

# 2014 Opportunities in the Italian Cancer Diagnostics Market

## Table of Contents

### **I. Introduction**

### **II. Major Product Development Opportunities**

- A. Reagent Kits and Test Systems/Panels
- B. Instrumentation
- C. Computers, Software and Automation
- D. Auxiliary Products

### **III. Design Criteria for Decentralized Testing Products**

### **IV. Alternative Market Penetration Strategies**

- A. Internal Development
- B. Collaborative Arrangements
- C. University Contracts
- D. Distribution Strategies
  - 1. Marketing Approaches
  - 2. Product Complexity
  - 3. Customer Preference
  - 4. Established Suppliers
  - 5. Emerging Suppliers
  - 6. Major Types of Distributors
  - 7. Market Segmentation Factor

### **V. Potential Market Entry Barriers and Risks**

- A. Market Maturity
- B. Cost Containment
- C. Competition
- D. Technological Edge and Limitations
- E. Patent Protection
- F. Regulatory Constraints
- G. Decentralized Testing Market Challenges

## Table of Contents

### **VI. Worldwide Market and Technology Overview**

#### A. Cancer Statistics and Etiology

1. Breast Cancer
2. Lung Cancer
3. Colon and Rectum Cancer
4. Prostate Cancer
5. Stomach Cancer
6. Leukemia
7. Lymphoma
8. Oral Cancer
9. Skin Cancer
10. Uterine Cancer
11. Ovarian Cancer
12. Bladder Cancer

#### B. Major Current And Emerging Cancer Diagnostic Tests

1. Introduction
2. Tumor Marker Classification
3. ACTH
4. Alpha-Fetoprotein (AFP)
5. Beta-2 Microglobulin
6. CA 15-3/27.29
7. CA 19-9
8. CA-125
9. Calcitonin
10. Carcinoembryonic Antigen (CEA)
11. Estrogen and Progesterone Receptors
12. Ferritin
13. Gastrin
14. Human Chorionic Gonadotropin (HCG)
15. Insulin
16. NSE
17. Occult Blood
18. PAP Smear/HPV
19. Prostatic Acid Phosphatase (PAP)
20. Prostate-Specific Antigen (PSA)
21. Squamous Cell Carcinoma Antigen (SCC)
22. T and B Lymphocytes

## Table of Contents

- 23. TdT
- 24. Thyroglobulin
- 25. Tissue Polypeptide Antigen (TPA)
- 26. Biochemical Tumor Markers
  - ADA
  - B-Protein
  - PNP
  - 5'-Nucleotidase
- 27. Oncogenes
  - Abl/abl-bcr
  - AIB1
  - BCL-2
  - BRCA1
  - CD44
  - C-fos
  - C-myb
  - C-myc
  - CYP-17
  - Erb-B
  - HPC1
  - N-myc
  - P40
  - P51
  - P53
  - PIK3CA
  - PTI-1
  - Ras
  - Reg
  - Sis
  - Src
- 28. Polypeptide Growth Factors
  - Basic Fibroblast Growth Factor
  - Beta-TGF
  - Cachectin (TNT)
  - Calmodulin
  - ECFR
  - Nerve Growth Factor (NGF)
  - Epidermal Growth Factor (EGF)
  - Ornithine Decarboxylase
  - Transferrin
  - Transforming Growth Factor-Alpha

## Table of Contents

- 29. Ectopic Hormones
- 30. Colony Stimulating Factors
- 31. Lymphokines
  - Alpha-Interferon
  - B Cell Growth Factors
  - B Cell Growth Factor (BCGF)
  - Gamma-Interferon
  - Interleukin-1 (IL-1)
  - Macrophage Activating Factor
- 32. Immunohistochemical Stains
- 33. Emerging Tumor Markers
  - N-Acetylglucosamine
  - Actin
  - Alpha-Actin
  - Antineuronal Antibodies
  - 7B2
  - B72.3
  - Bax
  - BCD-F9
  - BLCA-4
  - Blood Group Antigens A,B,H
  - CA 50
  - CA 72-4/TAG-72
  - CA 195
  - CA-242
  - CA-549
  - CAM 26
  - CAR-3
  - Cathepsin-D
  - Chromogranin A and B
  - Cluster 1 Antigen
  - Cluster-5/5A Antigen
  - CTA
  - CU18
  - DR-70
  - DU-PAN-2
  - Endometrial Bleeding Associated Factor
  - Endostatin
  - Epithelial Membrane Antigen
  - Feulgen Hydrolysis
  - Fibronectin

