

Future of Molecular Diagnostics: Innovative Technologies Driving Market Opportunities

Introduction

The report analyzes current and potential world molecular diagnostics markets and advances in the field. The report forecasts future growth to 2015, and segments the market by test and geography. Also included are profiles of companies marketing key products, and analyses of key drivers.

Scope

- Explains how molecular diagnostics represents a business opportunity for the IVD industry.
- Evaluates drivers and trends behind the growth of molecular diagnostics.
- Reviews key challenges facing molecular diagnostic manufacturers and companies seeking to enter the market.
- Analyzes markets by key types of testing, product, and country, and reviews top products and opportunities.
- Profiles key players, including established companies and growing firms with innovative technologies.

Research and Analysis Highlights

Two important growth drivers in the clinical setting for molecular diagnostics include the need for new biomarker assays as well as for techniques that lower the cost per test, and which improve ease of use, data quality and turnaround time.

By far, most of the established market for molecular diagnostics lies in the North American region. The market is building in Europe, but is still at relatively an early stage in the rest of the world. Geographically, the US and European markets are the most advanced in terms of adoption of molecular testing and make up the majority of the market.

In the current market for HPV, only about 20% of women over the age of 30 are screened for HPV using DNA-based tests in conjunction with a standard Pap smear, which leaves a lot of room for market growth.

Key Reasons to Purchase this Research

- Understand each market in terms of size as well as its future potential.
- Understand which key products are already in the market place for each market segment analyzed.
- Evaluates which segment future opportunities may lie for companies.
- Understand key issues & challenges facing molecular diagnostics makers & their component suppliers thus helping potential entrants review the issues
- Learn about possible products from recent market developments mentioned in the report.

Table of Contents

Advances in molecular diagnostics

Executive summary 12

Introduction 12

Trends and drivers 13

Market developments 14

Markets 15

Chapter 1 Introduction 18

Summary 18

Perspective 19

Perspective 19

An emerging science 19

Understanding the human genome 21

Molecular level analysis 22

Personalized care 22

Individualized response 23

Early-stage diagnosis 25

Infectious disease 26

Viruses 27

Oncology 28

Diagnostics business opportunity 30

A growing role in diagnostics 30

Companion diagnostics and therapies 31

Diagnostics allowing early detection and treatment 32

Increased efficiency 33

Optimizing drug therapy 33

Significant regulatory concerns 34

Strengthening oversight 34

Improving patient outcomes 36

Optimizing instrumentation and chemistries 38

Advances in sample preparation needed 39

Automation 41

Chapter 2 Trends and drivers 48

Summary 48

Integral to traditional labs 49

Improved assay/test efficiencies 50

Targeting antibiotic resistance 52

Next generation ultrasensitive molecular diagnostics 54

Platform variety 55

PCR 56

Microfluidics 58

Biochips/microarrays 59

Others 60

Challenges and issues 62

Re-emergence of infectious diseases and other threats 64

Establishing accepted regulatory processes 66

Reimbursement 68

Medicare coverage 69

Chapter 3 Market developments 7

Summary 72

Extracting microRNAs from tissue 73

Cystic fibrosis genetic screening 74

PET scanning 75

Expanded medicare coverage 76

Ionian Technologies-Roche collaboration 77

Leukemia diagnostic kit cleared 77

New lung cancer test 78

AMD diagnostic 79

Key biomarker gene 80

Point of care instrumentation 81

Genotyping test launch 82

Innovative colon cancer diagnostic 83

Innovative pancreatic cancer diagnostic 84

Brain cancer companion diagnostic 85

Rapid thermocycling 86

Acquisition of AcroMetrix 87

Real-time PCR 87

APiX detection kit 88

Biomarker analysis 88
Genetic dermatology 89
Genome sequencing agreement 90

Chapter 4 Markets 92

Summary 92

Overview 93

Growth drivers 94
Future opportunities 95

World market forecasts 99

Geographical segmentation 101
Type of testing 103
Blood screening 103
HPV testing 105
Hospital acquired infections 108
HIV/HCV testing 110
Genetic testing 113
Oncology 116
STD testing 118

