

THE GLOBAL BLOOD INDUSTRY



HLC008J
March 2015

Melissa Elder
Project Analyst

ISBN: 1-62296-071-8



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
information@bccresearch.com

TABLE OF CONTENTS

TOPIC	PAGE NO.
CHAPTER 1 INTRODUCTION	2
STUDY GOAL AND OBJECTIVES	2
REASONS FOR DOING THIS STUDY	2
CONTRIBUTION OF THE STUDY AND INTENDED AUDIENCE	2
SCOPE AND FORMAT	3
METHODOLOGY AND INFORMATION SOURCES	3
ANALYST'S CREDENTIALS	4
RELATED BCC REPORTS	4
BCC RESEARCH WEBSITE	4
DISCLAIMER	5
CHAPTER 2 SUMMARY	7
OVERVIEW	7
MAJOR FINDINGS	7
<i>SUMMARY TABLE GLOBAL SALES OF BLOOD PRODUCTS, THROUGH 2019 (\$ MILLIONS)</i>	8
<i>SUMMARY FIGURE GLOBAL SALES OF BLOOD PRODUCTS, 2011-2019 (\$ MILLIONS)</i>	8
CHAPTER 3 OVERVIEW	11
THE BLOOD INDUSTRY	11
BLOOD INDUSTRY TERMS AND ABBREVIATIONS[1]	11
HISTORY OF THE BLOOD INDUSTRY	15
<i>TABLE 1 TIMELINE OF THE BLOOD INDUSTRY</i>	15
BLOOD AND ITS COMPONENTS	17
<i>TABLE 2 COMPOSITION OF BLOOD</i>	17
PLASMA	17
CELLULAR ELEMENTS	18
Red and White Blood Cells	18
Platelets	19
IMMUNOGLOBULIN PRODUCTS	19
THE DANGERS OF TRANSFUSED BLOOD	19
RISKS ASSOCIATED WITH TRANSFUSION	20
National Healthcare Safety Network -Biovigilance Component Hemovigilance Module Surveillance	20
Diseases Contracted from Blood Transfusions and Related Identification Testing	21
<i>TABLE 3 MAJOR DISEASES CONTRACTED FROM BLOOD TRANSFUSIONS, U.S. ANALYSIS</i>	21
HIV/AIDS	22
<i>TABLE 4 CBER LICENSED HIV DONOR SCREENING TESTS (LAST UPDATED JULY 2014)</i>	23
Hepatitis A	24
Hepatitis B	24
<i>TABLE 5 CBER-LICENSED SCREENING TESTS FOR HEPATITIS B (LAST UPDATED JULY 2014)</i>	25
Hepatitis C	26

TOPIC	PAGE NO.
<i>TABLE 6 CBER-LICENSED SCREENING TESTS FOR HEPATITIS C (LAST UPDATED JULY 2014)</i>	26
Hepatitis D	27
Hepatitis E	27
Human T-Cell Lymphotropic Virus-(HTLV-I, -II)	28
<i>TABLE 7 CBER-LICENSED SCREENING TESTS FOR HTLV-I AND HTLV-II (LAST UPDATED JULY 2014)</i>	28
Cytomegalovirus	28
<i>TABLE 8 CBER-LICENSED SCREENING TESTS FOR CMV (LAST UPDATED JULY 2014)</i>	29
West Nile Virus	29
<i>TABLE 9 CBER LICENSED SCREENING TESTS FOR WEST NILE (LAST UPDATED JULY 2014)</i>	30
"Mad Cow Disease"-Creutzfeldt-Jakob Disease (CJD)	30
Syphilis	31
Advances in Rapid Syphilis Detection	32
<i>TABLE 10 CBER-APPROVED MANUFACTURERS FOR SYPHILIS TESTS (LAST UPDATED JULY 2014)</i>	33
Chagas Disease	33
<i>TABLE 11 CBER-LICENSED SCREENING TESTS FOR T. CRUZI (LAST UPDATED JULY 2014)</i>	35
Chlamydia Trachomatis	35
<i>TABLE 12 CBER-APPROVED MANUFACTURERS FOR CHLAMYDIA SCREENING TESTS (LAST UPDATED JULY 2014)</i>	36
Neisseria Gonorrhoea	36
<i>TABLE 13 CBER-LICENSED SCREENING TESTS FOR GONORRHEA (LAST UPDATED JULY 2014)</i>	37
EFFORTS TO CREATE A VIRUS-FREE BLOOD SUPPLY	37
Plasma Treatments	37
Trinitrobutyl Phosphate and Sodium Cholate	37
Methylene Blue-treated Plasma	38
Amatosalen HCL-Treated Plasma	38
Platelet Treatments	38
RBCs	39
NEGATIVE REACTIONS FROM BLOOD TRANSFUSIONS	39
BLOOD/PLASMA COMPONENT RISKS	41
CHAPTER 4 THE BLOOD MANAGEMENT SYSTEM: BLOOD COLLECTION, PROCESSING AND USE	43
BLOOD COLLECTION	43
TYPES OF BLOOD ESTABLISHMENTS AND BLOOD FACILITIES	43
Major Facilities	43
Auxiliary Facilities	44
Transfusion Services	44
ORGANIZATIONS COLLECTING BLOOD	45
<i>TABLE 14 FDA-REGISTERED BLOOD ESTABLISHMENTS BY STATE¹ AND POSSESSION</i>	45
For-Profit Blood Collection	47
Plasma Collection Centers	47
National Donor Deferral Registry	48

TOPIC	PAGE NO.
Nonprofit Blood Collection	48
American Red Cross	48
Community Blood Banks	48
Hospitals	49
Additional Blood Collection Sites	49
BLOOD DONATION DEMOGRAPHICS	49
Global Demographic Trends	50
<i>TABLE 15 ESTIMATED WORLD POPULATION ANNUAL GROWTH BY SELECTED AGE GROUP AND SELECTED YEARS, THROUGH 2030 (MILLIONS)</i>	50
<i>FIGURE 1 ESTIMATED WORLD POPULATION BY SELECTED AGE GROUP AND SELECTED YEARS, 2000-2030 (MILLIONS)</i>	50
<i>TABLE 16 GLOBAL POPULATION BY SELECTED COUNTRY, THROUGH 2015 (MILLIONS)</i>	51
<i>FIGURE 2 GLOBAL POPULATION BY SELECTED COUNTRY, 2010 AND 2015 (MILLIONS)</i>	52
U.S. DEMOGRAPHICS	52
<i>TABLE 17 U.S. POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)</i>	52
<i>FIGURE 3 U.S. POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)</i>	53
Gender, Age and Life Expectancy	53
<i>TABLE 18 ESTIMATES OF EXPECTED U.S. LIFE EXPECTANCY AT BIRTH WITH PROJECTIONS BY GENDER, 2000 AND 2020 (YEARS)</i>	54
<i>FIGURE 4 ESTIMATES OF EXPECTED U.S. LIFE EXPECTANCY AT BIRTH WITH PROJECTIONS BY GENDER, 2000-2020 (YEARS)</i>	54
EUROPEAN DEMOGRAPHICS	55
<i>TABLE 19 EUROPE POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)</i>	55
<i>FIGURE 5 EUROPE POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)</i>	55
ASIA-PACIFIC DEMOGRAPHICS	55
<i>TABLE 20 ASIA-PACIFIC POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)</i>	56
<i>FIGURE 6 ASIA-PACIFIC POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)</i>	56
Global Life Expectancy	56
<i>TABLE 21 GLOBAL LIFE EXPECTANCY AT BIRTH BY SELECTED COUNTRY, 1980 AND 2013 (YEARS)</i>	57
<i>FIGURE 7 GLOBAL LIFE EXPECTANCY AT BIRTH BY SELECTED COUNTRY, 1980 AND 2013 (YEARS)</i>	57
DONOR RECRUITMENT AND REGULATIONS	58
BLOOD SCREENING AND EVALUATION	58
METHODS FOR COLLECTING BLOOD FROM A DONOR	59
Manual Collection	59
Automated Collection	60
Plasmapheresis	60
Plateletpheresis	61
Leukopheresis	61
Red Blood Cell Apheresis	61
PLASMA COLLECTION	61