## Table of Contents

- FSH
- (1->3)-L-fucosyltransferase
- Gastrin-Releasing Peptide (GRP)
- GDCFP-15
- Glucagon
- Glycoamines
- H23
- Her-2
- Human Carcinoma Antigen
- HPA
- HSP27
- Intermediate Filaments
- Cytokeratins/CK18/Cyfra 21-1
- Desmin
- Gliofibrillary Acid Protein
- Neurofilaments
- Vimentin
- KA 93
- Kinases
- KP16D3
- LAI
- Leukocyte Common Antigen
- Lewis Antigens
- Lysophosphatidic Acid (LPA)
- Ma 695/Ma 552
- MABDF3
- MAG
- ME1
- Minactivin
- MN/CA9
- MSA
- Mucin Cancer Antigen (MCA)
- Multiple Tumor Suppressor 1
- Myosin
- NEA-130
- NMP22
- OA-519
- Opioid Peptides
- P-glycoprotein
- Pancreatic Oncofetal Antigen (POA)
- Placental Lactogen
- PR92

## Table of Contents

- Proliferative Index, Ki-67
- Px
- RB Inactivation/Deletion
- Ret
- SCCL 175
- Selectin
- Sialic Acid
- Sialyl SSEA-1/SLX
- SN10
- Somatostatin
- TA-90
- TABA
- Tachykinin
- TAG 12
- TPS
- Troponin
- Tubulin
- VCAM
- VEGF
- Villen

### C. Instrumentation Review And Market Needs

### D. Current and Emerging Technologies

1. Monoclonal and Polyclonal Antibodies
2. Immunoassays
  - a. Technological Principle
  - b. Radioimmunoassay (RIA)
  - c. Enzyme Immunoassays (EIA)
    - Overview
    - ELISA
    - Immunofiltration
    - Particle-Membrane Capture Immunoassay
    - Enzyme Amplification
  - d. Fluorescent Immunoassays
  - e. Luminescence
    - Chemiluminescence
    - Bioluminescence
  - f. Latex Agglutination
    - g. Immunoprecipitation
  - h. Affinity Chromatographu
  - e. Liposome Flow-Injection Immunoassay

## Table of Contents

3. Molecular Diagnostics
  - a. Technology Overview
  - b. Amplification Methods
4. Chromosome Analysis
  - a. Chronic Myelogenous Leukemia (CML)
  - b. Acute Myeloid Leukemia (AML)
  - c. Acute Lymphoblastic Leukemia (ALL)
  - d. Malignant Lymphomas Lymphoid Malignancies
  - e. Chronic Lymphocytic Leukemia (CLL)
  - f. Solid Cancers
  - g. Chromosomal Translocation and Oncogenes
5. Artificial Intelligence
6. Flow Cytometry
7. Two Dimensional Gel Electrophoresis (2-DGE)
8. Biosensors
9. Competing/Complementing Technologies
  - a. CT
  - b. MRI
  - c. NMR
  - d. PET
  - e. Photonics Spectroscopy

### E. Personal Testing

## **VII. Italy**

- A. Executive Summary
- B. Business Environment
- C. Market Structure
- D. Market Size, Growth and Major Suppliers' Sales  
And Market Shares

## **VIII. Competitive Profiles**

- Abbott
- AdnaGen
- Agilent Technologies
- Applied Gene Technologies
- Arca/Nuvelo
- Beckman Coulter/Danaher
- Becton Dickinson
- Biomedical Diagnostics

