors	139	
10.4.3.4	Epidermal Growth Factor Receptor (EGFR)	139	
10.4.3.5	Lysophospholipids	141	
10.4.4	Cervical Cancer	141	
10.4.5	Colon Cancer DNA Testing	142	
10.5	Pharmacogenomic Cancer Testing	146	
11.	HPV Testing	149	
11.1	Overview	149	
11.2	U.S. Market	151	
11.3	European Market	152	
11.4	Other Markets	154	
11.5	The Association of HPV and Cervical Cancer		155
11.6	Assays for HPV	156	
12.	Biochips for Clinical Applications	159	
12.1	Roche AmpliChip	167	
12.2	Amersham CodeLink	168	
12.3	Breast Cancer DNA Chips	168	
12.4	Osmetech eSensor	169	
12.5	Affymetrix GeneChip System 3000Dx v.2	169	

12.6	Caliper and Cepheid	170
12.7	Agilent Technologies 2100 Lab-on-a-Chip	170
13.	HIV	171
13.1	U.S. Testing Market	171
13.2	World Testing Market	175
13.2.1	Asia	176
13.2.2	Japan	178
13.2.3	Sub-Saharan Africa	178
13.2.4	Rest of World	178
13.3	Major Players	179
14.	Cellular Imaging Cytopathology and Histopathology	181
14.1	Segment Overview	181
14.2	The Market	181
14.3	Market Drivers	183
14.4	Market Restraints	183
14.5	Cytology and Histology Technology Platforms	183
14.5.1	Cytology Screening Procedures and Pap Smear Technology	184
14.5.2	Histology	189
14.5.3	Market Drivers	190
14.5.4	ISH Staining	190
14.5.5	Special-Stains Staining	191
14.6	Third-Party Reimbursement	191
14.7	Competition	191
15.	Infectious Disease Testing	196
15.1	Streptococcus Testing	196
15.2	Chlamydia Testing	201
15.3	Mononucleosis	203
15.4	Gonorrhea	204
15.5	Influenza	206
15.6	Malaria	207
15.7	Tuberculosis	216
15.8	Methicillin-Resistant Staphylococcus aureus (MRSA)	223
16.	High-Growth Testing Diagnostic Trends	226
16.1	Genetic Testing	226
16.2	Quality Measures	226
16.3	Moderators of Growth	226
16.3.1	Diagnostics and the Aging Population	226
16.3.2	Individualized Medicine	226
16.3.3	Genetic Testing	226
16.4	Workforce Issues	228
16.5	Reimbursement	228
16.5.1	Cardiovascular	229
16.5.2	Screening for Diabetes	230
16.5.3	CPT Test Codes and Payment Amounts	230
16.6	Rapid Near-Patient Testing in Hospitals	233
16.7	Satellite Facilities	233
16.8	Regionalization of Laboratory Care	234
16.9	Requirements for High-Growth Testing	235
16.10	Clinical Laboratory Improvement Act (CLIA)	236
17.	Business Trends in the Industry	239
17.1	Sector Consolidation	239
17.2	Diagnostic Testing Growth Trends	239
17.3	Acquisition, License Agreements, Internal Development, Partnerships	240
17.4	Product Testing Depth in High-Growth Testing	245
17.5	Government Regulation	245
17.5.1	U.S. Regulations	245