TOPIC	PAGE NO.
Commercial Nature of Plasmapheresis	62
Global Nature of the Plasma Industry	62
Plasma Fractionators	62
Distributors/Brokers	63
BLOOD TYPING AND TESTING FOR DISEASES	63
Blood Typing	63
<i>TABLE 22 TESTS ROUTINELY PERFORMED ON BLOOD DONATIONS</i>	64
<i>TABLE 23 BLOOD TYPE ANTIGEN/ANTIBODY REACTIONS</i>	65
Methods of Typing	65
Manual Blood Typing Methods	65
Slide/Tile Testing	65
Tube Testing	65
Microplate	66
Automated Blood Typing and Screening Methods	66
Blood Testing	66
Blood Storage	67
BLOOD PROCESSING	67
Preparation and Use of the Components	67
Red Blood Cell Components	67
Platelets	67
Plasma	68
BLOOD TRANSFUSIONS	68
Transfusion in the U.S.	68
Testing before Transfusion	68
Manual Crossmatch Techniques	68
Major Crossmatch	68
Minor Crossmatch	68
Antibody Screen	69
Coombs Test	69
TYPES OF TRANSFUSIONS	69
Whole Blood	69
Packed Red Blood Cells	70
Platelets	70
Leukocytes	71
Fresh Frozen Plasma (FFP)	71
<i>TABLE 24 SELECTED USES OF FFP</i>	71
Cryoprecipitate	72
Coagulation Factors	72
<i>TABLE 25 LISTING OF BLOOD PRODUCTS FOR THERAPEUTIC USE</i>	72
Immune Serum Globulin/IMIG/IGIV	73
Factor VIII	73
Factor IX and Factor IX Complex	74
Factor VIIa	74
Fibrin/Thrombin	74
Therapeutic Apheresis	74
Experimental Blood and Plasma Products	75
BLOOD MANAGEMENT ISSUES	75

TOPIC	PAGE NO.
AVAILABILITY ISSUES	76
BLOODLESS SURGERY	76
Bloodless Medicine and Surgery Hospital Directory	77
SAFETY ISSUES: RISK MANAGEMENT	81
<i>TABLE 26 FACTORS TO REDUCE RISKS OF TRANSFUSION-ASSOCIATED DISEASES</i>	82
Better Donor Screening	82
Better Viral Screening Tests	82
Get More Repeat Donors	82
Develop Better Viral Inactivation Processes	82
Selective Use of Blood Derivative Products	83
BLOOD TRANSFUSION FATALITIES	83
<i>TABLE 27 TRANSFUSION-RELATED FATALITIES BY COMPLICATION, FY2008 -FY2012</i>	84
<i>TABLE 28 FATALITIES NOT RELATED TO TRANSFUSION OR TRANSFUSION NOT RULED OUT, FY2008-FY2012</i>	84
<i>TABLE 29 POST-DONATION "NOT RULED OUT" FATALITY REPORTS BY DONATED PRODUCT, FY2008-FY2012</i>	85
CHAPTER 5 REGULATION OF THE BLOOD BUSINESS	87
REGULATION OF THE U.S. BLOOD BUSINESS	87
<i>TABLE 30 FEDERAL ORGANIZATIONS RESPONSIBLE FOR U.S. BLOOD SAFETY</i>	87
STATUTORY AUTHORITY OF THE FDA	88
Center for Biologics Evaluation and Research	89
Office of Regulatory Affairs (ORA)	90
Office of Biologics, the Division of Blood and Blood Products	90
<i>TABLE 31 FDA AUTHORITY IN REGULATING BLOOD BANKING AND BLOOD PRODUCTS</i>	91
THE MAJOR REGULATIONS AND POLICY MATTERS CONCERNING THE U.S. BLOOD SUPPLY	91
The Clinical Laboratory Improvement Act of 1988 (CLIA)	91
The FDA'S Five Layers	92
Donor Screening	92
Blood Testing	92
Donor Deferral Lists	93
Quarantine	93
Problems and Deficiencies	93
The FDA Blood Action Plan	93
Team Biologics	94
Program Alignment Action Plan for Fiscal 2015	94
Fuel, Phone Excise Taxes	94
HOW REGULATIONS ARE IMPLEMENTED	95
Inspecting Blood Banks and Plasma Collection Facilities	95
<i>TABLE 32 MAJOR AREAS OF CONCERN FOR INSPECTING BLOOD FACILITIES</i>	95
GUIDANCE FOR INDUSTRY RECOGNITION AND USE OF A STANDARD FOR THE UNIFORM LABELING OF BLOOD AND BLOOD COMPONENTS	96
OTHER ORGANIZATIONS INVOLVED IN BLOOD REGULATION	96
National Heart, Lung and Blood Institute (NHLBI)	96
Blood Diseases and Resources Program	97
Health Care Financing Administration (HCFA)	97

TOPIC	PAGE NO.
The Department of Defense	97
State Regulatory Agencies	98
VOLUNTARY REGULATION BY PROFESSIONAL AND TRADE ASSOCIATIONS	98
PPTA: Plasma Protein Therapeutics Association	98
America's Blood Centers (ABC)	99
THE EUROPEAN UNION (EU) BLOOD DIRECTIVE	99
The International Society for Blood Transfusion - ISBT 128	100
CHAPTER 6 THE GLOBAL BLOOD AND BLOOD PRODUCTS MARKET OVERVIEW	102
DRIVING FORCES OF THE INDUSTRY	102
<i>FIGURE 8 VARIABLES INFLUENCING THE DYNAMICS OF DEMAND FOR BLOOD FOR TRANSFUSION</i>	102
MARKET SUMMARY	103
<i>FIGURE 9 BLOOD MARKET COST AND PRICING ANALYSIS</i>	104
PRICING OF BLOOD	104
<i>TABLE 33 U.S. COST OF BLOOD COMPONENTS, ESTIMATED, THROUGH 2014 (\$)</i>	105
National Blood Exchange (NBE)	106
RBCs and Leukoreduced RBCs	106
Platelets	106
Random Donor Platelets	107
Fresh Frozen Plasma (FFP)	107
Cryoprecipitate	107
Washed Cells	107
Deglycerolized Cells	107
Granulocytes	107
Gamma-Irradiated Blood	108
PATTERNS OF TRANSFUSION PROCEDURES	108
Leukoreduction	108
Impact of Autologous Donations	109
Types of Autologous Transfusions	110
Risks of PABD	110
Procedure Codes for Blood Transfusions and Related Services	111
<i>TABLE 34 U.S. BLOOD TRANSFUSION AND RELATED SERVICES CODES</i>	111
CHAPTER 7 BLOOD INDUSTRY ANALYSIS	113
GLOBAL MARKETS FOR WHOLE BLOOD COLLECTIONS	113
LOCAL EFFORTS AND IMPROVEMENTS	113
Africa	114
South Africa	114
Asia	115
China	115
India	115
Japan	116
Pakistan	116
Islamic Republic of Iran	116
Sri Lanka	116
Vietnam	117
Europe	117

