

## AUTOIMMUNE DISEASE DIAGNOSTICS: GLOBAL MARKETS



**PHM160A**  
**September 2014**

Anandi Karumbati  
***Project Analyst***

ISBN: 1-56965-914-1



**BCC Research**  
**49 Walnut Park, Building 2**  
**Wellesley, MA 02481 USA**  
**866-285-7215 (toll-free within the USA),**  
**or (+1) 781-489-7301**  
**[www.bccresearch.com](http://www.bccresearch.com)**  
**[information@bccresearch.com](mailto:information@bccresearch.com)**

## TABLE OF CONTENTS

TOPIC	PAGE NO.
CHAPTER 1 INTRODUCTION	2
STUDY GOALS AND OBJECTIVES	2
SCOPE OF REPORT	2
INTENDED AUDIENCE	3
INFORMATION SOURCES	3
ANALYST CREDENTIALS	3
RELATED BCC RESEARCH REPORTS	3
BCC RESEARCH WEBSITE	4
DISCLAIMER	4
CHAPTER 2 EXECUTIVE SUMMARY	6
<i>SUMMARY TABLE GLOBAL MARKET FOR AUTOIMMUNE DIAGNOSTICS, THROUGH 2019 (\$ MILLIONS)</i>	7
<i>SUMMARY FIGURE GLOBAL MARKET FOR AUTOIMMUNE DIAGNOSTICS, 2012-2019 (\$ MILLIONS)</i>	7
CHAPTER 3 AUTOIMMUNE DISEASE OVERVIEW	9
CAUSES OF AUTOIMMUNE DISEASES	10
INTRINSIC FACTORS	10
Immune Dysfunction	10
<i>TABLE 1 ASSOCIATION OF IMMUNE DYSFUNCTION SYNDROMES ASSOCIATE WITH AUTOIMMUNE DISEASES</i>	10
Gender	11
Age	11
ENVIRONMENTAL FACTORS	12
<i>TABLE 2 INFECTIOUS ETIOLOGIES OF SELECTED AUTOIMMUNE DISEASES</i>	13
Lifestyle Factors	13
<i>TABLE 3 LIST OF AUTOIMMUNE AND AUTOIMMUNE RELATED DISEASES</i>	14
<i>FIGURE 1 U.S. PREVALENCE OF SELECTED AUTOIMMUNE DISEASES (NUMBER OF CASES PER 100,000)</i>	17
CHAPTER 4 OVERVIEW OF AUTOIMMUNE DISEASE DIAGNOSTICS	20
INTRODUCTION	20
<i>TABLE 4 AUTOANTIBODIES AND ASSOCIATED DISEASES</i>	20
TECHNOLOGIES CURRENTLY USED FOR AUTOIMMUNE DISEASE DIAGNOSIS	21
<i>TABLE 5 COMMON TECHNOLOGIES USED IN AUTOIMMUNE DIAGNOSTICS</i>	22
INDIRECT IMMUNOFLUORESCENCE (IIF-ANA)	22
Indications	22
Methodology	22
<i>FIGURE 2 IIF-ANA TEST METHODOLOGY</i>	23
Test Results	23
<i>TABLE 6 ANA PATTERNS AND ASSOCIATED DISEASES</i>	24
Advantages and Limitations of the IIF-ANA Test	24
<i>TABLE 7 CONDITIONS ASSOCIATED WITH POSITIVE IIF-ANA RESULTS</i>	25
ENZYME-LINKED IMMUNOABSORBENT ASSAY (ELISA) FOR ANA	26
Indication	26

<b>TOPIC</b>	<b>PAGE NO.</b>
Methodology	26
<i>FIGURE 3 ELISA METHODOLOGY</i>	26
Advantages and Limitations of the ELISA Assay for ANA	27
<b>WESTERN BLOT FOR ANA</b>	27
Indications	27
Methodology	27
<i>FIGURE 4 WESTERN BLOT METHODOLOGY</i>	27
Test Results	28
Advantages and Limitations of the Western Blot assay for ANA	28
<b>DOT BLOT</b>	28
Indications	28
Methodology	29
Test Results	29
<i>FIGURE 5 DOT BLOT TEST ASSAY METHODOLOGY</i>	29
Advantages and Limitations of the Dot Blot Assay	30
<b>LINE BLOT</b>	30
Indications	30
Methodology	30
Test Results	30
<i>FIGURE 6 ANA LINE ASSAY METHODOLOGY</i>	30
Advantages and Limitations of the Line Blot Assay for ANA	31
<b>MULTIPLEX IMMUNOASSAY</b>	31
Flow cytometry	32
Indications	32
Methodology	32
Test Results	32
<i>FIGURE 7 ANA FLOW CYTOMETRY ASSAY METHODOLOGY</i>	32
Advantages and Limitations of the Flow Cytometry for ANA	32
<b>Microarray</b>	33
Indications	33
Methodology	33
Advantages and Limitations of Microarray for ANA	33
<b>AGGLUTINATION</b>	33
Indications	33
Methodology	33
<i>FIGURE 8 ANA AGGLUTINATION ASSAY METHODOLOGY</i>	33
Advantages and Limitations of Agglutination for ANA	34
<b>DOUBLE IMMUNE DIFFUSION (DID)</b>	34
Indications	34
Methodology	34
<i>FIGURE 9 ANA DOUBLE IMMUNE DIFFUSION ASSAY METHODOLOGY</i>	34
Advantages and Limitations of Double Immune Diffusion for ANA	35
<b>COUNTERIMMUNOELECTROPHORESIS (CIEP)</b>	35
Indication	35
Methodology	35
<i>FIGURE 10 COUNTERIMMUNOELECTROPHORESIS METHODOLOGY</i>	35
Advantages and Limitations of Counterimmunoelectrophoresis for ANA	36

