

TriMark Publications

February 2012  
Volume: TMRPOC12-0201



**POINT OF CARE  
DIAGNOSTIC TESTING  
WORLD MARKETS**  
*(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

**TABLE OF CONTENTS**

1.	Overview	17
1.1	About This Report	17
1.2	Scope of the Report	19
1.3	Objectives	19
1.4	Methodology	19
1.5	Executive Summary	20
2.	Overview of Diagnostic Testing Point of Care	27
2.1	Key Issues in the POC Diagnostic Testing Sector	27
2.1.1	Current Market Trends and Drivers	27
2.1.2	Effectiveness of POCT	29
2.1.3	New Growth Areas for POCT	29
2.1.4	Advantages of POCT in a Clinical Setting	29
2.1.5	Pricing and Reimbursement Issues	30
2.1.6	Key Customer Segments	30
2.2	Global Point of Care Marketplace	30
2.3	Shifts from Central Lab Testing to POCT	32
2.4	Geographical Distribution	32
2.5	Challenges of POCT	35
2.6	Key Issues for POCT	36
2.6.1	Locations of POCT	36
2.6.2	Milestones in Technology Development	38
2.6.3	Drive for Decentralization from Lab to Patient	39
2.6.4	Competitive Landscape for POCT	39
2.7	The Future of POCT	40
3.	Summary Analysis of the Global POCT Market: Value, Growth Rates and Market Share	42
3.1	Global POCT Market	42
4.	Analysis of the U.S. POCT Market: Value, Growth Rates and Market Share	53
5.	Analysis of the European POCT Market: Value, Growth Rates and Market Shares	62
6.	Analysis of the POCT Markets for Japan, China and India: Value, Growth Rates and Market Share	83
6.1	Summary Analysis of the Japanese POCT Market	89
6.2	Summary Analysis of the Indian POCT Market	91
6.3	Summary Analysis of the Chinese POCT Market	94
7.	Analysis of the Rest of World (ROW) POCT Market: Value, Growth Rates and Market Share	104
7.1	Summary Analysis of the ROW POCT Market Revenues	104
7.1.1	Summary Analysis of the Argentinian POCT Market	110
7.1.2	Summary Analysis of the Australian POCT Market	111
7.1.3	Summary Analysis of the Brazilian POCT Market	111
7.1.4	Summary Analysis of the Canadian POCT Market	112
7.1.5	Summary Analysis of the Russian POCT Market	112
7.1.6	Summary Analysis of the Middle East POCT Market	113
7.1.7	Summary Analysis of the African POCT Market	114
7.1.8	Summary Analysis of the Asia (Other) POCT Market	115
7.1.9	Summary Analysis of the Latin America (Other) POCT Market	118
8.	Review of the Market Segments, Reagents and Equipment	120
8.1	Blood Glucose Monitoring	120
8.1.1	Introduction to Blood Glucose Monitoring	120

8.1.2	Types of Blood Glucose Testing	121	
8.1.2.1	Fasting Blood Sugar (FBS) or Fasting Plasma Glucose (FPG)	121	121
8.1.2.2	Two-Hour Postprandial Blood Sugar or Two-Hour PC	121	121
8.1.2.3	Random Blood Sugar (RBS)	121	
8.1.2.4	Glucose Urine Test	121	
8.1.2.5	Blood Glucose Test Strip	121	
8.1.2.6	Glycosylated Hemoglobin (HbA1C)	122	
8.1.2.7	Intravenous Glucose Tolerance Test (IVGTT)	122	
8.1.2.8	Oral Glucose Tolerance Test (OGTT)	122	
8.1.3	Segmentation of POC Blood Glucose Testing	122	
8.1.3.1	Continuous Blood Glucose Monitoring (CBGM)	122	
8.1.3.2	Self-Monitoring Blood Glucose (SMBG) Testing	123	
8.1.3.3	Minimally-Invasive and Non-Invasive Blood Glucose Testing	123	123
8.1.3.4	Emerging Glucose Monitoring Technologies	124	
8.1.3.5	Optical Transducer Technologies	124	
8.1.3.6	Transdermal Sensor Technologies	125	
8.1.3.7	Invasive Glucose Sensor Technologies	127	
8.1.4	Review of Selected POC Blood Glucose Monitoring Systems	127	127
8.1.5	Review of Company Products	131	
8.1.5.1	LifeScan	131	
8.1.5.2	Roche Accu-Chek	134	
8.1.5.3	Abbott Diabetes Care	136	
8.1.5.4	HemoCue	137	
8.1.5.5	Stanbio/GDS Technology	137	
8.1.5.6	Abaxis, Inc.	138	
8.1.5.7	Arkray (Japan)	139	
8.1.5.8	Accurex (India)	139	
8.1.5.9	Home Diagnostics, Inc.	139	
8.1.5.10	Nova Biomedical	139	
8.1.5.11	Bayer Diagnostics	140	
8.1.5.11.1	Hemoglobin A1c Measurements	141	
8.1.5.12	AgaMatrix	142	
8.1.5.13	Akray	142	
8.1.5.14	EKF Diagnostics	142	
8.1.5.15	ACON	142	
8.1.5.16	Biosite (Now Part of Alere)	143	
8.1.5.17	Siemens Healthcare Diagnostics	143	143
8.1.5.18	Infopia	143	
8.1.5.19	Diasys	143	
8.1.5.20	Quotient Dx	143	
8.1.5.21	Cholestech (Acquired by Inverness Medical Innovations, Now Named Alere)	143	143
8.1.5.22	Bio-Rad	144	
8.1.5.23	Axis-Shield	144	
8.1.5.24	Abaxis, Inc.	144	
8.1.6	Market Share for Glucose Testing	144	
8.1.7	Competitive Analysis for the Glucose POCT Sector	145	145
8.1.8	Market Analysis	146	
8.1.8.1	Market Drivers	146	
8.1.8.2	Market Restraints	146	
8.1.9	POC Glucose Testing Assay Market and Technology Trends	146	146
8.1.9.1	POC Glucose Testing Assay Market Trends	146	
8.1.9.2	POC Glucose Testing Assay Technology Trends	147	
8.1.9.3	POC Glucose Testing Assay Strategic Recommendations	147	147
8.2	Blood Gas and Electrolytes	148	
8.2.1	Background to POC Blood Gas and Electrolyte Testing	148	148
8.2.1.1	Acid-Base Balance and the Lungs	150	

8.2.1.2	Respiratory Acidosis	150	
8.2.1.3	Respiratory Alkalosis	150	
8.2.1.4	Metabolic (or Non-Respiratory) Acidosis	150	
8.2.1.5	Metabolic (or Non-Respiratory) Alkalosis	150	
8.2.1.6	Increasing Popularity of POC Blood Gas and Electrolyte Testing	151	
8.2.2	Market Segmentation (Segmentation by Type of Blood Gas Monitoring Equipment)	151	
8.2.2.1	Intermittent Blood Gas Monitoring Equipment	151	
8.2.2.2	Continuous Blood Gas Monitoring Equipment	151	
8.2.2.3	EABG Monitors	152	
8.2.2.4	IABG Monitors	152	
8.2.2.5	Portable Blood Gas Analyzers	152	
8.2.2.6	Patient-Attached On-Demand Blood Gas Analyzers	152	
8.2.3	Applications for POCT Blood Gas and Electrolyte Analyzers	153	
8.2.4	Emerging Technologies	153	
8.2.5	Whole-Blood Lactate	153	
8.2.6	Creatinine	153	
8.2.7	Review of Selected Blood Gas and Electrolyte Analyzers	154	
8.2.8	Review of Company Products	156	
8.2.8.1	Roche Corporation	156	
8.2.8.2	TechnoMedica	156	
8.2.8.3	Siemens Healthcare Diagnostics	156	
8.2.8.4	Instrumentation Laboratory	157	
8.2.8.5	Nova Biomedical	157	
8.2.8.6	Radiometer	158	
8.2.8.7	Abbott Point of Care	158	
8.2.8.8	Span Diagnostics	159	
8.2.8.9	Nexus Dx AVOXimeter Systems for CO-oximetry	159	
8.2.8.10	ITC (Nexus Dx)	160	
8.2.8.11	Alere	161	
8.2.8.12	Abaxis, Inc.	161	
8.2.8.13	Opti Medical	161	
8.2.8.14	Arkray USA	161	
8.2.9	Market Share for Blood Gas and Electrolyte Testing	162	
8.2.10	Competitive Analysis for the Blood Gas and Electrolyte Point of Care Testing Sector	162	
8.2.11	Market Analysis	163	
8.2.11.1	Market Drivers	163	
8.2.11.2	Market Restraints	164	
8.2.12	POC Blood Gas and Electrolyte Testing Assay Market and Technology Trends	165	
8.2.12.1	POC Blood Gas and Electrolyte Testing Assay Market Trends	165	
8.2.12.2	POC Blood Gas and Electrolyte Testing Assay Technology Trends	165	
8.2.12.3	POC Blood Gas and Electrolyte Testing Assay Strategic Recommendations	165	
8.3	Rapid Coagulation Tests	166	
8.3.1	Background to Rapid Coagulation Tests	166	
8.3.2	Review of Selected POC Rapid Coagulation Analyzers	172	
8.3.3	Review of Company Products	174	
8.3.3.1	Roche Diagnostics Corp.	174	
8.3.3.2	Abbott Laboratories	175	
8.3.3.3	International Technidyne Corporation Nexus DX	176	
8.3.3.4	Medtronic	178	
8.3.3.5	Alere HemoSense	178	
8.3.3.6	Helena Laboratories Point of Care	179	
8.3.3.7	Sienco, Inc.	180	
8.3.3.8	Accumetrics	181	
8.3.3.9	Alere	181	
8.3.3.10	ITC	182	
8.3.3.11	Instrumentation Laboratory's GEM PCL Plus	182	

