GLOBAL & USA CANCER BIOMARKER MARKET to 2018 (Identification, Technologies, Market Analysis, Competitor Profiles, Companion Diagnostic Co-Development, Business Strategies, Industry Trends, and Pipeline Analysis)

Table of Contents
1.0 Executive Summary 13
1.1 Objectives of Report 13
1.2 Data Sources and Methodology 15
1.3 Key Findings and Observations 15
1.3.1 What Makes Cancer Biomarkers so Important for the Healthcare Industry? 15
1.3.2 What Technologies are Used to Identify Novel Biomarkers? 16
1.3.3 Increase in Cancer Prevalence is Propelling the Oncogenic Biomarker Market 16
1.3.4 Global and US Economic Impact of Cancer 16
1.3.5 How Cancer Biomarkers are Revolutionizing Cancer Treatment 17
1.3.6 What are the most Significant and Strategic Cancer Biomarkers? 17
1.3.7 Global Biomarker Test Market Analysis 18
1.3.8 Global Cancer Biomarker Market Analysis 18
1.3.9 Oncology Biomarker Market Main Industry Players 19
1.3.10 Drivers, Restraints, Opportunities and Challenges of the Cancer Biomarker Market 19

2.0 Global Burden of Cancer 20
2.1 Global Cancer Statistics 20
2.2 Lung Cancer Globally 25
2.3 Lung Cancer Mutation Analysis 28
2.4 Colorectal (Bowel) Cancer Globally 29
2.5 Prostate Cancer Globally 31
2.6 Breast Cancer Globally 33
2.7 Global Economic Impact of Cancer 39
2.8 Cancer in the USA 40
2.9 Breast Cancer in the US 43
2.10 Lung Cancer in the US 44
2.11 Colorectal Cancer in the US 45
2.12 Prostate Cancer in the US 50
2.13 Skin Cancer in the US 52

3.0 Oncogenic Biomarkers – An Overview 54
3.1 Biomarker Discovery to Clinical Validation 56
3.2 Specific Technologies Used in Biomarker Discovery 57
3.2.1 Proteomics 57
3.2.2 Mass Spectrometry Based Technologies 57
3.2.3 Principles of Diagnostic Mass Spectrometry 58
3.2.4 Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) 58
3.2.5 Nano LC-MS/MS 59
3.2.6 MALDI-TOF 59
3.3 Glycomics 60
3.4 Metabolomics 61
3.5 Peptidomics 62
3.5.1 Enzyme-Linked Immunosorbent Assay (ELISA) 62
3.6 Selected (Multiple) Reaction Monitoring 66
3.7 DNA Based Techniques 67
3.7.1 Microarrays 67
3.7.2 Small Molecule Real Time (SMRT) DNA Sequencing 69
3.7.3 Digital PCR 69
3.7.4 Next Generation Sequencing 70

© Kelly Scientific Publications 2014
### 3.7.5 Second-Generation Sequencing Platforms

Second-Generation Sequencing Platforms provide a more cost-effective and faster alternative to traditional sequencing methods. They have revolutionized the field of genomics by making high-throughput sequencing more accessible and efficient.

### 3.7.6 Whole Genome Sequencing

Whole Genome Sequencing (WGS) is the process of determining the DNA sequence of an entire genome. This technology has become a cornerstone in the study of cancer genomics, enabling the identification of genetic alterations that contribute to cancer development.

### 3.7.7 Epigenomics

Epigenomics is the study of epigenetic modifications such as DNA methylation and histone modifications. These changes can affect gene expression without altering the DNA sequence and are implicated in various diseases, including cancer.

### 3.7.8 Bioinformatics and Next Generation Sequencing

Bioinformatics and Next Generation Sequencing (NGS) have become crucial tools in cancer research. They are used to analyze and interpret large datasets generated by sequencing technologies, aiding in the identification of cancer-related genes and pathways.

### 3.7.9 Third Generation Sequencing

Third-Generation Sequencing (3G-Seq) technologies, such as Oxford Nanopore Technologies, offer additional flexibility and lower costs compared to traditional NGS methods. They are particularly useful for applications requiring rapid sequencing of large molecules.

### 4.0 Biomarker Validation

#### 4.1 Introduction

Biomarker validation is a critical step in translating research findings into clinical practice. It involves rigorous testing to ensure that a biomarker accurately predicts disease, response to treatment, or patient outcome.

#### 4.2 Phases of Biomarker Validation

The validation process typically includes phases such as discovery, proof-of-concept, clinical validation, and regulatory approval.

#### 4.3 Biomarker Validation and Clinical Trials

Biomarkers are often studied in clinical trials to assess their accuracy, reliability, and clinical utility. These trials help in determining whether a biomarker can be used to guide treatment decisions or predict response to therapy.

### 5.0 Current and Prospective Oncogenic Biomarkers

#### 5.1 Catalogue of Somatic Mutations in Cancer (COSMIC)

COSMIC is a database that catalogs somatic mutations across various cancer types, providing a comprehensive resource for researchers.

#### 5.2 P53 Transcription Factor Oncogenic Mutations

P53, a tumor suppressor gene, is frequently mutated in cancer. Understanding its role in oncogenesis is crucial for developing targeted therapies.

#### 5.3 Epidermal Growth Factor Receptor (EGFR)

EGFR is a key target in cancer therapy. Its activation and resistance mutations have significant implications for the development of targeted therapies.

#### 5.4 BRCA-Mutant Cancers

BRCA mutations are associated with increased risk of various cancers, particularly breast and ovarian. Identification of BRCA status is critical for personalized treatment strategies.

#### 5.5 PARP-Inhibitors are Making a Comeback

PARP inhibitors have emerged as a promising class of drugs in the treatment of cancer, particularly in the context of BRCA1 and BRCA2 mutations.

#### 5.6 PTEN – Current Leader in Pipeline Oncogenic Biomarkers

PTEN is a tumor suppressor gene whose loss or dysfunction is associated with many cancers. Its status is a valuable biomarker in clinical settings.