17.5.1.1	Importing Medical Devices into the U.S.	247
17.5.1.2	Exporting Medical Devices from the U.S.	247
17.5.2	U.K Regulations	248
17.5.3	E.U. Regulations	249
17.5.4	Japanese Regulations	250
17.6	Increased Market Penetration in High-Growth Testing	253
18.	Important Technology Trends	254
19.	Company Profiles	258
19.1	Accurex Biomedical, Pvt., Ltd.	258
19.2	Adeza Biomedical Corporation (Hologic)	258
19.3	Agilent Technologies, Inc.	258
19.4	Ambri, Ltd.	259
19.5	American Bio Medica Corp.	259
19.6	Ani Biotech	261
19.7	Applied Spectral Imaging	262
19.8	Avitar, Inc.	263
19.9	Axis-Shield	264
19.10	Bayer Corporation	265
19.11	Beckman Coulter	265
19.12	Becton Dickinson	268
19.13	Biomerica	268
19.14	Bio-Rad, Inc.	269
19.15	Cozart Bioscience	270
19.16	Denka Seiken Co., Ltd.	270
19.17	diaDexus LLC	270
19.18	Enterix, Inc. (Subsidiary of Quest Diagnostics)	271
19.19	Genetix	272
19.20	Genzyme Diagnostics	272
19.21	Hologic, Inc.	274
19.22	Iatron	275
19.23	Inverness Medical Innovations	275
19.24	Jiangnan Biotech	277
19.25	Johnson & Johnson	278
19.26	Kyowa Medex Co., Ltd.	279
19.27	LifePoint, Inc.	279
19.28	LifeScan	279
19.29	Matritech	280
19.30	Medix Biochemica	281
19.31	Myriad Genetics	281
19.32	OraSure	283
19.33	Pheromone Sciences	284
19.34	Polymedco	285
19.35	Procrea	286
19.36	QIAGEN	286
19.37	Quidel	286
19.38	Roche Diagnostics	288
19.39	Shanghai Siic Kehua Biotech Co., Ltd. (Kehua Biotech)	290
19.40	Shionogi & Co.	290
19.41	Siemens	290
19.42	Spectral Diagnostics, Inc.	291
19.43	Third Wave Technologies	293
20.	Appendix 1: Opportunities in the Chinese Biotech Market	295
21.	Appendix 2: Opportunities in the Indian Diagnostics Market	306

INDEX OF TABLES

Table 1.1: Emerging Technology Platforms Driving High-Growth Diagnostics Market Segments	12
Table 1.2: Market Trends in the High-Growth Diagnostics Space	13
Table 2.1: U.S. Population Dynamics, 2005–2015	15
Table 2.2: World Population and Growth, 2000–2025	16
Table 2.3: Total Japanese Population and Aging Demographics Forecast	16
Table 2.4: Worldwide Market Share In Vitro Diagnostic Companies, 2007	17
Table 2.5: Worldwide In Vitro Diagnostics Market Size, 2003–2012	17
Table 2.6: U.S. In Vitro Central Lab Diagnostic Testing, 2003–2012	17
Table 2.7: Worldwide Near-Patient Diagnostic Testing, 2002–2012	17
Table 3.1: High-Growth Market Segments Overview, 2008	22
Table 3.2: U.S. High-Growth Diagnostic Testing Market Segments, 2007	26
Table 3.3: Regional Comparison of GDP, Healthcare and IVD, 2006	28
Table 3.4: German Diagnostics Products Market Sales, 2000–2008	29
Table 3.5: The German Patient Care Lab Test Market, 2002–2012	30
Table 3.6: The German Alternate Site Testing Market (POL), 2002–2012	30
Table 3.7: The German Hospital Point of Care Market, 2002–2012	30
Table 3.8: German Clinical Diagnostic Rapid Test Market Segments	31
Table 3.9: List of Diagnostics Companies in the U.K.	37
Table 3.10: Major U.K. IVD Manufacturers	37
Table 3.11: U.S. IVD Manufacturers Doing Business in the U.K.	37
Table 3.12: Other European Companies That Manufacture IVD Products in the U.K.	38
Table 3.13: Japanese In Vitro Diagnostic Testing Market, 2000–2012	39
Table 3.14: Japan's Diagnostics Market Sales, 1997–2006	39
Table 3.15: Companies with Leading Market Share of Japanese Diagnostics, by Segment	40
Table 3.16: Chinese Diagnostics Products Market Sales, 2000–2012	41
Table 3.17: Disease Burden in China: Urban and Rural	42
Table 4.1: Global Market for HBV Diagnostic Testing, 2000–2012	46
Table 4.2: U.S. Market for HBV Diagnostic Testing, 2000–2012	46
Table 4.3: Serological Diagnosis of Hepatitis B Virus Infections	48
Table 4.4: Lower Detection Limits of HBV DNA Assays	49
Table 4.5: Summary of Hepatitis B Test Technology	52
Table 4.6: Global Market for HCV Diagnostic Testing, 2000–2008	57
Table 4.7: U.S. Market for HCV Diagnostic Testing, 2000–2008	57
Table 4.8: Efficiency of Available HCV Screening Tests	58
Table 4.9: Recommendations for Diagnostic Testing for Hepatitis C	60
Table 4.10: Hepatitis C Statistics	60
Table 4.11: Gen-Probe Clinical Diagnostic Products Test for the Detection of HCV	62
Table 5.1: Biomarkers in Heart Failure	66
Table 5.2: Medication Chart for Cardiovascular Disease	67
Table 5.3: Acute Myocardial Infarction Facts	67
Table 5.4: Emergency Room Admissions in the U.S., 1997–2005	68
Table 5.5: Market Growth Drivers for Cardiac Markers	68
Table 5.6: Market Barriers to Growth for Cardiac Markers	68
Table 5.7: Specific Cardiac Markers	69
Table 5.8: Cardiac Markers after Onset of Myocardial Infarction	69
Table 5.9: The Cardiac Marker Market for Testing in the U.S., 2001–2010	72
Table 5.10: Market Share of Cardiac Marker Segment	72
Table 5.11: U.S. Market for Point of Care Cardiac Marker Testing, 2000–2010	75
Table 5.12: BNP Characteristics	77
Table 5.13: Global Sales of BNP Diagnostic Tests, 2000–2010	78
Table 5.14: Market Share of BNP Assays in the U.S.	78
Table 5.15: Market Share of NT-proBNP Assays in the U.S.	79
Table 5.16: Cardiovascular Risk Classification by CRP Level	83
Table 5.17: Clinical Characteristics of D-dimer	83