8.3.3.12	Others	182	
8.3.3.13	Self-Monitoring Products	182	
8.3.3.14	Platelet Function and Antiplatelet Drug Assessment		182
8.3.4	Connectivity Issues	183	
8.3.5	Cost Benefits	183	
8.3.6	Quality Control Issues	184	
8.3.7	Certification for POC Coagulation Devices		184
8.3.8	D-Dimer Testing	185	
8.3.9	Market Analysis	185	
8.3.9.1	Market Share for POCT Coagulation Testing		185
8.3.9.2	Competitive Analysis of Sector Companies		186
8.3.9.3	Market Drivers	186	
8.3.9.4	Market Restraints	187	
8.3.9.5	POC Coagulation Testing Assay Market Trends		187
8.3.9.6	POC Coagulation Testing Assay Technology Trends		188
8.3.9.7	POC Coagulation Testing Assay Strategic Recommendations		188
8.3.9.8	SWOT Analysis: Summary of Strengths, Weaknesses, Opportunities and Threats in the Coagulation POC Market	189	
8.4	POC Rapid Cardiac Markers	189	
8.4.1	Background to POC Rapid Cardiac Marker Testing		190
8.4.2	Cardiac Marker Tests	191	
8.4.2.1	Creatine Kinase (CK)	191	
8.4.2.2	Myoglobin	191	
8.4.2.3	Cardiac Troponins T (TnT), I (TnI) and C (TnC)		192
8.4.2.4	C-Reactive Protein (CRP)	192	
8.4.2.5	Homocysteine	192	
8.4.3	Emerging Markers	193	
8.4.3.1	B-Type Natriuretic Peptide (BNP)		193
8.4.3.2	Myeloperoxidase (MPO)	193	
8.4.3.3	Ischemia-Modified Albumin (IMA)	193	
8.4.3.4	Glycogen Phosphorylase Isoenzyme BB (GPBB)		194
8.4.3.5	Fatty Acid-Binding Proteins (FABPs)	194	
8.4.4	Review of Selected POC Cardiac Biomarker Analyzers		194
8.4.5	Review of Company Products	196	
8.4.5.1	Alere Triage Cardiac Panel	196	
8.4.5.2	Roche Diagnostics	197	
8.4.5.3	Ani Biotech	198	
8.4.5.4	Response Biomedical Corporation		199
8.4.5.5	Siemens Healthcare Diagnostics (f/k/a Bayer Healthcare Diagnostics, Diagnostic Products Corporation and Dade Behring)	200	
8.4.5.6	Lab21 Ltd.	200	
8.4.5.7	Abbott Laboratories	200	
8.4.5.8	LifeSign (Princeton BioMediTech Corp.)		200
8.4.5.9	Mitsubishi Kagaku Iatron	200	
8.4.5.10	Alpha Scientific	201	
8.4.5.11	bioMérieux	201	
8.4.5.12	Nexus	201	
8.4.5.13	Princeton BioMeditech		201
8.4.5.14	Randox Laboratories	201	
8.4.5.15	Market Share for Cardiac Marker Testing		202
8.4.6	Market Analysis	202	
8.4.6.1	Market Drivers	202	
8.4.6.2	Market Restraints	204	
8.4.7	POC Cardiac Marker Testing Assay Market and Technology Trends		205
8.4.7.1	POC Cardiac Marker Testing Assay Market Trends		205
8.4.7.2	POC Cardiac Marker Testing Assay Technology Trends		205

8.4.7.3	POC Cardiac Marker Testing Assay Strategic Recommendations	206
8.5	POC Substance Abuse Testing	207
8.5.1	Background to POC Substance Abuse Testing	207
8.5.2	Substance Abuse Test Types	213
8.5.2.1	Urine Substance/Drug Screening	213
8.5.2.2	Hair Tests for Substance Abuse and Screening	214
8.5.2.3	Blood Tests for Substance Abuse and Screening	214
8.5.2.4	Saliva Tests for Substance Abuse and Screening	214
8.5.2.5	Sweat Tests for Substance Abuse and Screening	214
8.5.3	Alcohol Abuse and Screening	215
8.5.4	Saliva Testing	215
8.5.5	Qualitative Analysis	216
8.5.5.1	Market Drivers	216
8.5.5.2	Market Restraints	216
8.5.6	Review of Selected POC Substance Abuse Analyzers	217
8.5.7	Review of Company Products	218
8.5.7.1	Alere	218
8.5.7.2	Abbott Diagnostics	219
8.5.7.3	Roche Diagnostics	219
8.5.7.4	BioScan Screening Systems, Inc.	220
8.5.7.5	American Bio Medica Corp.	220
8.5.7.6	Phamatech, Inc.	224
8.5.7.7	First Check Medical	224
8.5.7.8	OraSure	225
8.5.7.9	Avitar, Inc.	225
8.5.7.10	Concateno	225
8.5.7.11	Pathtech	225
8.5.7.12	Alfa Scientific Designs, Inc.	226
8.5.7.13	TCPI, Inc.	227
8.5.7.14	Roche	227
8.5.7.15	Biophor Diagnostics	227
8.5.7.16	Randox Laboratories	227
8.5.7.17	Branan Medical	227
8.5.7.18	Concateno	228
8.6	POC Pregnancy and Fertility Tests	229
8.6.1	Background to POC Pregnancy and Fertility Tests	229
8.6.2	Review of Selected POC Pregnancy Testing Devices	229
8.6.3	Review of Company Products	231
8.6.3.1	Quidel	231
8.6.3.2	Abbott Diagnostics	231
8.6.3.3	Alere	231
8.6.3.4	Worldwide Medical Corporation	232
8.6.3.5	Genzyme Diagnostics	232
8.6.3.6	Siemens Diagnostics	232
8.6.3.7	Orgenics	232
8.6.3.8	LifeSign	232
8.6.3.9	Stanbio	233
8.6.3.10	Market Analysis	233
8.6.3.10.1	Competitive Sector Analysis	233
8.7	Fecal Occult Blood	233
8.7.1	Background to POC Fecal Occult Blood Testing	234
8.7.2	Review of Selected POC Fecal Occult Testing Devices	236
8.7.3	Review of Company Products	238
8.7.3.1	Helena Laboratories	238
8.7.3.2	Biomerica	238
8.7.3.3	Beckman Coulter	238

