



EUROPEAN POINT OF CARE DIAGNOSTIC TESTING MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

TABLE OF CONTENTS

| | | | |
|-------|--|----|----|
| 1. | Overview | 10 | |
| 1.1 | About This Report | 10 | |
| 1.2 | Scope of this Report | 10 | |
| 1.3 | Methodology | 11 | |
| 1.4 | Executive Summary | 13 | |
| 2. | Background to the European Market for Point of Care Testing (POCT) | | 17 |
| 2.1 | Background and Definition of Point of Care Testing | | 17 |
| 2.2 | POCT Application Areas | | 17 |
| 2.2.1 | POCT in the Primary Care Environment | | 17 |
| 2.2.2 | POCT in the Operating Room | | 18 |
| 2.2.3 | POCT in the Intensive Care Unit (ICU) | | 18 |
| 2.2.4 | POCT in Accident and Emergency (A&E) | | 18 |
| 2.2.5 | POCT in the Patient Transport Setting | | 18 |
| 2.2.6 | POCT in the Home Environment | | 18 |
| 2.2.7 | POCT in the Community | | 19 |
| 2.2.8 | POCT in Sports Medicine | | 19 |
| 2.2.9 | POCT in the Physician's Office Laboratory (POL)/Home Care Clinic | | 19 |
| 2.3 | Qualitative Market Analysis | | 19 |
| 2.3.1 | Market Drivers | | 19 |
| 2.3.2 | Market Restraints | | 21 |
| 2.3.3 | Advantages of POCT | | 23 |
| 2.3.4 | Disadvantages of POCT | | 23 |
| 2.4 | Regulatory Environment, Issues and Challenges | | 24 |
| 2.5 | Overview of the European Healthcare Systems | | 27 |
| 2.6 | Procurement Process of Point of Care Testing Products | | 29 |
| 2.7 | Secondary Care Structure and Organization within the E.U. | | 31 |
| 2.8 | Product Pricing Policy and Issues | | 35 |
| 2.9 | Technological Advances and Developments | | 35 |
| 2.9.1 | Device Miniaturization and Microfluidic Technologies | | 35 |
| 2.9.2 | Minimally Invasive and Non-Invasive POCT Technologies | | 35 |
| 2.9.3 | Advances in Wireless Technologies | | 36 |
| 2.9.4 | Automation of POCT | | 36 |
| 2.9.5 | Developments in New Genomic Technologies (Genotyping, Haplotyping and Sequencing Technologies) | | 36 |
| 2.9.6 | Advances in Informatics Technologies | | 38 |
| 2.9.7 | Pharmacogenetic Testing | | 39 |
| 2.9.8 | Multi Assay Technologies in POCT | | 39 |
| 2.10 | Future Trends and Developments | | 40 |
| 3. | The European Market for Blood Glucose POCT | | 41 |
| 3.1 | Background to POC Blood Glucose Testing | | 41 |
| 3.2 | Types of Blood Glucose Testing | | 42 |
| 3.2.1 | Fasting Blood Sugar (FBS) or Fasting Plasma Glucose (FPG) | | 42 |
| 3.2.2 | Two-Hour Postprandial Blood Sugar or Two-Hour PC | | 42 |
| 3.2.3 | Random Blood Sugar (RBS) | | 42 |
| 3.2.4 | Urine Glucose Test | | 42 |
| 3.2.5 | Blood Glucose Test Strip | | 42 |
| 3.2.6 | Glycosylated Hemoglobin (HbA1C) | | 43 |
| 3.2.7 | Intravenous Glucose Tolerance Test (IVGTT) | | 43 |
| 3.2.8 | Oral Glucose Tolerance Test (OGTT) | | 43 |
| 3.3 | Segmentation of POC Blood Glucose Testing | | 43 |
| 3.3.1 | Continuous Blood Glucose Monitoring (CBGM) | | 43 |
| 3.3.2 | Self-Monitoring Blood Glucose (SMBG) Testing | | 44 |

| | | |
|-----------|--|----|
| 3.3.3 | Minimally Invasive and Non-Invasive Blood Glucose Testing | 44 |
| 3.4 | Emerging Glucose Monitoring Technologies | 44 |
| 3.4.1 | Optical Transducer Technologies | 45 |
| 3.4.2 | Transdermal Sensor Technologies | 46 |
| 3.4.3 | Invasive Glucose Sensor Technologies | 47 |
| 3.5 | Review of Selected POC Blood Glucose Monitoring Systems | 47 |
| 3.6 | Market Revenue Analysis | 51 |
| 3.6.1 | European Market Revenues Analysis | 51 |
| 3.6.2 | National Market Revenue Analysis | 52 |
| 3.7 | Market Share Analysis | 53 |
| 3.7.1 | European Market Share Analysis | 53 |
| 3.7.2 | European Market Share Analysis | 54 |
| 4. | The European Market for Blood Gas and Electrolyte POCT | 58 |
| 4.1 | Background to POC Blood Gas and Electrolyte Testing | 58 |
| 4.1.1 | Acid-base Balance and the Lungs | 58 |
| 4.1.2 | Respiratory Acidosis | 58 |
| 4.1.3 | Respiratory Alkalosis | 58 |
| 4.1.4 | Metabolic (or Non-Respiratory) Acidosis | 58 |
| 4.1.5 | Metabolic (or Non-Respiratory) Alkalosis | 59 |
| 4.1.6 | Increasing Popularity of POC Blood Gas and Electrolyte Testing | 59 |
| 4.2 | Market Segmentation | 59 |
| 4.2.1 | Types of Blood Gas Monitoring Equipment | 59 |
| 4.2.1.1 | Intermittent Blood Gas Monitoring Equipment | 59 |
| 4.2.1.2 | Continuous Blood Gas Monitoring Equipment | 59 |
| 4.2.1.2.1 | Extra-Arterial Blood Gas (EABG) Monitors | 60 |
| 4.2.1.2.2 | Intra-Arterial Blood Gas (IABG) Monitors | 60 |
| 4.2.1.3 | Portable, Blood Gas Analyzers | 61 |
| 4.2.1.4 | Patient Attached, On-Demand Blood Gas Analyzers | 61 |
| 4.3 | Applications for POCT Blood Gas and Electrolyte Analyzers | 61 |
| 4.4 | Qualitative Analysis | 61 |
| 4.4.1 | Market Drivers | 61 |
| 4.4.2 | Market Restraints | 62 |
| 4.5 | Emerging Technologies | 62 |
| 4.6 | Review of Selected Blood Gas and Electrolyte Analyzers | 62 |
| 4.7 | Market Revenue Analysis | 64 |
| 4.7.1 | European Market Revenues Analysis | 64 |
| 4.7.2 | National Market Revenue Analysis | 65 |
| 4.8 | Market Share Analysis | 65 |
| 4.8.1 | European Market Share Analysis | 65 |
| 4.8.2 | National Market Share Analysis | 66 |
| 5. | The European Market for Rapid Coagulation Testing | 70 |
| 5.1 | Background to Rapid Coagulation Testing | 70 |
| 5.1.1 | Hemostasis | 70 |
| 5.1.2 | Coagulation | 70 |
| 5.1.2.1 | The Intrinsic Pathway | 71 |
| 5.1.2.2 | The Extrinsic Pathway | 71 |
| 5.1.3 | Activation of Prothrombin to Thrombin | 73 |
| 5.2 | Blood Coagulation Tests | 73 |
| 5.2.1 | Bleeding Time Tests | 73 |
| 5.2.2 | Thrombin Time | 74 |
| 5.2.3 | The Prothrombin Time (PT) Test | 74 |
| 5.2.4 | The Partial Thromboplastin Time (PPT) Test | 74 |
| 5.2.5 | The Fibrinogen Test | 75 |
| 5.2.6 | Standard Test Results | 76 |