Table 6.1: Global Market for Cancer Cytogenetic Diagnostic Testing, 2000-2012	96
Table 6.2: U.S. Market for Cancer Cytogenetic Diagnostic Testing, 2000-2012	97
Table 6.3: Genetic Testing: Consequences and Challenges	97
Table 6.4: CF Carrier Risk by Ethnic Group	98
Table 6.5: Reasons for CF Testing	98
Table 6.6: CF Gene Detection Rates Vary by Ethnic Background	99
Table 6.7: Global Market for CF Diagnostic Testing, 2000-2010	100
Table 6.8: U.S. Market for CF Diagnostic Testing, 2000-2010	100
Table 6.9: Commercial CF Screening Products	100
Table 6.10: Emerging CF Screening Products	101
Table 7.1: The Fertility Testing Market in the U.S., 2000-2008	103
Table 9.1: U.S. Population of Diabetics by Group	113
Table 9.2: Percentage of U.S. Adults Using Diabetes Medication, by Age, 1997-2006	114
Table 9.3: Health Care Utilization by the Diabetes Patient	114
Table 9.4: The Global Population of Persons with Diabetes, 1995 and 2025	116
Table 9.5: Market for Glucose Testing in the U.S., 2001-2012	116
Table 9.6: The Worldwide Market for Glucose Testing, 2000-2012	117
Table 9.7: Major Players in Point of Care and Near-Patient Testing for OTC Glucose Meters	117
Table 10.1: Women's Cancer Incidence Estimates in the U.S., 2008	125
Table 10.2: Five-Year Disease-Free Survival by Stage at Diagnosis	125
Table 10.3: TPA Marker Sensitivity	134
Table 11.1: HPV Risk Factors	149
Table 11.2: HPV and Cervical Carcinoma	150
Table 11.3: Global HPV-Testing Market Size, 2003-2011	150
Table 11.4: HPV and Cervical Carcinoma Risk	151
Table 11.5: Reflex HPV Testing with Cytology	156
Table 11.6: Predictability of HPV Test by Abnormal Pap Smear Type	157
Table 11.7: Incidence of Cervical Cancer and Cytological Abnormalities	157
Table 11.8: Long-Term Trends in HPV Testing	158
Table 12.1: Biochip Revenues and Growth Rates by Application	159
Table 12.2: Total Biochip Market: Worldwide Revenue Forecasts, 2000-2010	163
Table 12.3: Total Biochip Market: U.S. Revenue Forecasts, 2000-2010	164
Table 13.1: AIDS Statistics for the U.S.: Diagnoses, Deaths and Burden, 2002-2006	171
Table 13.2: U.S. HIV Statistics, 2007	171
Table 13.3: Births of HIV Infected Babies in U.S., 2000-2009	172
Table 13.4: Rapid HIV Tests on the Market	173
Table 13.5: U.S. High-Growth Testing Market for HIV, 2001-2012	175
Table 13.6: Global HIV Statistics, 2007	176
Table 14.1: Estimated Cervical Cancer Cases/Deaths Worldwide	187
Table 14.2: Medicare Reimbursement for Cervical Pathology Procedures	191
Table 15.1: U.S. Strep Testing Market Size, 2000-2008	197
Table 15.2: Rapid Strep Tests on the Market	197
Table 15.3: U.S. Market for Rapid Point of Care Strep Tests	198
Table 15.4: The U.S. Chlamydia Testing Market, 2001-2009	201
Table 15.5: Rapid Tests for Chlamydia	201
Table 15.6: Rapid Tests for Gonorrhea	205
Table 15.7: Commercially-Available Rapid Tests for Malaria	214
Table 15.8: FIND Partners	221
Table 15.9: Global Market Potential for TB Diagnostic Testing, 2000-2010	223
Table 15.10: MRSA Diagnostics Currently on the Market	225
Table 16.1: New CPT Test Codes Introduced in 2008	232
Table 18.1: Employment of Clinical Laboratory Workers, 2006-2016	255
Table 20.1: China Biotech Reagents Market	301
Table 20.2: Biotechnology Projects Between China and the West	302
Table 21.1: Overview of Healthcare in India	309