#### 5.7 Ataxia Telangiectasia Mutated (ATM) – A Pipeline Target

ATM is involved in DNA repair pathways and is mutated in a variety of cancers. Research into ATM and its role in cancer is ongoing.

#### 5.8 TMPRSS2-ERG – A Promising Prostate Cancer Biomarker

The TMPRSS2-ERG fusion gene is a significant biomarker in prostate cancer, with implications for diagnosis and treatment.

#### 5.9 MiR-17/92 Cluster – The Oncomir with Biomarker Potential

MiR-17/92 is a microRNA cluster that is frequently upregulated in various cancers. Its deregulation can predict cancer pathogenesis and has potential as a diagnostic and prognostic biomarker.

### 6.0 Cancer Biomarker Test Market Analysis 2013-2018

The cancer biomarker test market is driven by the growing demand for personalized medicine and the need to improve diagnostic accuracy. Key drivers include advancements in sequencing technologies and the increasing importance of molecular testing in clinical decision-making.

© Kelly Scientific Publications 2014
6.10 Proteomic and Genomic Technologies are Preferred as Methods of Detection by End-Users

7.0 Oncology Biomarker Market Main Industry Players
7.1 23andMe
7.2 Affymetrix
7.3 Ambry Genetics
7.4 Astex Pharmaceuticals
7.5 Atossa Genetics
7.6 CuraGen
7.7 Celera Corporation (Quest Diagnostics)
7.8 Cellidex Therapeutics
7.9 deCode Genetics (Amgen)
7.10 Foundation Medicine
7.11 Illumina
7.12 Genelex
7.13 Genomic Health
7.14 Myriad
7.15 Nodality
7.16 OriGene Technologies
7.17 Randox
7.18 Qiagen

8.0 Oncology Biomarker Market Products and Kits
8.1 Oncology Companion Diagnostic Tests
8.1.1 HER2 Tests in Breast Cancer Patients
8.2 23andMe
8.3 Affymetrix
8.4 Ambry Genetics
8.4.1 BRCAPlus
8.4.2 BreastNext
8.4.3 CancerNext
8.4.4 ColoNext
8.4.5 OvaNext
8.4.6 PancNext
8.4.7 RenalNext
8.4.8 Hereditary Diffuse Gastric Cancer Test
8.5 Astex Pharmaceuticals
8.6 Atossa Genetics
8.6.1 Mammary Aspirate Specimen Cytology Test (MASCT™)
8.6.2 ForeCYTE Breast Health Test (SM)
8.6.3 ArgusCYTE Breast Health Test (SM)
8.6.4 FullCYTE Breast Health Test
8.6.5 NextCYTE Breast Health Test
8.7 BioMerieux
8.7.1 THxID™-BRAF Kit
8.8 Celera (Quest Diagnostics)
8.9 deCode Genetics
8.9.1 deCODE Breast Cancer™
8.9.2 deCODE Prostate Cancer™
8.9.3 deCODE AF™
8.9.4 deCODE Complete™
8.9.5 deCODE Cancer™
8.9.6 deCODE Services
8.10 Foundation Medicine
8.10.1 FoundationOne

© Kelly Scientific Publications 2014
8.10.2 FoundationOne Hem
8.11 Illumina
8.11.1 Illumina New-Generation Sequencing Technology
8.11.2 Illumina HiSeq 2500/1500
8.11.3 Illumina HiSeq 2000/1000
8.11.4 Genome Analyzer IIx
8.11.5 Illumina MiSeq
8.11.6 Illumina HiScanHQ
8.11.7 Illumina HiScan and iScan Array
8.12 Genelex
8.13 Genomic Health
8.13.1 Oncotype DX Breast Cancer Test
8.13.2 Oncotype DX Colon Cancer Test
8.13.3 Oncotype DX Prostate Cancer Assay
8.14 Myriad Genetics
8.14.1 BRACAnalysis®
8.14.2 Comprehensive BRACAnalysis®
8.14.3 BRACAnalysis® Rearrangement Test (BART)
8.14.4 Single Site BRACAnalysis®
8.14.5 Multisite 3 BRACAnalysis®
8.14.6 COLARIS®/COLARIS AP®
8.14.7 MELARIS®
8.14.8 PANEXIA®
8.14.9 OnDose®
8.14.10 PREZEOnt™
8.14.11 THERAGUIDE® 5FU
8.14.12 ProLaris®
8.15 Nodility
8.16 OriGene
8.16.1 TissueScan™ Cancer cDNA Arrays
8.17 Randox
8.17.1 Tumor PSA Marker Array
8.17.2 Tumor Marker Array 3
8.17.3 KRAS/ BRAF/PIK3CA Array
8.18 Qiagen
8.18.1 Genotyping Products
8.18.2 QIAsymphony Platform
8.18.3 Therascreen® EGFR RGQ PCR Kit
8.18.4 Therascreen KRAS RGQ PCR System
8.18.5 Therascreen® IDH1/2 test
8.19 Roche
8.19.1 Cobas® EGFR Mutation Test
9.11 Genelex  
9.12 Genomic Health  
9.13 Myriad  
9.14 Nodality  
9.15 Qiagen  

10.0 Objective Business and Strategic Analysis of the Cancer Biomarker Market  
10.1 Drivers of Oncogenic Biomarker Market  
10.1.1 High demand and Unmet Need Enhances the Global Biomarker Market  
10.1.2 Biomarkers are Highly Specific Diagnostic and Prognostic Clinical Tools  
10.1.3 Increasing Cancer Prevalence Globally  
10.1.4 FDA Support Increases Biomarker Development  
10.1.5 More Streamlined Clinical Trials  
10.1.6 Significant Growth of High-Impact Oncogenic Biomarker Research  
10.1.7 Advancements in Discovery Technologies  
10.2 Challenges of the Oncogenic Biomarker Market  
10.2.1 Variability of Biomarkers within Different Cancer Subtypes  
10.2.2 Integration of Genomics and Biomarker Diagnostics into the Healthcare System  
10.2.3 Ethical Considerations  
10.3 Restraints of the Cancer Biomarker Market  
10.3.1 Initial Investment into Biomarker Discovery and Development  
10.3.2 Are Biomarkers Profitable for Smaller Companies?  
10.4 Opportunities for the Cancer Biomarker Market  
10.4.1 Personalized Medicine Market Opportunities  
10.4.2 Companion Diagnostics  