| | | | |
|-------|---|-----|-----|
| 5.3 | Qualitative Analysis | 76 | |
| 5.3.1 | Market Drivers | 76 | |
| 5.3.2 | Market Restraints | 77 | |
| 5.4 | Review of Selected POC Rapid Coagulation Analyzers | | 77 |
| 5.5 | Market Revenue Analysis | 79 | |
| 5.5.1 | European Market Revenue Analysis | 79 | |
| 5.5.2 | National Market Revenue Analysis | 80 | |
| 5.6 | Market Share Analysis | 81 | |
| 5.6.1 | European Market Share Analysis | 81 | |
| 5.6.2 | National Market Share Analysis | 81 | |
| 6. | The European Market for POC Cardiac BioMarker Testing | | 85 |
| 6.1 | Background to POC Cardiac Markers Testing | 85 | |
| 6.2 | Cardiac Marker Tests | 85 | |
| 6.2.1 | Creatine Kinase (CK) | 85 | |
| 6.2.2 | Myoglobin | 86 | |
| 6.2.3 | Cardiac Troponins T (TnT), I (TnI) and C (TnC) | | 86 |
| 6.2.4 | C-reactive Protein (CRP) | 86 | |
| 6.2.5 | Homocysteine | 87 | |
| 6.3 | Emerging Markers | 87 | |
| 6.3.1 | B-type Natriuretic Peptide (BNP) | 87 | |
| 6.3.2 | Myeloperoxidase (MPO) | 87 | |
| 6.3.3 | Ischemia Modified Albumin (IMA) | 88 | |
| 6.3.4 | Glycogen Phosphorylase Isoenzyme BB (GPBB) | 88 | |
| 6.3.5 | Fatty Acid-Binding Proteins (FABPs) | 88 | |
| 6.4 | Qualitative Analysis | 89 | |
| 6.4.1 | Market Drivers | 89 | |
| 6.4.2 | Market Restraints | 89 | |
| 6.5 | Review of Selected POC Cardiac Biomarkers Analyzers | | 90 |
| 6.6 | Market Revenue Analysis | 91 | |
| 6.6.1 | European Market Revenue Analysis | 91 | |
| 6.6.2 | National Market Revenue Analysis | 92 | |
| 6.7 | Market Share Analysis | 93 | |
| 6.7.1 | European Market Share Analysis | 93 | |
| 6.7.2 | National Market Share Analysis | 94 | |
| 7. | The European Market for POC Substance Abuse Testing | | 98 |
| 7.1 | Background to POC Substance Abuse Testing | 98 | |
| 7.2 | Substance Abuse Test Types | 100 | |
| 7.2.1 | Urine Substance/Drug Screening | 100 | |
| 7.2.2 | Hair Tests for Substance Abuse and Screening | 101 | |
| 7.2.3 | Blood Tests for Substance Abuse and Screening | 101 | |
| 7.2.4 | Saliva Tests for Substance Abuse and Screening | 101 | |
| 7.2.5 | Sweat Tests for Substance Abuse and Screening | 101 | |
| 7.2.6 | Alcohol Abuse and Screening | 101 | |
| 7.3 | Qualitative Analysis | 102 | |
| 7.3.1 | Market Drivers | 102 | |
| 7.3.2 | Market Restraints | 103 | |
| 7.4 | Review of Selected POC Substance Abuse Analyzers | | 103 |
| 7.5 | Market Revenue Analysis | 105 | |
| 7.5.1 | European Market Revenue Analysis | 105 | |
| 7.5.2 | National Market Revenue Analysis | 105 | |
| 7.6 | Market Share Analysis | 106 | |
| 7.6.1 | European Market Share Analysis | 106 | |
| 7.6.2 | National Market Share Analysis | 107 | |