INDEX OF FIGURES

Figure 2.1: U.S. Lab Industry Market Share, 2007	18
Figure 2.2: Major Lab Testing Segments, U.S.	19
Figure 3.1: Total Spending on Healthcare in the U.S., 2007	25
Figure 3.2: International Per Capita Spending on Healthcare, 2006	29
Figure 3.3: Japan IVD Sales by Segment, 2006	40
Figure 14.1: Worldwide Incidence Rates of Cervical Cancer Per 100,000 Females	185
Figure 15.1: Global Incidence of Malaria	208
Figure 15.2: Mode of Action of Common Malaria RDT Format	211
Figure 15.3: FIND Pipeline for TB Diagnostics	220
Figure 21.1: Indian Diagnostics Market Segments, 2007	307

SAMPLE

1. Overview

1.1 Statement of Report

The purpose of this report is to describe the specific market segment of the *in vitro* diagnostics market called high-growth diagnostic testing. It examines the clinical measurement devices and their reagents and supplies as utilized in hospitals, clinics and doctor's offices. Each diagnostic segment described in this report offers an outstanding opportunity for high market growth within the next five years. Our analysis is arranged to provide the reader with an overview of the outstanding diagnostic test growth market segments that are poised for unusual advances in sales and earnings as the diagnostic market becomes an increasingly important segment of the health delivery system. Each high-growth market segment is accompanied by analysis and forecasts by product type and application.

This analysis provides an overview of the newest growth areas of the diagnostic testing market, including the latest information regarding new products and important industry trends. Forecasts of the market and analyses of products in the worldwide diagnostics market will provide a basis for understanding the significance of new developments and future possibilities within the diagnostic testing segment.

The principal objectives of this review are to:

- Identify viable technology drivers through a comprehensive look at various platform technologies for high-growth segments of the diagnostic testing markets.
- Obtain a complete understanding of the chief high-growth diagnostic test predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic value, from their basic principles to their applications.
- Discover feasible market opportunities via an identification of high-growth applications in different diagnostic testing areas, with a focus on the biggest and fastest expanding markets for diseases.
- Focus on global industry development through an in-depth analysis of the major world markets for high-growth diagnostic testing, including forecasts for growth.
- Project and forecast the future of the IVD market. Market figures regarding the current value of the high-growth testing market are taken from the most recent available data of the global diagnostic industry.

This report provides:

- An improved understanding of the current state and future of the most exciting high-growth diagnostic testing market segments.
- The latest information on the leading companies engaged in R&D and diagnostic testing products in the pipeline.
- The analyst's perspective of recent diagnostic test developments, and revelations on how these influence selected markets.
- Knowledge of the diagnostic testing market as an area of growth, research and investment.

The following categories of diagnostic testing segments are covered herein:

- Hepatitis testing.
- Cardiac monitoring.
- Cytogenetic testing.
- Fertility testing.
- Laboratory genomics.
- Glycosylated hemoglobin and glucose monitoring.
- Cancer marker testing.
- HPV.
- Biochips for clinical applications.
- HIV.
- Cellular imaging cytopathology and histopathology.
- Infectious disease testing.

