## Future of Cardiovascular Diagnostics: Impact of Technological Advances on Growth Opportunities and Market Outlook

### **Introduction**

The report analyzes a variety of cardiac biomarkers currently on the market, including those used to determine cholesterol and lipoprotein levels, cardiac necrosis, thrombosis, inflammation and genetic variants. Furthermore, a large number of biomarkers are currently under evaluation, and if successful, may provide cardiologists with a more comprehensive assessment of cardiovascular risk and prognosis.

### **Scope**

- Analyzes key IVD and imaging technologies, and their applications for early diagnosis, treatment and patient monitoring in CVD.
- Assesses current approaches being adopted by the leading IVD and emerging market entrants.
- Profiles leading companies developing novel technologies for IVD and diagnostic imaging.
- Analyses potential of products and technologies for improving diagnosis and guiding treatment decisions earlier during the course of CVD.
- Reviews benefits associated with different approaches to IVD and diagnostic imaging.

### **Research and analysis highlights**

Increasingly, IVD testing is being used by cardiologists in conjunction with diagnostic imaging to stratify patient risk, improve diagnosis, minimize the use of invasive procedures and improve patient management.

Several tests are now available that can indentify asymptomatic patients that are at high risk of CV disease, allowing for early dietary and lifestyle interventions and the prescription of preventative medicine if necessary.

Extensive research indicates that the application of IVD and diagnostic imaging in cardiovascular disease may lead to significant reductions in healthcare costs by increasing the speed of diagnosis, avoiding the need for expensive treatments and reducing mortality rates through early screening programs.

#### Key reasons to purchase this research

- Discover the reasons for the increasing usage of IVD and diagnostic imaging modalities in recent years.
- Identify the technologies at the forefront of cardiovascular IVD and diagnostic imaging.
- Assess the IVD and healthcare industry's responses to the demands of cardiologists and radiologists.
- Examine the strategies that the leading IVD and healthcare companies use in order to remain ahead in the CV diagnostics field.

# Table of Contents

Cardiovascular Diagnostics Executive Summary 10 Cardiovascular disease & diagnostics 10 Current cardiac diagnostic modalities 11 Novel cardiac diagnostic modalities 12 The market, trends & future directions 13 Chapter 1 Cardiovascular disease & diagnostics 16 Introduction 17 Cardiovascular disease 20 Cardiovascular risk factors 23 Diagnosis of cardiovascular diseases 25 Cardiovascular screening 25 Conclusions on CVD diagnosis and screening 27 Cardiovascular diagnostics 28 Cardiovascular in vitro diagnostics: biomarkers and tests 28 Cholesterol testing 28 Lipoprotein & apolipoprotein profiling 30 **Cholesterol guidelines 31** Case study: Atherotech VAP technology 32 Cardiac biomarkers 34 In vivo cardiovascular diagnostics: options & applications 36 Diagnostic imaging for coronary artery disease 38 Diagnostic imaging for stroke 40 Diagnostic imaging for pulmonary embolism 40 Conclusions on diagnostic imaging modalities 41 Report outline 41 Chapter 2 Current cardiac diagnostic modalities 44 Introduction 45 Coronary artery disease diagnostic tests 46 In vitro diagnosis of CAD 46 In vivo diagnosis of CAD 49 Conclusions on diagnostic tests for CAD 54 Acute coronary syndromes diagnostics 55 In vitro diagnosis for ACS 56 In vivo diagnosis of ACS 59 Conclusions on diagnostic tests for heart attack patients 62 Heart failure 62 In vitro diagnosis of heart failure 64 In vivo diagnosis of heart failure 65 Conclusion on diagnostic tests for CHF 68 Stroke 68

In vivo diagnosis of stroke 69 In vitro diagnosis of stroke 71 Conclusion on diagnostic tests for stroke 73 Deep vein thrombosis & pulmonary embolism 73 In vitro tests for PE 74 In vivo diagnosis of PE 76 Conclusion on diagnostic tests for DVT & PE 78 Coagulation diagnostics 78 Genotyping in cardiovascular disease 80 Cytochrome P450 80 ApoE genotyping 80 Cardiac channelopathies 81 Thrombophilia genotyping 81 Overall conclusions 82 Chapter 3 Novel cardiac diagnostic modalities 86 Introduction 87 Challenges 87 Tough economic environment 87 Healthcare coverage & regulation 89 Payment & reimbursement 89 Emerging markets 90 Conclusions on challenges 92 **Opportunities 92** New cardiac biomarkers 93 Pharmacogenomics 99 Genetic biomarkers to guide treatment decisions 100 Genetic biomarkers of cardiovascular risk 101 Point of care testing 104 Novel imaging agents 107 Cardiovascular molecular imaging 109 Novel imaging modalities 110 Case study: Magnetic Particle Imaging (Philips Healthcare) 110 Hybrid imaging systems 111 PFT-MRI 112 PET-CT 112 SPECT-CT 113 Computer assisted diagnosis & artificial intelligence 113 Conclusions 114 Overall conclusions 114 Chapter 4 The market, trends & future directions 118 Market analysis 119 The IVD market 119 The cardiovascular IVD market 123 The diagnostic imaging market 128