| | | |
|--------|---|-----|
| 8. | The European Market for POC Infectious Disease Testing | 111 |
| 8.1 | Background to POC Infectious Disease Testing | 111 |
| 8.2 | Types of Diagnosis for Infectious Diseases | 112 |
| 8.2.1 | Microbial Culture | 112 |
| 8.2.2 | Microscopy | 112 |
| 8.2.3 | Biochemical Tests | 112 |
| 8.2.4 | Molecular Diagnostics | 112 |
| 8.3 | Diagnostic Platforms for Infectious Diseases | 113 |
| 8.3.1 | Centralized Laboratory Testing for Infectious Diseases | 113 |
| 8.3.2 | POC Testing for Infectious Diseases | 113 |
| 8.4 | Emerging Technologies | 114 |
| 8.5 | Qualitative Analysis | 114 |
| 8.5.1 | Market Drivers | 114 |
| 8.5.2 | Market Restraints | 115 |
| 8.6 | Review of Selected POC Infectious Disease Testing Devices | 115 |
| 8.7 | Market Revenue Analysis | 117 |
| 8.7.1 | European Market Revenue Analysis | 117 |
| 8.7.2 | National Market Revenue Analysis | 118 |
| 8.8 | Market Share Analysis | 118 |
| 8.8.1 | European Market Share Analysis | 118 |
| 8.8.2 | National Market Share Analysis | 119 |
| 9. | The European Market for POC Urine Strip Testing | 123 |
| 9.1 | Background to POC Urine Strip Testing | 123 |
| 9.2 | Emerging Technologies | 125 |
| 9.3 | Review of Selected POC Urine Strip Testing | 125 |
| 9.4 | Market Revenue Analysis | 127 |
| 9.4.1 | European Market Revenue Analysis | 127 |
| 9.4.2 | National Market Revenue Analysis | 128 |
| 9.5 | Market Share Analysis | 128 |
| 9.5.1 | European Market Share Analysis | 128 |
| 9.5.2 | National Market Share Analysis | 129 |
| 10. | The European Market for POC Pregnancy Testing | 132 |
| 10.1 | Background to POC Pregnancy Testing | 132 |
| 10.2 | Review of Selected POC Pregnancy Testing Devices | 132 |
| 10.3 | Market Revenue Analysis | 134 |
| 10.3.1 | European Market Revenue Analysis | 134 |
| 10.3.2 | National Market Revenue Analysis | 134 |
| 10.4 | Market Share Analysis | 135 |
| 10.4.1 | European Market Share Analysis | 135 |
| 10.4.2 | National Market Share Analysis | 136 |
| 11. | The European Market for POC Fecal Occult Testing | 139 |
| 11.1 | Background to POC Fecal Occult Testing | 139 |
| 11.2 | Review of Selected POC Fecal Occult Testing Devices | 140 |
| 11.3 | Market Revenue Analysis | 142 |
| 11.3.1 | European Market Revenue Analysis | 142 |
| 11.3.2 | National Market Revenue Analysis | 143 |
| 11.4 | Market Share Analysis | 144 |
| 11.4.1 | European Market Share Analysis | 144 |
| 11.4.2 | National Market Share Analysis | 144 |
| 12. | The European Market for POC Cholesterol Testing | 147 |
| 12.1 | Background to POC Cholesterol Testing | 147 |
| 12.2 | POC Cholesterol Testing Devices | 148 |

| | | |
|--------|---|-----|
| 12.2.1 | Review of Selected POC Cholesterol Testing Devices | 148 |
| 12.2.2 | Product Comparison of Leading Suppliers | 149 |
| 12.2.3 | Launch Dates of Leading Products in Europe | 152 |
| 12.3 | Market Revenue Analysis | 152 |
| 12.3.1 | European Market Revenue Analysis | 152 |
| 12.3.2 | National Market Revenue Analysis | 153 |
| 12.4 | Market Share Analysis | 153 |
| 12.4.1 | European Market Share Analysis | 153 |
| 12.4.2 | National Market Share Analysis | 154 |
| 13. | Profile of Leading Suppliers | 157 |
| 13.1 | Abaxis, Inc. | 157 |
| 13.2 | Abbott Laboratories | 159 |
| 13.3 | ACON Laboratories, Inc. | 161 |
| 13.4 | AgaMatrix, Inc. | 161 |
| 13.5 | Alere, Inc. | 162 |
| 13.6 | Bayer AG | 164 |
| 13.7 | LifeScan (Johnson & Johnson) | 166 |
| 13.8 | International Technidyne Corporation (ITC) Nexus Dx (Warburg Pincus, LLC) | 167 |
| 13.9 | NOVA Biomedical | 168 |
| 13.10 | F. Hoffman-La Roche Ltd. | 168 |
| 13.11 | A Menarini Diagnostics | 170 |
| 13.12 | Medtronic, Inc. | 171 |
| 13.13 | Radiometer Medical (Danaher Corporation) | 172 |
| 13.14 | Instrumentation Laboratory (IL)/Werfen Group | 174 |
| 13.15 | Siemens | 174 |
| 14. | Glossary of Abbreviations and Acronyms | 176 |

INDEX OF FIGURES

| | | |
|-------------|--|----|
| Figure 2.1: | Available forms of Connectivity Technology for POCT Devices | 22 |
| Figure 2.2: | Conformity Assessment Route, Annexes and Quality System Standards by IVD Device Category | 25 |
| Figure 5.1: | The Coagulation Cascade | 72 |
| Figure 5.2: | Coagulation Testing | 75 |

INDEX OF TABLES

| | | |
|------------|---|----|
| Table 1.1: | European Revenue Analysis and Forecasts for POC Market, 2007-2017 | 13 |
| Table 1.2: | Segment Revenue Analysis and Forecasts for POC Market, 2007-2017 | 14 |
| Table 1.3: | European Revenue Forecasts for POC Market, 2007-2017 | 15 |
| Table 1.4: | European Market Share Analysis for POC Market, 2010 | 16 |
| Table 2.1: | Total Expenditure on Healthcare, Percentage GDP of Selected Countries, 2002-2008 | 28 |
| Table 2.2: | Models of Public-Private Partnership in Hospital Provision | 32 |
| Table 2.3: | Common Genotype Techniques | 37 |
| Table 3.1: | Summary of Emerging Glucose Sensor Technologies, 2011 | 46 |
| Table 3.2: | Selected POC Blood Glucose Monitoring Systems, 2011 | 48 |
| Table 3.3: | European Revenue Forecasts for POC Blood Glucose Monitoring Systems, 2007-2017 | 52 |
| Table 3.4: | National Revenue Forecasts by Country for POC Blood Glucose Monitoring Systems, 2007-2017 | 53 |
| Table 3.5: | European Market Share Analysis for POC Blood Glucose Monitoring Systems, 2010 | 54 |
| Table 3.6: | French Market Share Analysis for POC Blood Glucose Monitoring Systems, 2010 | 54 |
| Table 3.7: | German Market Share Analysis for POC Blood Glucose Monitoring Systems, 2010 | 55 |