## Table of Contents

- bioMerieux
- Bio-Rad
- CellSearch
- Cepheid
- Correlogic Systems/Vermillion
- Decode
- Diadexus
- Diagnocure
- Diasorin
- Eiken Chemical
- Epigenomics
- Enterix
- Enzo Biochem
- Exact Sciences
- Fujirebio/Innogenetics
- Guided Therapeutics
- Hologic/Gen-Probe
- Kreatech
- Kyowa Medex
- Life Technologies
- Mackay Life Sciences
- Myriad Genetics
- Nanogen Elitech
- OncoLab
- Ortho-Clinical Diagnostics
- Panacea Pharmaceuticals
- Polartech
- Polymedco
- PreMD
- Qiagen/Ipsogen
- Quest Diagnostics
- Radient Pharmaceuticals
- Roche
- Scienion
- Sequenom
- Siemens Healthcare
- Takara Bio
- Targeted Diagnostics & Therapeutics
- Tosoh
- Veridex
- Wako Pure Chemicals
- Wallac/PE
- Zila



## **Table of Contents**

**IX. Appendixes: Appendix I:** Major Universities and Research Centers Developing Cancer Diagnostic Technology and Applications

**Appendix II:** Assumed Currency Exchange Rates

## **List of Tables**

Tumor Marker Classification

Major Companies Developing or Marketing  
ACTH Tests

Major Companies Developing or Marketing  
AFP Tests

Major Companies Developing or Marketing  
Beta-2 Microglobulin Tests

Major Companies Developing or Marketing  
CA 15-3/27.29 Tests

Major Companies Developing or Marketing  
CA 19-9 Tests

Major Companies Developing or Marketing  
CA 125 Tests

Major Companies Developing or Marketing  
Calcitonin Tests

Major Companies Developing or Marketing  
CEA Tests

Major Companies Developing or Marketing  
Estrogen Receptor Tests

Major Companies Developing or Marketing  
Progesterone Receptor Tests

Major Companies Developing or Marketing  
Ferritin Tests

Major Companies Developing or Marketing  
Gastrin Tests

Major Companies Developing or Marketing  
HCG Tests

## **List of Tables**

Major Companies Developing or Marketing  
Insulin Tests

Major Companies Developing or Marketing  
NSE Tests

Major Companies Developing or Marketing  
Occult Blood Tests

Major Companies Developing or Marketing  
PAP Smear/HPV Tests

Major Companies Developing or Marketing  
PAP Tests

Major Companies Developing or Marketing  
PSA Tests

Major Companies Developing or Marketing  
Lymphocyte Subclassification Tests

Biochemical Markers Potential Applications  
In Cancer Diagnosis

Oncogenes Potential Applications  
In Cancer Diagnosis

Major Companies Developing or Marketing  
Oncogene Tests

Growth Factors Potential Applications  
In Cancer Diagnosis

Colony Stimulating Factors Potential  
Applications in Cancer Diagnosis

Lymphokines Potential Applications In Cancer Diagnosis

Immunohistochemical Stains Potential  
Applications in Cancer Diagnosis

## **List of Tables**

Executive Summary Table: Italy, Total Tumor Marker Test Volume and Diagnostics Sales Forecast by Market Segment

Italy, Estimated Cancer Death Rates Per 100,000 Population

Italy, Laboratories Performing Tumor Marker Tests by Market Segment

Italy, Hospital Laboratories Performing Tumor Marker Tests by Bed Size

Italy, Commercial/Private Laboratories Performing Tumor Markers by Annual Test Volume