Benefits of Investing in our Cutting-Edge Reports

Clients receive complementary content* with mid-level and enterprise wide licences

Post-sale complementary consultation with senior expert analyst is included

Use of tables and figures in your own reports and presentations is permitted

Each report provides straight-talking strategic analysis & sector intelligence

All reports are updated each quarter to give you the most up-to-date information

WE WANT TO MAXIMIZE YOUR BUSINESS POTENTIAL

* Subject to terms & conditions negotiated with Kelly Scientific Publications prior to sale

List of Figures

© Kelly Scientific Publications 2014
Figure 9.8: Affymetrix Revenue Derived from the US, 2009-2012
Figure 9.9: Affymetrix Net Loss, 2009-2012
Figure 9.10: Affymetrix Research and Development Funding, 2009-2012
Figure 9.11: Affymetrix Revenue Generated within USA (Percentage) 2010-2012
Figure 9.12: Astex Pharmaceuticals Priority Pipeline Products SGI-110 and AT13387 by Indication, Clinical Phase and Timeline
Figure 9.13: Astex Pharmaceuticals Revenue Generated 2008-2012
Figure 9.14: Astex Pharmaceuticals Net Income 2009-2012
Figure 9.15: Atossa Genetics Total Revenue (US$) 2011, 2012
Figure 9.16: Atossa Genetics Revenue (US$) Generated by MASCT Sales and ForeCYTE & ArgusCYTE Diagnostic Testing, 2012
Figure 9.17: Atossa Genetics Percentage Revenue Generated by MASCT Sales and ForeCYTE & ArgusCYTE Diagnostic Testing, 2012
Figure 9.18: Quest Diagnostics Revenue ($ Billions) 2008-2013
Figure 9.19: Quest Diagnostics Operating Revenue ($ Billions) 2008-2013
Figure 9.20: Quest Diagnostics Net Income ($ Billions) 2008-2013
Figure 9.21: Celera (Quest Diagnostics) Historic Revenue Generated 2008-2010
Figure 9.22: Celera (Quest Diagnostics) Historic Gross Margin Generated 2008-2010
Figure 9.23: Celera (Quest Diagnostics) Historic Revenue Generated– Laboratory Services and Products 2008-2010
Figure 9.24: Celera (Quest Diagnostics) Historic Revenue (%) Generated by Distribution Agreement with Abbott 2008-2010
Figure 9.25: Celera (Quest Diagnostics) Historic Research and Development Spending 2008-2010
Figure 9.26: deCode Genetics Historic Net Loss Incurred 2004-2008
Figure 9.27: Foundation Medicine International Sales – FoundationOne 2012-2013
Figure 9.28: Foundation Medicine International Revenue 2012-2013
Figure 9.29: Foundation Medicine Geographical (USA) Revenue Percentage 2011-2013
Figure 9.30: Illumina Revenue Generated ($ Billions) 2010-2013
Figure 9.31: Illumina Net Income Generated ($ Billions) 2010-2013
Figure 9.32: Genomic Health Oncotype DX Test Revenue 2008-2013
Figure 9.33: Myriad Revenue Generated 2007-2014
Figure 9.34: Operating Income Generated by Myriad 2007-2013
Figure 9.35: Myriad Revenue Generated by Molecular Diagnostic Testing and Companion Diagnostic Services, 2012-2013
Figure 9.36: Future Molecular Diagnostic Pipeline of Myriad
Figure 9.37: Customer Profile of Qiagen – Percentage of Net Sales 2012/2013
Figure 9.38: Qiagen Global Net Sales 2007-2013
Figure 9.39: Qiagen Operating Income 2007-2013
Figure 9.40: Qiagen Global Net Income 2007-2013

List of Tables
Table 2.1: QUICKFACTs- Top Five Most Frequent Cancers in Men and Women, Globally

Table 2.2: Main Clinical Stages of Lung Cancer

Table 2.3: Current Therapeutic Options for Lung Cancer

Table 2.4: QUICKFACTs- Estimated Age-Standardised Incidence Rate per 100,000 of Breast Cancer per Country, Worldwide

Table 2.5: Risk Factors of Colorectal Cancer

Table 3.1: Important Advantages of Using Biomarkers as Diagnostic Tools

Table 3.2: Biomarkers in Early Drug Development and Decision Making

Table 3.3: Biomarkers in Later Drug Development and Decision Making

Table 3.4: Functions of Biomarkers within the Healthcare Setting

Table 3.5: Ideal Attributes of Clinical Oncogenic Biomarkers

Table 3.6: Main Technologies Used in the Discovery of Biomarkers

Table 3.7: Proteomic Technologies Used in Biomarker Discovery

Table 3.8: Types of Cancer Aided Diagnostically by Mass Spectrometry

Table 3.9: Recommendations for Use of MALDI-TOF MS in Cancer Diagnostics

Table 3.10: Metabolomic Discovered Potential Oncogenic Biomarkers

Table 3.11: Cancer Biomarkers in Clinical Practice Using ELISA Technology

Table 3.12: Putative Cancer Biomarkers that can be Detected using ELISA Technology

Table 3.13: Advantages of Selected (Multiple) Reaction Monitoring Technique in Biomarker Discovery