TOPIC	PAGE NO.
Britain	117
France	117
Germany	117
Russia	117
Montenegro	118
Netherlands	118
Switzerland	118
Turkey	118
North America and Caribbean	119
Canada	119
Haiti	119
Oceania Region	119
Australia	119
New Zealand	120
Cook Islands	120
South America	120
Argentina	120
Bolivia	120
Brazil	120
U.S. BLOOD COLLECTION DATA	121
<i>TABLE 35 U.S. BLOOD COLLECTION AND TRANSFUSION DATA, THROUGH 2019* (MILLION UNITS/PINTS)</i>	122
<i>FIGURE 10 U.S. BLOOD COLLECTION AND TRANSFUSION DATA, 2007-2019 (MILLION UNITS/PINTS)</i>	122
GLOBAL MARKETS FOR SOURCE PLASMA COLLECTIONS	123
<i>TABLE 36 ESTIMATED AND PROJECTED GLOBAL PLASMA COLLECTIONS AND VALUES, THROUGH 2019 (\$ BILLIONS, MILLIONS ML)</i>	123
<i>FIGURE 11 ESTIMATED AND PROJECTED GLOBAL PLASMA COLLECTIONS MARKET VALUE, 2013-2019 (\$ BILLIONS)</i>	124
GLOBAL MARKETS FOR BLOOD THERAPEUTICS	124
<i>TABLE 37 GLOBAL SALES OF PLASMA THERAPEUTICS*, THROUGH 2019 (\$ MILLIONS)</i>	124
<i>FIGURE 12 GLOBAL SALES OF PLASMA THERAPEUTICS*, 2011-2019 (\$ MILLIONS)</i>	125
<i>FIGURE 13 MARKET SHARE FOR PLASMA THERAPEUTIC SALES BY REGION, 2014 (%)</i>	125
PLASMA AND PLASMA-DERIVED PRODUCTS	126
Plasma Therapeutic Products	126
<i>TABLE 38 GLOBAL MARKET SIZE PLASMA THERAPEUTIC DERIVATIVES BY TYPE, THROUGH 2019 (\$ MILLIONS)</i>	126
<i>FIGURE 14 GLOBAL MARKET SIZE PLASMA THERAPEUTIC DERIVATIVES BY TYPE, 2011-2019 (\$ MILLIONS)</i>	126
ALBUMIN AND PLASMA PROTEIN FRACTION (PPF)	127
Recombinant Human Albumin	128
Albumin Market Dynamics	128
<i>TABLE 39 ALBUMIN AND PLASMA PROTEIN FRACTION (PPF) PRODUCTS (%)</i>	129
Albumin and PPF Market Size	129
<i>TABLE 40 GLOBAL MARKET FOR ALBUMIN AND PPF, THROUGH 2019 (\$ MILLIONS)</i>	130
<i>FIGURE 15 GLOBAL MARKET FOR ALBUMIN AND PPF, 2011-2019 (\$ MILLIONS)</i>	130
<i>TABLE 41 GLOBAL MARKET FOR ALBUMIN AND PPF BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	130

TOPIC	PAGE NO.
<i>FIGURE 16 GLOBAL MARKET FOR ALBUMIN AND PPF BY REGION, 2011-2019 (\$ MILLIONS)</i>	131
Albumin and PPF Market Trends	131
CLOTTING FACTORS	132
<i>TABLE 42 EXAMPLES OF COMMON BLOOD CLOTTING FACTORS</i>	132
Hemophilia	133
<i>TABLE 43 GLOBAL AND U.S. HEMOPHILIA STATISTICS</i>	133
Market Demand and Market Size	134
<i>TABLE 44 GLOBAL MARKET FOR PLASMA-DERIVED AND RECOMBINANT CLOTTING FACTORS, THROUGH 2019 (\$ MILLIONS)</i>	134
<i>FIGURE 17 GLOBAL MARKET FOR PLASMA-DERIVED AND RECOMBINANT CLOTTING FACTORS, 2011-2019 (\$ MILLIONS)</i>	134
<i>FIGURE 18 GLOBAL MARKET SHARE OF CLOTTING FACTOR SALES BY HUMAN AND RECOMBINANT PRODUCTS, 2014 (%)</i>	135
<i>TABLE 45 GLOBAL MARKET FOR PLASMA-DERIVED AND RECOMBINANT CLOTTING FACTORS BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	136
<i>FIGURE 19 GLOBAL MARKET FOR PLASMA-DERIVED AND RECOMBINANT CLOTTING FACTORS BY REGION, 2011-2019 (\$ MILLIONS)</i>	136
Factor VIII	137
<i>TABLE 46 APPROVED FACTOR VIII PRODUCTS</i>	137
<i>TABLE 47 GLOBAL MARKET SHARE FACTOR VIII COMPANIES, 2014 (%/\$ MILLIONS)</i>	139
<i>FIGURE 20 GLOBAL MARKET SHARE OF FACTOR VIII COMPANIES, 2014 (%)</i>	139
<i>FIGURE 21 GLOBAL MARKET SHARE OF FACTOR VIII SALES BY HUMAN AND RECOMBINANT PRODUCTS, 2014 (%)</i>	140
Factor IX	140
<i>TABLE 48 APPROVED FACTOR IX PRODUCTS</i>	141
<i>TABLE 49 GLOBAL MARKET SHARE FACTOR IX COMPANIES, 2014 (%/\$ MILLIONS)</i>	141
<i>FIGURE 22 GLOBAL MARKET SHARE OF FACTOR IX COMPANIES, 2014 (%)</i>	141
<i>FIGURE 23 GLOBAL MARKET SHARE OF FACTOR IX SALES BY HUMAN AND RECOMBINANT PRODUCTS, 2014 (%)</i>	142
Factor VIIa	142
Biosimilar Factor VIIa Development	143
<i>TABLE 50 APPROVED FACTOR VII PRODUCTS</i>	144
<i>TABLE 51 GLOBAL MARKET SHARE OF FACTOR IX COMPANIES, 2014 (%/\$ MILLIONS)</i>	144
<i>FIGURE 24 GLOBAL MARKET SHARE OF FACTOR IX COMPANIES, 2014 (%)</i>	144
Factor XIII	145
<i>TABLE 52 APPROVED FACTOR XIII PRODUCTS</i>	145
Prothrombin Complex Concentrates	145
<i>TABLE 53 APPROVED PROTHROMBIN COMPLEX CONCENTRATE PRODUCTS</i>	145
IMMUNOGLOBULINS	146
IVIG	146
<i>TABLE 54 SELECTED CONDITIONS TREATED BY IVIG</i>	147
<i>TABLE 55 APPROVED IMMUNOGLOBULINS</i>	148
Hyperimmunes	150
<i>TABLE 56 APPROVED HYPERIMMUNE IMMUNOGLOBULINS</i>	151
Other	152
IMIG	152
IMMUNOGLOBULIN MARKET SIZE	153

