



In Vitro Diagnostics: *Technologies and Global Markets*

January 2018

Jon Evans

Report Code: HLC186B



Table of Contents

- Chapter 1: Introduction 1**
 - Study Goals and Objectives 1
 - Reasons for Doing This Study 1
 - Intended Readership 2
 - Scope of Report 2
 - Methodology 3
 - Geographic Breakdown 3
 - Analyst's Credentials 5
 - Related BCC Research Reports 5
- Chapter 2: Summary and Highlights 7**
 - Global Market Trends 7
- Chapter 3: Market Landscape 11**
 - Market Overview and Segmentation 11
 - Key Findings 11
 - Factors Influencing the Global IVD Market 12
 - Challenges 14
 - Regulatory Landscape 16
- Chapter 4: Market Breakdown by Product Segment 25**
 - Introduction 25
 - Description 25
 - Immunochemistry 25
 - POC Testing 25
 - Molecular Diagnostics 25
 - Hematology 25
 - Clinical Microbiology 26
 - Tissue Diagnostics 26
 - Trends in IVD Segments 26
 - Competitive Structure 28
 - Market Share Analysis 28
- Chapter 5: Global Immunochemistry Market 31**
 - Applications 32
 - Blood Gas, Electrolytes and Metabolites (BGEM) 32
 - Endocrine 33
 - Infectious Diseases 33
 - Cancer 33
 - Urinalysis 33
 - Diabetes 34
 - Cardiology 34
 - Blood Screening 34
 - Others 35
- Chapter 6: Global POC Testing Market 39**
 - Applications 40
 - Glucose Testing 40

BGEM	40
Cardiac Marker Testing	41
Infectious Disease Testing	41
Pregnancy and Fertility Testing	41
Drug and Alcohol Abuse Testing	41
Hematology and Hemostasis Testing	42
Cholesterol Testing	42
Urine Chemistry Testing	42
Tumor Marker Testing	42
Other POC Testing	43
Chapter 7: Global Hematology Market	47
Applications	49
Routine Hematology Tests	49
Hemostasis	49
Chapter 8: Global Molecular Diagnostics Market	54
Applications	55
Infectious Diseases	55
Blood Screening	56
Oncology	56
Genetic Testing	57
Others (Companion Diagnostics, Prenatal Genetic Tests and Rare Diseases)	57
Chapter 9: Global Clinical Microbiology Market	90
Applications	91
Blood Culture	91
General Culture (urine/saliva/stool/sputum/CSF and other Body fluids)	91
Identification and Antibiotic Susceptibility Testing	92
Chapter 10: Global Tissue Diagnostics Market	102
Applications	103
Cancer Diagnosis	103
Tissue Typing	103
Pathogen Detection	104
Chapter 11: Market Breakdown by End Users	108
Introduction	108
Trends	108
Chapter 12: Global IVD Market Products	111
Introduction	111
Trends	111
Chapter 13: Regional Analysis	114
Introduction	114
North America	114
Europe	114
Asia-Pacific	114
LAAM	115
International Health Expenditure and Trends	115
North America	117
Europe	121

Western Europe.....	124
Central and Eastern Europe.....	128
Asia-Pacific.....	129
Latin America, Africa and Middle East (LAAM).....	137
Chapter 14: Emerging Global Technology and Trends	145
Trends	145
Industry Developments	146
Opportunity Areas	156
IVD for Neglected Infectious Diseases	156
Portable Devices Compatible with Simple Detection Platforms	156
Chemistry-Based Portable Analyzers	157
Improved Sample Preservation Technologies	157
New Detection Technologies.....	158
Alternative Technologies to PCR.....	159
Key Biomarkers for Diseases of the Developing World	159
Microfluidic Platform-based POC Tests for Remote Settings.....	160
Combining Multiple Detection Technologies into a Single Instrument	161
Chapter 15: Mergers and Acquisitions	163
Chapter 16: Patent Review	168
Immunochemistry	168
Point of Care Testing	175
Molecular Diagnostics	185
Hematology.....	191
Clinical Microbiology	201
Tissue Diagnostics	206
Chapter 17: Company Profiles.....	220
Appendix	235
List of IVD Market Participants	235
List of Abbreviations	236
About BCC Research	238
About BCC Research	239
BCC Membership.....	239
BCC Custom Research.....	239