| | |
|--|-----|
| Table 3.8: Italian Market Share Analysis for POC Blood Glucose Monitoring Systems, 2010 | 55 |
| Table 3.9: Spanish Market Share Analysis for POC Blood Glucose Monitoring Systems, 2010 | 55 |
| Table 3.10: U.K. Market Share Analysis for POC Blood Glucose Monitoring Systems, 2010 | 56 |
| Table 3.11: Benelux Market Share Analysis for POC Blood Glucose Monitoring Systems, 2010 | 56 |
| Table 3.12: Scandinavian Market Share Analysis for POC Blood Glucose Monitoring Systems, 2010 | 56 |
| Table 3.13: Rest-of-Europe Market Share Analysis for POC Blood Glucose Monitoring Systems, 2010 | 57 |
| Table 4.1: Selected POC Blood Gas and Electrolyte Analyzers, 2011 | 63 |
| Table 4.2: European Revenue Forecasts for POC Blood Gas Analysis Systems, 2007-2017 | 64 |
| Table 4.3: National Revenue Forecasts by Country for POC Blood Gas Analysis Systems, 2007-2017 | 65 |
| Table 4.4: European Market Share Analysis for POC Blood Gas Analysis Systems, 2010 | 66 |
| Table 4.5: French Market Share Analysis for POC Blood Gas Analysis Systems, 2010 | 67 |
| Table 4.6: German Market Share Analysis for POC Blood Gas Analysis Systems, 2010 | 67 |
| Table 4.7: Italian Market Share Analysis for POC Blood Gas Analysis Systems, 2010 | 67 |
| Table 4.8: Spanish Market Share Analysis for POC Blood Gas Analysis Systems, 2010 | 68 |
| Table 4.9: U.K. Market Share Analysis for POC Blood Gas Analysis Systems, 2010 | 68 |
| Table 4.10: Benelux Market Share Analysis for POC Blood Gas Analysis Systems, 2010 | 68 |
| Table 4.11: Scandinavian Market Share Analysis for POC Blood Gas Analysis Systems, 2010 | 69 |
| Table 4.12: Rest-of-Europe Market Share Analysis for POC Blood Gas Analysis Systems, 2010 | 69 |
| Table 5.1: Selected POC Rapid Coagulation Analyzers, 2011 | 77 |
| Table 5.2: European Revenue Forecasts for POC Rapid Coagulation Analyzer Systems, 2007-2017 | 80 |
| Table 5.3: National Revenue Forecasts by Country for POC Rapid Coagulation Analyzer Systems, 2007-2017 | 80 |
| Table 5.4: European Market Share Analysis for POC Rapid Coagulation Analyzer Systems, 2010 | 81 |
| Table 5.5: French Market Share Analysis for POC Rapid Coagulation Analyzer Systems, 2010 | 82 |
| Table 5.6: German Market Share Analysis for POC Rapid Coagulation Analyzer Systems, 2010 | 82 |
| Table 5.7: Italian Market Share Analysis for POC Rapid Coagulation Analyzer Systems, 2010 | 82 |
| Table 5.8: Spanish Market Share Analysis for POC Rapid Coagulation Analyzer Systems, 2010 | 83 |
| Table 5.9: U.K. Market Share Analysis for POC Rapid Coagulation Analyzer Systems, 2010 | 83 |
| Table 5.10: Benelux Market Share Analysis for POC Rapid Coagulation Analyzer Systems, 2010 | 83 |
| Table 5.11: Scandinavian Market Share Analysis for POC Rapid Coagulation Analyzer Systems, 2010 | 84 |
| Table 5.12: Rest-of-Europe Market Share Analysis for POC Rapid Coagulation Analyzer Systems, 2010 | 84 |
| Table 6.1: Selected POC Cardiac Biomarkers, 2011 | 90 |
| Table 6.2: European Revenue Forecasts for POC Cardiac Marker Devices, 2007-2017 | 92 |
| Table 6.3: National Revenue Forecasts by Country for POC Cardiac Marker Devices, 2007-2017 | 92 |
| Table 6.4: European Market Share Analysis for POC Cardiac Marker Devices, 2010 | 94 |
| Table 6.5: French Market Share Analysis for POC Cardiac Marker Devices, 2010 | 94 |
| Table 6.6: German Market Share Analysis for POC Cardiac Marker Devices, 2010 | 95 |
| Table 6.7: Italian Market Share Analysis for POC Cardiac Marker Devices, 2010 | 95 |
| Table 6.8: Spanish Market Share Analysis for POC Cardiac Marker Devices, 2010 | 95 |
| Table 6.9: U.K. Market Share Analysis for POC Cardiac Marker Devices, 2010 | 96 |
| Table 6.10: Benelux Market Share Analysis for POC Cardiac Marker Devices, 2010 | 96 |
| Table 6.11: Scandinavian Market Share Analysis for POC Cardiac Marker Devices, 2010 | 96 |
| Table 6.12: Rest-of-Europe Market Share Analysis for POC Cardiac Marker Devices, 2010 | 97 |
| Table 7.1: Selected POC Substance/Drug Abuse Testing Devices, 2011 | 103 |
| Table 7.2: European Revenue Forecasts for POC Substance/Drug Abuse Testing Device Market, 2007-2017 | 105 |
| Table 7.3: National Revenue Forecasts by Country for POC Substance/Drug Abuse Testing Device Market, 2007-2017 | 106 |
| Table 7.4: European Market Share Analysis for POC Substance/Drug Abuse Testing Device Market, 2010 | 107 |
| Table 7.5: French Market Share Analysis for POC Substance/Drug Abuse Testing Device Market, 2010 | 107 |
| Table 7.6: German Market Share Analysis for POC Substance/Drug Abuse Testing Device Market, 2010 | 108 |
| Table 7.7: Italian Market Share Analysis for POC Substance/Drug Abuse Testing Device Market, 2010 | 108 |
| Table 7.8: Spanish Market Share Analysis for POC Substance/Drug Abuse Testing Device Market, 2010 | 108 |
| Table 7.9: U.K. Market Share Analysis for POC Substance/Drug Abuse Testing Device Market, 2010 | 109 |
| Table 7.10: Benelux Market Share Analysis for POC Substance/Drug Abuse Testing Device Market, 2010 | 109 |