Italy, Total Tumor Marker Test Volume Forecast by Market Segment

Italy, All Market Segments Major Cancer Diagnostic Test Volume Forecast

Italy, Hospital Laboratories Major Tumor Marker Test Volume Forecast

Italy, Commercial/Private Laboratories Major Tumor Marker Test Volume Forecast

Italy, Total Tumor Marker Test Market Forecast by Market Segment

Italy, All Market Segments Major Tumor Marker Sales Forecast by Test

Italy, Hospital Laboratories Major Tumor Marker Forecast by Test

Italy, Commercial/Private Laboratories Major Tumor Marker Sales Forecast by Test

## **List of Tables**

Italy, ACTH Test Volume and Diagnostics  
Sales Forecast by Market Segment

Italy, AFP Test Volume and Diagnostics  
Sales Forecast by Market Segment

Italy, Beta-2 Microglobulin Test Volume  
And Diagnostics Sales Forecast by Market Segment

Italy, CA 15-3/27.29 Test Volume and  
Diagnostics Sales Forecast by Market Segment

Italy, CA-19-9 Test Volume and Diagnostics  
Sales Forecast by Market Segment

Italy, CA 125 Test Volume and Diagnostics  
Sales Forecast by Market Segment

Italy, Calcitonin Test Volume and Diagnostics  
Sales Forecast by Market Segment

Italy, CEA Test Volume and Diagnostics Sales  
Forecast by Market Segment

Italy, Chromogranin Test Volume  
And Diagnostics Sales Forecast by Market Segment

Italy, Colon Specific Antigen Test Volume  
And Diagnostics Sales Forecast by Market Segment

Italy, Cytokeratins Test Volume and  
Diagnostics Sales Forecast by Market Segment

Italy, Estrogen Receptor Test Volume and  
Diagnostics Sales Forecast by Market Segment

Italy, Ferritin Test Volume and Diagnostics  
Sales Forecast by Market Segment

Italy, Gastrin Test Volume and Diagnostics  
Sales Forecast by Market Segment

## **List of Tables**

Italy, HCG Test Volume and Diagnostics  
Sales Forecast by Market Segment

Italy, Insulin Test Volume and Diagnostics  
Sales Forecast by Market Segment

Italy, Lymphocyte Subtyping Test Volume  
And Diagnostics Sales Forecast by Market  
Segment

Italy, NSE Test Volume and Diagnostics Sales  
Forecast by Market Segment

Italy, Occult Blood Test Volume and Diagnostics  
Sales Forecast by Market Segment

Italy, Oncogenes Test Volume and Diagnostics  
Sales Forecast by Market Segment

Italy, Pancreatic Oncofetal Antigen Test  
Volume and Diagnostics Sales Forecast  
By Market Segment

Italy, PAP Smear Test Volume and  
Diagnostics Sales Forecast by Market Segment

Italy, Parathyroid Hormone Test Volume and  
Diagnostics Sales Forecast by Market Segment

Italy, Progesterone Receptor Test Volume and  
Diagnostics Sales Forecast by Market Segment

Italy, PAP Test Volume and Diagnostics Sales  
Forecast by Market Segment

Italy, PSA Test Volume and Diagnostics Sales  
Forecast by Market Segment

Italy, S-100 Test Volume and Diagnostics  
Sales Forecast by Market Segment

## **List of Tables**

Italy, Serotonin Test Volume and  
Diagnostics Sales Forecast by Market Segment

Italy, Sialic Acid Test Volume and  
Diagnostics Sales Forecast by Market Segment

Italy, Squamous Cell Carcinoma Antigen Test  
Volume and Diagnostics Sales Forecast  
By Market Segment

Italy, TDT Test Volume and Diagnostics Sales  
Forecast by Market Segment

Italy, Thymidine Kinase Test Volume and  
Diagnostics Sales Forecast by Market Segment

Italy, Thyroglobulin Test Volume and  
Diagnostics Sales Forecast by Market Segment

Italy, TPA Test Volume and Diagnostics Sales  
Forecast by Market Segment

Italy, Total Tumor Markers  
Sales by Major Suppliers

Italy, AFP Testing Market Diagnostics  
Sales by Major Supplier

Italy, CEA Testing Market Diagnostics  
Sales by Major Supplier

Italy, PSA Testing Market Diagnostics  
Sales by Major Supplier