



MEDICAL DEVICES



PHARMACEUTICALS



CHEMICALS



FOOD & BEVERAGE



ELECTRONICS

## **Emerging Point-of-Care Testing Markets: Cancer Clinics, Ambulatory Center, Surgery Centers, Nursing Homes, Birth Centers**

### ***Table of Contents and List of Tables***

Copyright VENTURE PLANNING GROUP  
This material is confidential for use by our clients only  
and may not be reprinted or reproduced.

VPG Publications, Consulting, Clients [www.VPGcorp.com](http://www.VPGcorp.com)

VPG Market Research Reports [www.VPGMarketResearch.com](http://www.VPGMarketResearch.com)

Partner Reports [www.LeadingMarketResearch.com](http://www.LeadingMarketResearch.com)

**VENTURE PLANNING GROUP** 1271 Avenue of the Americas, Suite 4300 New York, NY 10020  
Phone + 1 212 564 2838 Fax + 1 212 564 8133 [reports@vpgcorp.com](mailto:reports@vpgcorp.com)

## Table of Contents

### Introduction

### Rationale for Testing Decentralization

1. Overview
2. Regulatory Trends
3. Economic Trends
4. Demographic Trends
5. Technological Trends
6. Social Trends
7. Quality of Care
8. Defensive Medicine
9. Quality Control Issues

### **Worldwide Market and Technology Overview**

#### **A. Major Routine Chemistry Tests**

1. Albumin
2. Alkaline Phosphatase
3. ALT/SGPT
4. Ammonia
5. Amylase
6. AST/SGOT
7. Bilirubin
8. Blood Gases
9. Blood Urea Nitrogen (BUN)
10. Calcium
11. Cholesterol
12. Cholinesterase
13. Creatinine
14. Electrolytes
  - a. Carbon Dioxide/Bicarbonate
  - b. Chloride
  - c. Potassium
  - d. Sodium
15. Ferritin
16. Folate/Folic Acid

## **Table of Contents (continued)**

17. Fructosamine
18. Gamma-Glutamyl Transpeptidase (GGT)
19. Glucose
20. High Density Lipoprotein (HDL)
21. Iron
22. Lactate Dehydrogenase (LDH)
23. Magnesium
24. Phosphorus
25. Protein
26. Triglycerides
27. Troponin
28. Uric Acid
29. Urinalysis
30. Vitamin B12

### **Infectious Disease Tests**

1. AIDS
2. Adenovirus
3. Campylobacter
4. Candida
5. Chlamydia
6. Clostridium Difficile
7. Cytomegalovirus
8. Enteroviruses
9. Epstein-Barr Virus
10. Gonorrhea
11. Helicobacter Pylori
12. Hepatitis
  - a. Hepatitis A
  - b. Hepatitis B
  - c. Hepatitis C
  - d. Hepatitis D
13. Herpes Simplex Virus
14. Human Herpes Virus-6 (HHV-6)
15. Influenza Viruses
16. Legionella
17. Lyme Disease
18. Measles (Rubeola)
19. Meningitis

## Table of Contents (continued)

20. Mononucleosis
21. Mumps
22. Mycoplasma
23. Papillomaviruses
24. Pneumonia
25. Respiratory Syncytial Virus (RSV)
26. Rheumatoid Arthritis
27. Rotavirus (Reovirus)
28. Rubella (German Measles)
29. Salmonellosis
30. Shigellosis
31. Staphylococcus Aureus
32. Streptococci
33. Syphilis

### **Tumor Markers**

1. Alpha-Fetoprotein (AFP)
2. Carcinoembryonic Antigen (CEA)
3. Occult Blood
4. Prostatic Acid Phosphatase (PAP)
5. Prostate-Specific Antigen (PSA)

### **Major Routine and Special Hematology Tests**

1. CBC Analysis
  - a. Hemoglobin Concentration
  - b. Hematocrit Determination
  - c. Red Blood Cell Count
  - d. Platelets