Chapter 5 Corporate profiles 124

Abbott Molecular 124

Company description 124

AcroMetrix 125

Company description 125

Adnavance Technologies Inc. 126

Company description 126

Affymetrix 127

Company description 127

Asuragen Inc. 128

Company description 128

AutoGenomics Inc. 129

Company description 129

Beckman Coulter Inc. 130

Company description 130

Becton Dickinson 131

Company description 131

Biocartis SA 132

Company description 132

BioHelix 133

Company description 133

bioMérieux SA 134

Company description 134

Bio-Rad Laboratories Inc. 135

Company description 135

Celera 136

Company description 136

Cepheid 137

Company description 137

CombiMatrix Corp. 138

Company description 138

Cytocell Ltd. 139

Company description 139

DiagnoCure Inc. 140

Company description 140

Diasorin SpA 141

Company description 141

Dx Assays 142

Company description 142

EliTech Group 143

Company description 143

Enzo Biochem 144

Company description 144

EraGen Biosciences 145

Company description 145

Fujirebio Diagnostics Inc. 146

Company description 146

Gen-Probe Inc. 147

Company description 147

Gene Express Inc. 148

Company description 148

GE Healthcare 149

Company description 149

Genomic Health Inc. 150

Company description 150

IBT Laboratories 151

Company description 151

Illumina Inc. 152

Company description 152

IntelligentMDx 153

Company description 153

InVivoScribe Technologies Inc. 154

Company description 154

IRIS International Inc. 155

Company description 155

Kreatech Diagnostics 156

Company description 156

Luminex Molecular Diagnostics Inc. 157

Company description 157

Myriad Genetics Inc. 158

Company description 158

Nanosphere Inc. 159

Company description 159

Norgen Biotek 160

Company description 160

Novartis International AG 161

Company description 161

OncoVista Inc. 162

Company description 162

Pall Gene Systems 163

Company description 163

Pathwork Diagnostics 164

Company description 164

PrimerADx 165

Company description 165

Orion Genomics 166

Company description 166

Osmetech Molecular Diagnostics 167

Company description 167

Qiagen NV 168

Company description 168

RedPath Integrated Pathology Inc. 169

Company description 169

Roche Diagnostics 170

Company description 170

Rosetta Genomics Ltd. 171

Company description 171

Seegene 172

Company description 172

Siemens Healthcare 173

Company description 173

Singulex 174

Company description 174

viii

Thorne Diagnostics Inc. 175

Company description 175

TrovaGene Inc. 176

Company description 176

Veridex LLC 177

Company description 177

Vita Genomics Inc. 178

Company description 178

Chapter 6 Appendix 180

Methodology 180

Glossary 181

Endnotes 184

Index 191

List of Figures

Figure 1.1: Molecular diagnostics: predicting response, early treatment of disease 25

Figure 2.2: Molecular Diagnostics 29

Figure 2.3: Integrating molecular diagnostics with therapeutics 32

Figure 2.4: Changing treatment protocols in clinical practice 42

Figure 3.5: Clinical potential of molecular diagnostics 49

Figure 3.6: Molecular diagnostics: challenges for developers 64

Figure 5.7: World Market for molecular diagnostics by geography, 2010 103

Figure 5.8: World Market for molecular diagnostics by application, 2010 103

Figure 5.9: Molecular diagnostics diagnosing cancer 117

List of Tables

Table 5.1: Key players in molecular diagnostics 100

Table 5.2: World market for molecular diagnostics, 2009-2015, (\$m) 101

Table 5.3: World Market for molecular diagnostics by geography, 2010, (\$m) 102

Table 5.4: World Market for molecular diagnostics by application, 2010, (\$m) 102

Table 5.5: Molecular diagnostics blood screening market, breakup by competition, (\$m) 105

Table 5.6: Molecular diagnostics HPV testing market, breakup by competition, (\$m) 108

Table 5.7: Molecular diagnostics hospital acquired infections testing market, breakup by competition, (\$m) 109

Table 5.8: Molecular diagnostics HIV/HCV testing market, breakup by competition, (\$m) 112

Table 5.9: Molecular diagnostics genetic testing market, breakup by competition, (\$m) 116

Table 5.10: Molecular diagnostics oncology testing market, breakup by competition, (\$m) 118

Table 5.11: Molecular diagnostics STD testing market, breakup by company, (\$m) 122