TOPIC	PAGE NO.
SUMMARY OF PERFORMANCE METHODS IN THE DETECTION OF AUTOIMMUNE ANTIBODIES	37
TABLE 8 PERFORMANCE OF LABORATORY METHODS IN DETECTION OF AUTOIMMUNE ANTIBODIES	37
AUTOIMMUNE PRODUCTS SOLD BY COMPANIES	38
TABLE 9 AUTOIMMUNE PRODUCTS SOLD BY SELECTED MULTINATIONAL COMPANIES, BY TECHNOLOGY	38
TABLE 10 PRODUCTS SOLD BY SELECTED AUTOIMMUNE-SPECIALIZED COMPANIES, BY TECHNOLOGY	39
EMERGING TECHNOLOGIES IN AUTOIMMUNE DIAGNOSTICS	39
BIOINFORMATICS	39
Companies and Research Institutes Using Bioinformatics	39
BIOMARKERS	40
Companies and Research Institutes Using Biomarkers	41
APPLICATIONS FOR MOBILE PHONES	42
LAB AUTOMATION	42
CHAPTER 5 GLOBAL AUTOIMMUNE DISEASE DIAGNOSTICS MARKET	45
METHODOLOGY	45
FIGURE 11 GLOBAL PREVALENCE OF THE FIVE MAJOR AUTOIMMUNE DISEASES	46
FIGURE 12 GLOBAL INCIDENCE OF THE FIVE MAJOR AUTOIMMUNE DISEASES	46
MARKET SIZE	47
PRE-TREATMENT MARKET	47
TABLE 11 MARKET SIZE FOR PRE-TREATMENT PANEL BY DISEASE TYPE, THROUGH 2019 (\$ MILLIONS)	48
TABLE 12 MARKET SIZE FOR PRE-TREATMENT AUTOIMMUNE SPECIFIC TESTS BY DISEASE TYPE, THROUGH 2019 (\$ MILLIONS)	48
TABLE 13 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL BY REGION, THROUGH 2019 (\$ MILLIONS)	49
FIGURE 13 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR ALL DISEASES BY REGION, 2019 (\$ MILLIONS)	49
TABLE 14 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL BY GENDER, THROUGH 2019 (\$ MILLIONS)	50
DURING-TREATMENT MARKET	51
TABLE 15 MARKET SIZE FOR DURING-TREATMENT DIAGNOSTICS BY DISEASE TYPE, THROUGH 2019 (\$ MILLIONS)	51
TABLE 16 MARKET SIZE FOR DURING-TREATMENT DIAGNOSTICS BY REGION, THROUGH 2019 (\$ MILLIONS)	52
RHEUMATOID ARTHRITIS	53
CLINICAL BACKGROUND	53
CLINICAL MANIFESTATIONS AND SYMPTOMS	53
TABLE 17 CLASSIFICATION OF RHEUMATOID ARTHRITIS	53
CURRENT BIOMARKERS TO DIAGNOSE RHEUMATOID ARTHRITIS	54
LABORATORY TESTS	54
FIGURE 14 FREQUENCY OF ORDERING MULTIPLE AUTOANTIBODY TESTS FOR RHEUMATOID ARTHRITIS DIAGNOSIS (%)	54
MARKET SIZE	55
TABLE 18 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR RHEUMATOID ARTHRITIS BY REGION, THROUGH 2019 (\$ MILLIONS)	56