TOPIC	PAGE NO.
<i>TABLE 57 GLOBAL MARKET FOR IMMUNOGLOBULINS, THROUGH 2019 (\$ MILLIONS)</i>	153
<i>FIGURE 25 GLOBAL MARKET FOR IMMUNOGLOBULINS, 2011-2019 (\$ MILLIONS)</i>	153
<i>TABLE 58 GLOBAL MARKET FOR IMMUNOGLOBULINS BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	154
<i>FIGURE 26 GLOBAL MARKET FOR IMMUNOGLOBULINS BY REGION, 2011-2019 (\$ MILLIONS)</i>	154
Respiratory Syncytial Virus	155
Hepatitis B Immune Globulin	155
Alpha-1-Proteinase Inhibitor	156
Other Immunoglobulin Segments	156
CMV Immunoglobulin	156
Rabies Immunoglobulin	157
Rho(D) Immunoglobulin	157
Tetanus Immunoglobulin (TIG)	157
Vaccinia Immune Globulin Intravenous (VIG)	157
Varicella Immunoglobulin	158
<i>TABLE 59 GLOBAL MARKET SHARE OF IMMUNOGLOBULIN COMPANIES, 2014</i>	158
<i>FIGURE 27 GLOBAL MARKET SHARE OF IMMUNOGLOBULIN COMPANIES, 2014 (%)</i>	158
FIBRIN SEALANTS AND THROMBIN	159
<i>TABLE 60 APPROVED FIBRIN SEALANTS AND FIBRIN PRODUCTS</i>	160
Fibrin Sealants and Thrombin Market Size	160
<i>TABLE 61 GLOBAL MARKET FOR FIBRIN SEALANTS AND THROMBIN, THROUGH 2019 (\$ MILLIONS)</i>	161
<i>FIGURE 28 GLOBAL MARKET FOR FIBRIN SEALANTS AND THROMBIN, 2011- 2019 (\$ MILLIONS)</i>	161
<i>TABLE 62 GLOBAL MARKET FOR FIBRIN SEALANTS AND THROMBIN BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	161
<i>FIGURE 29 GLOBAL MARKET FOR FIBRIN SEALANTS AND THROMBIN BY REGION, 2011-2019 (\$ MILLIONS)</i>	161
<i>TABLE 63 GLOBAL MARKET SHARE OF FIBRIN SEALANTS AND THROMBIN PRODUCT COMPANIES, 2014 (%/\$ MILLIONS)</i>	162
<i>FIGURE 30 GLOBAL MARKET SHARE OF FIBRIN SEALANTS AND THROMBIN PRODUCT COMPANIES, 2014 (%)</i>	163
ANTITHROMBIN III	163
<i>TABLE 64 APPROVED ANTITHROMBIN PRODUCTS</i>	164
Antithrombin Market Size	164
<i>TABLE 65 GLOBAL MARKET FOR ANTITHROMBIN, THROUGH 2019 (\$ MILLIONS)</i>	164
<i>FIGURE 31 GLOBAL MARKET FOR ANTITHROMBIN, 2011-2019 (\$ MILLIONS)</i>	164
<i>TABLE 66 GLOBAL MARKET FOR ANTITHROMBIN BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	165
<i>FIGURE 32 GLOBAL MARKET FOR ANTITHROMBIN BY REGION, 2011-2019 (\$ MILLIONS)</i>	166
GLOBAL MARKETS FOR BLOOD TYPING AND SCREENING PRODUCTS	166
<i>TABLE 67 GLOBAL MARKETS FOR BLOOD TYPING AND SCREENING PRODUCTS BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	166
<i>FIGURE 33 GLOBAL MARKETS FOR BLOOD TYPING AND SCREENING PRODUCTS BY REGION, 2011-2019 (\$ MILLIONS)</i>	166
<i>FIGURE 34 MARKET SHARE FOR BLOOD TYPING AND SCREENING PRODUCT SALES BY REGION, 2014 (%)</i>	167

TOPIC	PAGE NO.
<i>TABLE 68 GLOBAL MARKETS FOR BLOOD TYPING AND SCREENING PRODUCTS, THROUGH 2019 (\$ MILLIONS)</i>	169
<i>FIGURE 35 GLOBAL MARKET FOR BLOOD TYPING AND SCREENING PRODUCTS, 2011-2019 (\$ MILLIONS)</i>	169
SCREENING BLOOD	169
POLYMERASE CHAIN REACTION (PCR) AMPLIFICATION	170
<i>TABLE 69 SELECTED PCR DONOR SCREENING TESTS</i>	170
NUCLEIC ACID AMPLIFICATION TEST (NAAT)	170
<i>TABLE 70 SELECTED NAT DONOR SCREENING TESTS</i>	171
IMMUNOASSAY	171
<i>TABLE 71 SELECTED IMMUNOASSAY DONOR SCREENING TESTS</i>	171
MARKET SIZE OF BLOOD TESTING PRODUCTS FOR DONOR SCREENING	173
<i>TABLE 72 GLOBAL BLOOD DONOR SCREENING TESTING MARKET BY TYPE OF TESTS, THROUGH 2019 (\$ MILLIONS)</i>	173
<i>FIGURE 36 GLOBAL BLOOD DONOR SCREENING TESTING MARKET BY TYPE OF TEST, 2011- 2019 (\$ MILLIONS)</i>	173
BLOOD TYPING	174
<i>TABLE 73 BLOOD GROUP AND RH TYPE AND COMPATIBLE BLOOD FOR TRANSFUSION</i>	175
MARKET STRUCTURE AND PARTICIPANTS	175
Manual Typing Methods	175
Automated Blood Typing	176
Beckman Coulter	176
Immucor	176
Ortho Clinical Diagnostics	177
MARKET SIZE OF BLOOD TYPING	178
<i>TABLE 74 GLOBAL BLOOD TYPING MARKET: INSTRUMENTS AND SUPPLIES BY TYPE, THROUGH 2019 (\$ MILLIONS)</i>	178
<i>FIGURE 37 GLOBAL BLOOD TYPING MARKET: INSTRUMENTS AND SUPPLIES BY TYPE, 2011-2019 (\$ MILLIONS)</i>	178
GLOBAL MARKETS FOR BLOOD PROCESSING EQUIPMENT AND ASSOCIATED PRODUCTS	179
<i>TABLE 75 GLOBAL SALES OF BLOOD COLLECTION AND PROCESSING EQUIPMENT AND DISPOSABLES, THROUGH 2019 (\$ MILLIONS)</i>	180
<i>FIGURE 38 GLOBAL SALES OF BLOOD COLLECTION AND PROCESSING EQUIPMENT AND DISPOSABLES, 2011-2019 (\$ MILLIONS)</i>	180
<i>FIGURE 39 MARKET SHARE FOR BLOOD COLLECTION AND PROCESSING EQUIPMENT AND DISPOSABLE SALES BY REGION, 2014 (%)</i>	181
<i>TABLE 76 GLOBAL MARKET FOR BLOOD AND PLASMA COLLECTION/ TRANSFUSION PRODUCTS, THROUGH 2019 (\$ MILLIONS)</i>	182
<i>FIGURE 40 GLOBAL MARKET FOR BLOOD AND PLASMA COLLECTION/ TRANSFUSION PRODUCTS, 2011-2019 (\$ MILLIONS)</i>	182
COLLECTION PRODUCTS	182
<i>TABLE 77 GLOBAL MARKET FOR BLOOD COLLECTION PRODUCTS BY TYPE, THROUGH 2019 (\$ MILLIONS)</i>	182
<i>FIGURE 41 GLOBAL MARKET FOR COLLECTION PRODUCTS BY TYPE, 2011-2019 (\$ MILLIONS)</i>	183
BLOOD AND PLASMA COLLECTION SUPPLIES	184
Plasma Collection Sets	184
Blood Bags	184