| | |
|---|-----|
| Table 7.11: Scandinavian Market Share Analysis for POC Substance/Drug Abuse Testing Device Market, 2010 | 109 |
| Table 7.12: Rest-of-Europe Market Share Analysis for POC Substance/Drug Abuse Testing Device Market, 2010 | 110 |
| Table 8.1: Selected POC Infectious Disease Testing Devices, 2011 | 115 |
| Table 8.2: European Revenue Forecasts for POC Infectious Disease Testing Devices Market, 2007-2017 | 117 |
| Table 8.3: National Revenue Forecasts by Country for POC Infectious Disease Testing Devices Market, 2007-2017 | 118 |
| Table 8.4: European Market Share Analysis for POC Infectious Disease Testing Devices, 2010 | 119 |
| Table 8.5: French Market Share Analysis for POC Infectious Disease Testing Devices, 2010 | 119 |
| Table 8.6: German Market Share Analysis for POC Infectious Disease Testing Devices, 2010 | 120 |
| Table 8.7: Italian Market Share Analysis for POC Infectious Disease Testing Devices, 2010 | 120 |
| Table 8.8: Spanish Market Share Analysis for POC Infectious Disease Testing Devices, 2010 | 120 |
| Table 8.9: U.K. Market Share Analysis for POC Infectious Disease Testing Devices, 2010 | 121 |
| Table 8.10: Benelux Market Share Analysis for POC Infectious Disease Testing Devices, 2010 | 121 |
| Table 8.11: Scandinavian Market Share Analysis for POC Infectious Disease Testing Devices, 2010 | 122 |
| Table 8.12: Rest-of-Europe Market Share Analysis for POC Infectious Disease Testing Devices, 2010 | 122 |
| Table 9.1: Selected POC Urine Strip Testing, 2011 | 126 |
| Table 9.2: European Revenue Forecasts for POC Urine Strip Testing Products Market, 2007-2017 | 127 |
| Table 9.3: National Revenue Forecasts by Country for POC Urine Strip Testing Products Market, 2007-2017 | 128 |
| Table 9.4: European Market Share Analysis for POC Urine Strip Testing Products, 2010 | 129 |
| Table 9.5: French Market Share Analysis for POC Urine Strip Testing Products, 2010 | 129 |
| Table 9.6: German Market Share Analysis for POC Urine Strip Testing Products, 2010 | 129 |
| Table 9.7: Italian Market Share Analysis for POC Urine Strip Testing Products, 2010 | 130 |
| Table 9.8: Spanish Market Share Analysis for POC Urine Strip Testing Products, 2010 | 130 |
| Table 9.9: U.K. Market Share Analysis for POC Urine Strip Testing Products, 2010 | 130 |
| Table 9.10: Benelux Market Share Analysis for POC Urine Strip Testing Products, 2010 | 131 |
| Table 9.11: Scandinavian Market Share Analysis for POC Urine Strip Testing Products, 2010 | 131 |
| Table 9.12: Rest-of-Europe Market Share Analysis for POC Urine Strip Testing Products, 2010 | 131 |
| Table 10.1: Selected POC Pregnancy Testing Devices, 2011 | 133 |
| Table 10.2: European Revenue Forecasts for POC Pregnancy Testing Devices Market, 2007-2017 | 134 |
| Table 10.3: National Revenue Forecasts by Country for POC Pregnancy Testing Devices Market, 2007-2017 | 135 |
| Table 10.4: European Market Share Analysis for POC Pregnancy Testing Devices, 2010 | 136 |
| Table 10.5: French Market Share Analysis for POC Pregnancy Testing Devices, 2010 | 136 |
| Table 10.6: German National Market Share Analysis for POC Pregnancy Testing Devices, 2010 | 136 |
| Table 10.7: Italian Market Share Analysis for POC Pregnancy Testing Devices, 2010 | 137 |
| Table 10.8: Spanish Market Share Analysis for POC Pregnancy Testing Devices, 2010 | 137 |
| Table 10.9: U.K. Market Share Analysis for POC Pregnancy Testing Devices, 2010 | 137 |
| Table 10.10: Benelux Market Share Analysis for POC Pregnancy Testing Devices, 2010 | 138 |
| Table 10.11: Scandinavian Market Share Analysis for POC Pregnancy Testing Devices, 2010 | 138 |
| Table 10.12: Rest-of-Europe Market Share Analysis for POC Pregnancy Testing Devices, 2010 | 138 |
| Table 11.1: Selected POC Fecal Occult Testing Devices, 2011 | 141 |
| Table 11.2: European Revenue Forecasts for POC Fecal Occult Testing Devices Market, 2007-2017 | 143 |
| Table 11.3: National Revenue Forecasts by Country for POC Fecal Occult Testing Devices Market, 2007-2017 | 143 |
| Table 11.4: European Market Share Analysis for POC Fecal Occult Testing Devices, 2010 | 144 |
| Table 11.5: French Market Share Analysis for POC Fecal Occult Testing Devices, 2010 | 145 |
| Table 11.6: German Market Share Analysis for POC Fecal Occult Testing Devices, 2010 | 145 |
| Table 11.7: Italian Market Share Analysis for POC Fecal Occult Testing Devices, 2010 | 145 |
| Table 11.8: Spanish Market Share Analysis for POC Fecal Occult Testing Devices, 2010 | 145 |
| Table 11.9: U.K. Market Share Analysis for POC Fecal Occult Testing Devices, 2010 | 146 |
| Table 11.10: Benelux Market Share Analysis for POC Fecal Occult Testing Devices, 2010 | 146 |
| Table 11.11: Scandinavian Market Share Analysis for POC Fecal Occult Testing Devices, 2010 | 146 |
| Table 11.12: Rest-of-Europe Market Share Analysis for POC Fecal Occult Testing Devices, 2010 | 146 |