Analyses include the use of charts and graphs measuring product growth and trends within the marketplace. In addition, a discussion of research in the illness provides the reader with a deeper understanding of possibilities for future diagnosis and avenues for possible research and development budgets. Company-specific information—including product pipeline status, and research and development trends—is provided throughout the report. Additionally, this analysis will:

- Assess the high-growth diagnostic testing market drivers and bottlenecks, from the perspective of the diagnostics industry, as well as medical and scientific communities.
- Discuss the potential benefits provided by the high-growth diagnostic testing market to various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the high-growth diagnostic testing market, and analyze the current size and growth of individual segments.
- Provide current and forecasted market shares by company.
- Discuss business opportunities in the high-growth diagnostic testing segment.
- Provide strategic recommendations for exceptional near-term business opportunities.
- Assess current commercial uses of the high-growth diagnostic testing market.

We answer the following questions in this report:

- What are the near-term business opportunities in the high-growth diagnostic testing market?
- What are the current and forecasted sizes of the high-growth diagnostic testing market?
- What are the business models currently used by companies in the high-growth diagnostic testing market?
- How will diagnostic manufacturers, researchers, physicians, patients and payers influence the high-growth diagnostic testing market?
- What are the drivers and bottlenecks influencing the high-growth diagnostic testing market?
- What are the technologies used in high-growth diagnostic testing?
- Who holds proprietary rights to the high-growth diagnostic testing market technology?
- What are current applications of this technology?
- What regulatory processes must the high-growth diagnostic technologies undergo in the U.S., Japan, China and Europe?
- How will new high-growth diagnostic testing technologies change treatment and payment paradigms?
- How will high-growth diagnostic testing technologies reduce adverse drug reactions and decrease total patient care costs?
- How will high-growth diagnostic testing technologies reduce healthcare expenditures?

1.2 Scope of this Report

The emphasis in this review is on those companies that are actively developing and marketing high-growth diagnostic testing technologies. The reader should consult other TriMark Publications reports at www.trimarkpublications.com for a detailed discussion of the important individual market segments which are related to the high-growth diagnostic testing technologies market such as hepatitis testing, cardiac markers, cancer testing, infectious disease markers and other exciting new diagnostic methods.

This analysis concentrates on high-growth testing market segments in important worldwide markets such as the U.S., Japan, China and Europe, including Germany, the U.K., and other countries of the European Union. It focuses primarily on the hospital market and commercial laboratory segment, and, separately, on a description of the instruments, reagents and supplies marketed by major companies in this segment. The report discusses market size, growth rates, and market components, and five-year projections for each of the important high-growth tests.

1.3 Methodology

The information in this report is based upon interviews with sales and marketing professionals of companies in the high-growth testing market. People from virtually every company mentioned in this analysis were queried, some several times, about their companies' products and marketing strategies as well as their overall thoughts about their industry segment. Information was also obtained from interviews with founders, CEOs and vice presidents of some

of the companies discussed in this report. The structure of hospital laboratories and near-patient facilities was derived from interviews with laboratory directors and medical technologists working in these areas.

Sources of information for the study were trade association publications and meetings, product brochures and catalogs and company literature. Where the companies under discussion were publicly held, an examination of the annual reports, 10k filings and financial reports were used as the basis of the data reported. Important data sources include the Health for All Database of the World Health Organization (WHO), data published by the statistical office of the European Communities (Eurostat), as well as various health data from the United Nations (UN) and the Organisation for Economic Co-operation and Development (OECD). Where possible and practicable, the most recent data available have been used.

The author of this report is a Ph.D. in biochemistry with many decades of experience in science writing and as a medical industry analyst. He has been a senior director of several large regional and national healthcare laboratories. The editor is a Ph.D. in biotechnology with an extensive background in molecular biology.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information set forth 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, 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 with regard to 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 and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research of the past three years as part of this data collection. We also extract qualified data feeds from e-questionnaires and primary research responses for this compilation.

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 our 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. The study's conclusions are verified through intensive interviewing of top-ranking companies in the industry.

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:

- 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' 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.
- 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.