<b>TOPIC</b>	<b>PAGE NO.</b>
<i>FIGURE 15 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR RHEUMATOID ARTHRITIS BY REGION, 2019 (\$ MILLIONS)</i>	56
<i>TABLE 19 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR RHEUMATOID ARTHRITIS BY GENDER, THROUGH 2019 (\$ MILLIONS)</i>	57
<i>TABLE 20 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR RHEUMATOID ARTHRITIS BY TEST TYPE, THROUGH 2019 (\$ MILLIONS)</i>	58
<i>TABLE 21 MARKET SIZE FOR DURING-TREATMENT DIAGNOSIS OF RHEUMATOID ARTHRITIS BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	58
<i>TABLE 22 MARKET SIZE FOR DURING-TREATMENT DIAGNOSIS OF RHEUMATOID ARTHRITIS BY GENDER, THROUGH 2019 (\$ MILLIONS)</i>	59
COMPANIES SUPPLYING DIAGNOSTIC KITS	59
<i>TABLE 23 SELECTED COMPANIES OFFERING DIAGNOSTIC KITS FOR RHEUMATOID ARTHRITIS</i>	59
INFLAMMATORY BOWEL DISEASE	60
CLINICAL BACKGROUND	60
CLINICAL MANIFESTATIONS AND SYMPTOMS	60
MARKET SIZE	61
<i>TABLE 24 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR IBD BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	61
<i>FIGURE 16 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR IBD BY REGION, 2019 (\$ MILLIONS)</i>	62
<i>TABLE 25 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR IBD BY GENDER, THROUGH 2019 (\$ MILLIONS)</i>	62
<i>TABLE 26 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR IBD BY TEST TYPE, THROUGH 2019 (\$ MILLIONS)</i>	63
<i>TABLE 27 MARKET SIZE FOR DURING-TREATMENT DIAGNOSIS OF IBD BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	63
<i>TABLE 28 MARKET SIZE FOR DURING-TREATMENT DIAGNOSIS OF IBD BY GENDER, THROUGH 2019 (\$ MILLIONS)</i>	64
CURRENT BIOMARKERS FOR IBD	64
<i>TABLE 29 CURRENT BIOMARKERS FOR IBD DIAGNOSIS AND CLASSIFICATION</i>	64
EMERGING BIOMARKERS	65
LABORATORY TESTS	65
COMPANIES OFFERING TESTS FOR IBD	66
<i>TABLE 30 COMPANIES WITH TESTS FOR INFLAMMATORY BOWEL DISEASE DIFFERENTIAL DIAGNOSIS</i>	66
TYPE 1 DIABETES	66
CLINICAL BACKGROUND	66
CLINICAL MANIFESTATIONS AND SYMPTOMS	66
Symptoms	67
CURRENT BIOMARKERS FOR TYPE 1 DIABETES	67
EMERGING BIOMARKERS	67
LABORATORY TESTS	67
MARKET SIZE	68
<i>TABLE 31 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL OF TYPE 1 DIABETES BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	68
<i>FIGURE 17 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL OF TYPE 1 DIABETES BY REGION, 2019 (\$ MILLIONS)</i>	69
<i>TABLE 32 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR TYPE 1 DIABETES BY GENDER, THROUGH 2019 (\$ MILLIONS)</i>	69

<b>TOPIC</b>	<b>PAGE NO.</b>
TABLE 33 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR TYPE 1 DIABETES BY TEST TYPE, THROUGH 2019 (\$ MILLIONS)	70
TABLE 34 MARKET SIZE FOR DIAGNOSTIC DURING-TREATMENT OF TYPE 1 DIABETES BY REGION, THROUGH 2019 (\$ MILLIONS)	70
TABLE 35 MARKET SIZE FOR DIAGNOSTIC DURING-TREATMENT OF TYPE 1 DIABETES BY GENDER, THROUGH 2019 (\$ MILLIONS)	71
COMPANIES OFFERING TESTS FOR TYPE 1 DIABETES	71
TABLE 36 SELECTED COMPANIES WITH TESTS FOR TYPE 1 DIABETES DIFFERENTIAL DIAGNOSIS	71
MULTIPLE SCLEROSIS	72
CLINICAL BACKGROUND	72
CLINICAL MANIFESTATIONS AND SYMPTOMS	72
CURRENT BIOMARKERS	73
EMERGING BIOMARKERS	73
LABORATORY TESTS	73
MARKET SIZE	74
TABLE 37 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY REGION, THROUGH 2019 (\$ MILLIONS)	74
FIGURE 18 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY REGION, 2019 (\$ MILLIONS)	75
TABLE 38 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY GENDER, THROUGH 2019 (\$ MILLIONS)	75
TABLE 39 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY TEST TYPE, THROUGH 2019 (\$ MILLIONS)	76
TABLE 40 MARKET SIZE FOR DURING-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY REGION, THROUGH 2019 (\$ MILLIONS)	76
TABLE 41 MARKET SIZE FOR DURING-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY GENDER, THROUGH 2019 (\$ MILLIONS)	77
COMPANIES SUPPLYING DIAGNOSTIC KITS FOR MS	77
TABLE 42 SELECTED COMPANIES OFFERING DIAGNOSTIC KITS FOR MS	77
SYSTEMIC LUPUS ERYTHEMATOSUS	78
CLINICAL BACKGROUND	78
SYMPTOMS	78
CURRENT BIOMARKERS	78
LABORATORY TESTS	78
MARKET SIZE	79
TABLE 43 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL OF SLE BY REGION, THROUGH 2019 (\$ MILLIONS)	79
FIGURE 19 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL OF SLE BY REGION, 2019 (\$ MILLIONS)	79
TABLE 44 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR SLE BY GENDER, THROUGH 2019 (\$ MILLIONS)	80
TABLE 45 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL OF SLE BY TEST TYPE, THROUGH 2019 (\$ MILLIONS)	81
TABLE 46 MARKET SIZE FOR DIAGNOSTIC PANEL DURING-TREATMENT OF SLE BY REGION, THROUGH 2019 (\$ MILLIONS)	81
TABLE 47 MARKET SIZE FOR DIAGNOSTIC DURING-TREATMENT OF SLE BY GENDER, THROUGH 2019 (\$ MILLIONS)	82
COMPANIES OFFERING DIAGNOSTIC KITS FOR SLE	82
TABLE 48 COMPANIES WITH DIAGNOSTIC KITS FOR SLE	82