TOPIC	PAGE NO.
PLASMA AND BLOOD COLLECTION EQUIPMENT	184
Blood Salvage	185
Other Collection Equipment	185
MARKET PARTICIPANTS	185
Haemonetics	185
PCS2	185
Cymbal	186
MCS+ 8150 System	186
MCS+ 9000 System	186
Cell Saver Systems	186
OrthoPAT System	186
ACP 215 System	186
Fresenius Kabi (Fenwal Inc.)	187
Apheresis Collections	187
Autopheresis-C	187
Alyx Component Collection System	187
Amicus Separator	187
Aurora	187
Terumo BCT	188
TRANSFUSION PRODUCTS	188
<i>TABLE 78 GLOBAL MARKET FOR TRANSFUSION PRODUCTS BY TYPE, THROUGH 2019 (\$ MILLIONS)</i>	189
<i>FIGURE 42 GLOBAL MARKET FOR TRANSFUSION PRODUCTS BY TYPE, 2011-2019 (\$ MILLIONS)</i>	189
Transfusion Sets	189
Blood Filter Market	190
Transfusion Equipment	190
Accessories	190
CHAPTER 8 BLOOD RESEARCH AND DEVELOPMENT	192
DEDICATED BLOOD RESEARCH FACILITIES	192
JEROME H. HOLLAND LABORATORY (ARC)	192
NATIONAL BLOOD FOUNDATION (NBF)	192
STEM CELL RESEARCH	192
BLOOD SUBSTITUTES	193
RECOMBINANT DEVELOPMENT ACTIVITIES	194
NEW DEVELOPMENTS IN IMMUNOGLOBULINS	194
CSL BEHRING'S COMMITMENT TO CLOTTING FACTOR DEVELOPMENT	194
FIBRIN SEALANT AND GLUE DEVELOPMENTS	195
ALBUMIN AND IVIG TREATMENT FOR ALZHEIMER'S DISEASE	195
<i>TABLE 79 CLINICAL TRIAL: ALBUMIN IN ALZHEIMER'S TREATMENT</i>	195
INVESTIGATIONAL DEVICE TO HELP IMPROVE BLOOD SUPPLY SAFETY	196
THE VETERINARY BLOOD MARKET	196
<i>TABLE 80 DOG AND CAT BLOOD TYPES AND DESCRIPTIONS</i>	197
<i>TABLE 81 REGIONAL VETERINARY BLOOD BANKS</i>	197
CHAPTER 9 TECHNOLOGY	200
CLASSICAL FRACTIONATION METHODS	200

TOPIC	PAGE NO.
COHN FRACTIONATION	200
ADVANCED FRACTIONATION METHODS	200
AMPLIFICATION METHODS	201
POLYMERASE CHAIN REACTION (PCR)	201
NUCLEIC ACID AMPLIFICATION TECHNOLOGY (NAT)	201
IMMUNOASSAY	201
ENZYLE IMMUNOASSAY (EIA)	201
Basic EIA	202
<i>FIGURE 43 THE BASIC ENZYME IMMUNOASSAY (EIA) PROCESS</i>	202
Alternate EIA Methods	202
Second-Antibody Precipitation Method	202
Double-Antibody Sandwich Method	203
Reverse-Sandwich Method	203
Reverse-Sandwich Inhibition Method	203
PATENT ANALYSIS	203
<i>TABLE 82 RECENTLY ISSUED PATENTS</i>	204
<i>TABLE 83 PATENTS BY COUNTRY OF ORIGIN</i>	205
<i>TABLE 84 RECENT PATENTS BY ASSIGNEE</i>	206
FRESENIUS MEDICAL CARE	206
ORTHO-CLINICAL DIAGNOSTICS INC.	207
ABBOTT LABORATORIES	207
ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY	207
AUBURN UNIVERSITY	208
CERNER INNOVATION INC.	208
CHANGCHUN INSTITUTE OF APPLIED CHEMISTRY CHINESE ACADEMY OF SCIENCES	208
FENWAL INC.	208
GELANUS B.V.	208
MICRONICS INC.	209
NEW YORK BLOOD CENTER INC.	209
TERUMO KABUSHIKI KAISHA	209
PATENT EXAMPLES	210
RECENT PATENTS	210
Blood Transfusions: Six Patents	210
Blood Bank: Three Patents	212
Blood Donor: Three Patents	214
CHAPTER 10 FDA LICENSED BLOOD ESTABLISHMENTS	217
GUIDANCE FOR INDUSTRY RECOGNITION AND USE OF A STANDARD FOR THE UNIFORM LABELING OF BLOOD AND BLOOD COMPONENTS	217
LABELING STANDARDS	217
REPORTING REQUIREMENTS FOR LICENSED ESTABLISHMENTS	217
FDA-LICENSED ESTABLISHMENTS	217
CHAPTER 11 COMPANY PROFILES	242
ABBOTT LABORATORIES	242
<i>TABLE 85 ABBOTT'S SALES HISTORY, 2012-2014* (\$ MILLIONS)</i>	243
<i>FIGURE 44 ABBOTT'S SALES HISTORY, 2012-2014* (\$ MILLIONS)</i>	243

TOPIC	PAGE NO.
ASTRAZENECA PLC	244
TABLE 86 ASTRAZENECA'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	244
FIGURE 45 ASTRAZENECA'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	244
BAXTER INTERNATIONAL INC.	245
TABLE 87 BAXTER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	246
FIGURE 46 BAXTER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	246
BAYER AG	247
TABLE 88 BAYER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	247
FIGURE 47 BAYER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	247
BIO-RAD LABORATORIES INC.	248
TABLE 89 BIO-RAD'S SALES HISTORY, 2012-2014* (\$ THOUSANDS)	249
FIGURE 48 BIO-RAD'S SALES HISTORY, 2012-2014* (\$ THOUSANDS)	249
CSL BEHRING	249
TABLE 90 CSL LIMITED'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	250
FIGURE 49 CSL LIMITED'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	250
ENTEGRION INC.	251
GRIFOLS INTERNATIONAL, S.A./TALECRIS	251
TABLE 91 GRIFOLS' SALES HISTORY, 2012-2014* (\$ MILLIONS)	252
FIGURE 50 GRIFOLS' SALES HISTORY, 2012-2014* (\$ MILLIONS)	252
HAEMONETICS CORP.	253
TABLE 92 HAEMONETICS' SALES HISTORY, 2012-2014* (\$ MILLIONS)	253
FIGURE 51 HAEMONETICS' SALES HISTORY, 2012-2014* (\$ MILLIONS)	253
HOLOGIC INC.	254
TABLE 93 HOLOGIC'S SALES HISTORY, 2012-2014 (\$ MILLIONS)	255
FIGURE 52 HOLOGIC'S SALES HISTORY, 2012-2014 (\$ MILLIONS)	255
LFB GROUP	255
TABLE 94 LFB GROUP'S SALES HISTORY, 2012-2013 (\$ MILLIONS)	256
FIGURE 53 LFB GROUP'S SALES HISTORY, 2012-2013 (\$ MILLIONS)	256
NOVO NORDISK A/S	257
TABLE 95 NOVO NORDISK'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	257
FIGURE 54 NOVO NORDISK'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	257
OCTAPHARMA AG	258
TABLE 96 OCTAPHARMA'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	259
FIGURE 55 OCTAPHARMA'S SALES HISTORY 2012-2014* (\$ MILLIONS)	259
PFIZER INC.	259
TABLE 97 PFIZER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	260
FIGURE 56 PFIZER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	260
ROCHE HOLDING LTD.	261
TABLE 98 ROCHE'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	262
FIGURE 57 ROCHE'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	262
SANOFI S/A	262
TABLE 99 SANOFI'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	263
FIGURE 58 SANOFI'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	264
CHAPTER 12 APPENDIX: MAJOR SOURCES OF INFORMATION	266
COMPANIES	266
ABAXIS INC.	266