8.7.3.4	Worldwide Medical	238	
8.7.3.5	Aerscher Diagnostics	239	
8.7.3.6	Enterix	239	
8.7.3.7	Medix Biochemica	239	
8.7.3.8	Orion Diagnostica	239	
8.7.3.9	ACON Laboratories' Mission FOB Reagent Strips	239	
8.7.3.10	Alere's Products	240	
8.7.3.11	Immunostics' Hema-Screen	240	
8.7.3.12	Princeton BioMeditech's BioSign iFOBT	240	
8.7.3.13	Quest Diagnostics' InSure FIT	240	
8.7.3.14	Quidel's QuickVue iFOB	240	
8.7.4	Market Share for Fecal Occult Blood Testing	240	
8.7.4.1	Company Analysis for the Fecal Occult Blood POCT Sector	240	240
8.7.5	Market Analysis	241	
8.7.5.1	Market Drivers	241	
8.7.5.2	Market Restraints	241	
8.7.5.3	POC Fecal Occult Blood Testing Assay Market and Technology Trends	241	241
8.7.5.3.1	POC Fecal Occult Blood Testing Assay Market Trends	241	
8.7.5.3.2	Fecal Occult Blood Testing Assay Technology Trends	242	
8.7.5.3.3	POC Fecal Occult Blood Testing Assay Strategic Recommendations	242	242
8.8	POC Infectious Disease Testing	243	
8.8.1	Background to POC Infectious Disease Testing	243	
8.8.2	Types of Diagnosis for Infectious Diseases	244	
8.8.2.1	Microbial Culture	244	
8.8.2.2	Microscopy	244	
8.8.2.3	Biochemical Tests	245	
8.8.2.4	Molecular Diagnostics	245	
8.8.3	Diagnostic Platforms for Infectious Diseases	246	
8.8.3.1	Centralized Laboratory Testing for Infectious Diseases	246	246
8.8.3.2	POC Testing for Infectious Diseases	246	
8.8.4	Emerging Technologies	246	
8.8.5	Qualitative Analysis	247	
8.8.5.1	Market Drivers	247	
8.8.5.2	Market Restraints	247	
8.8.6	Review of Selected POC Infectious Disease Testing Devices	247	
8.9	POC Urine Strip Testing	250	
8.9.1	Background to POC Urine Strip Testing	250	
8.9.2	Emerging Technologies	252	
8.9.3	Review of Selected POC Urine Strip Testing Devices	253	253
8.10	POC Cholesterol Testing	254	
8.10.1	Background to POC Cholesterol Testing	254	
8.10.2	POC Cholesterol Testing Devices	256	
8.10.2.1	Review of Selected POC Cholesterol Testing Devices	256	256
8.10.3	Review of Company Products	257	
8.10.3.1	Cholestech (Now Alere)	257	
8.10.3.2	Actimed Laboratories	259	
8.10.3.3	StatSite Meter	259	
8.10.3.4	Polymer Technology Systems	259	
8.10.3.5	PreMD, Inc. (f/k/a International Medical Innovations, Inc. [IMI])	259	259
8.10.3.6	Abaxis, Inc.	259	
8.10.3.7	Miraculins' PREVU Point of Care Skin Sterol Test	260	
8.10.4	Product Comparison of Leading Suppliers	260	
8.10.5	Launch Dates of Leading Products in Europe	262	
8.11	Miscellaneous POC Tests	262	
8.11.1	Triage <i>C. difficile</i> Panel	262	
8.11.2	Ketoacids	263	

8.11.3	Acetaminophen	263	
8.11.4	Estriol	263	
8.11.5	POC <i>H. pylori</i> Testing	264	
8.12	POC Vaginal Fluid pH and Vaginitis Testing		268
8.13	POC Cancer Testing	268	
8.13.1	Prostate-Specific Antigen (PSA)		268
8.13.2	Bladder Cancer	269	
8.13.3	Other Rapid Cancer Tests		272
8.14	Fetal Status (PROM)	273	
8.15	Osteoporosis	273	
8.16	Hemodynamic Monitoring		273
8.17	Heparin-Induced Thrombocytopenia		275
8.18	HIV	275	
8.18.1	Whole-Blood, Serum or Plasma-Based HIV Tests		277
8.18.1.1	Bio-Rad Laboratories	277	
8.18.1.2	Orgenics (Inverness, Now Alere)		277
8.18.1.3	StatSure Diagnostic Systems		278
8.18.1.4	Trinity Biotech	278	
8.18.1.5	Savyon Diagnostics	278	
8.18.1.6	MedPharm	278	
8.18.1.7	American Bio Medica Corp.		279
8.18.1.8	Chembio Diagnostics	279	
8.18.1.9	OraSure Technologies	279	
8.18.1.10	Alere	280	
8.18.1.11	Hema Diagnostics Systems	280	
8.18.1.12	bioLytical Laboratories' INSTI Kit		281
8.18.1.13	bioMérieux's VIKIA HIV-1/2 Test		281
8.18.1.14	Chembio Diagnostics' Dual-Path Platform Technology Products		281
8.18.1.15	Daktari Diagnostics' Daktari CD4		281
8.18.1.16	EY Laboratories' InstantCHEK		281
8.18.1.17	IND Diagnostic's One-Step Anti-HIV (1+2) Test		281
8.18.1.18	IQuum's Liat System	281	
8.18.1.19	Lab21's Biotec Tests	282	
8.18.1.20	MedMira's HIV Tests	282	
8.18.1.21	YD Diagnostics' AIDScan	282	
8.18.2	Saliva-Based HIV Tests	282	
8.18.2.1	OraSure Collection Device	283	
8.18.2.2	SureStat	284	
8.18.2.3	Calypte	284	
8.18.3	Urine-Based HIV Tests	284	
8.18.3.1	MedMira Laboratories, Inc.	284	
8.18.3.2	Medical Services International, Inc.		285
8.18.3.3	Maxim Biomedical	285	
8.18.3.4	Wampole Laboratories		285
8.19	Infectious Diseases	285	
8.19.1	<i>C. difficile</i>	285	
8.19.2	Giardia	286	
8.19.3	Dengue Fever	287	
8.19.4	Malaria Testing	287	
8.19.5	Rapid Influenza Testing		289
8.19.6	<i>Streptococcus</i> Testing	292	
8.19.7	Chlamydia	294	
8.19.8	Mononucleosis	294	
8.19.9	Rubella	296	
8.19.10	<i>Staphylococcus aureus</i> and MRSA		296
8.19.11	Hepatitis	297	

8.19.12	<i>E. coli</i> O157	300	
8.19.13	Gonorrhea Testing	300	
8.19.14	Smallpox	300	
8.19.15	SARS	301	
8.19.16	Rabies	301	
8.19.17	Tuberculosis	301	
8.19.18	Avian Flu	302	
8.19.19	West Nile Virus	303	
8.19.20	Herpes Simplex Virus Type-2	303	
8.19.21	Legionella	303	
8.19.22	RSV	303	
8.19.23	Leptospirosis	305	
8.19.24	Sexually-Transmitted Diseases	305	
8.19.25	Infant Jaundice	306	
8.19.26	Anthrax	307	
8.20	Homeland Defense (Plague and Tularemia)		309
8.21	BSE (Mad Cow Disease)	309	
8.22	Tuberculosis	309	
8.23	Typhoid	309	
8.24	Avian Flu	310	
8.25	Food Pathogens (Salmonella, Listeria, Campylobacter)		310
8.26	Ruptured Fetal Membranes	311	
8.27	Alcohol	312	
8.28	Microalbumin Testing	312	
8.29	Labor and Delivery Testing	312	
8.29.1	Alere Triage PLGF	312	
8.29.2	Amnisure	312	
8.29.3	Medix Biochemica	313	
8.30	Sperm Fertility	313	
8.31	Surgical Coagulation and Hemostasis Management		314
8.32	Respiratory Tests	314	
8.33	C-Reactive Protein	314	
9.	POCT: Growth Regulators		315
9.1	Moderators of Growth	315	
9.2	Personnel Acceptance	315	
9.3	Key People for POCT	316	
9.4	Information Management Issues	316	
9.4.1	Elements of Information Management for POCT: Information-Processing Capabilities		318
9.4.2	Data Mining	318	
9.4.3	Middleware	318	
9.4.4	Web Portals	319	
9.4.5	POCT-1A Standard	319	
9.5	Key Elements for POCT	320	
9.6	POCT and Reimbursement	320	
9.7	Effectiveness of Clinical Outcomes	322	
9.8	Rapid Near-Patient Testing in Hospitals	323	
9.9	Satellite Facilities	323	
9.10	Regionalization of Laboratory Care	324	
9.11	Requirements for POCT	325	
9.12	Locations of POC for Patient Care	326	
9.13	Benefits of POCT	327	
9.14	Cost Elements of POCT	328	
9.15	Necessary Functions in POCT	328	
9.16	Turnaround Time (TAT) for POCT	328	
9.17	Clinical Laboratory Improvement Amendments (CLIA)		329