Table 3.14: Major Advantages of Microarray Assays

Table 3.15: Applications of Microarrays

Table 3.16: Applications of Microarray Technology in Cancer Diagnostics

Table 3.17: Commercially Available Microarray Kits for Cancer Diagnostics

Table 3.18: Recommendations for Use of Microarrays in Cancer Diagnostics

Table 3.19: Digital PCR in Comparison to Real-time PCR and Traditional PCR

Table 3.20: Advantages of Digital PCR

Table 3.21: Applications of Digital PCR

Table 4.1: Current General Classes of Biomarker Assay as Defined by the American Association of Pharmaceutical Scientists

Table 4.2: Comparison of Validative Properties of Different Bioassay Classes

Table 5.1: Catalogue of Somatic Mutations in Cancer (COSMIC) Current Statistics

Table 5.2: Important Genetic Oncogenic Biomarkers and Their Application in Treatment

Table 5.3: P53 Somatic Mutation Prevalence by Tumor Site

Table 5.4: P53 Germline Mutation Prevalence by Tumor Site

Table 5.5: List of P53 Down-regulated Gene Targets

Table 5.6: List of P53 Up-regulated Gene Targets

Table 5.7: Positive Regulators of Epidermal Growth Factor Receptor (EGFR) Activity

Table 5.8: Types of Cancer Associated with EGFR Over-expression

Table 5.9: EGFR-Activating and Resistance Mutations Identified in Lung Adenocarcinoma

Table 5.10: Current Next Generation EGFR Inhibitors that Target the T790M Mutation

Table 5.11: Prevalence of Deleterious Mutations in BRCA1 and BRCA2 Genes

Table 5.12: Prevalence of Deleterious Mutations in BRCA1 and BRCA2 in Individuals of Ashkenazi Ancestry

Table 5.13: Risk Factors for Hereditary Breast and Ovarian Cancer (HBOC)

Table 5.14: PARP Inhibitors in Late-Stage Development

Table 5.15: Novel and Potential Biomarkers Within the PARP-Inhibitor Response Pathway

Table 5.16: Negative Regulators of PTEN Protein Expression

Table 5.17: Positive Regulators of PTEN Protein Expression

Table 5.18: ATM Molecular Targets and Protein Interactions

Table 5.19: Key Facts Regarding MiR-17/92 Cluster

© Kelly Scientific Publications 2014
Table 5.20: Expression Levels of Individual MiR-17/92 Biomarkers in Cancer, Cardiovascular Disease, Alzheimer's, Multiple Sclerosis, Aging and Normal Development
Table 5.21: Functional and Validated Positive Regulators of MiR-17/92
Table 5.22: Functional and Validated Negative Regulators of MiR-17/92
Table 5.23: Potential Regulators of MiR-17/92
Table 5.24: Cellular Signal Transduction Pathways Regulated by the MiR-17/92 Cluster
Table 5.25: Specific Cell Death Protein Targets of the MiR-17/92 Cluster
Table 5.26: Specific Cell Cycle Arrest Protein Targets of the MiR-17/92 Cluster
Table 5.27: Specific Cell Cycle Regulation Protein Targets of the MiR-17/92 Cluster
Table 5.28: Specific Heart and Lung Development Protein Targets of the MiR-17/92 Cluster
Table 5.29: Specific Cell Proliferation Protein Targets of the MiR-17/92 Cluster

Table 6.1: Global Biomarker Market Worth (Billions) and CAGR (%) 2011-2018
Table 6.2: Main Diagnostic Areas Within Oncology Biomarker Market
Table 6.3: Future Diagnostic Areas With High Potential Within Oncology Biomarker Market
Table 6.4: Global Cancer Profiling Technology Market Worth (Billions) and CAGR 2013-2018
Table 6.5: Global Cancer Biomarker Market Worth (Billions) and CAGR (%) 2009-2018
Table 6.6: USA Cancer Biomarker Market Share Compared to Global Biomarker Market 2013-2018
Table 6.7: Main Sub-Sets of Oncogenic Biomarker Research Published 2008-2013

Table 7.1: Patent Listing of Affymetrix Array technology
Table 7.2: Patent Listing of Affymetrix Genotyping Technology
Table 7.3: Patent Listing of Affymetrix Expression and Profiling Technology
Table 7.4: Advantages of Astex Pharmaceuticals Pyramid™ Fragment-Drug-Discovery System
Table 7.5: Astex Pharmaceuticals Pipeline Portfolio
Table 7.6: Astex Pharmaceuticals Pipeline Portfolio Funded Completely by Partner Companies
Table 7.7: Potential Business Partnerships of Celldex Therapeutics
Table 7.8: Illumina Core Technologies
Table 7.9: Illumina Core Technology Applications
Table 7.10: Illumina Instrument Product Portfolio
Table 7.11: Illumina Assay Product Portfolio
Table 7.12: Genetic Test Panel Available from Genelex for Research Institutions and Clinical Trials
Table 7.13: Pre-Clinical, Clinical and Commercial Applications of SCNP by Nodality
Table 7.14: Qiagen Timeline of Events, 1994-2012
Table 7.15: QUICKFACTs - Range of Product Groups from Qiagen