### **Endocrine Function Tests**

1. Cortisol
2. Follicle-Stimulating Hormone (FSH)
3. Gastrin
4. Human Chorionic Gonadotropin (HCG)
5. LH
6. Prolactin
7. T3
8. T3 Uptake
9. Free T3
10. Thyroxine (T4)
11. Free T4
12. TBG
13. TSH

## Table of Contents (continued)

### **Therapeutic Drug Monitoring (TDM)**

1. Overview
2. Carbamazepine
3. Digoxin
4. Gentamicin
5. Lidocaine
6. Lithium
7. Phenytoin/Dilantin
8. Procainamide
9. Quinidine
10. Theophylline
11. Valproic Acid

### **Coagulation Tests**

1. Introduction
2. Activated Partial Thromboplastin Time (APTT)
3. Alpha-2 Antiplasmin
4. Antithrombin III
5. Bleeding Time
6. D-Dimer
7. Factor VIII
8. Fibrin Degradation Products
9. Fibrinogen
10. Heparin
11. Proteins C and S
12. Prothrombin Time (PT)
13. Thrombin Time

### **Immunoprotein Tests**

1. CRP
2. Immunoglobulins

### **Drugs of Abuse**

1. Overview
2. Test Methodologies
3. Amphetamines
4. Barbiturates
5. Benzodiazepines
6. Cannabinoids/Marijuana
7. Cocaine

## Table of Contents (continued)

- 8. Lysergic Acid Diethylamide (LSD)
- 9. Methadone
- 10. Methaqualone
- 11. Opiates
- 12. Phencyclidine

### **Instrumentation**

#### **1. Chemistry Analyzers Manufactured by:**

- Abaxis
- Abbott
- Alfa Wassermann
- Awareness Technologies
- Beckman Coulter/Danaher
- bioMerieux
- Carolina Chemistries
- Horiba
- Inverness
- Medica
- Nova Biomedical
- Ortho-Clinical Diagnostics
- Polimedco
- Randox
- Roche

#### **2. Hematology Analyzers Manufactured by:**

- Abbott
- Becton Dickinson
- Beckman Coulter/Danaher
- Biocode
- Drew-Scientific
- Diesse Ves Matic
- Horiba
- Menarini
- Nihon Kohden
- Polymedco
- Sysmex

#### **3. Coagulation Analyzers Manufactured by:**

- Behnk Elektronik
- Bio/Data
- Cardiovascular Diagnostics

## Table of Contents (continued)

- Diagnostica Stago
- Helena Laboratories
- Instrumentation Laboratory
- ITC Hemochron
- Roche
- Siemens
- Sysmex
- Teco Medical Instruments
- Trinity Biotech

### **Current and Emerging Technologies**

#### **1. Monoclonal Antibodies**

#### **2. Immunoassays**

- a. Technological Principle
- b. Enzyme Immunoassays (EIA)
  - ? Overview
  - ? ELISA
  - ? Dot Immunobinding Assays
  - ? Capillary Immunoassays
  - ? Particle-Membrane Capture Immunoassay
  - ? Enzyme Amplification
- c. Fluorescent Immunoassays
  - ? Fluorescent Polarization
  - ? Time-Resolved Pulse Fluorescence
- d. Luminescence
  - ? Chemiluminescence
  - ? Bioluminescence
- e. Latex Agglutination
- f. Immunoprecipitation

#### **3. Dry Chemistry**

#### **4. Biosensors**

#### **5. IT and Automation**

#### **6. Molecular Diagnostics**

- a. Technology Overview
- b. Amplification Methods
  - ? Polymerase Chain Reaction
  - ? Ligase Chain Reaction
  - ? Branched DNA
  - ? Q-Beta Replicase
  - ? Strand Displacement Activation
  - ? Self-Sustained Sequence Replicase