9.18	Sexually-Transmitted Diseases in Underdeveloped Countries	331
9.19	Sources of Error in POC Testing	331
10.	Business Trends in the POC Sector	334
10.1	Sector Consolidation	334
10.2	Diagnostic Testing Growth Trends	335
10.2.1	Opportunities for Healthcare Stakeholders	336
10.3	Acquisition, License Agreements, Internal Development and Partnerships	336
10.4	Product Testing Depth in POCT	340
10.5	Government Regulation	340
10.5.1	U.S. Regulation	340
10.5.1.1	Importing Medical Devices into the U.S.	341
10.5.1.2	Exporting Medical Devices from the U.S.	342
10.5.2	E.U. Regulation	343
10.5.3	Japanese Regulation	346
10.5.4	Korean Regulation	346
10.6	Post-Filing Regulations for POC Devices	347
10.7	Exporting Unapproved POCTs	348
10.8	Analyte-Specific Reagents (“Home-Brew” Tests)	348
10.9	Medical Device Registration	349
10.10	Product Labeling	349
10.11	Punitive FDA Actions	349
10.12	CLIA '88 and State Laboratory Laws	349
10.13	Impact of Regulations on the Industry	350
10.14	Minimizing Regulatory Barriers	351
10.15	Waived Testing	353
11.	Technology Platform Innovations in POCT	354
11.1	Latest POCT Technological Platforms	354
11.1.1	Device Miniaturization and Microfluidic Technologies	354
11.1.2	Minimally-Invasive and Non-Invasive POCT Technologies	354
11.1.3	Advances in Wireless Technologies	354
11.1.4	Automation of POCT	355
11.1.5	Developments in New Genomic Technologies (Genotyping, Haplotyping and Sequencing Technologies)	355
11.1.6	Advances in Informatics Technologies	357
11.1.7	Pharmacogenetic Testing	358
11.1.8	Multi-Assay Technologies in POCT	358
11.2	Developments in Key Technologies	358
11.2.1	Medical and Biological Sensors and Sensor Systems	358
11.2.2	Recent Biosensor Product Introductions and the Latest Innovative Developments	359
11.2.2.1	Nanoscale Sensors for the Detection of Cancer Biomarkers	359
11.2.2.2	ForteBio Introduces Dip and Read Protein G Biosensor for Octet Instruments	360
11.2.2.3	ForteBio Launches New Octet RED96 System and Dip and Read Protein L Biosensor	360
11.2.2.4	AgaMatrix Europe Limited Introduces New Jazz™ Blood Glucose Meter in the U.K.	360
11.2.2.5	STMicroelectronics to Manufacture the World’s Smallest Biosensors	361
11.2.2.6	Universal Biosensors Advances POC Molecular Diagnostic Opportunity	361
11.2.2.7	Clinitek Advantus—A Semi-Automated Urine Analyzer for POC Testing	361
11.2.2.8	NOVA 16 STAT Chemistry Analyzer Offers the First All-Electrode-Based Seven-Test Chemistry Profile	361
11.3	Sensor Systems for Diagnostic Applications	362
11.4	Nanogen (The ELITech Group) Third-Generation POC Analyzer	365
11.5	Philips Development of Magnotech Technology	365
11.6	Quidel Corporation MChip, AVR Chip and F Chip	365
11.7	Sanofi-Aventis	366

12.	Data Management and Connectivity	368	
12.1	Wireless LANs	368	
12.2	Connectivity Platforms	370	
12.2.1	DataLink Data Management System	371	
12.2.2	RALS-Plus	372	
12.2.2.1	International Technidyne Corporation HEMOCHRON Signature Elite		373
12.2.2.2	Siemens Diagnostics Rapidpoint Coag	374	
12.2.2.3	Radiometer	374	
12.2.2.4	HemoCue's DM Hemoglobin	374	
12.2.2.5	Roche Diagnostics	374	
12.2.3	BD.id	375	
12.2.4	Medical Implant Communications Service (MICS)		375
12.2.5	Conworx Technology	375	
12.2.6	Lab Data Systems	375	
12.2.7	Medasys	376	
12.2.8	NoemaLife	376	
12.3	Advantages of POCT Connectivity	376	
12.3.1	Cost-Benefit Analysis of POCT and IT Connectivity		377
12.3.2	Hospital Network Issues	377	
12.4	POCT Analyzer Connectivity Software Solutions	377	
12.5	POCT2-P	379	
13.	Corporate Profiles	380	
13.1	Abaxis, Inc.	380	
13.2	Abbott Laboratories	384	
13.3	Accumetrics, Inc.	387	
13.4	AccuTech, LLC	388	
13.5	ACON Laboratories, Inc.	388	
13.6	Acrongenomics	388	
13.7	AgaMatrix	388	
13.8	Aerschler Diagnostics	389	
13.9	Akers Biosciences, Inc.	389	
13.10	Alere	390	
13.11	Alfa Scientific Designs, Inc.	394	
13.12	American Bio Medica Corporation		395
13.13	Ani Biotech Oy Ltd.	396	
13.14	Ark Therapeutics	396	
13.15	Arkray, Inc.	397	
13.16	Atonomics A/S	397	
13.17	Audit Diagnostics	397	
13.18	Augurix Diagnostics Ltd.		398
13.19	Axis-Shield	398	
13.20	Axxin	398	
13.21	Bayer Corp.	399	
13.22	Beckman Coulter	400	
13.23	BioLytical Laboratories		403
13.24	Biomerica, Inc.	403	
13.25	bioMérieux	404	
13.26	BiOracle	405	
13.27	Bio-Rad Laboratories, Inc.	405	
13.28	BioScan Screening Systems, Inc.	406	
13.29	BioSite	406	
13.30	Calmark Sweden AB	406	
13.31	Calypte Biomedical Corporation		406
13.32	Chembio Diagnostic, Inc	407	
13.33	Chempaq A/S	408	

13.34	Cholestech	408	
13.35	Claros Diagnostics	408	
13.36	CompuCyte Corporation		408
13.37	Concateno Plc	409	
13.38	Diagnostics Chemicals Ltd.		409
13.39	Dexcom	409	
13.40	Enigma Diagnostics Ltd.		409
13.41	EY Laboratoires, Inc.	410	
13.42	Eurotrol	410	
13.43	Exalenz Bioscience	411	
13.44	GenBio	411	
13.45	Genzyme Diagnostics	411	
13.46	Helena Laboratories	412	
13.47	Hema Diagnostic Systems, LLC		412
13.48	HemoCue AB	413	
13.49	HemoSense	413	
13.50	Home Diagnostics (Nipro Diagnostics)		413
13.51	IND Diagnostic	413	
13.52	Instrumentation Laboratory (IL)/Werfen Group		413
13.53	International Technidyne Corporation	414	
13.54	Jant Pharmacal Corporation	414	
13.55	Johnson & Johnson	414	
13.56	Lein Applied Diagnostics		416
13.57	LifeAssays AB	416	
13.58	LifeSign, LLC	416	
13.59	Medica	416	
13.60	Medical Automation Systems		416
13.61	Mediwatch	416	
13.62	Medix Biochemica	417	
13.63	MedMira Laboratories		417
13.64	MELA Sciences (Formerly Electro-Optical Sciences)		418
13.65	A. Menarini Diagnostics	419	
13.66	Meretek Diagnostics Group	419	
13.67	Meridian Bioscience	420	
13.68	Micronics	422	
13.69	Minimed	422	
13.70	Mitsubishi Chemical Holdings USA, Inc.		422
13.71	Mitsubishi Kagaku Iatron	423	
13.72	Nanogen (ELITech Group)	423	
13.73	New Horizons Diagnostics	424	
13.74	Nexus DX/ITC	424	
13.75	Nova Biomedical	424	
13.76	OraSure Technologies, Inc		426
13.77	Orion Diagnostica	427	
13.78	Polymedco, Inc.	428	
13.79	Polymer Technology Systems, Inc.		429
13.80	Prima Biomedical Company	429	
13.81	QBC Diagnostics	429	
13.82	Qualigen	430	
13.83	Quest Diagnostics, Inc.	430	
13.84	Quidel Corporation	431	
13.85	Radiometer Medical	435	
13.86	Response Biomedical	438	
13.87	Roche Diagnostics	439	
13.88	Savyon Diagnostics	441	
13.89	Selfcare, Inc.	443	

13.90	Shionogi & Co., Ltd.	443	
13.91	Siemens AG	443	
13.92	Guided Therapeutics, Inc. (SpectRx, Inc.)		444
13.93	Spectral Diagnostics	444	
13.94	StatSure Diagnostic Systems, Inc.		444
13.95	Strategic Diagnostics	445	
13.96	Trinity Biotech, Plc	445	
13.97	Väsamed, Inc.	448	
14.	POCT Sector Trends and Forecasts	449	
14.1	Home Care Analysis as Part of Near-Patient Testing		449
14.2	Non-Traditional Collection for POCT	449	
14.3	New Systems for Critical Care and Near-Patient Testing		449
14.4	Utility of Near-Patient Testing in Critical-Care Settings		450
14.5	Physician's Office Market	450	
14.6	Information Management Advances	451	
14.7	Test-Ordering Patterns and Demand for POCT		451
14.8	Demand for Emergency Department Services		451
14.9	Move Away from the Central Laboratory		452
14.10	Healthcare Cost Controls	453	
14.11	Mergers and Acquisitions in POCT	453	
14.12	Competition for Services	454	
14.13	Drivers of POCT	454	
14.14	Confluence of New Technology	454	
14.15	Difficulties of Design for POC Products	455	
14.16	European Hospital Structure	455	
14.17	The Biggest New Opportunities in POCT	455	
15.	Corporate Directory	456	