Table 8.1: Types of Diagnostic Tests Available to Determine HER2 Status in Breast Cancer Patients
Table 8.2: Validated HER2 Tests for Cancer
Table 8.3: Advantages and Limitations of IHC HER2 testing applied to breast cancer
Table 8.4: In-Situ Hybridization Determination of HER2 Expression by PathVysion® and HER2 FISH pharmDxTM
Table 8.5: HER2 CISH Determination
Table 8.6: Validated FISH Kits for HER2 Testing in Breast Cancer
Table 8.7: Validated SISH Kits for HER2 Testing in Breast Cancer
Table 8.8: Validated CISH Kits for HER2 Testing in Breast Cancer
Table 8.9: Advantages and Limitations of ISH Techniques Applied to HER2 Testing in Breast Cancer
Table 8.10: 23andMe Disease Risk Genetic Test Panel
Table 8.11: 23andMe Carrier Status Genetic Test Panel
Table 8.12: 23andMe Drug Response Genetic Marker Test Panel
Table 8.13: 23andMe Genetic Traits Test Panel
Table 8.14: 23andMe Patient Overview of Affymetrix
Table 8.15: Microarray Products by Affymetrix
Table 8.16: Affymetrix Research Services Laboratory (ARSL) Premier Services
Table 8.17: Genetic Applications of Axiom® Technology by Affymetrix
Table 8.19: Clinical Diagnostic Test Kits Available from Ambry Genetics
Table 8.20: Ambry Genetics Cancer Test Portfolio and Genetic Biomarkers
Table 8.21: Ambry Genetics Comprehensive List of Genetic Tests by Disease and Genetic Biomarkers
Table 8.22: Ambry Genetics BRCA1/2 Breast Cancer Test Portfolio
Table 8.23: Ambry Genetics Genome Sequencing Services
Table 8.24: Ambry Genetics New Generation Sequencing Platform Portfolio & Applications
Table 8.25: Range of Small Molecule Therapeutics Available from Astex Pharmaceuticals
Table 8.26: Genetic Tests Available from BHL/Celera
Table 8.27: Panel of BHL Clinical Diagnostic Tests
Table 8.28: Genetic Diagnostic Tests Available from deCode Genetics
Table 8.29: Disease States that are Included in the deCODE Complete™ Genetic Screen
Table 8.30: Panel of Diseases Screened for in the deCODE Cancer™ Test
Table 8.31: deCODE Genetics Genotyping and Sequencing Service
Table 8.32: deCODE Genetics Data Management, Protection and Storage Service
Table 8.33: deCODE Genetics Sequence Inputation and Data Analysis Service
Table 8.34: FoundationOne Assay Technical Specifications
Table 8.35: FoundationOne Assay Oncogenic Gene Portfolio
Table 8.36: FoundationOne Heme Assay Oncogenic Gene Portfolio
Table 8.37: Illumina HiSeq 2500/1500 Performance Parameters
Table 8.38: Illumina HiSeq 2000/1000 Performance Parameters
Table 8.39: Genome Analyzer IIX Performance Parameters
Table 8.40: Illumina MiSeq Product Specifications
Table 8.41: Illumina HiScanHQ Product Specifications
Table 8.42: Illumina HiScan and iScan Array Product Applications
Table 8.43: Illumina HiScan and iScan Array Kits
Table 8.44: Predictive Genetic Tests Available from Myriad
Table 8.45: Services offered with BRACAnalysis® Testing from Myriad
Table 8.46: Advantages of BRACAnalysis® Testing
Table 8.47: QUICK FACTs- Prevalence of Deleterious Mutations in BRCA1 & BRCA2 Genes
Table 8.48: QUICK FACTs- prevalence of deleterious mutations in BRCA1 and BRCA2 in individuals of Ashkenazi Ancestry
Table 8.49: QUICK FACTs- Risk Factors for Hereditary Breast and Ovarian Cancer (HBOC)
Table 8.50: QUICKFACTs- BRACAnalysis® Panel of Assays
Table 8.51: COLARIS® Test Range by Myriad
Table 8.52: COLARIS AP® Test Range by Myriad
Table 8.53: MELARIS® Test Range from Myriad
Table 8.54: Personalized Medicine Tests from Myriad
Table 8.55: The Prolaris Score for Prostate Cancer
Table 8.56: OnDose® Testing Procedure from Myriad
Table 8.57: OriGene TissueScan cDNA Array Oncology Product Portfolio
Table 8.58: Qiagen Genotyping Products for Sample Collection, stabilization and Storage
Table 8.59: Qiagen Genotyping Products for Genomic DNA Isolation and Purification
Table 8.60: Qiagen Genotyping Products for PCR Based Genotyping Analysis
Table 8.61: Qiagen Products for Genotyping Analysis
Table 8.62: Qiagen Genotyping Products for PCR Detection
Table 8.63: Qiagen Assays for Genetic Analysis
Table 8.64: Qiagen Pyrosequencing-Based Genetic Analysis Products
Table 8.65: Specifications and Features of Qiagen’s QIAsymphony and QIAsymphony RGQ
Table 9.1: Drug Classes Investigated by 23andMe Using Genome Wide Association Studies
Table 9.2: Acquisition Profile of Affymetrix
Table 9.3: Genetic Applications of Axiom® Technology by Affymetrix
Table 9.4: Diversified Business Units of Affymetrix
Table 9.5: Affymetrix AgBio Microarray Portfolio

© Kelly Scientific Publications 2014
Table 9.6: BioMerieux Immunodiagnostic Product Portfolio 195
Table 9.7: BioMerieux Microbiology Product Portfolio 196
Table 9.8: BioMerieux Molecular Diagnostic Product Portfolio 198
Table 9.9: Celera (Quest Diagnostics) Historic Operating (Loss) (US$) – Laboratory Services and Products 2008-2010 204
Table 9.10: Diagnostic Test Product Categories Manufactured by BHL/Celera and Exclusively Distributed by Abbott 204
Table 9.11: Celldex Therapeutics R&D Expenses ($) 2010-2012 207
Table 9.12: Price Listing of Genelex Familial Genetic Tests 213
Table 9.13: Myriad - Core Business Decisions and Impact on Industry 217
Table 9.14: Future Test Portfolio of Myriad 218
Table 9.15: Nodality’s Single Cell Network Profiling (SCNP) Technology as a Systems Based Biology Approach to Drug Discovery and Validation 219

Table 10.1: Drivers of the Oncogenic Biomarker Market 227
Table 10.2: Integration of Genomics and Biomarker Diagnostics into the Healthcare System 228
Table 10.3: Challenges of the Cancer Biomarker Market 228
1.0 Executive Summary

“GLOBAL & USA CANCER BIOMARKER MARKET to 2018 (Identification, Technologies, Market Analysis, Competitor Profiles, Companion Diagnostic Co-development, Business Strategies, Industry Trends, and Pipeline Analysis)” by Kelly Scientific Publications is a comprehensive report on the cancer biomarker industry and its impact on the health system. This report tackles the growing market interest in oncogenic biomarkers, personalized medicine, companion diagnostics and the associated market environment.