TOPIC	PAGE NO.
CHAPTER 6 INDUSTRY ANALYSES	84
TABLE 49 AUTOIMMUNE DISEASE DIAGNOSTICS INDUSTRY VALUE CHAIN	84
DEMAND CHAIN ANALYSIS	84
CUSTOMERS (PATIENTS)	84
TABLE 50 PER CAPITA HEALTH EXPENDITURE BY REGION (\$)	85
FIGURE 20 PER CAPITA MEAN HEALTH EXPENDITURE BY REGION (\$)	86
PAYERS	86
TABLE 51 PERCENTAGE OF HEALTH EXPENDITURES IN ASIA, BY PAYER TYPE, 2013 (%)	87
TABLE 52 PERCENTAGE OF HEALTH EXPENDITURES IN AFRICA, BY PAYER TYPE, 2013 (%)	87
TABLE 53 PERCENTAGE OF HEALTH EXPENDITURES IN CENTRAL AMERICA, BY PAYER TYPE, 2013 (%)	88
TABLE 54 PERCENTAGE OF HEALTH EXPENDITURES IN NORTH AMERICA, BY PAYER TYPE, 2013 (%)	88
TABLE 55 PERCENTAGE OF HEALTH EXPENDITURES IN SOUTH AMERICA, BY PAYER TYPE, 2013 (%)	88
TABLE 56 PERCENTAGE OF HEALTH EXPENDITURES IN EUROPE, BY PAYER TYPE, 2013 (%)	89
TABLE 57 PERCENTAGE OF HEALTH EXPENDITURES IN THE MIDDLE EAST, BY PAYER TYPE, 2013 (%)	89
TABLE 58 PERCENTAGE OF HEALTH EXPENDITURES IN OCEANIA, BY PAYER TYPE, 2013 (%)	90
FIGURE 21 SUMMARY CHART OF PROPORTION OF HEALTH EXPENDITURES BY PAYER TYPE, BY REGION, 2013 (%)	90
FIGURE 22 PAYER TYPE BY COUNTRY INCOME LEVEL, 2013 (%)	91
SUPPLY CHAIN ANALYSIS	92
LABORATORIES	92
TABLE 59 MAJOR INDEPENDENT LABORATORIES BY REVENUE AND NUMBER OF EMPLOYEES, 2013	93
TABLE 60 COMPARISON OF MARGIN AND COST STRUCTURE OF DIAGNOSTICS LABS FOR SELECTED COUNTRIES (%)	93
MANUFACTURERS	94
TABLE 61 MAJOR MANUFACTURERS OF AUTOIMMUNE DISEASE DIAGNOSTICS BY REVENUE* AND NUMBER OF EMPLOYEES, 2013	94
CHAPTER 7 GOVERNMENT REGULATIONS	97
EUROPEAN REGULATIONS	97
REGULATION IN NORTH AMERICAN COUNTRIES	97
U.S. REGULATIONS	97
TABLE 62 DIFFERENCES BETWEEN U.S. AND EUROPEAN GOVERNMENT REGULATIONS FOR MEDICAL DEVICES	99
CANADIAN REGULATIONS	99
REGULATION IN SOUTH AMERICA	99
REGULATION IN ASIA	100
TABLE 63 REGULATION OF MEDICAL DIAGNOSTICS IN SELECTED ASIAN COUNTRIES	100
REGULATION IN OCEANIA	101
FUTURE REGULATORY TRENDS	101

<b>TOPIC</b>	<b>PAGE NO.</b>
CHAPTER 8 KEY CHALLENGES IN THE INDUSTRY	103
STANDARDIZATION OF TEST RESULTS	103
LACK OF AWARENESS AMONG PATIENTS OF AUTOIMMUNE COMPLICATIONS	104
SHORTAGE OF SKILLED TECHNICIANS FOR PERFORMING DIAGNOSTIC ASSAYS	104
<i>TABLE 64 CHALLENGES FACED BY IMMUNOASSAY KIT/ INSTRUMENT MANUFACTURERS</i>	105
<i>TABLE 65 CHALLENGES FACED BY IMMUNOASSAY CLINICAL LABORATORIES</i>	106
<i>TABLE 66 IMMUNOASSAY CHALLENGES FACED BY PHYSICIANS</i>	106
CHAPTER 9 PATENT ANALYSES	108
PATENTS BY DISEASE TYPE	108
<i>TABLE 67 PATENTS RELATED TO TYPE 1 DIABETES, 2007-2013</i>	108
<i>TABLE 68 PATENTS RELATED TO MULTIPLE SCLEROSIS, 2011</i>	108
<i>TABLE 69 PATENTS RELATED TO IRRITABLE BOWEL SYNDROME, 2001-FEB 2014</i>	109
<i>TABLE 70 PATENTS RELATED TO SYSTEMIC LUPUS ERYTHEMATOSUS, 2008-2012</i>	109
<i>TABLE 71 PATENTS RELATED TO RHEUMATOID ARTHRITIS, 1995-2011</i>	110
SELECTED PATENTS BY MANUFACTURER	110
PATENTS BY MULTINATIONAL COMPANIES	110
Abbott	110
<i>TABLE 72 ABBOTT PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2008 AND 2012</i>	110
Bio-rad	111
<i>TABLE 73 BIO-RAD PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2002-2013</i>	111
Biomerieux	111
<i>TABLE 74 BIOMERIEUX PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2012 AND 2013</i>	111
Hitachi	112
<i>TABLE 75 HITACHI PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2000</i>	112
Life Technologies	112
<i>TABLE 76 LIFE TECHNOLOGIES PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2012</i>	112
Roche	113
<i>TABLE 77 ROCHE PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2014</i>	113
Siemens Healthcare	113
<i>TABLE 78 SIEMENS HEALTHCARE PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2013</i>	113
Thermo Fisher (Phadia)	114
<i>TABLE 79 THERMO FISHER PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2008-2013</i>	114
PATENTS BY AUTOIMMUNE SPECIALIZED COMPANY	114
Aesku	114
<i>TABLE 80 AESKU PATENTS FOR NOVEL BIOMARKERS, 2010 AND 2013</i>	114
<i>TABLE 81 AESKU PATENTS FOR DIAGNOSTIC METHODS, 2013</i>	115
Euroimmun	115
<i>TABLE 82 EUROIMMUN PATENTS FOR NOVEL BIOMARKERS, 2009-2013</i>	115
<i>TABLE 83 EUROIMMUN PATENTS FOR DIAGNOSTIC METHODS, 2013 AND 2014</i>	116



