

Biomarkers in Biochips and Microarrays: Innovative Technologies, Growth Opportunities and Future Market Outlook

Introduction

The report provides a strategic insight into the use of biomarkers in biochip and microarray testing. It offers an analysis of the current market landscape, industry forecasts, and overview of the key players and their areas of expertise.

Scope

- In-depth examination of the various forms of microarrays and biochips.
- Overview of the main industry players and their fields of expertise.
- Analysis of the current market landscape.
- Industry forecasts.

Research and analysis highlights

At present, the leading microarray players are Affymetrix, Agilent, Illumina, and Roche/NimbleGen. Apart from a small number of "heavy hitters", this market is very fragmented.

Many microarray players are preparing to move into diagnostics, either by cultivating multiple diagnostics industry partners (such as Affymetrix) or by forming diagnostics divisions (such as Illumina).

Nucleic acid-based molecular diagnostics, currently worth \$3 billion, offers many more opportunities than the existing heavily research-oriented microarray market. The latter market grew very strongly between 1997 and 2003, but is now firmly entrenched in a phase of more modest growth.

Key reasons to purchase this research

- Gain an insight into the R&D history of microarrays and biochips.
- Understand the various forms of microarrays and their uses.
- Identify who the industry's key players are.
- Uncover what lies in store for the microarray market in the future.