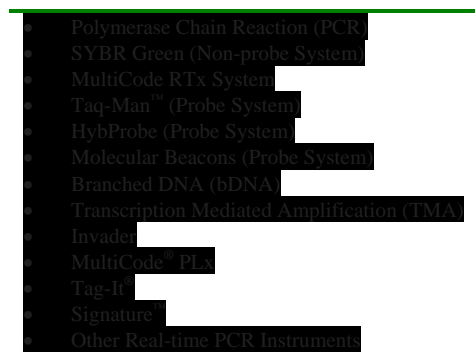
1.4 Executive Summary

There will be a steady increase in demand for new diagnostic testing services in the next ■■■-year period, along with pressures to improve the quality of healthcare delivered in the clinic, and also to lower its costs. Clinical labs experienced a substantial growth during the last decade. According to industry sources, the clinical lab diagnostic testing market is currently at \$■■■■ in the U.S., and is growing at an annual rate of ■■■%. The anatomic pathology and esoteric service markets are estimated to account for approximately \$■■■■ and \$■■■■, respectively, of the \$■■■■ industry, with the other \$■■■■ made up of routine testing, cytology and drugs-of-abuse testing. Although the industry is heavily regulated, advances in technology to make new testing available and existing testing more cost-efficient, in conjunction with the aging population, have the potential to spur industry-wide volume growth. The clinical lab market is projected to grow by ■■■% over the next ■■■ years, following the general healthcare trend of increasing expenditure as a percentage of GDP. While lab expenditures constitute only ■■■% of all healthcare spending, lab testing is usually involved in some way with almost all of the diagnostic decisions made with regard to healthcare.

The high-growth diagnostic products segments are poised for a major new phase of growth fueled by the availability of new technology coming out of the point of care segment and human genome research; and also the higher interest of individual patients and general healthcare consumers to take charge of their own health status. Continuous improvements in technology are resulting in a growing number of new *in vitro* diagnostic tests that combine high levels of accuracy with rapid, easy-to-use product formats. The combination of the new molecular diagnostic technology platforms and traditional PCR will provide customers with a highly sensitive, accurate and rapid solution that is even more robust than either of them alone. These innovative combinations will provide the rich environment for diagnostic tests that grow more than ■■■% per year in net sales dollars.

Many high-growth *in vitro* diagnostic products and services are specifically targeted at markets outside of the traditional hospital or clinical laboratory such as the point of care setting or genetic screening. Competition in the development and marketing of high-growth diagnostic products is intense, and diagnostic technologies have been subject to rapid change. We estimate that the competitive factors determining success in the diagnostic market include convenience, privacy, price and product performance as well as the distribution, advertising, promotion and brand name recognition of the marketer.

Table 1.1: Emerging Technology Platforms Driving High-Growth Diagnostics Market Segments



Source: Biotechnology Associates

Expiration of basic PCR patents in [REDACTED] opened additional opportunities for new diagnostic test markets. Compared to traditional methods, molecular diagnostics offers better performance, shorter testing times and objective results that do not require interpretation by highly-trained technologists. Most of all, clinicians are now able to provide patients and the community with more consistent, affordable and higher-quality healthcare. Expertise in nucleic acid testing (NAT) products and the associated technology platforms has enabled a number of companies to enter this high-growth segment and to obtain U.S. Food and Drug Administration (FDA) approvals for products that detect a wide variety of infectious microorganisms. According to industry consultants, the worldwide molecular diagnostics market in [REDACTED] was approximately \$ [REDACTED]; it is expected to reach \$ [REDACTED] by [REDACTED]. NAT currently represents a small portion of the estimated \$ [REDACTED] worldwide market for human diagnostic clinical testing products, and is projected to reach \$ [REDACTED] by [REDACTED].

This report's primary focus is on market products in high-growth segments of the estimated \$ [REDACTED] *in vitro* diagnostics (IVD) market, \$ [REDACTED] biodefense market and \$ [REDACTED] genomic research market. There are a few (perhaps ten) large dominant global players. These are matched by hundreds of small companies with a few or one product aiming at niche markets, for example, fetal development or early labor tests; in [REDACTED] worldwide sales of glucose monitoring meters were \$ [REDACTED]. Industry observers estimate the current market for diabetes devices alone is worth \$ [REDACTED] worldwide and \$ [REDACTED] in the U.S. Worldwide glucose monitoring product sales are growing by about [REDACTED] % annually and are projected to reach \$ [REDACTED] by [REDACTED]. The global POC market is currently estimated at almost \$ [REDACTED]. Meanwhile, sales of nucleic acid tests are booming, driven by STDs, HIV viral load, and blood banking. This industry segment is currently estimated at \$ [REDACTED], and is projected to reach \$ [REDACTED] by [REDACTED].