| | |
|--|-----|
| Table 12.1: Selected POC Cholesterol Testing Devices, 2011 | 149 |
| Table 12.2: European Revenue Forecasts for POC Cholesterol Testing Products Market, 2007-2017 | 152 |
| Table 12.3: National Revenue Forecasts by Country for POC Cholesterol Testing Products Market, 2007-2017 | 153 |
| Table 12.4: European Market Share Analysis for POC Cholesterol Testing Products Market, 2010 | 154 |
| Table 12.5: French Market Share Analysis for POC Cholesterol Testing Products Market, 2010 | 154 |
| Table 12.6: German Market Share Analysis for POC Cholesterol Testing Products Market, 2010 | 154 |
| Table 12.7: Italian Market Share Analysis for POC Cholesterol Testing Products Market, 2010 | 155 |
| Table 12.8: Spanish Market Share Analysis for POC Cholesterol Testing Products Market, 2010 | 155 |
| Table 12.9: U.K. Market Share Analysis for POC Cholesterol Testing Products Market, 2010 | 155 |
| Table 12.10: Benelux Market Share Analysis for POC Cholesterol Testing Products Market, 2010 | 156 |
| Table 12.11: Scandinavian Market Share Analysis for POC Cholesterol Testing Products Market, 2010 | 156 |
| Table 12.12: Rest-of-Europe Market Share Analysis for POC Cholesterol Testing Products Market, 2010 | 156 |
| Table 13.1: Abaxis, Inc. Net Sales by Business Sector, 2008-2010 | 158 |
| Table 13.2: Abaxis, Inc. Net Sales by Geographic Region, 2008-2010 | 159 |
| Table 13.3: Abbott Laboratories Net Sales by Business Sector, 2008-2010 | 160 |
| Table 13.4: Abbott Laboratories Net Sales by Geographic Region, 2008-2010 | 160 |
| Table 13.5: Alere, Inc. Net Sales by Business Sector, 2008-2010 | 164 |
| Table 13.6: Alere, Inc. Net Sales by Geographic Region, 2008-2010 | 164 |
| Table 13.7: Bayer AG Net Sales by Business Sector, 2008-2010 | 165 |
| Table 13.8: Bayer AG Net Sales by Geographic Region, 2008-2010 | 165 |
| Table 13.9: Johnson & Johnson Net Sales by Major Medical and Diagnostics Businesses, 2008-2010 | 167 |
| Table 13.10: Roche Group Net Sales by Business Sector, 2008-2010 | 169 |
| Table 13.11: Roche Group Net Sales by Geographic Region (Pharmaceuticals), 2009 and 2010 | 170 |
| Table 13.12: Roche Group Net Sales by Sub-Division (Diagnostics), 2008-2010 | 170 |
| Table 13.13: Medtronic Net Sales by Segment, 2008-2010 | 172 |
| Table 13.14: Danaher Corporation Net Sales by Business Sector, 2008-2010 | 173 |
| Table 13.15: Danaher Corporation Net Sales by Geographic Region, 2008-2010 | 173 |

1. Overview

Point of care testing (POCT) enables rapid diagnostic tests to be performed while the patient is at the point of care facility where results can be obtained immediately, rather than waiting hours or even days for outside lab results to arrive. The purpose of this report is to analyze the European market for POCT, which is a sector of the overall European *in vitro* diagnostics (IVD) category. This study examines these clinical measurement devices and their reagents and supplies as utilized in near-patient environments like hospitals, clinics and doctor's offices. An analysis of analytes that are related to the common chemical constituents of blood, plasma or serum at the point of care of the patient is addressed. Moreover, the study defines the volume of sales and analyzes the factors that influence the size and the growth of the various European market segments. This report analyzes in detail the important sections of the point of care diagnostics sector including: blood glucose, blood gas and electrolytes, rapid coagulation, cardiac markers, substance abuse, infectious diseases, urine strip, pregnancy, fecal occult, cholesterol, and many others. The analysis surveys almost all of the companies known to be marketing, manufacturing or developing instruments and reagents for the point of care market in the European market, which include: France, Germany, Italy, Spain, the U.K., the Benelux countries, Scandinavia and the Rest of Europe (ROE). Each company is discussed in extensive depth with a section on its history, product line, business and marketing analysis, and a subjective commentary of the company's market position.

1.1 About This Report

The purpose of this report is to provide a background and definition of POCT or near patient testing (NPT), provide details of the application areas and indications of POCT or NPT, provide a qualitative analysis with a description of the major market drivers and market restraints influencing the growth and development of the market, description of the advantages and disadvantages of POCT or NPT together with a review of the regulatory environment including an analysis of the key market issues and challenges.

- Present an overview of the European healthcare systems, describe the procurement process for POCT or NPT products, provide a short review of the latest technological advances and developments together with an analysis and prediction for the future trends and developments in POCT or NPT within Europe.
- Analyze and review the market dynamics for each of the major market segments in the European POCT or NPT market. *i.e.*, blood glucose testing, blood gas and electrolytes testing, rapid coagulation testing, rapid cardiac markers, substance abuse testing, infectious disease testing, urine strip testing, pregnancy testing, fecal occult blood analysis and cholesterol testing.
- Review the major and leading products currently available for each of the market segments examined and profiles of the leading companies who operate in these markets.
- Provide a detailed market analysis for the European Point of Care Diagnostics market by geographic region and by individual market segment.
- Analyze the market growth rates during the forecast period between [REDACTED] and [REDACTED] and provides historical revenue data by geographic region and by market segment.
- Examine the market shares of the leading suppliers for each of the major geographic regions *i.e.*, France, Germany, Italy, Spain, the U.K., the Benelux, Scandinavia and the Rest of Europe (ROE) and by each individual market segment.