<b>TOPIC</b>	<b>PAGE NO.</b>
IMMCO	116
<i>TABLE 84 IMMCO PATENTS FOR NOVEL BIOMARKERS, 2004 AND 2008</i>	116
<i>TABLE 85 IMMCO PATENTS FOR DIAGNOSTIC METHODS, 2011</i>	117
Inova	117
<i>TABLE 86 INOVA PATENTS RELATED TO AUTOIMMUNE DIAGNOSTICS, 2008-2013</i>	117
Orgentec Diagnostika	118
<i>TABLE 87 ORGENTEC DIAGNOSTIKA PATENTS RELATED TO AUTOIMMUNE DIAGNOSTICS, 2011 AND 2013</i>	118
CHAPTER 10 COMPANY PROFILES	120
COMPANY LISTINGS	120
ABBOTT	120
<i>TABLE 88 FINANCIAL DETAILS OF ABBOTT, 2011-2013 (\$ MILLIONS/%)</i>	120
BECTON DICKINSON	121
<i>TABLE 89 FINANCIAL DETAILS OF BECTON DICKINSON, 2011-2013 (\$ MILLIONS/%)</i>	122
BIOMERIEUX SA	123
<i>TABLE 90 FINANCIAL DETAILS OF BIOMERIEUX, 2010-2012 (MILLIONS/%)</i>	123
BIO-RAD	124
<i>TABLE 91 FINANCIAL DETAILS OF BIO-RAD, 2010-2012 (\$ MILLIONS/%)</i>	124
BIO REFERENCE LABS	124
<i>TABLE 92 FINANCIAL DETAILS OF BIO REFERENCE, 2011-2013 (\$ MILLIONS/%)</i>	125
DANAHER CORP.	126
<i>TABLE 93 FINANCIAL DETAILS OF DANAHER, 2011-2013 (\$ MILLIONS/%)</i>	127
HEMAGEN DIAGNOSTICS	128
<i>TABLE 94 FINANCIAL DETAILS OF HEMAGEN DIAGNOSTICS, 2010-2012 (\$ MILLIONS/%)</i>	128
LABCORP	128
<i>TABLE 95 FINANCIAL DETAILS OF LABCORP, 2011-2013 (\$ MILLIONS/%)</i>	129
QUEST DIAGNOSTICS	129
<i>TABLE 96 FINANCIAL DETAILS OF QUEST DIAGNOSTICS, 2011-2013 (\$ MILLIONS/%)</i>	130
ROCHE HOLDINGS	131
<i>TABLE 97 FINANCIAL DETAILS OF ROCHE, 2011-2013 (\$ MILLIONS/%)</i>	131
SIEMENS HEALTHCARE DIAGNOSTICS	132
<i>TABLE 98 FINANCIAL DETAILS OF SIEMENS HEALTHCARE, 2011-2013 (MILLIONS/%)</i>	132
SONIC HEALTHCARE	133
<i>TABLE 99 FINANCIAL DETAILS OF SONIC HEALTHCARE, 2011-2013 (AU\$ MILLIONS/%)</i>	133
THERMO FISHER (TMO)	134
<i>TABLE 100 FINANCIAL DETAILS OF THERMO FISHER, 2011-2013 (\$ MILLIONS/%)</i>	135
TRINITY BIOTECH GROUP (IMMCO DIAGNOSTICS)	136
<i>TABLE 101 FINANCIAL DETAILS OF TRINITY BIOTECH, 2011-2013 (\$ MILLIONS/%)</i>	137
CHAPTER 11 APPENDIX: KEY MERGERS AND ACQUISITIONS	139
<i>TABLE 102 KEY MERGERS AND ACQUISITIONS</i>	139