TriMark believes that markets will continue to develop for new applications for NAT technology, both in clinical and non-clinical fields. Among clinical fields, we believe NAT technology will be used in new applications, such as genetic predisposition testing and pharmacogenomics, which involves the study of the relationship between nucleic acid sequence variations in an individual's genome and the individual's response to a particular drug. We expect that nucleic acid assays will be used in the field of pharmacogenomics to screen patients prior to administering new drugs. Genetic testing to identify individuals at risk of certain diseases and pathological syndromes is emerging as an additional market for NAT technology. Nucleic acid-based testing for SNPs and other genetic anomalies can be used to determine an individual's predisposition to such conditions as thrombosis or blood clotting.

We see significant opportunities to grow the high-growth diagnostic testing business outside of the U.S. For example, we expect that the enhanced organization will play a critical role in the further commercialization of high-growth diagnostic tests like HPV, tests for cervical cancer screening, urine strip testing in less developed regions, infectious disease testing and hepatitis screening. The high-growth *in vitro* diagnostic testing market segment is characterized by growth frequently above [REDACTED] % per year, and occasionally much more. More established testing market segments like hepatitis, HIV or glycohemoglobin are in the former range of growth. Newer segments like laboratory genomics and biochips are in the [REDACTED] % range of growth, but start from a low base in the \$ [REDACTED] per

year range, compared to the nearly \$ [redacted] estimate for more mature testing segments like hepatitis. The major players using the following strategies are pursuing growth in the high-growth sector:

- Improving profit margins through improved product pricing and operational efficiencies.
- Securing a stronger new product pipeline from internal research and development.
- Pursuing licensing and acquisitions opportunities, when financially and strategically attractive.
- Launching diagnostic test business under brand by leveraging marketing and distributing strength in the U.S., maximizing worldwide sales through current and newly identified sales channels in Europe and the rest of world.
- Launching a new and improved CLIA-waived test worldwide.
- Launching rapid diagnostic tests on a worldwide basis in conjunction with a development partner such as a pharmaceutical company.
- Expanding development and marketing collaborations with large pharmaceutical and other healthcare companies.
- Identifying business development opportunities in the form of product or company acquisitions to enhance product portfolio and further leverage distribution channels worldwide.
- Expanding international sales through external alliances, collaborations and sales focus.

TriMark believes that significant market potential exists for rapid diagnostics with novel applications that are capable of precise quantitative measurement of single or multiple analytes. Rapid, point of care testing is optimal to significantly improve patient care and reduce healthcare costs, especially for acute conditions. However, diagnostic needs and objectives vary from hospital to hospital. Therefore, most diagnostic reagent manufacturers have made their tests available on a centralized automated testing platform in addition to their own existing technology platforms.

Table 1.2: Market Trends in the High-Growth Diagnostics Space

• Tests based upon molecular diagnostic (nucleic acid) technology platforms
• Move toward marketing rapid point of care test kits
• Tests developed as CLIA-waived tests
• Cost per test less of an issue with high demand diagnostic tests
• Coupling the diagnostic test with high profile diseases, e.g., ovarian or breast cancer
• Move toward bringing complicated tests into a single expert lab
• Move for CLIA regulatory oversight using expert labs, rather than FDA using diagnostic kits
• Move away from central lab “big iron” chemistry analyzers
• Focus on improving patient outcomes with diagnostic tests
• Move to reduce expertise needed to run tests because of shortage of trained personnel
• More diagnostic start-ups to develop tests with high growth potential
• Increased M&As as larger players acquire exciting new test technology

Source: Biotechnology Associates

Rapid identification of biological agents is critical to national defense, for example, the application of technology to the detection of biological agents in the water supply. There is currently a need for optimizing a platform for specific use as a field-deployable system to enable biodefense first responders, such as fire and police departments, to rapidly and more accurately detect signature nucleic acid sequences of known biological pathogens (e.g., anthrax and plague). Public attention to agricultural biotechnology continues to grow. Several companies are developing a diagnostic tool to detect genetically modified organisms (GMOs) and address the need to rapidly identify biologic contamination. Approximately \$ [redacted] was spent on genomic and proteomic research in [redacted], and this figure is projected to grow by at least [redacted]% each year for the next [redacted] years. The underlying technology must be applicable to both disease and population-driven genomics and are best developed through corporate partnerships.