Cancer biomarkers are molecular or genetic moieties (e.g., cells, proteins/peptides, genetic mutations, gene products, enzymes, or hormones) that not only are readily identifiable, but easily quantified in the lab setting. They function primarily to identify or correlate significantly with the severity or occurrence of a certain disease state. The rise in number of oncogenic biomarkers over the last number of years has massive potential in the healthcare industry and serves to propel both the personalized medicine and companion diagnostic markets.

One of the most important aspects of biomarkers is their use to diagnose and assess the progress of disease states in patients. As quantitative markers, these agents also offer the ability to monitor response to certain drug treatments and so are important in the area of personalized medicine.

Individualized, targeted or personalized medicine aims to increase the efficacy of therapeutics via genetic testing and companion diagnostics. Personalized therapeutics and associated companion diagnostics will be more specific and effective thereby giving pharma/biotech companies a significant advantage to recuperate R&D costs. Personalized medicine will reduce the frequency of adverse drug reactions and therefore have a dramatic impact on health economics. Developmental and diagnostic companies will benefit from lower discovery and commercialization costs and more specific market subtypes.

This report describes the current technologies that are propelling the cancer biomarker and companion diagnostic market. It examines the current genetic diagnostic tests and companion diagnostic assays that are in use by the medical and pharmaceutical industry today. Current developments in personalized medicine and the pharmacogenomics revolution are discussed. The emerging trends that appear in the global market and the most developed market (US) are elucidated and analysed. This study reveals market figures of the overall biomarker market and the cancer biomarker space (2013-2018). Forecast projections and future growth rates are provided to give the reader a forthcoming perspective of this growing industry.

The study also provides a comprehensive financial, business strategy and product review of key players in the cancer biomarker industry. Strategic drivers and restraints of this market are revealed and market opportunities and challenges are identified.

In summary, the cancer biomarker and associated companion diagnostic market have huge opportunities for growth. This industry will revolutionize the healthcare system and will improve therapeutic effectiveness and reduce the severity of adverse effects. It has enormous potential for investment and the emergence of genetic-based in vitro diagnostics.

1.1 Objectives of Report

This is a comprehensive account of the market size, segmentation, key players, SWOT analysis, influential technologies, and business and economic environments. The report is supported by 280 tables & figures over 232 pages. This report is presented as follows:
GLOBAL & USA CANCER BIOMARKER MARKET to 2018

- By **Company** (e.g., 23andMe, AFFYMETRIX, ATOSSA GENETICS, NODALITY, deCode /Amgen, CELERA, MYRIAD, FOUNDATION MEDICINE, GENOMIC HEALTH)
- By **Geography** (Global, US)
- By **Sub-market** (Global Biomarker Market, Cancer Biomarker Market, Global Cancer Profiling Technology Market)

A wealth of **financial data & business strategy information** is provided including:

- Up-to-date company financials, sales & revenue figures
- Revenue and market forecasts up to 2018
- Business model strategies for diagnostic, pharmaceutical and biotechnology companies
- Therapeutics and Companion Diagnostics (e.g., BRAC Analysis, Oncotype Dx, KRAS Mutations)
- Comprehensive account of company product financials, portfolios & kits

**SWOT. Economic & Regulatory Environment** specifics include:

- Key strengths, weaknesses and threats influencing leading player position within the market
- Technologies driving the market (e.g., New-Generation Sequencing Technologies, Ultra-High Throughput Sequencing)
- Top fastest growing market segments and emerging opportunities
- Top pharmaceutical companies within the cancer biomarker market
- Comprehensive product portfolios, R&D activity and pipeline therapeutics
- M&A activity and future strategies of top companies
- Approved biomarker companion diagnostic tests
- High demand and Unmet Need Enhances the Global Biomarker Market
- FDA Support Increases Biomarker Development
- More Streamlined Clinical Trials
- Significant Growth of High-Impact Oncogenic Biomarker Research
- Advancements in Discovery Technologies
- Challenges of the Oncogenic Biomarker Market
- Variability of Biomarkers within Different Cancer Subtypes
- Integration of Genomics and Biomarker Diagnostics into the Healthcare System
- Ethical Considerations

This report highlights a number of significant pharmacos and gives details of their operations, products, financials and business strategy.

- 23andMe
- Affymetrix
- Ambry Genetics
- Astex Pharmaceuticals
- Atossa Genetics
- BioMerieux
- CuraGen
- Celera Corporation (Quest Diagnostics)
- CellDex Therapeutics
- deCode Genetics (Amgen)
- Foundation Medicine
- Illumina
- Genelex
1.2 Data Sources and Methodology

The project leader and author of this research obtained a Ph.D. in Medicine from the Royal College of Surgeons in Ireland, following completion of a M.Sc. in Biotechnology (NUIG) and an honours degree in Biochemistry from Trinity College Dublin. She has extensive experience in genetics, biomarker and pharmacogenomic research and development and has conducted post-doctoral studies and lecturing in Trinity College Dublin. With many years of medical writing and publishing the author also has extensive experience and knowledge of molecular biology, immunology, bioinformatics and diagnostic testing. As a pharma/biotech industry analyst she has significant expertise in laboratory diagnostic testing and instrument and reagent development technology.

Sources of information for this report were collected and compiled from company specific corporate websites, annual reports, press-releases, international scientific and medical journals and news and research reports. Graphical and numerical data have been referenced and sourced accordingly. Specific websites were consulted and referenced throughout the completion of this report including that of the Food and Drug Association (www.fda.gov), the National Cancer Institute and other government agencies worldwide. Kelly Scientific Publications has used the most recent statistical and numerical data available. The most reliable of data sources were used in the production of this report, however we cannot guarantee complete accuracy or completeness from secondary information sources.