**LIST OF TABLES**

<b>TABLE HEADING</b>	<b>PAGE NO.</b>
SUMMARY TABLE GLOBAL MARKET FOR AUTOIMMUNE DIAGNOSTICS, THROUGH 2019 (\$ MILLIONS)	7
TABLE 1 ASSOCIATION OF IMMUNE DYSFUNCTION SYNDROMES ASSOCIATE WITH AUTOIMMUNE DISEASES	10
TABLE 2 INFECTIOUS ETIOLOGIES OF SELECTED AUTOIMMUNE DISEASES	13
TABLE 3 LIST OF AUTOIMMUNE AND AUTOIMMUNE RELATED DISEASES	14
TABLE 4 AUTOANTIBODIES AND ASSOCIATED DISEASES	20
TABLE 5 COMMON TECHNOLOGIES USED IN AUTOIMMUNE DIAGNOSTICS	22
TABLE 6 ANA PATTERNS AND ASSOCIATED DISEASES	24
TABLE 7 CONDITIONS ASSOCIATED WITH POSITIVE IIF-ANA RESULTS	25
TABLE 8 PERFORMANCE OF LABORATORY METHODS IN DETECTION OF AUTOIMMUNE ANTIBODIES	37
TABLE 9 AUTOIMMUNE PRODUCTS SOLD BY SELECTED MULTINATIONAL COMPANIES, BY TECHNOLOGY	38
TABLE 10 PRODUCTS SOLD BY SELECTED AUTOIMMUNE-SPECIALIZED COMPANIES, BY TECHNOLOGY	39
TABLE 11 MARKET SIZE FOR PRE-TREATMENT PANEL BY DISEASE TYPE, THROUGH 2019 (\$ MILLIONS)	48
TABLE 12 MARKET SIZE FOR PRE-TREATMENT AUTOIMMUNE SPECIFIC TESTS BY DISEASE TYPE, THROUGH 2019 (\$ MILLIONS)	48
TABLE 13 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL BY REGION, THROUGH 2019 (\$ MILLIONS)	49
TABLE 14 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL BY GENDER, THROUGH 2019 (\$ MILLIONS)	50
TABLE 15 MARKET SIZE FOR DURING-TREATMENT DIAGNOSTICS BY DISEASE TYPE, THROUGH 2019 (\$ MILLIONS)	51
TABLE 16 MARKET SIZE FOR DURING-TREATMENT DIAGNOSTICS BY REGION, THROUGH 2019 (\$ MILLIONS)	52
TABLE 17 CLASSIFICATION OF RHEUMATOID ARTHRITIS	53
TABLE 18 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR RHEUMATOID ARTHRITIS BY REGION, THROUGH 2019 (\$ MILLIONS)	56
TABLE 19 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR RHEUMATOID ARTHRITIS BY GENDER, THROUGH 2019 (\$ MILLIONS)	57
TABLE 20 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR RHEUMATOID ARTHRITIS BY TEST TYPE, THROUGH 2019 (\$ MILLIONS)	58
TABLE 21 MARKET SIZE FOR DURING-TREATMENT DIAGNOSIS OF RHEUMATOID ARTHRITIS BY REGION, THROUGH 2019 (\$ MILLIONS)	58
TABLE 22 MARKET SIZE FOR DURING-TREATMENT DIAGNOSIS OF RHEUMATOID ARTHRITIS BY GENDER, THROUGH 2019 (\$ MILLIONS)	59
TABLE 23 SELECTED COMPANIES OFFERING DIAGNOSTIC KITS FOR RHEUMATOID ARTHRITIS	59
TABLE 24 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR IBD BY REGION, THROUGH 2019 (\$ MILLIONS)	61
TABLE 25 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR IBD BY GENDER, THROUGH 2019 (\$ MILLIONS)	62
TABLE 26 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR IBD BY TEST TYPE, THROUGH 2019 (\$ MILLIONS)	63
TABLE 27 MARKET SIZE FOR DURING-TREATMENT DIAGNOSIS OF IBD BY REGION, THROUGH 2019 (\$ MILLIONS)	63
TABLE 28 MARKET SIZE FOR DURING-TREATMENT DIAGNOSIS OF IBD BY GENDER, THROUGH 2019 (\$ MILLIONS)	64