List of Tables

Summary Table: Global Market for In Vitro Diagnostics (IVD), by Region, Through 2022 (\$ Millions).....	8
Table 1 Types of Diagnostic Tests and How They Are Regulated.....	17
Table 2 Changes in IVD Regulations in Asia-Pacific, 2017.....	21
Table 3 Global IVD Market, by Segment, Through 2022 (\$ Millions).....	27
Table 4 Global IVD Market Share, by Major Market Companies, 2017 (%).....	29
Table 5 Global Immunochemistry Market, by Application, Through 2022 (\$ Millions).....	35
Table 6 Global Immunochemistry Market, by Region, Through 2022 (\$ Millions).....	36
Table 7 Global POC Testing Market, by Application, Through 2022 (\$ Millions).....	43
Table 8 Global POC Testing Market, by Region, Through 2022 (\$ Millions).....	44
Table 9 Global Hematology Market, by Application, Through 2022 (\$ Millions).....	50
Table 10 Global Hematology Market, by Region, Through 2022 (\$ Millions).....	52
Table 11 Global Molecular Diagnostics Market, by Application, Through 2022 (\$ Millions).....	58
Table 12 Global Molecular Diagnostics Market, by Region, Through 2022 (\$ Millions).....	60
Table 13 List of Cleared or Approved Companion Diagnostic Devices, by Drug Trade Name (Generic)....	61
Table 14 List of Cleared or Approved Human Genetic Tests.....	84
Table 15 Global Clinical Microbiology Market, by Application, Through 2022 (\$ Millions).....	92
Table 16 Global Clinical Microbiology Market, by Region, Through 2022 (\$ Millions).....	93
Table 17 List of FDA-Approved Microbial Tests, 2017.....	94
Table 18 Global Tissue Diagnostics Market, by Application, Through 2022 (\$ Millions).....	104
Table 19 Global Tissue Diagnostics Market, by Region, Through 2022 (\$ Millions).....	106
Table 20 Global IVD Market, by Region, Through 2022 (\$ Millions).....	116
Table 21 Global IVD Market Share, by Region, 2016-2022 (%).....	117
Table 22 North American IVD Market, by Segment, Through 2022 (\$ Millions).....	117
Table 23 North American Immunochemistry Market by Segment, Through 2022 (\$ Millions).....	118
Table 24 North American POC Market, by Segment, Through 2022 (\$ Millions).....	119
Table 25 North American Hematology Market, by Segment, Through 2022 (\$ Millions).....	119
Table 26 North American Molecular Diagnostics Market, by Segment, Through 2022 (\$ Millions).....	120
Table 27 North American Microbiology Market, by Segment, Through 2022 (\$ Millions).....	120
Table 28 North American Tissue Diagnostics Market, by Segment, Through 2022 (\$ Millions).....	120
Table 29 European IVD Market, by Segment, Through 2022 (\$ Millions).....	124
Table 30 European Immunochemistry Market, by Segment, Through 2022 (\$ Millions).....	126
Table 31 European POC Market, by Segment, Through 2022 (\$ Millions).....	126
Table 32 European Hematology Market, by Segment, Through 2022 (\$ Millions).....	127
Table 33 European Molecular Diagnostics Market, by Segment, Through 2022 (\$ Millions).....	127
Table 34 European Microbiology Market, by Segment, Through 2022 (\$ Millions).....	127
Table 35 European Tissue Diagnostics Market, by Segment, Through 2022 (\$ Millions).....	128
Table 36 Asia-Pacific IVD Market Share, by Country, 2017 (%).....	130
Table 37 Asia-Pacific IVD Market, by Segment, Through 2022 (\$ Millions).....	131
Table 38 Asia-Pacific Immunochemistry Market, by Segment, Through 2022 (\$ Millions).....	134
Table 39 Asia-Pacific POC Market, by Segment, Through 2022 (\$ Millions).....	135
Table 40 Asia-Pacific Hematology Market, by Segment, Through 2022 (\$ Millions).....	135
Table 41 Asia-Pacific Molecular Diagnostics Market, by Segment, Through 2022 (\$ Millions).....	136
Table 42 Asia-Pacific Microbiology Market, by Segment, Through 2022 (\$ Millions).....	136
Table 43 Asia-Pacific Tissue Diagnostics Market, by Segment, Through 2022 (\$ Millions).....	136
Table 44 LAAM IVD Market, by Segment, Through 2022 (\$ Millions).....	137
Table 45 LAAM Immunochemistry Market, by Segment, Through 2022 (\$ Millions).....	141
Table 46 LAAM POC Market, by Segment, Through 2022 (\$ Millions).....	142

Table 47 LAAM Hematology Market, by Segment, Through 2022 (\$ Millions)	142
Table 48 LAAM Molecular Diagnostics Market, by Segment, Through 2022 (\$ Millions)	143
Table 49 LAAM Microbiology Market, by Segment, Through 2022 (\$ Millions)	143
Table 50 LAAM Tissue Diagnostics Market, by Segment, Through 2022 (\$ Millions)	143
Table 51 IVD High-Complexity U.S. FDA Product Approvals, 2017	146
Table 52 Diagnostics Manufacturer Mergers and Acquisitions, 2004-2017	164
Table 53 Immunochemistry In vitro Diagnostics Patents Granted, 2016 and 2017.....	168
Table 54 POC In vitro Diagnostics Patents Granted, 2016 and 2017	175
Table 55 Molecular In Vitro Diagnostics Patents Granted, 2016 and 2017	185
Table 56 Hematology In Vitro Diagnostics Patents Granted, 2017 (First Three Quarters of the Year)* .	191
Table 57 Clinical Microbiology In Vitro Diagnostics Patents Granted, 2016 and 2017	201
Table 58 Tissue In Vitro Diagnostics Patents Granted, 2016 and 2017	206
Table 59 Significant Companies Purchased by Thermo Fisher Scientific	232