## Table of Contents (continued)

### **Worldwide Business Environment**

#### **U.S.A.**

##### **A. Market Overview**

###### **1. Business Environment**

- a. Health Care Expenditures
- b. Cost Consciousness
- c. Reimbursement
- d. Industry Consolidation
- e. Managed Care
  - ? PPO
  - ? HMO
- f. Hospitals
- g. Admissions
- h. Length of Stay
- i. Industry Diversification
- j. Physician Demographics
- k. Aging Population
  - ? More Chronic Illness
  - ? Disease Incidence
  - ? Susceptibility to Iatrogenesis
  - ? Multiple Illnesses Cases

###### **l. Laboratory Regulations**

###### **2. Market Structure**

- a. Hospitals
- b. Commercial/Private Laboratories

##### **B. Cancer Clinics**

- 1. Introduction
- 2. Market Summary
- 3. Test Volume and Sales Forecasts

##### **C. Ambulatory Care Centers**

- 1. Introduction
- 2. Market Summary
- 3. Market Structure
- 4. Test Volume and Sales Forecasts

##### **D. Surgery Centers**

- 1. Introduction
- 2. Market Summary
- 3. Market Structure
- 4. Test Volume and Sales Forecasts



## **Table of Contents (continued)**

### E. Nursing Homes

1. Introduction
2. Market Summary
3. Market Structure
4. Test Volume and Sales Forecasts

### F. Birth Centers

1. Introduction
2. Market Summary
3. Market Structure
4. Test Volume and Sales Forecasts

### G. Major Suppliers' Instrument Placements, Installed Base, Consumables Sales and Market Shares

## **Major Product Development Opportunities**

- A. Routine and Special Chemistry
- B. Microbiology/Infectious Diseases
- C. Hematology and Flow Cytometry
- D. Coagulation

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

## **Alternative Market Penetration Strategies**

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

## Table of Contents (continued)

### 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

### Company Profile

- Abbott
- ADI/America Diagnostica
- Agilent Technologies
- Alere/Biosite/Inverness
- Axis-Shield
- Beckman Coulter/Danaher
- Becton Dickinson
- Bio/Data
- Biomerieux
- Bio-Rad
- Cepheid
- Chrono-Log
- Corgenix
- Decode Genetics
- Diadexus
- Diagnocure
- Diagnostica Stago/Trinity Biotech
- Diamedix/Erba
- Diasorin
- Eiken Chemical
- EKF Diagnostics
- Fujirebio
- Grifols
- Helena Laboratories
- Hologic/Gen-Probe
- Horiba
- Instrumentation Laboratory
- International Technidyne/Nexus DX
- Kreatech/Leica
- Kyowa Medex

## Table of Contents (continued)

- Lonza
- Mackay Life Sciences
- Matritech/Alere
- Nihon Kohden
- Ortho-Clinical Diagnostics
- Polartechnics
- Polymedco
- Qiagen
- Roche
- SDIX
- Sequenom
- Siemens
- Sienco
- Sysmex
- Takara Bio
- ThermoFisher
- Tosoh
- Wako
- Zycare/Alere