1.3 Key Findings and Observations

1.3.1 What Makes Cancer Biomarkers so Important for the Healthcare Industry?

Cancer biomarkers are molecular or genetic moieties (e.g., cells, proteins/peptides, genetic mutations, gene products, enzymes, or hormones) that not only are readily identifiable, but easily quantified in the lab setting. They function primarily to identify or correlate significantly with the severity or occurrence of a certain disease state. The rise in number of oncogenic biomarkers over the last number of years has massive potential in the healthcare industry and serves to propel both the personalized medicine and companion diagnostic markets.

One of the most import aspects of biomarkers is their use to diagnose and assess the progress of disease states in patients. As quantitative markers, these agents also offer the ability to monitor response to certain drug treatments and so are important in the area of personalized medicine.

Biomarkers offer significant potential in advancing modern medicine with regards to improving patient diagnosis and treatment options. As many biomarkers are of genetic origin, they can also be used as predisposition markers. Other advantages of these molecular tools include the stratification of patient populations and an increased drug specificity to maximize efficacy and minimize toxicity. Therapies will become more specific as a result of using biomarkers as diagnostic tools, and this will in turn ensure that patients are more responsive to treatment without experiencing un-necessary adverse effects.
1.3.2 What Technologies are Used to Identify Novel Biomarkers?

The main technologies that are used to discover biomarkers include bioinformatics, genomics, next generation sequencing, proteomics, nanobiology, systems biology and also the use of stem cells. This report gives a comprehensive analysis of the most important techniques used in industry and R&D today, and reveals which technologies hold the most promise within the market. The report also delves into the complicated practice of biomarker validation and assesses the different phases of validation – from identification to quality control monitoring.

Table 1: Main Technologies Used in the Discovery of Biomarkers

<table>
<thead>
<tr>
<th>Genomics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Next Generation Sequencing</td>
</tr>
<tr>
<td>Bioinformatics</td>
</tr>
<tr>
<td>Proteomics</td>
</tr>
<tr>
<td>Metabolomics</td>
</tr>
<tr>
<td>Nanobiology</td>
</tr>
<tr>
<td>Systems Biology</td>
</tr>
<tr>
<td>Imaging Technologies</td>
</tr>
<tr>
<td>Stem Cells</td>
</tr>
</tbody>
</table>

1.3.3 Increase in Cancer Prevalence is Propelling the Oncogenic Biomarker Market

Over 32 million people globally are living with cancer in 2014. According to Cancer Research UK, over 14.1 million new cancer cases were diagnosed in 2012. Of these, 7.4 million men and 6.6 million women were diagnosed. The most common cancers reported are:

- Lung
- Breast
- Colorectal (bowel)
- Prostate

These four cancer subtypes account for 40% of total. In 2012 alone, 8.2 million people died from cancer globally, with 60% of these occurring in less developed regions. Lung, liver, stomach and bowel cancers were responsible for the majority of these deaths, with lung cancer the most significant killer at 20% or 1.59 million deaths. Liver cancer killed 0.8 million in 2012, with stomach cancer killing 0.7 million.

Cancer is the second most common cause of death in the US today, killing one in every four. The National Cancer Institute estimates that 13.7 million Americans have had cancer in the past or are currently suffering from this disease. Recent statistics from the American Cancer Society (ACS) estimated over 580,000 US citizens died from cancer in 2013. Of these, 174,100 deaths could have been prevented. The World Cancer Research Fund estimated that up to 33% of US cancers in 2013 were attributed to lifestyle factors.
Table 2: Top Five Most Frequent Cancers in Men and Women, Globally

<table>
<thead>
<tr>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>Breast</td>
<td>Lung</td>
</tr>
<tr>
<td>Prostate</td>
<td>Colorectum</td>
<td>Breast</td>
</tr>
<tr>
<td>Colorectum</td>
<td>Cervix uteri</td>
<td>Colorectum</td>
</tr>
<tr>
<td>Stomach</td>
<td>Lung</td>
<td>Stomach</td>
</tr>
<tr>
<td>Liver</td>
<td>Stomach</td>
<td>Prostate</td>
</tr>
</tbody>
</table>

Figure 1: Percentage of Lung, Breast and Colorectal Cancer Diagnoses Globally

1.3.4 Global and US Economic Impact of Cancer

GLOBOCAN estimates that by 2025, 19.3 million new cancer cases annually will be diagnosed. This will be primarily due to an aging population. Furthermore, the majority of these cases will occur in less developed regions of the world.

The American Cancer Society estimates that the global economic burden of cancer is in the region of $900 billion annually. This is $1.5 of worldwide GDP figures. The top cancers that contribute to this economic burden are lung, colorectal and breast cancer, costing over $188 billion, $99 billion, and $88 billion respectively.

The National Institutes of Health (NIH) indicated that the economic burden of cancer in the US is over $200 billion, annually. This is divided into direct medical costs ($77 billion) and indirect mortality costs ($123 billion) that includes the cost of lost productivity.
1.3.5  How Cancer Biomarkers are Revolutionizing Cancer Treatment

Breast cancer and the use of Herceptin as treatment is an important example of how biomarker detection saves lives and money. Breast cancer is the second highest frequency of cancer globally with a reported 10.9% of total cancer diagnoses. Herceptin (trastuzumab, Genentech) was FDA approved for use in breast cancer patients in 1998 at a cost of between $50,000 to $100,000 annually. However, subsequent analysis indicated that Herceptin was only effective in 25-30% of women whose tumour cells over synthesized the protein human epidermal growth factor-2 HER2/Neu.