TOPIC	PAGE NO.
ABBOTT LABORATORIES	266
ALBUMIN BIOSCIENCE	266
ALERE INC.	266
ALFA SCIENTIFIC DESIGNS INC.	266
AMERICAN RED CROSS	267
ARKRAY INC.	267
ARYOGEN BIOPHARMA CO.	267
ASTRAZENECA PLC	267
AVIOQ INC.	267
BAXTER INTERNATIONAL INC.	268
BAYER AG	268
BECKMAN COULTER INC.	268
BECTON, DICKINSON, & CO.	268
BIOGEN IDEC	268
BIOMERIEUX FRANCE	268
BIO PRODUCTS LABORATORY LTD.	269
BIO-RAD LABORATORIES INC.	269
BIOTEST AG	269
BRISTOL-MYERS SQUIBB CO.	269
BTG INTERNATIONAL	269
BTNX INC.	269
CANGENE CORP. (SEE EMERGENT BIOSOLUTIONS)	270
CHARTER MEDICAL LTD.	270
CHURCH & DWIGHT CO. INC.	270
CSL BEHRING	270
DANAHER CORP.	270
EMERGENT BIOSOLUTIONS	270
ENTEGRION INC.	270
FORA CARE INC.	271
FRESENIUS KABI AG	271
FUJIREBIO DIAGNOSTICS INC.	271
GAMBRO INC.	271
G.E. HEALTHCARE LTD.	271
GLAXOSMITHKLINE PLC	272
GRIFOLS INTERNATIONAL, S.A.	272
HAEMONETICS CORP.	272
HAEMOTRONIC S.P.A.	272
HEMACARE CORP.	272
HEMOCUE AB	273
HOLOGIC INC.	273
IMMUCOR INC.	273
INTERNATIONAL TECHNIDYNE CORP.	273
JANT PHARMACAL CORP.	273
JOHNSON & JOHNSON	273
KEDRION S.P.A	274
LFB GROUP	274
MERIDIAN BIOSCIENCE INC.	274

TOPIC	PAGE NO.
NATIONAL GENETICS INSTITUTE	274
NEXTRON MEDICAL TECHNOLOGIES	274
NIPRO DIAGNOSTICS INC.	274
NOVA BIOMEDICAL CORP.	275
NOVARTIS AG	275
NOVO NORDISK A/S	275
NOVOZYMES BIOPHARMA DK A/S	275
OCTAPHARMA AG	275
OMRIX BIOPHARMACEUTICALS LTD. (SEE JOHNSON & JOHNSON)	275
ORASURE TECHNOLOGIES INC.	276
ORTHO CLINICAL DIAGNOSTICS INC.	276
PALL CORP.	276
PFIZER INC.	276
PHAMATECH INC.	276
PRINCETON BIOMEDITECH CORP.	276
QIAGEN N.V.	277
QUEST DIAGNOSTICS	277
QUIDEL CORP.	277
RESPONSE BIOMEDICAL CORP.	277
REVO BIOLOGICS	277
ROCHE HOLDING LTD.	277
SANOFI S/A	278
SANQUIN BLOOD SUPPLY	278
SA SCIENTIFIC LTD.	278
SEKISUI DIAGNOSTICS	278
SIEMENS MEDICAL SOLUTIONS	278
SPECTRAL DIAGNOSTICS	279
STANBIO LABORATORY	279
TAKEDA PHARMACEUTICAL CO. LTD.	279
TERUMO BCT	279
TRINITY BIOTECH PLC	279
ZEUS SCIENTIFIC INC.	279
GLOBAL BLOOD DONATION SOURCES	280
AMERICAN ASSOCIATION OF BLOOD BANKS	280
AMERICAN FRIENDS OF MAGEN DAVID ADOM	280
ARMED SERVICES BLOOD PROGRAM	280
ASSOCIATION OF VOLUNTARY ITALIAN BLOOD DONORS	280
AUSTRALIAN RED CROSS	280
CANADIAN BLOOD SERVICES	281
HEARTLAND BLOOD CENTERS	281
HONG KONG RED CROSS	281
INDIAN RED CROSS SOCIETY	281
IRISH NATIONAL BLOOD CENTRE	281
JAPANESE RED CROSS SOCIETY	282
NATIONAL BLOOD SERVICE	282
NEW ZEALAND BLOOD SERVICE	282
SOUTH AFRICAN NATIONAL BLOOD SERVICE	282

TOPIC	PAGE NO.
WORLD HEALTH ORGANIZATION	282

LIST OF TABLES

TABLE HEADING	PAGE NO.
SUMMARY TABLE GLOBAL SALES OF BLOOD PRODUCTS, THROUGH 2019 (\$ MILLIONS)	8
TABLE 1 TIMELINE OF THE BLOOD INDUSTRY	15
TABLE 2 COMPOSITION OF BLOOD	17
TABLE 3 MAJOR DISEASES CONTRACTED FROM BLOOD TRANSFUSIONS, U.S. ANALYSIS	21
TABLE 4 CBER LICENSED HIV DONOR SCREENING TESTS (LAST UPDATED JULY 2014)	23
TABLE 5 CBER-LICENSED SCREENING TESTS FOR HEPATITIS B (LAST UPDATED JULY 2014)	25
TABLE 6 CBER-LICENSED SCREENING TESTS FOR HEPATITIS C (LAST UPDATED JULY 2014)	26
TABLE 7 CBER-LICENSED SCREENING TESTS FOR HTLV-I AND HTLV-II (LAST UPDATED JULY 2014)	28
TABLE 8 CBER-LICENSED SCREENING TESTS FOR CMV (LAST UPDATED JULY 2014)	29
TABLE 9 CBER LICENSED SCREENING TESTS FOR WEST NILE (LAST UPDATED JULY 2014)	30
TABLE 10 CBER-APPROVED MANUFACTURERS FOR SYPHILIS TESTS (LAST UPDATED JULY 2014)	33
TABLE 11 CBER-LICENSED SCREENING TESTS FOR T. CRUZI (LAST UPDATED JULY 2014)	35
TABLE 12 CBER-APPROVED MANUFACTURERS FOR CHLAMYDIA SCREENING TESTS (LAST UPDATED JULY 2014)	36
TABLE 13 CBER-LICENSED SCREENING TESTS FOR GONORRHEA (LAST UPDATED JULY 2014)	37
TABLE 14 FDA-REGISTERED BLOOD ESTABLISHMENTS BY STATE ¹ AND POSSESSION	45
TABLE 15 ESTIMATED WORLD POPULATION ANNUAL GROWTH BY SELECTED AGE GROUP AND SELECTED YEARS, THROUGH 2030 (MILLIONS)	50
TABLE 16 GLOBAL POPULATION BY SELECTED COUNTRY, THROUGH 2015 (MILLIONS)	51
TABLE 17 U.S. POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)	52
TABLE 18 ESTIMATES OF EXPECTED U.S. LIFE EXPECTANCY AT BIRTH WITH PROJECTIONS BY GENDER, 2000 AND 2020 (YEARS)	54
TABLE 19 EUROPE POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)	55
TABLE 20 ASIA-PACIFIC POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)	56
TABLE 21 GLOBAL LIFE EXPECTANCY AT BIRTH BY SELECTED COUNTRY, 1980 AND 2013 (YEARS)	57
TABLE 22 TESTS ROUTINELY PERFORMED ON BLOOD DONATIONS	64
TABLE 23 BLOOD TYPE ANTIGEN/ANTIBODY REACTIONS	65
TABLE 24 SELECTED USES OF FFP	71
TABLE 25 LISTING OF BLOOD PRODUCTS FOR THERAPEUTIC USE	72
TABLE 26 FACTORS TO REDUCE RISKS OF TRANSFUSION-ASSOCIATED DISEASES	82
TABLE 27 TRANSFUSION-RELATED FATALITIES BY COMPLICATION, FY2008 -FY2012	84
TABLE 28 FATALITIES NOT RELATED TO TRANSFUSION OR TRANSFUSION NOT RULED OUT, FY2008-FY2012	84
TABLE 29 POST-DONATION "NOT RULED OUT" FATALITY REPORTS BY DONATED PRODUCT, FY2008-FY2012	85
TABLE 30 FEDERAL ORGANIZATIONS RESPONSIBLE FOR U.S. BLOOD SAFETY	87
TABLE 31 FDA AUTHORITY IN REGULATING BLOOD BANKING AND BLOOD PRODUCTS	91