## **List of Tables**

Major Companies Developing or Marketing  
Albumin Tests

Major Companies Developing or Marketing  
Alkaline Phosphatase Tests

Major Companies Developing or Marketing  
ALT/SGPT Tests

Major Companies Developing or Marketing  
Amylase Tests

Major Companies Developing or Marketing  
AST/SGOT Tests

Major Companies Developing or Marketing  
Bilirubin Tests

Major Companies Developing or Marketing  
Blood Gas Analyzers

Major Companies Developing or Marketing  
BUN Tests

Major Companies Developing or Marketing  
Calcium Tests

Major Companies Developing or Marketing  
Cholesterol Tests

Major Companies Developing or Marketing  
Creatinine Tests

Major Companies Developing or Marketing  
Electrolyte Tests

Major Companies Developing or Marketing  
Ferritin Tests

## **List of Tables**

Major Companies Developing or Marketing  
GGT Tests

Major Companies Developing or Marketing  
Glucose Tests

Major Companies Developing or Marketing  
HDL Tests

Major Companies Developing or Marketing  
Iron Tests

Major Companies Developing or Marketing  
LDH Tests

Major Companies Developing or Marketing  
Magnesium Tests

Major Companies Developing or Marketing  
Phosphorus Tests

Major Companies Developing or Marketing  
Protein Tests

Major Companies Developing or Marketing  
Triglycerides Tests

Major Companies Developing or Marketing  
Uric Acid Tests

Major Companies Developing or Marketing  
Vitamin B-12/Folate Tests

Major Companies Developing or Marketing  
AIDS Tests

Major Companies Developing or Marketing  
Adenovirus Tests

## **List of Tables (continued)**

Major Companies Developing or Marketing  
Campylobacter Tests

Major Companies Developing or Marketing  
Candida Tests

Major Companies Developing or Marketing  
CMV Tests

Major Companies Developing or Marketing  
EBV Tests

Major Companies Developing or Marketing  
Gonorrhea Tests

Major Companies Developing or Marketing  
Helicobacter Pylori Tests

Major Companies Developing or Marketing  
Hepatitis Tests

Major Companies Developing or Marketing  
Herpes Tests

Major Companies Developing or Marketing  
Influenza Tests

Major Companies Developing or Marketing  
Legionella Tests

Major Companies Developing or Marketing  
Lyme Disease Tests

Major Companies Developing or Marketing  
Measles Tests

Major Companies Developing or Marketing  
Meningitis Tests

Major Companies Developing or Marketing  
Mononucleosis Tests

## **List of Tables (continued)**

Major Companies Developing or Marketing  
Mumps Tests

Major Companies Developing or Marketing  
Mycoplasma Tests

Major Companies Developing or Marketing  
Pneumonia Tests

Major Companies Developing or Marketing  
RSV Tests

Major Companies Developing or Marketing  
Rotavirus Tests

Major Companies Developing or Marketing  
Rubella Tests

Major Companies Developing or Marketing  
Salmonella Tests

Major Companies Developing or Marketing  
Shigella Tests

Major Companies Developing or Marketing  
Streptococci Tests

Major Companies Developing or Marketing  
Syphilis Tests

Major Companies Developing or Marketing  
AFP Tests

Major Companies Developing or Marketing  
CEA Tests

Major Companies Developing or Marketing  
Occult Blood Tests

## **List of Tables (continued)**

Major Companies Developing or Marketing  
Prostatic Acid Phosphatase Tests

Major Companies Developing or Marketing  
PSA Tests

Major Companies Developing or Marketing  
FSH Tests

Major Companies Developing or Marketing  
HCG Tests