## INDEX OF FIGURES

Figure 2.1:	Worldwide Distribution of IVD Testing, 2011	33	
Figure 2.2:	Top 13 Country IVD Testing Markets, 2011	34	
Figure 2.3:	Company Market Share for IVD Testing Markets, 2011	35	
Figure 3.1:	Total Global POCT Market, 2008-2018	43	
Figure 3.2:	Worldwide Distribution of POCT, 2011	51	
Figure 3.3:	Summary of Global POCT Markets by Market Segment, 2011	52	
Figure 4.1:	U.S. Revenues for POCT Market, 2008-2018	53	
Figure 4.2:	Summary of U.S. POCT Markets by Market Segment, 2011	61	
Figure 5.1:	European Revenues for POCT Market, 2008-2018	69	
Figure 6.1:	Summary Analysis of Japanese, Chinese and Indian POCT Market, 2008-2018	83	
Figure 6.2:	Japanese Revenues for POCT Market, 2008-2018	91	
Figure 6.3:	Indian Revenues for POCT Market, 2008-2018	94	
Figure 6.4:	Chinese Revenues for POCT Market, 2008-2018	97	
Figure 7.1:	Summary Analysis of ROW POCT Market, 2008-2018	104	
Figure 7.2:	Summary Analysis of Russian Revenues for POCT Products Market, 2008-2018	113	
Figure 7.3:	Summary Analysis of Middle East Revenues for POCT Products Market, 2008-2018	114	
Figure 7.4:	Summary Analysis of African Revenues for POCT Products Market, 2008-2018	115	
Figure 7.5:	Summary Analysis of Latin America (Other) Revenues for POCT Products Market, 2008-2018	119	
Figure 8.1:	Global POCT Share of Glucose Testing Market, 2011	144	
Figure 8.2:	Global POCT Share of Blood Gas and Electrolyte Testing Market, 2011	162	
Figure 8.3:	Global POCT Share of Coagulation Testing Market, 2011	185	
Figure 8.4:	Global POCT Share of Cardiac Marker Testing Market, 2011	202	

Figure 8.5: Global POCT Share of HIV Testing Market, 2008	277
Figure 8.6: Performance Metrics of ROM Diagnostic Methods	313
Figure 9.1: Annual Rate of Emergency Room Visits by Primary Expected Source of Payment	322
Figure 9.2: CLIA Laboratories by Certificate Types	329
Figure 10.1: Conformity Assessment Route, Annexes and Quality System Standards by IVD Device Category	344

## INDEX OF TABLES

Table 1.1: Summary of Global POCT Markets by Major Market Sub-Segment, 2011 and 2018	22
Table 1.2: Summary of U.S. POCT Markets by Major Market Sub-Segment, 2011 and 2018	22
Table 1.3: Summary of European POCT Markets by Major Market Sub-Segment, 2011 and 2018	23
Table 1.4: Summary of Asian POCT Markets by Major Market Sub-Segment, 2011 and 2018	23
Table 1.5: Summary of ROW POCT Markets by Major Market Sub-Segment, 2011 and 2018	24
Table 1.6: Worldwide POCT Market Size by Geographic Location, 2008-2018	24
Table 1.7: Global Market Share Analysis, 2011	25
Table 2.1: POCT Frequency in Hospitals	31
Table 2.2: Worldwide Distribution of IVD Testing, 2011	33
Table 2.3: Top 13 Country IVD Testing Markets, 2011	34
Table 2.4: Company Market Share for IVD Testing Markets, 2011	35
Table 2.5: Competitive Landscape for POC Diagnostic Testing	39
Table 3.1: Total Global POCT Market, 2008-2018	42
Table 3.2: Global Revenues for POC Blood Glucose Monitoring Systems, 2008-2018	43
Table 3.3: Global Revenues for POC Blood Gas and Electrolyte Analyzers, 2008-2018	44
Table 3.4: Global Revenues for POC Rapid Coagulation Analyzer Systems, 2008-2018	45
Table 3.5: Global Revenues for POC Cardiac Marker Devices, 2008-2018	46
Table 3.6: Global Revenues for POC Substance/Drug Abuse Testing Device Market, 2008-2018	46
Table 3.7: Global Revenues for POC Infectious Disease Testing Devices Market, 2008-2018	47
Table 3.8: Global Revenues for POC Urine Strip Testing Products Market, 2008-2018	47
Table 3.9: Global Revenues for POC Pregnancy Testing Devices Market, 2008-2018	48
Table 3.10: Global Revenues for POC Fecal Occult Testing Devices Market, 2008-2018	48
Table 3.11: Global Revenues for POC Cholesterol Testing Products Market, 2008-2018	49
Table 3.12: Global POCT Market Share Analysis, 2011	50
Table 3.13: Worldwide POCT Market Size by Geographic Location, 2008-2018	50
Table 3.14: Worldwide Distribution of POCT, 2011	51
Table 3.15: Summary of Global POCT Markets by Market Segment, 2011	51
Table 3.16: Worldwide POCT by Performance Location, 2011	52
Table 4.1: U.S. Revenues for POCT Market, 2008-2018	53
Table 4.2: U.S. Revenues for POC Blood Glucose Monitoring Systems, 2008-2018	54
Table 4.3: U.S. Revenues for POC Blood Gas and Electrolyte Analyzers, 2008-2018	55
Table 4.4: U.S. Revenues for POC Rapid Coagulation Analyzer Systems, 2008-2018	55
Table 4.5: U.S. Revenues for POC Cardiac Marker Devices, 2008-2018	56
Table 4.6: U.S. Manufacturer Market Share of U.S. POCT Cardiac Marker Market, 2011	56
Table 4.7: U.S. Revenues for POC Substance/Drug Abuse Testing Device Market, 2008-2018	57
Table 4.8: U.S. Revenues for POC Infectious Disease Testing Devices Market, 2008-2018	57
Table 4.9: U.S. Revenues for POC Urine Strip Testing Products Market, 2008-2018	58
Table 4.10: U.S. Revenues for POC Pregnancy Testing Devices Market, 2008-2018	58
Table 4.11: U.S. Revenues for POC Fecal Occult Testing Devices Market, 2008-2018	59
Table 4.12: U.S. Revenues for POC Cholesterol Testing Products Market, 2008-2018	59
Table 4.13: U.S. POCT Market Share Analysis, 2011	60
Table 4.14: U.S. POCT by Performance Location, 2010	60
Table 4.15: Summary of U.S. POCT Markets by Market Segment, 2011	60
Table 5.1: Models of Public-Private Partnership in Hospital Provision	65
Table 5.2: European Revenues for POCT Market, 2008-2018	68
Table 5.3: French Revenues for POCT Systems, 2008-2018	69

Table 5.4: German Revenues for POCT Systems, 2008-2018	70
Table 5.5: Italian Revenues for POCT Systems, 2008-2018	70
Table 5.6: Spanish Revenues for POCT Systems, 2008-2018	71
Table 5.7: U.K. Revenues for POCT Systems, 2008-2018	71
Table 5.8: Benelux Revenues for POCT Systems, 2008-2018	72
Table 5.9: Scandinavian Revenues for POCT Systems, 2008-2018	72
Table 5.10: Rest-of-Europe Revenues for POCT Systems, 2008-2018	73
Table 5.11: European Revenues for POC Blood Glucose Monitoring Systems, 2008-2018	74
Table 5.12: European Revenues for POC Blood Gas and Electrolyte Analyzers, 2008-2018	74
Table 5.13: European Revenues for POC Rapid Coagulation Analyzer Systems, 2008-2018	75
Table 5.14: European Revenues for POC Cardiac Marker Devices, 2008-2018	77
Table 5.15: European Revenues for POC Substance/Drug Abuse Testing Device Market, 2008-2018	78
Table 5.16: European Revenues for POC Infectious Disease Testing Devices Market, 2008-2018	79
Table 5.17: European Revenues for POC Urine Strip Testing Products Market, 2008-2018	79
Table 5.18: European Revenues for POC Pregnancy Testing Devices Market, 2008-2018	80
Table 5.19: European Revenues for POC Fecal Occult Testing Devices Market, 2008-2018	81
Table 5.20: European Revenues for POC Cholesterol Testing Products Market, 2008-2018	81
Table 5.21: European Market Share Analysis, 2011	82
Table 6.1: Summary Analysis of Japanese, Chinese and Indian POCT Market, 2008-2018	83
Table 6.2: Summary Analysis of Japanese, Chinese and Indian Revenues for POC Blood Glucose Monitoring Systems, 2008-2018	84
Table 6.3: Summary Analysis of Japanese, Chinese and Indian Revenues for POC Blood Gas and Electrolyte Analyzers, 2008-2018	84
Table 6.4: Summary Analysis of Japanese, Chinese and Indian Revenues for POC Rapid Coagulation Analyzer Systems, 2008-2018	85
Table 6.5: Summary Analysis of Japanese, Chinese and Indian Revenues for POC Cardiac Marker Devices, 2008-2018	85
Table 6.6: Summary Analysis of Japanese, Chinese and Indian Revenues for POC Substance/Drug Abuse Testing Device Market, 2008-2018	86
Table 6.7: Summary Analysis of Japanese, Chinese and Indian Revenues for POC Infectious Disease Testing Devices Market, 2008-2018	86
Table 6.8: Summary Analysis of Japanese, Chinese and Indian Revenues for POC Urine Strip Testing Products Market, 2008-2018	87
Table 6.9: Summary Analysis of Japanese, Chinese and Indian Revenues for POC Pregnancy Testing Devices Market, 2008-2018	87
Table 6.10: Summary Analysis of Japanese, Chinese and Indian Revenues for POC Fecal Occult Testing Devices Market, 2008-2018	88
Table 6.11: Summary Analysis of Japanese, Chinese and Indian Revenues for POC Cholesterol Testing Products Market, 2008-2018	88
Table 6.12: Summary Analysis of Japanese, Chinese and Indian Market Shares, 2011	89
Table 6.13: Japanese Population and Aging Demographics Forecast, 2000-2050	90
Table 6.14: Japanese Revenues for POCT Market, 2008-2018	90
Table 6.15: Indian Revenues for POCT Market, 2008-2018	94
Table 6.16: Chinese Revenues for POCT Market, 2008-2018	97
Table 7.1: Summary Analysis of ROW POCT Market, 2008-2018	104
Table 7.2: Summary Analysis of ROW Revenues for POC Blood Glucose Monitoring Systems, 2008-2018	105
Table 7.3: Summary Analysis of ROW Revenues for POC Blood Gas and Electrolyte Analyzers, 2008-2018	105
Table 7.4: Summary Analysis of ROW Revenues for POC Rapid Coagulation Analyzer Systems, 2008-2018	106
Table 7.5: Summary Analysis of ROW Revenues for POC Cardiac Marker Devices, 2008-2018	106
Table 7.6: Summary Analysis of ROW Revenues for POC Substance/Drug Abuse Testing Device Market, 2008-2018	107
Table 7.7: Summary Analysis of ROW Revenues for POC Infectious Disease Testing Devices Market, 2008-2018	107