<b>TABLE HEADING</b>	<b>PAGE NO.</b>
TABLE 29 CURRENT BIOMARKERS FOR IBD DIAGNOSIS AND CLASSIFICATION	64
TABLE 30 COMPANIES WITH TESTS FOR INFLAMMATORY BOWEL DISEASE DIFFERENTIAL DIAGNOSIS	66
TABLE 31 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL OF TYPE 1 DIABETES BY REGION, THROUGH 2019 (\$ MILLIONS)	68
TABLE 32 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR TYPE 1 DIABETES BY GENDER, THROUGH 2019 (\$ MILLIONS)	69
TABLE 33 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR TYPE 1 DIABETES BY TEST TYPE, THROUGH 2019 (\$ MILLIONS)	70
TABLE 34 MARKET SIZE FOR DIAGNOSTIC DURING-TREATMENT OF TYPE 1 DIABETES BY REGION, THROUGH 2019 (\$ MILLIONS)	70
TABLE 35 MARKET SIZE FOR DIAGNOSTIC DURING-TREATMENT OF TYPE 1 DIABETES BY GENDER, THROUGH 2019 (\$ MILLIONS)	71
TABLE 36 SELECTED COMPANIES WITH TESTS FOR TYPE 1 DIABETES DIFFERENTIAL DIAGNOSIS	71
TABLE 37 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY REGION, THROUGH 2019 (\$ MILLIONS)	74
TABLE 38 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY GENDER, THROUGH 2019 (\$ MILLIONS)	75
TABLE 39 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY TEST TYPE, THROUGH 2019 (\$ MILLIONS)	76
TABLE 40 MARKET SIZE FOR DURING-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY REGION, THROUGH 2019 (\$ MILLIONS)	76
TABLE 41 MARKET SIZE FOR DURING-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY GENDER, THROUGH 2019 (\$ MILLIONS)	77
TABLE 42 SELECTED COMPANIES OFFERING DIAGNOSTIC KITS FOR MS	77
TABLE 43 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL OF SLE BY REGION, THROUGH 2019 (\$ MILLIONS)	79
TABLE 44 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR SLE BY GENDER, THROUGH 2019 (\$ MILLIONS)	80
TABLE 45 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL OF SLE BY TEST TYPE, THROUGH 2019 (\$ MILLIONS)	81
TABLE 46 MARKET SIZE FOR DIAGNOSTIC PANEL DURING-TREATMENT OF SLE BY REGION, THROUGH 2019 (\$ MILLIONS)	81
TABLE 47 MARKET SIZE FOR DIAGNOSTIC DURING-TREATMENT OF SLE BY GENDER, THROUGH 2019 (\$ MILLIONS)	82
TABLE 48 COMPANIES WITH DIAGNOSTIC KITS FOR SLE	82
TABLE 49 AUTOIMMUNE DISEASE DIAGNOSTICS INDUSTRY VALUE CHAIN	84
TABLE 50 PER CAPITA HEALTH EXPENDITURE BY REGION (\$)	85
TABLE 51 PERCENTAGE OF HEALTH EXPENDITURES IN ASIA, BY PAYER TYPE, 2013 (%)	87
TABLE 52 PERCENTAGE OF HEALTH EXPENDITURES IN AFRICA, BY PAYER TYPE, 2013 (%)	87
TABLE 53 PERCENTAGE OF HEALTH EXPENDITURES IN CENTRAL AMERICA, BY PAYER TYPE, 2013 (%)	88
TABLE 54 PERCENTAGE OF HEALTH EXPENDITURES IN NORTH AMERICA, BY PAYER TYPE, 2013 (%)	88
TABLE 55 PERCENTAGE OF HEALTH EXPENDITURES IN SOUTH AMERICA, BY PAYER TYPE, 2013 (%)	88
TABLE 56 PERCENTAGE OF HEALTH EXPENDITURES IN EUROPE, BY PAYER TYPE, 2013 (%)	89

<b>TABLE HEADING</b>	<b>PAGE NO.</b>
TABLE 57 PERCENTAGE OF HEALTH EXPENDITURES IN THE MIDDLE EAST, BY PAYER TYPE, 2013 (%)	89
TABLE 58 PERCENTAGE OF HEALTH EXPENDITURES IN OCEANIA, BY PAYER TYPE, 2013 (%)	90
TABLE 59 MAJOR INDEPENDENT LABORATORIES BY REVENUE AND NUMBER OF EMPLOYEES, 2013	93
TABLE 60 COMPARISON OF MARGIN AND COST STRUCTURE OF DIAGNOSTICS LABS FOR SELECTED COUNTRIES (%)	93
TABLE 61 MAJOR MANUFACTURERS OF AUTOIMMUNE DISEASE DIAGNOSTICS BY REVENUE* AND NUMBER OF EMPLOYEES, 2013	94
TABLE 62 DIFFERENCES BETWEEN U.S. AND EUROPEAN GOVERNMENT REGULATIONS FOR MEDICAL DEVICES	99
TABLE 63 REGULATION OF MEDICAL DIAGNOSTICS IN SELECTED ASIAN COUNTRIES	100
TABLE 64 CHALLENGES FACED BY IMMUNOASSAY KIT/ INSTRUMENT MANUFACTURERS	105
TABLE 65 CHALLENGES FACED BY IMMUNOASSAY CLINICAL LABORATORIES	106
TABLE 66 IMMUNOASSAY CHALLENGES FACED BY PHYSICIANS	106
TABLE 67 PATENTS RELATED TO TYPE 1 DIABETES, 2007-2013	108
TABLE 68 PATENTS RELATED TO MULTIPLE SCLEROSIS, 2011	108
TABLE 69 PATENTS RELATED TO IRRITABLE BOWEL SYNDROME, 2001-FEB 2014	109
TABLE 70 PATENTS RELATED TO SYSTEMIC LUPUS ERYTHEMATOSUS, 2008-2012	109
TABLE 71 PATENTS RELATED TO RHEUMATOID ARTHRITIS, 1995-2011	110
TABLE 72 ABBOTT PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2008 AND 2012	110
TABLE 73 BIO-RAD PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2002-2013	111
TABLE 74 BIOMERIEUX PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2012 AND 2013	111
TABLE 75 HITACHI PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2000	112
TABLE 76 LIFE TECHNOLOGIES PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2012	112
TABLE 77 ROCHE PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2014	113
TABLE 78 SIEMENS HEALTHCARE PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2013	113
TABLE 79 THERMO FISHER PATENTS RELATED TO AUTOIMMUNE DISEASE DIAGNOSTICS, 2008-2013	114
TABLE 80 AESKU PATENTS FOR NOVEL BIOMARKERS, 2010 AND 2013	114
TABLE 81 AESKU PATENTS FOR DIAGNOSTIC METHODS, 2013	115
TABLE 82 EUROIMMUN PATENTS FOR NOVEL BIOMARKERS, 2009-2013	115
TABLE 83 EUROIMMUN PATENTS FOR DIAGNOSTIC METHODS, 2013 AND 2014	116
TABLE 84 IMMCO PATENTS FOR NOVEL BIOMARKERS, 2004 AND 2008	116
TABLE 85 IMMCO PATENTS FOR DIAGNOSTIC METHODS, 2011	117
TABLE 86 INOVA PATENTS RELATED TO AUTOIMMUNE DIAGNOSTICS, 2008-2013	117
TABLE 87 ORGENTEC DIAGNOSTIKA PATENTS RELATED TO AUTOIMMUNE DIAGNOSTICS, 2011 AND 2013	118
TABLE 88 FINANCIAL DETAILS OF ABBOTT, 2011-2013 (\$ MILLIONS/%)	120
TABLE 89 FINANCIAL DETAILS OF BECTON DICKINSON, 2011-2013 (\$ MILLIONS/%)	122
TABLE 90 FINANCIAL DETAILS OF BIOMERIEUX, 2010-2012 (MILLIONS/%)	123
TABLE 91 FINANCIAL DETAILS OF BIO-RAD, 2010-2012 (\$ MILLIONS/%)	124