TABLE HEADING	PAGE NO.
TABLE 32 MAJOR AREAS OF CONCERN FOR INSPECTING BLOOD FACILITIES	95
TABLE 33 U.S. COST OF BLOOD COMPONENTS, ESTIMATED, THROUGH 2014 (\$)	105
TABLE 34 U.S. BLOOD TRANSFUSION AND RELATED SERVICES CODES	111
TABLE 35 U.S. BLOOD COLLECTION AND TRANSFUSION DATA, THROUGH 2019* (MILLION UNITS/PINTS)	122
TABLE 36 ESTIMATED AND PROJECTED GLOBAL PLASMA COLLECTIONS AND VALUES, THROUGH 2019 (\$ BILLIONS, MILLIONS ML)	123
TABLE 37 GLOBAL SALES OF PLASMA THERAPEUTICS*, THROUGH 2019 (\$ MILLIONS)	124
TABLE 38 GLOBAL MARKET SIZE PLASMA THERAPEUTIC DERIVATIVES BY TYPE, THROUGH 2019 (\$ MILLIONS)	126
TABLE 39 ALBUMIN AND PLASMA PROTEIN FRACTION (PPF) PRODUCTS (%)	129
TABLE 40 GLOBAL MARKET FOR ALBUMIN AND PPF, THROUGH 2019 (\$ MILLIONS)	130
TABLE 41 GLOBAL MARKET FOR ALBUMIN AND PPF BY REGION, THROUGH 2019 (\$ MILLIONS)	130
TABLE 42 EXAMPLES OF COMMON BLOOD CLOTTING FACTORS	132
TABLE 43 GLOBAL AND U.S. HEMOPHILIA STATISTICS	133
TABLE 44 GLOBAL MARKET FOR PLASMA-DERIVED AND RECOMBINANT CLOTTING FACTORS, THROUGH 2019 (\$ MILLIONS)	134
TABLE 45 GLOBAL MARKET FOR PLASMA-DERIVED AND RECOMBINANT CLOTTING FACTORS BY REGION, THROUGH 2019 (\$ MILLIONS)	136
TABLE 46 APPROVED FACTOR VIII PRODUCTS	137
TABLE 47 GLOBAL MARKET SHARE FACTOR VIII COMPANIES, 2014 (%/\$ MILLIONS)	139
TABLE 48 APPROVED FACTOR IX PRODUCTS	141
TABLE 49 GLOBAL MARKET SHARE FACTOR IX COMPANIES, 2014 (%/\$ MILLIONS)	141
TABLE 50 APPROVED FACTOR VII PRODUCTS	144
TABLE 51 GLOBAL MARKET SHARE OF FACTOR IX COMPANIES, 2014 (%/\$ MILLIONS)	144
TABLE 52 APPROVED FACTOR XIII PRODUCTS	145
TABLE 53 APPROVED PROTHROMBIN COMPLEX CONCENTRATE PRODUCTS	145
TABLE 54 SELECTED CONDITIONS TREATED BY IVIG	147
TABLE 55 APPROVED IMMUNOGLOBULINS	148
TABLE 56 APPROVED HYPERIMMUNE IMMUNOGLOBULINS	151
TABLE 57 GLOBAL MARKET FOR IMMUNOGLOBULINS, THROUGH 2019 (\$ MILLIONS)	153
TABLE 58 GLOBAL MARKET FOR IMMUNOGLOBULINS BY REGION, THROUGH 2019 (\$ MILLIONS)	154
TABLE 59 GLOBAL MARKET SHARE OF IMMUNOGLOBULIN COMPANIES, 2014	158
TABLE 60 APPROVED FIBRIN SEALANTS AND FIBRIN PRODUCTS	160
TABLE 61 GLOBAL MARKET FOR FIBRIN SEALANTS AND THROMBIN, THROUGH 2019 (\$ MILLIONS)	161
TABLE 62 GLOBAL MARKET FOR FIBRIN SEALANTS AND THROMBIN BY REGION, THROUGH 2019 (\$ MILLIONS)	161
TABLE 63 GLOBAL MARKET SHARE OF FIBRIN SEALANTS AND THROMBIN PRODUCT COMPANIES, 2014 (%/\$ MILLIONS)	162
TABLE 64 APPROVED ANTITHROMBIN PRODUCTS	164
TABLE 65 GLOBAL MARKET FOR ANTITHROMBIN, THROUGH 2019 (\$ MILLIONS)	164
TABLE 66 GLOBAL MARKET FOR ANTITHROMBIN BY REGION, THROUGH 2019 (\$ MILLIONS)	165
TABLE 67 GLOBAL MARKETS FOR BLOOD TYPING AND SCREENING PRODUCTS BY REGION, THROUGH 2019 (\$ MILLIONS)	166
TABLE 68 GLOBAL MARKETS FOR BLOOD TYPING AND SCREENING PRODUCTS, THROUGH 2019 (\$ MILLIONS)	169

TABLE HEADING	PAGE NO.
TABLE 69 SELECTED PCR DONOR SCREENING TESTS	170
TABLE 70 SELECTED NAT DONOR SCREENING TESTS	171
TABLE 71 SELECTED IMMUNOASSAY DONOR SCREENING TESTS	171
TABLE 72 GLOBAL BLOOD DONOR SCREENING TESTING MARKET BY TYPE OF TESTS, THROUGH 2019 (\$ MILLIONS)	173
TABLE 73 BLOOD GROUP AND RH TYPE AND COMPATIBLE BLOOD FOR TRANSFUSION	175
TABLE 74 GLOBAL BLOOD TYPING MARKET: INSTRUMENTS AND SUPPLIES BY TYPE, THROUGH 2019 (\$ MILLIONS)	178
TABLE 75 GLOBAL SALES OF BLOOD COLLECTION AND PROCESSING EQUIPMENT AND DISPOSABLES, THROUGH 2019 (\$ MILLIONS)	180
TABLE 76 GLOBAL MARKET FOR BLOOD AND PLASMA COLLECTION/ TRANSFUSION PRODUCTS, THROUGH 2019 (\$ MILLIONS)	182
TABLE 77 GLOBAL MARKET FOR BLOOD COLLECTION PRODUCTS BY TYPE, THROUGH 2019 (\$ MILLIONS)	182
TABLE 78 GLOBAL MARKET FOR TRANSFUSION PRODUCTS BY TYPE, THROUGH 2019 (\$ MILLIONS)	189
TABLE 79 CLINICAL TRIAL: ALBUMIN IN ALZHEIMER'S TREATMENT	195
TABLE 80 DOG AND CAT BLOOD TYPES AND DESCRIPTIONS	197
TABLE 81 REGIONAL VETERINARY BLOOD BANKS	197
TABLE 82 RECENTLY ISSUED PATENTS	204
TABLE 83 PATENTS BY COUNTRY OF ORIGIN	205
TABLE 84 RECENT PATENTS BY ASSIGNEE	206
TABLE 85 ABBOTT'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	243
TABLE 86 ASTRAZENECA'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	244
TABLE 87 BAXTER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	246
TABLE 88 BAYER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	247
TABLE 89 BIO-RAD'S SALES HISTORY, 2012-2014* (\$ THOUSANDS)	249
TABLE 90 CSL LIMITED'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	250
TABLE 91 GRIFOLS' SALES HISTORY, 2012-2014* (\$ MILLIONS)	252
TABLE 92 HAEMONETICS' SALES HISTORY, 2012-2014* (\$ MILLIONS)	253
TABLE 93 HOLOGIC'S SALES HISTORY, 2012-2014 (\$ MILLIONS)	255
TABLE 94 LFB GROUP'S SALES HISTORY, 2012-2013 (\$ MILLIONS)	256
TABLE 95 NOVO NORDISK'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	257
TABLE 96 OCTAPHARMA'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	259
TABLE 97 PFIZER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	260
TABLE 98 ROCHE'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	262
TABLE 99 SANOFI'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	263