Major Companies Developing or Marketing  
LH Tests

Major Companies Developing or Marketing  
Prolactin Tests

Major Companies Developing or Marketing  
T3 Tests

Major Companies Developing or Marketing  
T4 Tests

Major Companies Developing or Marketing  
TSH Tests

Major Companies Developing or Marketing  
TDM Tests

Major Companies Developing or Marketing  
Digoxin Tests

Major Companies Developing or Marketing  
Lithium Tests

Major Companies Developing or Marketing  
Phenytoin/Dilantin Tests



## **List of Tables (continued)**

Major Companies Developing or Marketing  
Theophylline Tests

Major Companies Developing or Marketing  
Valproic Acid Tests

Major Companies Developing or Marketing  
APTT Tests

Major Companies Developing or Marketing  
Alpha-2 Antiplasmin Tests

Major Companies Developing or Marketing  
Antithrombin III Tests

Major Companies Developing or Marketing  
Bleeding Time Tests

Major Companies Developing or Marketing  
D-Dimer Tests

Major Companies Developing or Marketing  
Factor Assays Tests

Major Companies Developing or Marketing  
Fibrin Degradation Product Tests

Major Companies Developing or Marketing  
Fibrinogen Tests

Major Companies Developing or Marketing  
Heparin Tests

Major Companies Developing or Marketing  
Protein C Tests

## **List of Tables (continued)**

Major Companies Developing or Marketing  
Protein S Tests

Major Companies Developing or Marketing  
PT Tests

Major Companies Developing or Marketing  
Thrombin Time Tests

Major Companies Developing or Marketing  
CRP Tests

Major Companies Developing or Marketing  
Drugs of Abuse Tests

Cancer Clinics Total Diagnostics  
Sales Forecast by Market Segment

Cancer Clinics Reagent  
Sales Forecast by Market Segment

Cancer Clinics Instrument  
Sales Forecast by Market Segment

Cancer Clinics Major Tumor Markers Test  
Volume Forecast

Cancer Clinics Routine And Special Chemistry  
Test Volume Forecast

Cancer Clinics Routine Hematology/Flow Cytometry  
Test Volume Forecast

Cancer Clinics Endocrine Function Test Volume Forecast

Cancer Clinics Coagulation Test Volume Forecast

## **List of Tables (continued)**

Cancer Clinics Major Tumor  
Marker Sales Forecast by Test

Cancer Clinics Routine and Special Chemistry  
Reagent Market Forecast by Test

Cancer Clinics Hematology And Flow Cytometry  
Reagent Market Forecast

Cancer Clinics Endocrine  
Function Reagent Market Forecast

Cancer Clinics Coagulation  
Reagent Market Forecast

Ambulatory Care Centers Total  
Diagnostics Sales Forecast by Market Segment

Ambulatory Care Centers Reagent  
Sales Forecast by Market Segment

Ambulatory Care Centers  
Instrument Sales Forecast by Market Segment

Ambulatory Care Centers Estimated  
Number of Facilities and Patient Visits

Ambulatory Care Centers Most Frequent Diagnoses

Ambulatory Care Centers Routine  
and Special Chemistry Test Volume Forecast

Ambulatory Care Centers Routine  
Hematology Test Volume Forecast

Ambulatory Care Centers Microbiology  
and Serology Test Volume Forecast

## **List of Tables (continued)**

Ambulatory Care Centers  
Drugs of Abuse Test Volume Forecast

Ambulatory Care Centers  
Coagulation Test Volume Forecast

Ambulatory Care Centers Routine  
and Special Chemistry Reagent Market  
Forecast by Test

Ambulatory Care Centers Drugs  
of Abuse Reagent Market Forecast by Test

Ambulatory Care Centers  
Hematology Reagent Market Forecast

Ambulatory Care Centers Microbiology  
and Serology Reagent Market Forecast by Test