---

<b>TABLE HEADING</b>	<b>PAGE NO.</b>
TABLE 92 FINANCIAL DETAILS OF BIO REFERENCE, 2011-2013 (\$ MILLIONS/%)	125
TABLE 93 FINANCIAL DETAILS OF DANAHER, 2011-2013 (\$ MILLIONS/%)	127
TABLE 94 FINANCIAL DETAILS OF HEMAGEN DIAGNOSTICS, 2010-2012 (\$ MILLIONS/%)	128
TABLE 95 FINANCIAL DETAILS OF LABCORP, 2011-2013 (\$ MILLIONS/%)	129
TABLE 96 FINANCIAL DETAILS OF QUEST DIAGNOSTICS, 2011-2013 (\$ MILLIONS/%)	130
TABLE 97 FINANCIAL DETAILS OF ROCHE, 2011-2013 (\$ MILLIONS/%)	131
TABLE 98 FINANCIAL DETAILS OF SIEMENS HEALTHCARE, 2011-2013 (MILLIONS/%)	132
TABLE 99 FINANCIAL DETAILS OF SONIC HEALTHCARE, 2011-2013 (AU\$ MILLIONS/%)	133
TABLE 100 FINANCIAL DETAILS OF THERMO FISHER, 2011-2013 (\$ MILLIONS/%)	135
TABLE 101 FINANCIAL DETAILS OF TRINITY BIOTECH, 2011-2013 (\$ MILLIONS/%)	137
TABLE 102 KEY MERGERS AND ACQUISITIONS	139

**LIST OF FIGURES**

<b>FIGURE TITLE</b>	<b>PAGE NO.</b>
SUMMARY FIGURE GLOBAL MARKET FOR AUTOIMMUNE DIAGNOSTICS, 2012-2019 (\$ MILLIONS)	7
FIGURE 1 U.S. PREVALENCE OF SELECTED AUTOIMMUNE DISEASES (NUMBER OF CASES PER 100,000)	17
FIGURE 2 IIF-ANA TEST METHODOLOGY	23
FIGURE 3 ELISA METHODOLOGY	26
FIGURE 4 WESTERN BLOT METHODOLOGY	27
FIGURE 5 DOT BLOT TEST ASSAY METHODOLOGY	29
FIGURE 6 ANA LINE ASSAY METHODOLOGY	30
FIGURE 7 ANA FLOW CYTOMETRY ASSAY METHODOLOGY	32
FIGURE 8 ANA AGGLUTINATION ASSAY METHODOLOGY	33
FIGURE 9 ANA DOUBLE IMMUNE DIFFUSION ASSAY METHODOLOGY	34
FIGURE 10 COUNTERIMMUNOELECTROPHORESIS METHODOLOGY	35
FIGURE 11 GLOBAL PREVALENCE OF THE FIVE MAJOR AUTOIMMUNE DISEASES	46
FIGURE 12 GLOBAL INCIDENCE OF THE FIVE MAJOR AUTOIMMUNE DISEASES	46
FIGURE 13 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR ALL DISEASES BY REGION, 2019 (\$ MILLIONS)	49
FIGURE 14 FREQUENCY OF ORDERING MULTIPLE AUTOANTIBODY TESTS FOR RHEUMATOID ARTHRITIS DIAGNOSIS (%)	54
FIGURE 15 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR RHEUMATOID ARTHRITIS BY REGION, 2019 (\$ MILLIONS)	56
FIGURE 16 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR IBD BY REGION, 2019 (\$ MILLIONS)	62
FIGURE 17 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL OF TYPE 1 DIABETES BY REGION, 2019 (\$ MILLIONS)	69
FIGURE 18 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL FOR MULTIPLE SCLEROSIS BY REGION, 2019 (\$ MILLIONS)	75
FIGURE 19 MARKET SIZE FOR PRE-TREATMENT DIAGNOSTIC PANEL OF SLE BY REGION, 2019 (\$ MILLIONS)	79
FIGURE 20 PER CAPITA MEAN HEALTH EXPENDITURE BY REGION (\$)	86
FIGURE 21 SUMMARY CHART OF PROPORTION OF HEALTH EXPENDITURES BY PAYER TYPE, BY REGION, 2013 (%)	90
FIGURE 22 PAYER TYPE BY COUNTRY INCOME LEVEL, 2013 (%)	91