1.2 Scope of this Report

The principal objectives of this analysis have been to:

- Determine the value of the POCT or NPT market for each principle geographic market in Europe and by each of the main market segments for POCT or NPT products and devices.

- Assess the market growth rates for each principle geographic market in Europe and by each of the main market segments for POCT or NPT products and devices.
- Assess market opportunities and the potential market for POCT or NPT products and devices in Europe together with an evaluation of the potential opportunities for new and innovative technologies.
- Analyze the need for POCT or NPT products and devices for the different disease indications.
- Review the range and depth of products which are currently available in the European market together with a description of the main features and benefits for each major product by market segment.
- Determine the market share of the leading suppliers of POCT or NPT products and devices in Europe and identify companies in the second tier of suppliers and their contribution to the continuing development and growth of this market.

Key questions answered in this study are:

- Which of the individual segments for POCT products is the largest, highest growth rate and which offers the greatest potential?
- What are the revenues and growth rates for each of the identified market segments?
- Who are the leading suppliers of POCT products in Europe?
- What market drivers are responsible for the growth of POCT products and devices in Europe?
- Which market restraints are affecting the growth of POCT products and devices in Europe?
- How far the industry has progressed in developing POCT products and devices in Europe?
- What are the regulatory issues, challenges and requirements for POCT products and devices in Europe?
- What impacts have the European healthcare reforms made on the growth of POCT products and devices in Europe?

This report contains:

- A brief introduction and background to each of the individual market segments, backgrounds to the tests, the types of tests and emerging technologies where appropriate for each market segment.
- The value of the POCT or NPT market for each principle geographic market in Europe and by each of the main market segments for POCT or NPT products and devices.
- The market growth rates for each principle geographic market in Europe and by each of the main market segments for POCT or NPT products and devices.
- The market shares of the leading suppliers of POCT or NPT products and devices in Europe and identification of the second tier of suppliers and their contribution to the continuing development and growth of this market.
- The market opportunities and the potential market for POCT or NPT products and devices in Europe together with an evaluation of the potential opportunities for new and innovative technologies.
- A description of the products which are currently available in the European market together with a description of the main features and benefits for each major product by market segment.

1.3 Methodology

The author of this report is a Ph.D. in biochemistry from the University of Liverpool with many decades of experience in science writing and as a medical industry analyst. For this study, information on issues and challenges affecting and influencing the market for POCT products were gathered through an extensive variety of different sources. The editor 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 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.

Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites, as well as annual reports for publicly-held firms. Additional sources of information include non-governmental organizations (NGOs) such as the World Trade Organization

(WTO) including information obtained from Healthcare Systems in Transition (HiTs). HiTs are country-based reports that provide a detailed description of each healthcare system and of reform and policy initiatives in progress or under development. The Medicines and Healthcare products Regulatory Agency (MHRA) in the U.K. also provided valuable assistance and aid concerning the regulations, management and use of POCT devices. Other important data sources included a variety of different professional publications including *Point of Care: The Journal of Near-Patient Testing and Technology*, *Advance for Medical Laboratory Professionals*, *Clinical Chemistry*, *Clinical Laboratory News*, *European Hospital*, *The European Biopharmaceutical Review*.

In addition, a number of professional associations and societies were approached to gather specific product details and information. These included the American Association of Clinical Chemistry (AACC) including the Critical and Point of Care Testing Division (CPOCT) of the AACC, the U.K. Clinical Pathology Accreditation (CPA), the Royal College of Pathologists (U.K.), The Association of Practitioners with Specialist Interests (APWSI), The European Society of Intensive Care Medicine (ESICM), The European Society of Cardiology (ESC), The Association of Clinical Biochemists in Ireland and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and their individual national societies e.g., Société Française de Biologie Clinique (SFBC), France and Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin e.V. (DGKL), Germany.

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 TriMark believes to be reliable, but do not guarantee the accuracy, adequacy or completeness of any information or omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects and Sector Snapshots that it publishes annually. It extracts relevant data and analytics from TriMark's research in the past three years as part of this data collection. It also extracted qualified data feeds from e-questionnaire responses and primary research responses for this compilation.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases, and other published information as part of 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. The report conclusions are verified through intensive interviewing of the top-ranking companies in the industry.

TriMark Publications Report, Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report in TriMark Publications 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 data and proprietary databases.
- Formulating a study outline with the assigned writer, including important items, as follows:
 - 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.
- Completing a confirmatory primary research assessment of the report’s findings with the assistance of expert panel partners.

1.4 Executive Summary

This market research report examines the major and dynamic segments of the European POCT market and includes an analysis of the blood glucose testing, blood gas and electrolytes testing, rapid coagulation testing, rapid cardiac markers, substance abuse testing, infectious disease testing, urine strip testing, pregnancy testing, fecal occult blood analysis and cholesterol testing sub-segments. The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the European POCT market.

The European POCT market is a robust and dynamic market which has evolved into one of the largest sub-segments of the global medical equipment market. Significant and major technological advances and developments have occurred over the last couple of decades which have helped stimulate and acted as a major driver of the market. The major suppliers have progressively introduced new products which has increased the number and range of diagnostic applications and indications whilst supporting the healthcare professionals by improving the quality of patient care. The introduction of these new and innovative technologies has also helped to rejuvenate the market, retain and gain market share and improve their return on investment (ROI).

TriMark has determined that the accumulative value of the ten sub-segments studied in the selected geographic regions in the European Union (E.U.) amounted to \$ [redacted] in [redacted]. It is predicted that this will increase to \$ [redacted] (CAGR [redacted]%) by the end of the forecast in [redacted]. Table 1.1 illustrates the growth and development of the European market historically from [redacted] until the end of the forecast period and provides annual growth rates throughout this period.