Ambulatory Care Centers  
Coagulation Reagent Market Forecast

Surgery Centers Total Diagnostics  
Sales Forecast by Market Segment

Surgery Centers Reagent  
Sales Forecast by Market Segment

Surgery Centers Instrument  
Sales Forecast by Market Segment

Surgery Centers Most Frequently Performed Procedures

Surgery Centers Routine  
And Special Chemistry Test Volume Forecast

Surgery Centers Routine Hematology Test Volume Forecast

## **List of Tables (continued)**

Surgery Centers Coagulation Test Volume Forecast

Surgery Centers Microbiology  
and Serology Test Volume Forecast

Surgery Centers Routine and Special Chemistry  
Reagent Market Forecast by Test

Surgery Centers Hematology  
Consumable Market Forecast

Surgery Centers Coagulation Reagent Market Forecast

Nursing Homes Total Diagnostics  
Sales Forecast by Market Segment

Nursing Homes Reagent Sales Forecast  
by Market Segment

Nursing Homes Instrument Sales Forecast  
by Market Segment

Nursing Homes Estimated Number of Facilities,  
Beds and Occupancy Rate

Nursing Homes Routine and Special Chemistry  
Test Volume Forecast

Nursing Homes Coagulation Test Volume Forecast

Nursing Homes Routine Hematology Test Volume Forecast

## **List of Tables (continued)**

Nursing Homes Routine And Special Chemistry  
Reagent Market Forecast by Test

Nursing Homes Coagulation Reagent Market Forecast

Nursing Homes Hematology Reagent Market Forecast

Birth Centers Total Diagnostics Sales Forecast  
by Market Segment

Birth Centers Reagent Sales Forecast  
by Market Segment

Birth Centers Instrument Sales Forecast  
by Market Segment

Birth Centers Facilities, Patient Visits, and Births

Birth Centers Routine And Special Chemistry Test  
Volume Forecast

Birth Centers Profiles, Panels and Individual Tests

Birth Centers Microbiology  
and Serology Test Volume Forecast

Birth Centers Coagulation Test Volume Forecast

Birth Centers Routine Hematology Test Volume Forecast

Birth Centers Routine and Special Chemistry  
Reagent Market Forecast by Test

## **List of Tables (continued)**

Birth Centers Microbiology  
and Serology Testing Market Forecast

Birth Centers Hematology Reagent Market Forecast

Birth Centers Coagulation Reagent Market Forecast

Major Suppliers of Clinical Chemistry  
Diagnostics Products, Estimated Sales  
and Market Shares

Major Suppliers of Clinical Chemistry  
Reagents, Estimated Sales and Market Shares

Major Suppliers of Clinical Chemistry  
Analyzers, Estimated Sales and Market Shares

Major Suppliers of Immunodiagnostic  
Products, Estimated Sales and Market Shares

Major Suppliers of Immunoassay  
Reagents, Estimated Sales and Market Shares

Major Suppliers of Immunoassay  
Analyzers, Estimated Sales and Market Shares

AIDS Testing Market Estimated Market Shares  
of Major Suppliers

Chlamydia Testing Market  
Estimated Market Shares of Major Suppliers

CMV Testing Market  
Estimated Market Shares of Major Suppliers

Gonorrhea Testing Market  
Estimated Market Shares of Major Suppliers

## **List of Tables (continued)**

Helicobacter Pylori Testing Market  
Estimated Market Shares of Major Suppliers

Hepatitis Testing Market  
Estimated Market Shares of Major Suppliers

Herpes Testing Market  
Estimated Market Shares of Major Suppliers

Influenza Testing Market  
Estimated Market Shares of Major Suppliers

Lyme Disease Testing Market  
Estimated Market Shares of Major Suppliers

Mononucleosis Testing Market  
Estimated Market Shares of Major Suppliers

Rubella Testing Market  
Estimated Market Shares of Major Suppliers

Streptococci Testing Market  
Estimated Market Shares of Major Suppliers

Syphilis Testing Market  
Estimated Market Shares of Major Suppliers

AFP Testing Market By Major Suppliers

CA 15-3/27-29 Testing Market by Major Suppliers

CA 19-9 Testing Market by Major Suppliers

CEA Testing Market by Major Suppliers

PAP Testing Market by Major Suppliers

PSA Testing Market by Major Suppliers



## **List of Tables (continued)**

Hematology Analyzers Estimated Placements  
and Installed Base

Flow Cytometers Estimated Placements  
and Installed Base

Hematology Diagnostics Market  
Estimated Market Shares of Major Suppliers

Hematology Instrument Market  
Estimated Market Shares of Major Suppliers

Hematology Consumable Market  
Estimated Market Shares of Major Suppliers

Flow Cytometry Diagnostics Market  
Estimated Market Shares of Major Suppliers

Flow Cytometry Consumable Market  
Estimated Market Shares of Major Suppliers

Flow Cytometry Instruments Market  
Estimated Market Shares of Major Suppliers

Major Suppliers of Coagulation Diagnostic Products,  
Estimated Market Shares of Major Suppliers