Table 7.8: Summary Analysis of ROW Revenues for POC Urine Strip Testing Products Market, 2008-2018	108	
Table 7.9: Summary Analysis of ROW Revenues for POC Pregnancy Testing Devices Market, 2008-2018	108	
Table 7.10: Summary Analysis of ROW Revenues for POC Fecal Occult Testing Devices Market, 2008-2018	109	
Table 7.11: Summary Analysis of ROW Revenues for POC Cholesterol Testing Products Market, 2008-2018	109	
Table 7.12: Summary Analysis of ROW Market Shares, 2011	110	
Table 7.13: Summary Analysis of Argentinian Revenues for POCT Products Market, 2008-2018		110
Table 7.14: Summary Analysis of Australian Revenues for POCT Products Market, 2008-2018	111	
Table 7.15: Summary Analysis of Brazilian Revenues for POCT Products Market, 2008-2018	111	
Table 7.16: Summary Analysis of Canadian Revenues for POCT Products Market, 2008-2018	112	
Table 7.17: Summary Analysis of Russian Revenues for POCT Products Market, 2008-2018	112	
Table 7.18: Summary Analysis of Middle East Revenues for POCT Products Market, 2008-2018		113
Table 7.19: Summary Analysis of African Revenues for POCT Products Market, 2008-2018	114	
Table 7.20: Summary Analysis of Asia (Other) Revenues for POCT Products Market, 2008-2018		115
Table 7.21: Summary Analysis of Latin America (Other) Revenues for POCT Products Market, 2008-2018	118	
Table 8.1: Summary of Emerging Glucose Sensor Technologies, 2011	125	
Table 8.2: Selected POC Blood Glucose Monitoring Systems, 2011	128	
Table 8.3: Roche Diagnostics Glucose Testing Products	136	
Table 8.4: Market Share of Glucose POCT Diagnostic Testing Companies Worldwide, 2011	145	
Table 8.5: SWOT Analysis: Summary of Strengths, Weaknesses, Opportunities and Threats in the Glucose POC Market	148	
Table 8.6: Selected POC Blood Gas and Electrolyte Analyzers, 2011	155	
Table 8.7: Market Share of Blood Gas and Electrolyte POCT Diagnostic Testing Companies Worldwide, 2011	162	
Table 8.8: SWOT Analysis: Summary of Strengths, Weaknesses, Opportunities and Threats in the Blood Gas and Electrolyte POC Market	166	
Table 8.9: Selected POC Rapid Coagulation Analyzers, 2011	172	
Table 8.10: Actalyke XL	180	
Table 8.11: Actalyke Mini	180	
Table 8.12: Market Share for Coagulation POCT Diagnostic Testing Companies Worldwide, 2011	186	
Table 8.13: SWOT Analysis: Summary of Strengths, Weaknesses, Opportunities and Threats in the Coagulation POC Market	189	
Table 8.14: Selected POC Cardiac Biomarkers, 2011	195	
Table 8.15: Market Share of Cardiac Marker POCT Diagnostic Testing Companies Worldwide, 2011	202	
Table 8.16: POC Cardiac Marker Testing Market: Market Drivers Ranked in Order of Impact	204	
Table 8.17: POC Cardiac Marker Testing Market: Market Restraints Ranked in Order of Impact	205	
Table 8.18: SWOT Analysis: Summary of Strengths, Weaknesses, Opportunities and Threats in the Cardiac Marker POC Market	206	
Table 8.19: Drug Testing Needs Tier I for Rapid Serum POCT in the Emergency Department	212	
Table 8.20: Stat Urine Testing Drug Recommendations	212	
Table 8.21: Selected POC Substance/Drug Abuse Testing Devices, 2011	217	
Table 8.22: Selected POC Pregnancy Testing Devices, 2011	230	
Table 8.23: Selected POC Fecal Occult Testing Devices, 2011	236	
Table 8.24: ColoCARE Fecal Occult Blood Test	238	
Table 8.25: SWOT Analysis: Summary of Strengths, Weaknesses, Opportunities and Threats in the Fecal Occult Blood POC Market	243	
Table 8.26: Selected POC Infectious Disease Testing Devices, 2011	248	
Table 8.27: Selected POC Urine Strip Testing, 2011	253	
Table 8.28: Selected POC Cholesterol Testing Devices, 2011	257	
Table 8.29: Competitive Factors Related to HIV Tests	276	
Table 8.30: Largest POCT Diagnostic Companies Worldwide, 2008	277	
Table 8.31: Influenza Diagnostic Rapid Tests	290	
Table 8.32: Type of Hepatitis Test: Lateral Flow	299	

Table 8.33: Type of Hepatitis Test: Flow-Through	299
Table 8.34: Type of Hepatitis Test: Agglutination	300
Table 8.35: Type of Hepatitis Test: Immunoblot	300
Table 8.36: AmniSure	311
Table 9.1: Access Points	317
Table 9.2: Desktop Adapters—Four Computers	317
Table 9.3: Desktop Adapters—One Computer	317
Table 9.4: PCMCIA Adapters	317
Table 9.5: POCT1-Compliant Connectivity POC Instruments	320
Table 9.6: POCT Clinical Outcomes in Diabetic Ketoacidosis	323
Table 9.7: POCT Clinical Outcomes in Arterial Blood-Gas Measurements	323
Table 9.8: POCT in Three Hospitals—Cost Analysis with Labor Included	326
Table 9.9: POCT versus Central Lab—Cost Analysis for Glucose Testing	326
Table 9.10: CLIA Laboratories by Type of Facility	327
Table 9.11: Financial Comparison for Moderate and Waived CLIA Labs	330
Table 9.12: Top Ten CMS Survey Deficiencies for CLIA Laboratories	333
Table 10.1: Key Changes in IVD Business Structure	39
Table 11.1: Common Genotype Techniques	356
Table 12.1: Applications for Wireless LAN Technology	368
Table 12.2: Customized Reports Must Support CAP and JCAHO Requirements	371
Table 12.3: RALS-Plus POC Market Share	372
Table 12.4: Applications of RALS Connectivity with POCT Devices	373
Table 13.1: Abaxis Blood Analysis Diagnostic Tests	381
Table 13.2: Reagent Discs Offered with the Piccolo Chemistry Analyzers	382
Table 13.3: Abaxis, Inc. Financial Figures—Net Sales by Business Sector, 2008-2010	383
Table 13.4: Abaxis, Inc. Financial Figures—Net Sales by Geographic Region, 2008-2010	384
Table 13.5: Products Marketed by Abbott in the Diagnostic Market	385
Table 13.6: Abbott Laboratories Financial Figures—Net Sales by Business Sector, 2008-2010	386
Table 13.7: Abbott Laboratories Financial Figures—Net Sales by Geographic Region, 2008-2010	387
Table 13.8: Alere, Inc. Financial Figures—Net Sales by Business Sector, 2008-2010	394
Table 13.9: Alere, Inc. Financial Figures—Net Sales by Geographic Region, 2008-2010	394
Table 13.10: Bayer AG Financial Figures—Net Sales by Business Sector, 2008-2010	400
Table 13.11: Bayer AG Financial Figures—Net Sales by Geographic Region, 2008-2010	400
Table 13.12: Bio-Rad Laboratories, Inc. Financial Figures—Net Sales by Business Sector, 2008-2010	406
Table 13.13: Bio-Rad Laboratories, Inc. Financial Figures—Net Sales by Geographic Region, 2008-2010	406
Table 13.14: Johnson & Johnson Financial Figures—Net Sales by Major Medical and Diagnostics Businesses, 2008-2010	415
Table 13.15: Quidel Product Distribution and Sales, 2009 and 2010	432
Table 13.16: Danaher Corporation Financial Figures—Net Sales by Business Sector, 2008-2010	435
Table 13.17: Danaher Corporation Financial Figures—Net Sales by Geographic Region, 2008-2010	436
Table 13.18: Roche Group Financial Figures—Net Sales by Business Sector, 2008-2010	440
Table 13.19: Roche Group Financial Figures—Net Sales by Geographic Region, 2009 and 2010	441
Table 13.20: Roche Group Financial Figures—Net Sales by Sub-Division, 2008-2010	441
Table 14.1: Improvements in Achieving ED Operational Efficiency Using POCT	450
Table 14.2: Test Menu and TAT for ED	451
Table 14.3: Top Reasons Why POC Cardiac Marker Testing is Implemented in the ED	451
Table 14.4: Key Areas and Metrics that Hospitals Measure to Assess Efficiency of ED	452
Table 14.5: Estimates of Patient Costs by DRG	453