Leading IVD & imaging companies 132 Abbott, Illinois, US 132 Beckman Coulter, California, US 132 Becton Dickinson & Company, NJ, US 133 bioMérieux, Marcy L'Etoile, France 133 GE Healthcare, New York, US 134 Hitachi Medical Corporation, Tokyo, Japan 135 Inverness Medical Innovations, Inc., MA, US 135 Johnson & Johnson, NJ, US 136 Philips Healthcare, Amsterdam, the Netherlands 137 Roche, Basel, Switzerland 137 Siemens Healthcare, Berlin & Munich, Germany 138 Toshiba Medical Systems Corporation, Tokyo, Japan 139 M&A activity 140 Recent collaborations & agreements 145 Recent product launches & trends 148 Cardiovascular in vitro diagnostics 148 Cardiovascular diagnostic imaging 149 Future directions 152 Summary & overall conclusions 153 Chapter 5 Appendices 158 Primary research methodology 158 Glossary 159 Acknowledgements 163 Index 164 Bibliography & Endnotes 166 List of Figures Figure 1.1: Cardiovascular diagnostic platforms 18 Figure 1.2: CVD – breakdown of deaths in the US (2006) 22 Figure 1.3: Increased use of medicine reduces the risk of death after stroke and heart attack 26 Figure 1.4: Increased use of medicine reduces the risk of death after stroke and heart attack 27 Figure 1.5: VAP test – treatment guideline 33 Figure 2.6: Conventional coronary angiography 50 Figure 2.7: EBCT angiogram of heart and pulmonary arteries 52 Figure 2.8: Principals of MSCT angiography scan of heart and pulmonary arteries 53 Figure 2.9: Diagnosis & risk stratification of ACS patients 56 Figure 2.10: Profile of cardiac necrosis markers after acute MI 57 Figure 2.11: Typical electrocardiogram from a healthy adult heart 59 Figure 2.12: Typical electrogram observed during ACS patient with US/NSTEMI 60 Figure 2.13: Typical electrogram observed during ACS patient with STEMI 61 Figure 2.14: Diagnosis & risk stratification of HF patients 63 Figure 2.15: Echocardiogram 66

Figure 2.16: MUGA scan of the heart 67

Figure 2.17: Doppler Ultrasound in a) normal & b) stroke 69

Figure 2.18: MRI scan of brain following a stroke 70

Figure 2.19: Commercial MRI Units 71

Figure 2.20: Increased risk of stroke with elevated Lp-PLA2 (ARIC Study) 72

Figure 2.21: Roche's PoC CARDIAC D-Dimer test 75

Figure 2.22: Ventilation-perfusion scan for detecting PEs 76

Figure 2.23: Contrast enhanced CT image of PE 77

Figure 3.24: Global Population (2008) 91

Figure 3.25: Schematic of MPI technology 111

Figure 4.26: The IVD market – geographic split (2008) 119

Figure 4.27: The IVD market – segments (2008) 120

Figure 4.28: The IVD market – market leaders (2008) 121

Figure 4.29: Cardiovascular Diagnostics – Market Segments (2008) 124

Figure 4.30: Leading diagnostic imaging companies (2008) 129

Figure 4.31: Leading diagnostic imaging – market segments (2008) 130 List of Tables

Table 1.1: CVD – conditions & associated risk factors 20

Table 1.2: CVD – conditions & associated risk factors (continued) 21

- Table 1.3: Uncontrollable cardiovascular risk factors 23
- Table 1.4: Protective cardiovascular risk factors 23

 Table 1.5: Controllable / treatable cardiovascular risk factors 24

Table 1.6: ATPIII Classification of TC, LDL-C & HDL-C 32

Table 1.7: Commercially available cardiovascular diagnostics to assess acute coronary syndromes 34

Table 1.8: Commercially available diagnostics to assess cardiovascular risk, stroke & thrombosis 35

Table 1.9: Anatomical - In vivo imaging modalities 36

Table 1.10: Functional - In vivo imaging modalities 37

Table 1.11: Advantages & disadvantages of cardiac imaging modalities 38

 Table 1.12: In vivo imaging tests to assess cardiac anatomy & function 39

Table 2.13: Diagnostic tests - CAD 46

 Table 2.14: Diagnostics for ACS 55

Table 2.15: Diagnostic tests for heart failure 64

Table 2.16: Properties of BNP 64

Table 2.17: Leading diagnostics for stroke 68

Table 2.18: Leading thrombotic diagnostic tests 74

Table 3.19: COACH trial data on Galectin-3 95

 Table 3.20: Commercially available POC cardiac tests 106

Table 4.21: Medical Device Manufacturers & Suppliers in IVD 122

Table 4.22: Medical Device Manufacturers & Suppliers in IVD (continued) 123

Table 4.23: Cardiovascular focused IVD companies 126

 Table 4.24 Cardiovascular focused IVD companies (continued): 127

Table 4.25: Medical device manufacturers & suppliers in imaging 131

 Table 4.26: Recent M&A activity in the cardiovascular diagnostic arena 142

Table 4.27: Recent M&A activity in the cardiovascular diagnostic arena (continued) 143

Table 4.28: Recent M&A activity in the cardiovascular diagnostic arena (continued) 144

Table 4.29: Recent collaborations in the cardiovascular arena 146

 Table 4.30: Recent collaborations in the cardiovascular diagnostic arena (continued) 147

Table 4.31: Recent product launches in cardiovascular IVDs 148

 Table 4.32: Recent product launches in diagnostic imaging 151