LIST OF FIGURES

FIGURE TITLE	PAGE NO.
SUMMARY FIGURE GLOBAL SALES OF BLOOD PRODUCTS, 2011-2019 (\$ MILLIONS)	8
FIGURE 1 ESTIMATED WORLD POPULATION BY SELECTED AGE GROUP AND SELECTED YEARS, 2000-2030 (MILLIONS)	50
FIGURE 2 GLOBAL POPULATION BY SELECTED COUNTRY, 2010 AND 2015 (MILLIONS)	52
FIGURE 3 U.S. POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)	53
FIGURE 4 ESTIMATES OF EXPECTED U.S. LIFE EXPECTANCY AT BIRTH WITH PROJECTIONS BY GENDER, 2000-2020 (YEARS)	54
FIGURE 5 EUROPE POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)	55
FIGURE 6 ASIA-PACIFIC POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2050 (THOUSANDS)	56
FIGURE 7 GLOBAL LIFE EXPECTANCY AT BIRTH BY SELECTED COUNTRY, 1980 AND 2013 (YEARS)	57
FIGURE 8 VARIABLES INFLUENCING THE DYNAMICS OF DEMAND FOR BLOOD FOR TRANSFUSION	102
FIGURE 9 BLOOD MARKET COST AND PRICING ANALYSIS	104
FIGURE 10 U.S. BLOOD COLLECTION AND TRANSFUSION DATA, 2007-2019 (MILLION UNITS/PINTS)	122
FIGURE 11 ESTIMATED AND PROJECTED GLOBAL PLASMA COLLECTIONS MARKET VALUE, 2013-2019 (\$ BILLIONS)	124
FIGURE 12 GLOBAL SALES OF PLASMA THERAPEUTICS*, 2011-2019 (\$ MILLIONS)	125
FIGURE 13 MARKET SHARE FOR PLASMA THERAPEUTIC SALES BY REGION, 2014 (%)	125
FIGURE 14 GLOBAL MARKET SIZE PLASMA THERAPEUTIC DERIVATIVES BY TYPE, 2011-2019 (\$ MILLIONS)	126
FIGURE 15 GLOBAL MARKET FOR ALBUMIN AND PPF, 2011-2019 (\$ MILLIONS)	130
FIGURE 16 GLOBAL MARKET FOR ALBUMIN AND PPF BY REGION, 2011-2019 (\$ MILLIONS)	131
FIGURE 17 GLOBAL MARKET FOR PLASMA-DERIVED AND RECOMBINANT CLOTTING FACTORS, 2011-2019 (\$ MILLIONS)	134
FIGURE 18 GLOBAL MARKET SHARE OF CLOTTING FACTOR SALES BY HUMAN AND RECOMBINANT PRODUCTS, 2014 (%)	135
FIGURE 19 GLOBAL MARKET FOR PLASMA-DERIVED AND RECOMBINANT CLOTTING FACTORS BY REGION, 2011-2019 (\$ MILLIONS)	136
FIGURE 20 GLOBAL MARKET SHARE OF FACTOR VIII COMPANIES, 2014 (%)	139
FIGURE 21 GLOBAL MARKET SHARE OF FACTOR VIII SALES BY HUMAN AND RECOMBINANT PRODUCTS, 2014 (%)	140
FIGURE 22 GLOBAL MARKET SHARE OF FACTOR IX COMPANIES, 2014 (%)	141
FIGURE 23 GLOBAL MARKET SHARE OF FACTOR IX SALES BY HUMAN AND RECOMBINANT PRODUCTS, 2014 (%)	142
FIGURE 24 GLOBAL MARKET SHARE OF FACTOR IX COMPANIES, 2014 (%)	144
FIGURE 25 GLOBAL MARKET FOR IMMUNOGLOBULINS, 2011-2019 (\$ MILLIONS)	153
FIGURE 26 GLOBAL MARKET FOR IMMUNOGLOBULINS BY REGION, 2011-2019 (\$ MILLIONS)	154
FIGURE 27 GLOBAL MARKET SHARE OF IMMUNOGLOBULIN COMPANIES, 2014 (%)	158
FIGURE 28 GLOBAL MARKET FOR FIBRIN SEALANTS AND THROMBIN, 2011- 2019 (\$ MILLIONS)	161
FIGURE 29 GLOBAL MARKET FOR FIBRIN SEALANTS AND THROMBIN BY REGION, 2011-2019 (\$ MILLIONS)	161

FIGURE TITLE	PAGE NO.
FIGURE 30 GLOBAL MARKET SHARE OF FIBRIN SEALANTS AND THROMBIN PRODUCT COMPANIES, 2014 (%)	163
FIGURE 31 GLOBAL MARKET FOR ANTITHROMBIN, 2011-2019 (\$ MILLIONS)	164
FIGURE 32 GLOBAL MARKET FOR ANTITHROMBIN BY REGION, 2011-2019 (\$ MILLIONS)	166
FIGURE 33 GLOBAL MARKETS FOR BLOOD TYPING AND SCREENING PRODUCTS BY REGION, 2011-2019 (\$ MILLIONS)	166
FIGURE 34 MARKET SHARE FOR BLOOD TYPING AND SCREENING PRODUCT SALES BY REGION, 2014 (%)	167
FIGURE 35 GLOBAL MARKET FOR BLOOD TYPING AND SCREENING PRODUCTS, 2011-2019 (\$ MILLIONS)	169
FIGURE 36 GLOBAL BLOOD DONOR SCREENING TESTING MARKET BY TYPE OF TEST, 2011- 2019 (\$ MILLIONS)	173
FIGURE 37 GLOBAL BLOOD TYPING MARKET: INSTRUMENTS AND SUPPLIES BY TYPE, 2011-2019 (\$ MILLIONS)	178
FIGURE 38 GLOBAL SALES OF BLOOD COLLECTION AND PROCESSING EQUIPMENT AND DISPOSABLES, 2011-2019 (\$ MILLIONS)	180
FIGURE 39 MARKET SHARE FOR BLOOD COLLECTION AND PROCESSING EQUIPMENT AND DISPOSABLE SALES BY REGION, 2014 (%)	181
FIGURE 40 GLOBAL MARKET FOR BLOOD AND PLASMA COLLECTION/ TRANSFUSION PRODUCTS, 2011-2019 (\$ MILLIONS)	182
FIGURE 41 GLOBAL MARKET FOR COLLECTION PRODUCTS BY TYPE, 2011-2019 (\$ MILLIONS)	183
FIGURE 42 GLOBAL MARKET FOR TRANSFUSION PRODUCTS BY TYPE, 2011-2019 (\$ MILLIONS)	189
FIGURE 43 THE BASIC ENZYME IMMUNOASSAY (EIA) PROCESS	202
FIGURE 44 ABBOTT'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	243
FIGURE 45 ASTRAZENECA'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	244
FIGURE 46 BAXTER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	246
FIGURE 47 BAYER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	247
FIGURE 48 BIO-RAD'S SALES HISTORY, 2012-2014* (\$ THOUSANDS)	249
FIGURE 49 CSL LIMITED'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	250
FIGURE 50 GRIFOLS' SALES HISTORY, 2012-2014* (\$ MILLIONS)	252
FIGURE 51 HAEMONETICS' SALES HISTORY, 2012-2014* (\$ MILLIONS)	253
FIGURE 52 HOLOGIC'S SALES HISTORY, 2012-2014 (\$ MILLIONS)	255
FIGURE 53 LFB GROUP'S SALES HISTORY, 2012-2013 (\$ MILLIONS)	256
FIGURE 54 NOVO NORDISK'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	257
FIGURE 55 OCTAPHARMA'S SALES HISTORY 2012-2014* (\$ MILLIONS)	259
FIGURE 56 PFIZER'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	260
FIGURE 57 ROCHE'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	262
FIGURE 58 SANOFI'S SALES HISTORY, 2012-2014* (\$ MILLIONS)	264