Table 1.1: European Revenue Analysis and Forecasts for POC Market, [redacted]

| Year | Revenues (\$ Millions) | Revenue Growth Rate (%) |
|------------|------------------------|-------------------------|
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |

Source: Biotechnology Associates

Tables 1.2 and 1.3 provide a summary of the revenue and CAGRs by individual market sub-segment over the forecast period. The blood glucose testing market for POC products has been determined to be by far the largest sub-

segment and has been valued at \$ ██████ in ██████ and predicted to increase to \$ ██████ (CAGR █████%) by the end of the forecast period. The cardiac marker POC market is the second largest sub-segment and has been estimated to have been valued at \$ ██████ in ██████ and predicted to increase in value to \$ ██████ (CAGR █████%) by the end of the forecast period.

The blood gas and electrolyte POC market is the third largest sub-segment and has been estimated to have been valued at \$ ██████ in ██████ and predicted to increase in value to \$ ██████ (CAGR █████%) by the end of the forecast period. The smallest sub-segment in ██████ has been determined to be the urine strip testing POC market and this market has been estimated to have been valued at \$ ██████ in ██████ and predicted to increase in value to \$ ██████ (CAGR █████%) by the end of the forecast period. The urine strip testing market is recognized as having the lowest growth rates whilst sales of cholesterol POC testing products is expected to exhibit the highest growth rate over the forecast period.

Table 1.2: Segment Revenue Analysis and Forecasts for POC Market, ██████

| Year | Blood Glucose Testing | Blood Gas and Electrolytes | Rapid Coagulation Testing | Cardiac Markers Testing | Substance Abuse Testing | Infectious Disease Testing | Urine Strip Testing | Pregnancy Testing | Fecal Occult Testing | Cholesterol Testing |
|-------|-----------------------|----------------------------|---------------------------|-------------------------|-------------------------|----------------------------|---------------------|-------------------|----------------------|---------------------|
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |
| █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ | █████ |

Note: Revenues in \$ millions.
Source: Biotechnology Associates

Table 1.4 provides a summary of the revenue and CAGRs by individual national markets over the forecast period. The largest single geographic market incorporating the ten segments analyzed in this report within the E.U. is Germany with a total market value of \$ ██████ in ██████. By the end of the forecast period, the value of the German market is predicted to increase to \$ ██████ (CAGR █████%). The second largest geographic market is Italy with an overall value of \$ ██████ in ██████. By the end of the forecast period, the value of the Italian market is predicted to increase to \$ ██████ (CAGR █████%). France is in third position just behind Italy with an overall value of \$ ██████ in ██████. By the end of the forecast period, the value of the French market is expected to increase to \$ ██████ (CAGR █████%).

Table 1.3: European Revenue Forecasts for POC Market, [REDACTED]

| Year | France | Germany | Italy | Spain | U.K. | Benelux | Scandinavia | ROE |
|------------|------------|------------|------------|------------|------------|------------|-------------|------------|
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |

Note: Revenues in \$ millions.
Source: Biotechnology Associates

Table 1.5 provides a summary of the market shares for the top [REDACTED] suppliers of POC products in Europe. The overall market leader and supplier of POC products in Europe in [REDACTED] is Roche Diagnostics with estimated sales totaling \$[REDACTED] equivalent to a market share of [REDACTED] %.

The second largest supplier of POC products in Europe is Lifescan (J&J) with an estimated [REDACTED] % of the market and Abbott Laboratories in third position with a market share also of [REDACTED] %. Alere (Inverness Innovation) is in fourth position with sales attributed to Inverness Innovations Medical, Biosite, etc. with an estimated share of [REDACTED] %. With the addition of an estimated market share of [REDACTED] % of the total European POC market attributed to Cholesterol Corporation, Alere still remains in fourth position although this company is recognized as taking an aggressive approach to gaining market share in the European market.

Table 1.5 also provides a list of other companies involved in the European POC market. These companies have been divided into the first and second tier companies. The first tier having been shown to have a recognized market share of the total market whilst the second tier companies have been identified as operating in this market but with small market shares or who operate in niche market segments.

Table 1.4: European Market Share Analysis for POC Market, ■■■■

| Company | Revenues (\$ Millions) | Percentage (%) |
|---|------------------------|----------------|
| Roche Diagnostics | ■ | ■ |
| Lifescan (J&J) | ■ | ■ |
| Abbott Laboratories | ■ | ■ |
| Alere (Inverness Innovation) | ■ | ■ |
| Bayer Corporation | ■ | ■ |
| Siemens Healthcare Diagnostics | ■ | ■ |
| A. Menarini Diagnostics | ■ | ■ |
| Medtronic | ■ | ■ |
| LifeSign | ■ | ■ |
| Beckman Coulter | ■ | ■ |
| Radiometer/Danaher Corporation | ■ | ■ |
| bioMérieux | ■ | ■ |
| Quidel Corporation | ■ | ■ |
| Instrumentation Laboratory/Werfen Group | ■ | ■ |
| Others | ■ | ■ |
| Total | ■ | ■ |

Source: Biotechnology Associates

First Tier Other includes: American Bio Medica Corporation (ABMC), Response Biomedical Corporation, Cholestech Corporation, HemoCue AB, Trimega Laboratories, Alfa Scientific, Becton Dickinson Diagnostics, 3M, Bioscan Screening Systems, Sekisui Diagnostics (Genzyme Diagnostics), Princeton BioMeditech Corporation (PBM), Gen-Probe, Inc., Innogenetics NV, Dirui Industrial Co., Ltd., 77 Elektronika and Mitsubishi Chemical Medience Corporation.

Second Tier Other includes: Ani Biotech Oy, ELITech Clinical Systems, HUMAN Gesellschaft für Biochemica und Diagnostica mbH, Boditechmed, Inc., Veda Lab, France and Nanogen Advanced Diagnostics (the ELITech Group), ACON Laboratories, Inc., Allmedicus, Apex Biotechnology Corporation, ArithMed GmbH, AgaMatrix, Inc. (WaveSense), Arkray, Inc., Bio-Rad Laboratories, Cygnus, Inc., Dexcom, Inc., Everymed AB, EyeSense GmbH, Integrity Applications, Luminous Medical, Orsense, Polymer Technology Systems, Inc., Nova Biomedical, Nipro Diagnostics (formerly Home Diagnostics), Solianis Monitoring AG and Biochemical Systems International S.r.l.