## 1. Overview

Point of care testing (POCT) enables rapid diagnostic tests to be performed while the patient is at the point of care (POC) facility where results can be obtained immediately rather than waiting hours or even days for outside lab results to arrive. POCT covers: blood glucose testing, blood gas and electrolytes analysis, rapid coagulation testing, rapid cardiac markers diagnostics, drugs of abuse screening, urine strips testing, pregnancy testing, fecal occult blood analysis, food pathogens screening, hemoglobin diagnostics, infectious disease testing and cholesterol screening. This TriMark Publications report describes the POC testing segment of the diagnostic market. An analysis of analytes that are related to the common chemical constituents of blood, plasma/serum, urine and other body fluids at the point of care of the patient are addressed.

The two most important areas where such tests are measured for immediate results in a POC setting are hospital emergency rooms and critical-care clinics. The third place where these tests are frequently measured in what is characterized as a near-patient setting is in physician's office labs (POLs). Other testing areas of interest for these analytes are satellite labs, critical-care units, neonatal intensive-care units (NICUs), intensive-care units (ICUs) and home testing locations. Home testing is not directly covered in this report except in cases when the products and companies in this market segment are also actively used in the hospital and physician's office POC settings.

This report also examines the subsections of each POC market segment, including: glucose, blood gases, coagulation, cardiac markers, drugs of abuse, infectious disease and many others. Additionally, rapid detection of food pathogens and infectious pathogens (methicillin-resistant *Staphylococcus aureus* [MRSA], herpes simplex, avian flu, West Nile virus [WNV] and typhoid) is discussed.

This examination of POCT focuses on the POC segments in important worldwide markets, such as the U.S., Japanese, European, Asian and Rest-of-the-World (ROW) markets. An extensive review of POCT in this report includes the market for clinical equipment and supplies as well as the market for screening reagents and instruments for analysis of individual components in blood, serum, urine and other body fluids. This report defines the dollar volume of sales, both worldwide and in the U.S. market, and it analyzes the factors that influence the size and the growth of the market segments. Most of the companies known to be developing instruments and reagents for the clinical POC market are examined in this study. Each company is discussed in depth with a section on the history of the company, the product line, a business and marketing analysis and a subjective commentary of the position of the company in its market.

### 1.1 About This Report

A review of analytes that are related to the chemical and cellular constituents of blood, plasma or serum at the point of care of the patient is addressed in this study. The two most important areas where such tests are measured are in the hospital and the clinic environments (the emergency department and the critical-care section). Another important place where these tests are measured is in POLs. Newer testing areas of interest for these analytes are satellite labs, corporate facilities, law enforcement agencies and home testing locations. This report's emphasis is on companies that are actively developing and marketing clinical laboratory instrumentation, reagents and supplies for performing clinical diagnostic tests in the near-patient environment. The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for POCT.
- Understanding the different sectors of POCT, looking at the hospital market segment and, separately, at a description of the instruments, reagents and supplies marketed by major companies in each segment.
- Obtaining a complete understanding of the individual POC tests, from their basic principles to their clinical applications.
- Discovering feasible market opportunities by identifying high-growth applications in different analytical diagnostic areas, emphasizing the biggest and expanding markets.
- Focusing on global industry development through an in-depth analysis of the major world markets for POC technology, including growth forecasts.
- Presenting POCT figures regarding the market's current value, market projections, market share, key players and sector growth rates. The source of this information is the most current data derived from the global diagnostic industry.

This study contains:

- A detailed analysis of recent trends in the POC marketplace.
- In-depth profiles of the leading companies with POC tools and technologies.
- A forecast for the POC market in the biotechnology and diagnostic industries.
- Views and principles on the POC industry from leading industry experts.
- An analysis of potential new POC applications in the clinical sector.
- Market predictions and trends analysis concerning U.S. expenditures on POC solutions.
- Projections of POC market sizes for European and Asian markets.
- Projections for future applications of molecular diagnostic tests in POC-related screening.
- Analysis of commercial POC business strategies.
- The latest news and merger and acquisition (M&A) developments in the POC marketplace.
- A comprehensive overview of and insight into POC business strategies.
- An in-depth examination of the subsections of each market segment, including the POLs and clinic testing.

Analysis includes charts and graphs measuring product growth and trends within the marketplace. Company-specific information, including sales figures, product pipeline status and research and development (R&D) trends, is provided. This review will also:

- Assess POC market drivers and bottlenecks from medical and scientific community perspectives.
- Discuss the potential benefits of POC for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the POC market and analyze the current size and growth of individual segments.
- Provide current and forecasted market shares by company.
- Discuss profit and business opportunities by segment.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the POC market.

The following questions will also be addressed in this analysis:

- What are the near-term business opportunities in the POC market?
- What are the current and forecasted POC market sizes in the U.S., the European Union (E.U.), Japan and other key country markets?
- What are the business models currently used by companies in the POC market?
- How will manufacturers, researchers, physicians and patients influence this market?
- What are the drivers and restraints influencing the POC market?
- What are the technologies used in POC?
- Who holds the proprietary rights to the POC market technology platforms?
- In the U.S., Japan and the E.U., what regulatory processes apply to POC technologies?
- How will new POC technologies change diagnostic screening testing paradigms?
- How will new POC technologies reduce healthcare expenditures and affect R&D spending?

The report contains:

- A comprehensive overview of the several categories of POC technology platforms that are or will be revolutionizing the use of diagnostic tests in hospitals.
- A chapter on each of the important POC categories and applications.
- Full descriptions of the technologies involved and how they differ from existing and emerging technologies.
- Analysis of the technological approaches undertaken by various competitors, as well as industry and end-user responses to these products.
- Regulatory issues and legislation affecting the use and marketing of POC products.
- Market forecasts for each category of product, including profiles of selected competitors.

## 1.2 Scope of the Report

The POCT diagnostic product markets in the U.S., Japan and Europe—the world’s three largest analytical markets—are the focus of this study. Analysis of the diagnostic and POC activity of a number of other smaller country markets is also included. Primary attention is paid to the clinical market segment and, separately, to the instruments, reagents and supplies marketed by major companies in this segment. Market size, growth rates and market components for instruments, reagents, controls and consumables used in this area are also analyzed. In general, the non-professional (home care) market for self-testing is considered an entirely different market from professional (hospitals, clinics and doctor’s offices) testing and is not considered in this report in any detailed way. Other related areas, *e.g.*, infant jaundice evaluation, anthrax detection, homeland defense testing, bovine spongiform encephalopathy (BSE, *i.e.*, Mad Cow Disease), tuberculosis and food pathogens, are discussed. The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the POCT market.

## 1.3 Objectives

The key objective of this study is to conduct a comprehensive review of the POCT market with particular emphasis on emerging trends in equipment and supplies using screening reagents and instruments for analysis of individual components in tissue samples, blood, serum or plasma. Also examined are the sub-segments of each market segment, including physician’s office labs, specialty labs (*e.g.*, NICUs) and critical-care laboratories. In addition, this report reviews a number of institutions using these forms of POCT and includes a discussion of the factors that influence their purchasing decisions. The report surveys almost all of the companies known to be marketing, manufacturing or developing instruments and reagents for the POC market.

## 1.4 Methodology

The author of this report holds a Ph.D. in biochemistry from the University of Minnesota and has had post-doctoral experience at the University of Connecticut School of Medicine. He has taught at Quinnipiac University and the Tufts School of Medicine and has been a senior scientist at Pfizer Pharmaceutical Laboratories in drug development. He also has many decades of experience in science writing and as a medical industry analyst. He has over 30 years of experience in laboratory testing and instrument and reagent development technology as a licensed clinical laboratory director, as well as extensive experience in senior-level management positions in biotech and medical service companies. The editor of this report holds a Ph.D. in biochemistry from the University of Liverpool and has many decades of experience in science writing and as a medical industry analyst.

Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites as well as from annual reports for publicly-held firms. Additional sources of information include non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities such as the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates’ databases and from TriMark’s private data stores. The information in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information or omission or the results obtained from the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

### *Primary Sources*

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects, as well as from Sector Snapshots that it publishes annually. TriMark extracts relevant data and analytics from its research as part of this data collection.

## Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations.

## TriMark Publications Report Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available databases, proprietary databases, direct meetings and personal interviews with key personnel.
- Formulating a study outline with the assigned writer, including the following:
  - 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 and 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.

## 1.5 Executive Summary

TriMark estimates that the global *in vitro* diagnostic (IVD) testing market was valued at approximately \$ [REDACTED] in [REDACTED] and that the POCT market sub-segment was valued at \$ [REDACTED] in [REDACTED], or the equivalent of [REDACTED] % of the global IVD market. It is estimated that the global POCT market will exhibit a compound annual growth rate (CAGR) of [REDACTED] % between [REDACTED] and [REDACTED]. The table below provides a summary of the global POCT market segmented by individual major market sub-segment with market values for [REDACTED] and market projections to [REDACTED]. The U.S. is recognized as the largest single market for both IVD and POCT products, valued at \$ [REDACTED] and \$ [REDACTED], respectively. The POCT sub-segment represented an estimated [REDACTED] % of the U.S. IVD market in [REDACTED]. TriMark estimates that the U.S. POCT market will exhibit a CAGR of [REDACTED] % between [REDACTED] and [REDACTED]. The next table provides a summary of the U.S. POCT market segmented by individual market major market sub-segment with market values for [REDACTED] and market projections to [REDACTED].

**Table 1.1: Summary of Global POCT Markets by Major Market Sub-Segment, [REDACTED] and [REDACTED]**

Segment	[REDACTED]	[REDACTED]	[REDACTED]
Blood Glucose Monitoring	[REDACTED]	[REDACTED]	[REDACTED]
Blood Gas and Electrolytes	[REDACTED]	[REDACTED]	[REDACTED]
Rapid Coagulation	[REDACTED]	[REDACTED]	[REDACTED]
Rapid Cardiac Markers	[REDACTED]	[REDACTED]	[REDACTED]
Substance Abuse	[REDACTED]	[REDACTED]	[REDACTED]
Infectious Diseases	[REDACTED]	[REDACTED]	[REDACTED]
Urine Strip Tests	[REDACTED]	[REDACTED]	[REDACTED]
Pregnancy Tests	[REDACTED]	[REDACTED]	[REDACTED]
Fecal Occult Testing	[REDACTED]	[REDACTED]	[REDACTED]
Cholesterol	[REDACTED]	[REDACTED]	[REDACTED]
<b>Total Testing</b>	[REDACTED]	[REDACTED]	[REDACTED]

Source: Biotechnology Associates

**Table 1.2: Summary of U.S. POCT Markets by Major Market Sub-Segment, [REDACTED] and [REDACTED]**

Segment	[REDACTED]	[REDACTED]	[REDACTED]
Blood Glucose Monitoring	[REDACTED]	[REDACTED]	[REDACTED]
Blood Gas and Electrolytes	[REDACTED]	[REDACTED]	[REDACTED]
Rapid Coagulation	[REDACTED]	[REDACTED]	[REDACTED]
Rapid Cardiac Markers	[REDACTED]	[REDACTED]	[REDACTED]
Substance Abuse	[REDACTED]	[REDACTED]	[REDACTED]
Infectious Diseases	[REDACTED]	[REDACTED]	[REDACTED]
Urine Strip Tests	[REDACTED]	[REDACTED]	[REDACTED]
Pregnancy Tests	[REDACTED]	[REDACTED]	[REDACTED]
Fecal Occult Testing	[REDACTED]	[REDACTED]	[REDACTED]
Cholesterol	[REDACTED]	[REDACTED]	[REDACTED]
<b>Total Testing</b>	[REDACTED]	[REDACTED]	[REDACTED]

Source: Biotechnology Associates

TriMark has determined that Europe represents the largest regional market for both IVD and POCT products, valued at \$ [REDACTED] and \$ [REDACTED], respectively. The POCT sub-segment represented an estimated [REDACTED]% of the European IVD market in [REDACTED]. TriMark estimates that the European POCT market will exhibit a CAGR of [REDACTED]% between [REDACTED] and [REDACTED]. Germany is widely recognized as the largest single market for both IVD and POCT products within Europe, with market values of \$ [REDACTED] and \$ [REDACTED], respectively. The hospital and healthcare services structure in Germany makes it particularly suitable for the use of POCT products, leading to the higher percentage of POCT products as part of the IVD market. The next table provides a summary of the European POCT market segmented by individual major market sub-segment with market values for [REDACTED] and market projections to [REDACTED].

**Table 1.3: Summary of European POCT Markets by Major Market Sub-Segment, [REDACTED] and [REDACTED]**

Segment	[REDACTED]	[REDACTED]	[REDACTED]
Blood Glucose Monitoring	[REDACTED]	[REDACTED]	[REDACTED]
Blood Gas and Electrolytes	[REDACTED]	[REDACTED]	[REDACTED]
Rapid Coagulation	[REDACTED]	[REDACTED]	[REDACTED]
Rapid Cardiac Markers	[REDACTED]	[REDACTED]	[REDACTED]
Substance Abuse	[REDACTED]	[REDACTED]	[REDACTED]
Infectious Diseases	[REDACTED]	[REDACTED]	[REDACTED]
Urine Strip Tests	[REDACTED]	[REDACTED]	[REDACTED]
Pregnancy Tests	[REDACTED]	[REDACTED]	[REDACTED]
Fecal Occult Testing	[REDACTED]	[REDACTED]	[REDACTED]
Cholesterol	[REDACTED]	[REDACTED]	[REDACTED]
<b>Total Testing</b>	[REDACTED]	[REDACTED]	[REDACTED]

Source: Biotechnology Associates

For the purposes of this report, Japan, China and India are included within the regional analysis of Asia. Asia represents a major market, but there are significant differences in growth rates for each of the individual countries. It is estimated that the IVD and POCT markets are valued at \$ [REDACTED] and \$ [REDACTED], respectively. The POCT sub-segment represented an estimated [REDACTED]% of the Asian IVD market in [REDACTED]. TriMark estimates that the Asian POCT market will exhibit a CAGR of [REDACTED]% between [REDACTED] and [REDACTED]. The Japanese POCT market has slowed recently and is expected to see a CAGR of [REDACTED]%; it is estimated to have been valued at \$ [REDACTED] in [REDACTED]. In contrast, the emerging markets of India and China are exhibiting higher CAGRs of [REDACTED]% and [REDACTED]%, respectively, between [REDACTED] and [REDACTED] and are valued at \$ [REDACTED] and \$ [REDACTED] in [REDACTED], respectively. The next table provides a summary of the Asian POCT market segmented by individual major market sub-segment with market values for [REDACTED] and market projections to [REDACTED].

**Table 1.4: Summary of Asian POCT Markets by Major Market Sub-Segment, [REDACTED] and [REDACTED]**

Segment	[REDACTED]	[REDACTED]	[REDACTED]
Blood Glucose Monitoring	[REDACTED]	[REDACTED]	[REDACTED]
Blood Gas and Electrolytes	[REDACTED]	[REDACTED]	[REDACTED]
Rapid Coagulation	[REDACTED]	[REDACTED]	[REDACTED]
Rapid Cardiac Markers	[REDACTED]	[REDACTED]	[REDACTED]
Substance Abuse	[REDACTED]	[REDACTED]	[REDACTED]
Infectious Diseases	[REDACTED]	[REDACTED]	[REDACTED]
Urine Strip Tests	[REDACTED]	[REDACTED]	[REDACTED]
Pregnancy Tests	[REDACTED]	[REDACTED]	[REDACTED]
Fecal Occult Testing	[REDACTED]	[REDACTED]	[REDACTED]
Cholesterol	[REDACTED]	[REDACTED]	[REDACTED]
<b>Total Testing</b>	[REDACTED]	[REDACTED]	[REDACTED]

Source: Biotechnology Associates

Although the ROW segment represents the smallest geographic region, it is nevertheless a major growth opportunity and includes the emerging markets of Brazil and Russia. Included in this regional analysis are the Middle East, Africa, other Asian countries, Argentina, Australia, Canada and other Latin American countries. TriMark has determined that the IVD market for the ROW is valued at approximately \$ [REDACTED]. As a result of the analysis carried out during the preparation of this report, TriMark has concluded that the POCT market for the ROW was valued at \$ [REDACTED] in [REDACTED]. It is predicted that the market for POCT products in the ROW will be valued at \$ [REDACTED]