List of Figures

Summary Figure: Global Market for In Vitro Diagnostics (IVD), by Region,2016-2022 (\$ Millions).....	9
Figure 1 Global IVD Market, by Segment, 2016-2022 (\$ Millions).....	27
Figure 2 Global IVD Market Share, by Segment, 2017 (%)	28
Figure 3 Global Immunochemistry Market Share, by Application, 2017 (%).....	36
Figure 4 Global Immunochemistry Market, by Region, 2016-2022 (\$ Millions).....	37
Figure 5 Global POC Testing Market, by Application, 2016-2022 (\$ Millions).....	44
Figure 6 Global POC Testing Market, by Region, 2016-2022 (\$ Millions).....	45
Figure 7 Global Hematology Market, by Application, 2016-2022 (\$ Millions).....	50
Figure 8 Global Hematology Market Share, by Technique, 2017 (%).....	51
Figure 9 Global Hematology Market Share, by System, 2017 (%)	51
Figure 10 Global Hematology Market, by Region, 2016-2022 (\$ Millions).....	52
Figure 11 Global Molecular Diagnostics Market, by Application, 2016-2022 (\$ Millions)	58
Figure 12 Global Molecular Diagnostics Market Share, by Application, 2017 (%).....	59
Figure 13 Global Molecular Diagnostics Market Share, by Infectious Disease, 2017 (%)	59
Figure 14 Global Molecular Diagnostics Market, by Region, 2016-2022 (\$ Millions)	60
Figure 15 Global Clinical Microbiology Market, by Application, 2016-2022 (\$ Millions)	92
Figure 16 Global Clinical Microbiology Market Share, by Application, 2017 (%).....	93
Figure 17 Global Clinical Microbiology Market, by Region, 2016-2022 (\$ Millions)	94
Figure 18 Global Tissue Diagnostics Market, by Application, 2016-2022 (\$ Millions)	105
Figure 19 Global Tissue Diagnostics Market Share, by Application, 2017 (%).....	105
Figure 20 Global Tissue Diagnostics Market, by Region, 2016-2022 (\$ Millions)	106
Figure 21 Global IVD Market Share, by End User, 2017 (%)	109
Figure 22 Global IVD Market Share, by Product Type, 2017 (%).....	112
Figure 23 Total Health Expenditure as a Percentage of GDP for the Top Industrialized Economies, 2015 (%).....	116
Figure 24 European IVD Market Share, by Country, 2017 (%).....	122
Figure 25 Western European IVD Market Share, by Country, 2017 (%).....	123
Figure 26 Central and Eastern Europe IVD Market Share, by Country, 2017 (%)	123
Figure 27 Latin American IVD Market Share, by Country, 2017 (%)	138
Figure 28 Middle East and African IVD Market Share, by Region, 2017 (%).....	141



About BCC Research

About BCC Research

With our unparalleled 45-year history, BCC Research provides comprehensive analysis of global market sizing, forecasting and industry intelligence, covering markets where advances in science and technology are improving the quality, standard and sustainability of businesses, economies and lives.

BCC Membership

From market sizing and forecasts, to opportunity assessments and competitive analyses, our ever-expanding library gives you the data, insights and intelligence required to ensure your project is a success. Members benefit from ongoing, unlimited access to the category or collections of their choice, and most membership packages pay for themselves within two to three reports being accessed.

Did you buy this report? You may qualify to apply your purchase price towards a full membership. Call 866/285-7215 or e-mail info@bccresearch.com to request a demo.

BCC Custom Research

Our experts provide custom research projects to those working to identify new markets, introduce new products, validate existing market share, analyze competition and assess the potential for products to impact existing markets. With impressive academic credentials and broad and deep knowledge of global industrial markets, our independent analysts and consultants develop the facts, figures, analysis and assessments to inform the decisions that will move your company ahead. Confidential inquiries to: custom@bccresearch.com or 781/205-2429.

DISCLAIMER

The information developed in this report is intended to be as reliable as possible at the time of publication and is of a professional nature. This information does not constitute managerial, legal or accounting advice, nor should it be considered as a corporate policy guide, laboratory manual or an endorsement of any product, as much of the information is speculative in nature. BCC Research and the author assume no responsibility for any loss or damage that might result from reliance on the reported information or from its use.

ISBN: 978-1-62296-616-5
January 2018