By 2006 all invasive breast cancer patients were recommended to take the HER2 genetic test to identify if they would respond to Herceptin treatment. A further breakthrough in 2008 occurred when a more efficacious Herceptin formulation was approved. Since 2010, more than 420,000 women have been treated with Herceptin, globally.

Today, over 1.7 million women are diagnosed with breast cancer annually (GLOBOCAN). This is a 20% increase in incidence since 2008 estimates, and 14% increase in mortality rates. In 2012 alone, 522,000 women died of breast cancer, compared to 458,000 deaths in 2008.

Early screening and a highly specific biomarker assay is important in detecting cancer, especially in colorectal and prostate cancers as early symptoms are negligible. The use of biomarker companion diagnostics will not only save payers money, it will also promote more targeted therapeutics – thus providing patients with personalized cancer treatment. This has the added benefit of being more effective and having lower adverse reactions and toxicity profiles. Overall, the use of oncogenic biomarker tests and targeted cancer therapies will revolutionize cancer treatment in the short and longer terms.
1.3.6  What are the most Significant and Strategic Cancer Biomarkers?

This cutting-edge report provides a wealth of information on the current and prospective biomarkers in the cancer field. A comprehensive array of the most significant oncogenic biomarker families are analysed with respect to their mechanism of action, clinical functionality and also current clinical trials and studies that are investigating the following:

- P53 Transcription Factor Oncogenic Mutations
- Epidermal Growth Factor Receptor (EGFR)
- BRCA- Mutant Breast and Ovarian Cancer biomarkers
- PARP-Inhibitors
- PTEN – the Tumour Suppressor Gene
- Ataxia Telangiectasia Mutated (ATM)
- TMPRSS2-ERG
- MiR-17/92 Cluster
- Significant Molecular Targets of MiR-17/92

A number of cancer types have developed resistance to targeted therapies, and so this report also identifies current strategies to defeat resistance in certain biomarker types.

1.3.7  Global Biomarker Test Market Analysis

Kelly Scientific Publications estimate that the global biomarker market is currently worth $[_value] billion up from $[value] billion in 2012. Over the last number of years it has grown at a CAGR of [value]%, however this is expected to rise to [value]% between 2013 and 2018. By 2018, the global biomarker market is estimated to be worth over $[value].

The global biomarker market is segmented into the following therapeutic areas:

- Oncology
- Cardiology
- Neurology
- Infectious disease (e.g., HIV, TB)
- Renal disorders
- Diabetes
- Arthritis

Detailed analysis of this market is provided within this report. The cancer biomarker market is by far the most established within the biomarker space.
1.3.8 Global Cancer Biomarker Market Analysis

As early as 2009, the global cancer biomarker market was worth $4.1 billion and grew to $7.9 billion in 2013 with a CAGR of 18.1%. Over the next five years the market is expected to grow further, by a CAGR of 18.22% to reach over $18 billion in 2018. It is estimated that by 2018, 30% of cancer patients will have a predictive biomarker assay. Currently, 22% of pipeline therapeutics are being investigated in a subsection of patients defined by using a biomarker assisted assay. The cancer biomarker market has the largest share of the overall biomarker market at 45.6% in 2013 ($7.9 billion of $17.3 billion total). By 2018, the oncology biomarker market is expected to be worth $18 billion, compared to $40 billion in total.

Figure 2: Oncogenic Biomarker Share of Total Personalized Medicine Biomarker Space

Figure 4: Global Cancer Biomarker Market Worth (Billions) and CAGR (%) 2009-2018
There is considerable growth within the oncology biomarker market (18.2%) due to a number of reasons including:

- Rising prevalence of cancer rates globally
- Increased emphasis on early diagnosis
- Enhanced testing capabilities
- Increased awareness and uptake of high-throughput technologies
- Significant advancements in biomarker research
- Increase in number of targeted oncology therapy clinical trials
- US government initiatives
- Increased healthcare professional awareness
- Increased patient awareness
- Strength of the personalized medicine market
- Strength of the overall biomarker market

This report gives a full analysis of the above points and analyses how they will affect the market. In the near future, the oncology biomarker testing market will see the introduction of new assays entering the space. This is primarily due to the fact that technologies such as next generation sequencing will become more cost effective and affordable. Out-licensing and also the co-development of therapy-specific companion diagnostics will promote the market further. Initially, these assays require high levels of healthcare professional interpretation and they are complex to carry out, however over time these restraints will decrease and targeted biomarker evaluation will be more significantly integrated into the healthcare system.

1.3.9 Oncology Biomarker Market Main Industry Players

Competitor analysis of the main and upcoming market players is also included in this detailed report. We include up-to-date financial and business strategy analysis for each company, and also detail of every oncology biomarker assay that they provide. Pipeline portfolios are also included, as are current clinical trials, FDA approvals, business collaborations and mergers. The following companies have been analysed by experts at Kelly Scientific Publications:

- 23andMe
- Affymetrix
- Ambry Genetics
- Astex Pharmaceuticals
- Atossa Genetics
- BioMerieux
- CuraGen
- Celera Corporation (Quest Diagnostics)
- CellDex Therapeutics
- deCode Genetics (Amgen)
- Foundation Medicine
- Illumina
- Genelex
- Genomic Health
1.3.10 Drivers, Restraints, Opportunities and Challenges of the Cancer Biomarker Market

This analyses also provides you with a comprehensive account of the drivers and restraints of the global and US cancer biomarker markets. There is a general high demand for biomarker assays and corresponding targeted therapeutics and also an un-met need in the market space. Clinical trials are supporting market growth as they are more streamlined and increasing FDA and regulatory support is also proving positive. There has been a significant boost in oncogenic biomarker research publications over the last five years, and this is further enhancing R&D budgets and investment opportunities. A number of restraints such as initial investment, sample collection and storage and also regulatory hurdles were also identified. The cancer biomarker market however, has enormous potential not only within the overall biomarker space, but also within the personalized medicine and companion diagnostic markets.