

Table of Contents

Introduction

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

Table of Contents (continued)

- 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*
- 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*

Table of Contents (continued)

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*

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*

Table of Contents (continued)

- *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*
- *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*

Table of Contents (continued)

- *Minactivin*
- *MN/CA9*
- *MSA*
- *Mucin Cancer Antigen (MCA)*
- *Multiple Tumor Suppressor 1*
- *Myosin*
- *NEA-130*
- *NMP22*
- *OA-519*
- *Opiod Peptides*
- *P-glycoprotein*
- *Pancreatic Oncofetal Antigen (POA)*
- *Placental Lactogen*
- *PR92*
- *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**

1. *Abbott AxSYM*
2. *Abbott Architect c4000*
3. *Abbott Architect i2000 Series*
4. *Abbott Architect ci8200 System*

Table of Contents (continued)

5. Beckman Coulter UniCel Series
 6. Beckman Coulter Access
 7. Binding Site ESP600
 8. bioMerieux Mini Vidas
 9. Carolina Chemistries BioLis 24i
 10. DiaSorin Liaison
 11. Horiba ABX Pentra 400
 12. Inverness DS2
 13. J&J Vitros ECi/ECiQ
 14. J&J Vitros 3600
 15. J&J Vitros 5600
 16. Olympus AU5400
 17. Olympus AU3000i
 18. Olympus AU2700
 19. Roche Modular Analytics
 20. Roche Cobas Integra 400
 21. Roche Cobas Integra 400 Plus
 22. Roche Elecsys
 23. Roche Cobas c311
 24. Siemens ADVIA Centaur
 25. Siemens Dimension
 26. Siemens Dimension RxL Max
 27. Siemens Dimension Vista 500
 28. Siemens Immulite
 29. Siemens Stratus
 30. Tosoh AIA-Series
 31. Vital Diagnostics ATAC 8000
 32. Vital Diagnostics Envoy 500
- 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

Table of Contents (continued)

- d. *Fluorescent Immunoassays*
- e. *Luminescence*
 - *Chemiluminescence*
 - *Bioluminescence*
- f. *Latex Agglutination*
- g. *Immunoprecipitation*
- H. *Affinity Chromatographu*
- e. *Liposome Flow-Injection Immunoassay*
- 3. *Molecular Diagnostics*
 - a. *Technology Overview*
 - b. *Amplification Methods*
 - *PCR*
 - *DAP-PCR*
 - *Immuno-PCR*
 - *QC-PCR*
 - *CAR*
 - *DNA*
 - *HPA*
 - *LCR*
 - *NASBA*
 - *QBR*
 - *SDA*
 - *3 SR, and others*
- 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*

Table of Contents (continued)

- c. NMR
- d. PET
- e. Photonics Spectroscopy
- E. Personal Testing

U.S.A.

- A. Executive Summary
- B. Business Environment
 - 1. Health Care Expenditures
 - 2. Cost Consciousness
 - 3. Industry Consolidation
 - 4. Managed Care
 - 5. Hospitals
 - 6. Admissions
 - 7. Length of Stay
 - 8. Industry Diversification
 - 9. Physician Demographics
 - 10. Population Aging
 - a. Chronic Illness
 - b. Disease Incidence
 - c. Susceptibility to Iatrogenesis
 - d. Multiple Illness Cases
 - 11. Laboratory Regulations
- C. Market Structure
 - 1. Centralized Testing
 - a. Hospitals
 - b. Commercial/Private Laboratories
 - 2. POT/Decentralized Testing
 - a. Physician Offices/Group Practices
 - b. Cancer Clinics
 - c. Point-Of-Care Testing
 - d. Other Decentralized Testing Locations
- D. Market Size, Growth and Major Suppliers Sales, Instrument Placements and Market Shares

Table of Contents (continued)

Major Product Development Opportunities

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

Design Criteria for Decentralized Testing Products

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

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

Competitive Profiles

- Abbott
- AdnaGen
- Applied Gene Technologies

Table of Contents (continued)

- Arca
- Beckman Coulter/Danaher
- Becton Dickinson
- Biomedical Diagnostics
- bioMerieux
- Bio-Rad
- Cepheid
- Correlogic Systems
- Dako
- Decode
- Diadexus
- Diagnocure
- Diasorin
- Eiken Chemical
- Enterix
- Enzo Biochem
- Epigenomics
- Exact Sciences
- Fujirebio
- Gen-Probe
- Guided Therapeutics
- Hologic
- Ipsogen
- Kreatech
- Kyowa Medex
- Life Technologies
- Mackay Life Sciences
- Myriad Genetics
- Nanogen Elitech
- OncoLab
- Otho-Clinical Diagnostics
- Panacea Pharmaceuticals
- Polartechnics
- Polymedco
- PreMD
- Qiagen
- Radient Pharmaceuticals
- Roche

Table of Contents (continued)

- *Scienion*
- *Sequenom*
- *Siemens Healthcare*
- *Takara Bio*
- *Targeted Diagnostics & Therapeutics*
- *Tosoh*
- *Veridex*
- *Wako Pure Chemicals*
- *Wallac/PE*
- *Zila*

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*

List of Tables (continued)

*Major Companies Developing or Marketing
HCG Tests*

*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*

List of Tables (continued)

*Immunohistochemical Stains Potential
Applications in Cancer Diagnosis*

*Executive Summary Table: U.S., Hospital
Cancer Diagnostic Test Volume and Sales Forecast*

U.S., Estimated New Cancer Cases and Deaths

*U.S., Estimated Cancer Death Rates
Per 100,000 Population*

*U.S., Laboratories Performing Cancer Diagnostic
Tests*

*U.S., Hospital Laboratories Performing
Cancer Diagnostics Tests by Bed Size*

*U.S., Hospital Laboratories Major Cancer
Diagnostic Test Volume Forecast by Test*

*U.S., Total Cancer Diagnostics Sales
By Major Supplier*

*U.S., ACTH Testing Market Diagnostics
Sales by Major Supplier*

*U.S., AFP Testing Market Diagnostics
Sales by Major Supplier*

*U.S., Beta-2 Microglobulin Testing Market
Diagnostics Sales by Major Supplier*

*U.S., CA 15-3/27.29 Testing Market
Diagnostics Sales by Major Supplier*

*U.S., CA 19-9 Testing Market Diagnostics
Sales by Major Supplier*

*U.S., CA 125 Testing Market Diagnostics
Sales by Major Supplier*

List of Tables (continued)

*U.S., CEA Testing Market Diagnostics
Sales by Major Supplier*

*U.S., Ferritin Testing Market
Diagnostics Sales by Major Supplier*

*U.S., HCG Testing Market
Diagnostics Sales by Major Supplier*

*U.S., Insulin Testing Market
Diagnostics Sales by Major Supplier*

*U.S., Parathyroid Hormone Testing
Market Diagnostics Sales by Major Supplier*

*U.S., PAP Testing Market Diagnostics
Sales by Major Supplier*

*U.S., Progesterone Receptor Testing Market
Diagnostics Sales by Major Supplier*

*U.S., PSA Testing Market Diagnostics
Sales by Major Supplier*