Table of Contents

Advances in the use of biomarkers in biochip and microarray testing

Executive Summary 12

Biochips, biomarkers, and in vitro diagnostics 12

DNA microarrays 13

Protein microarrays 14

Tissue and cell microarrays 16

Lab-on-a-Chip technologies 17

Biochip companies 18

Market Analysis and Forecasts 18

Chapter 1 Biochips, biomarkers, and in vitro diagnostics 22

Summary 22

Biomarker-based IVDs 23

Introduction to biochips 23

Microarrays 23

Microfluidic chips 24

Background on nucleic acid and protein testing 25

Immunoassay technology 25

Immunoassay formats 26

Rapid immunochromatographic assays 28

Multiplexed assays 28

Nucleic acid testing 29

Probe-based NAT 30

Amplification technologies 32

Biomarker discovery and validation 33

Translating biomarkers into IVDs 35

Regulation of *in vitro* diagnostics 36

Europe 37

USA 37

Draft guidance on multivariate analysis 40

Chapter 2 DNA microarrays 44

Summary 44

Introduction 46

DNA microarray fabrication technologies 49

Standard microarrays 49

3-D DNA microarrays 53

Particle (bead)-based microarrays 54

Analytical uses of DNA microarrays 56

SNP genotyping 56

Detection of genetic imbalances 57

Gene expression profiling 59

Single-channel microarrays 60

Two-channel microarrays 62

Methods utilizing RT-PCR 64

MicroRNA expression profiling 65

Limitations and barriers to commercialization 66

Key commercial players 69

DNA microarray testing in cancer 70

Overview 71

Progress in breast cancer 74

Early detection 74

Classification, prognosis, and treatment 75

Tumors of unidentified origin 79

Other advances 80

DNA microarray testing in genetic disorders 82

Microarrays testing for adverse drug reactions 86

DNA microarray testing in transplant management 87

DNA microarray testing in other conditions 88

Expanding applications 91

Chapter 3 Protein microarrays 94

Summary 94

Introduction 96

Background on proteomics 97

Protein microarray technologies 100

Formats 102

Glass slides 102

Microwell/nanowell chips 103

Implementation 103

3.3.2.1 Forward-phase microarrays 103

Prospects for multiplex ELISAs 104

Reverse-phase microarrays 105

Detection of bound targets 106

SELDI ProteinChip technology 107

Fabrication technologies 109

Dispensing technology 109

Protein immobilization strategies 110

Surface chemistries 111

Analytical uses of protein microarrays 113

Commercial microarrays for clinical research 114

Protein microarray diagnostics in cancer 118

Chapter 4 Tissue and cell microarrays 124

Summary 124

Introduction 125

Tissue microarrays 127

Advantages 127

Construction 128

Sources of tissue 129

Scanning and analysis 130

Companies providing products and services 131

Uses of tissue microarrays 132

Clinical investigations in cancer 134

Initiatives using cell microarrays 135

Overview 135

Examples of diagnostic applications 137

Chapter 5 Lab-on-a-Chip Technologies 140

Summary 140

Introduction to microfluidics 141

Lab-on-a-chip devices 144

Construction methods 145

Companies and technologies 146

Multiplexed particle assays 150

Multiplexing at the microlevel 151

Particle encoding technologies 152

Applications of LoC devices 153

Changing diagnostics 154

Future role in PoC testing 155

Chapter 6 Biochip companies 160

Introduction/Summary 160

Accelr8 Technology Corporation 160

Company description 160

Microarray-based rapid bacterial analysis 161

Advanced Liquid Logic Inc 162

Company description 162

Digital Microfluidics devices 163

Affymetrix Inc 164

Company description 164

DNA and protein microarrays 165

Agendia BV 167

Company description 167

Gene expression microarray diagnostics 167

MammaPrint 167

TargetPrint 168

CupPrint 168

ColoPrint 168

Agilent Technologies Inc 169

Company description 169

DNA microarrays 169

Almac Group Ltd 170

Company description 170

Microarray-based gene expression profiling 171

Ambry Genetics Corp 171

Company description 171

Microarray-based cytogenetic testing 172

Applied Microarrays Inc 172

Company description 173

3-D DNA microarrays 173

Arrayit Corp 174

Company description 174

Universal DNA microarray-based diagnostics 174

ArrayXpress Inc 176

Company description 176

Microarray services 176

Atactic Technologies Inc 177

Company description 177

Specialty microarrays 177

Aushon BioSystems Inc 178

Company description 178

Protein microarrays and services 178

AutoGenomics Inc 179

Company description 179

3-D DNA microarrays for diagnostics 179

Beecher Instruments Inc 180

Company description 180

Tissue microarray products and services 181

BioArray Solutions Ltd 182

Company description 182

Bead-based microfluidic arrays 182

BioDot Inc 183

Company description 183

Protein biochip manufacture 183

Caliper Life Sciences Inc 184

Company description 184

Microfluidic lab-on-a-chip systems 184

CapitalBio Corp 185

Company description 185

Microarray systems and diagnostics 185

CombiMatrix Corp 187

Company description 187

DNA microarray technology and diagnostics 188

Cybrdi Inc 190

Company description 190

Tissue microarray products and services 190

Decision Biomarkers Inc 191

Company description 191

Microarrays for multiplex immunoassays 191

Epigenomics AG 192

Company description 192

Methylation microarrays for diagnostics 192

ExonHit Therapeutics SA 193

Company description 193

Differential gene expression profiling 194

Expression Analysis Inc 195

Company description 195

DNA microarray-based testing services 195

GeneNews Ltd 196

Company description 196

Gene expression diagnostics 196

GenTel BioSciences Inc 197

Company description 197

Protein microarrays and research kits 197

Illumina Inc 199

Company description 199

Bead-based microarrays 199

Imgenex Corp 200

Company description 200

Tissue microarrays 201

Iris BioTechnologies Inc 201

Company description 201

DNA microarrays for diagnostic profiling 201

LC Sciences LLC 203

Company description 203

Microarray products and services 203

Life Technologies Corp 204

Company description 204

Microarray/microfluidic research tools 204

Luminex Corp 205

Company description 205

Bead suspension microarrays and diagnostics 205

Maxwell Sensors Inc 207

Company description 207

Microarray and microfluidic products 207

Med BioGene Inc 208

Company description 208

Gene expression microarrays for diagnosis 208

Micronics Inc 209

Company description 209

Disposable microfluidic diagnostic labcards 209

Micronit Microfluidics BV 210

Company description 210

Microfluidic glass chips 211

Oxford Gene Technology Ltd 211

Company description 211

DNA and protein microarrays 212

Protein BioTechnologies Inc 212

Company description 212

Protein and tissue microarrays 212

Response Genetics Inc 213

Company description 213

Microarray gene expression cancer testing 213

Roche NimbleGen Inc 214

Company description 214

DNA microarray products and services 215

SABiosciences Corp 217

Company description 217

DNA microarrays and RT-PCR arrays 217

Signature Genomic Laboratories LLC 218

Company description 218

Microarray-based cytogenetic diagnostics 218

SomaLogic Inc 219

Company description 219

Aptamer microarrays 219

US Biomax Inc 220

Company description 220

Tissue microarrays 220

Xceed Molecular Corp 221

Company description 221

3-D DNA microarrays 222

Chapter 7 Market analysis and forecasts 224

Summary 224

Introduction 225

DNA microarray review 226

Market history 226

Some leading players 228

Market growth 230

Protein microarray review 232

Market history 232

Some leading players 234

Market growth 235

Market segmentation and forecasts 235

Market prospects 241

Chapter 8 Appendix 1 Abbreviations and Acronyms 246

Scientific/technical/medical terms 246

A2.2 Institutional/regulatory terms 247

Chapter 9 Appendix 2 Research Methodology 250

Index 251

List of Figures

Figure 1.1: Non-competitive “sandwich” assay 27

Figure 2.2: An approx 18,000-test gene microarray 46

Figure 3.3: Principle of a spatially addressable protein microarray 106

List of Tables

Table 2.1: Companies featured in Chapter 2 48

Table 2.2: DNA microarray technologies/products 49

Table 2.3: Systems for gene expression profiling 59

Table 2.4: Gene expression tests in breast cancer 70

Table 2.5: Other cancer tests 71

Table 2.6: DNA microarray testing in genetic disorders 82

Table 3.7: Companies featured in Chapter 3 97

Table 3.8: Protein microarray technologies/products 102

Table 3.9: Protein microarrays for clinical research 114

Table 3.10: Protein microarray-enabled cancer diagnostic discovery 118

Table 4.11: Companies and products featured in Chapter 4 126

Table 5.12: Companies and products featured in Chapter 5 143

Table 7.13: Microarray Industry Bibliometric Output, 2000-2008 231

Table 7.14: Snapshot of FDA approved in vitro diagnostic microarray products 237

Table 7.15: Microarray Forecasts (\$m) 240

Table 7.16: Leading Company Market Shares 241