









MEDICAL DEVICES

PHARMACEUTICALS

CHEMICALS

FOOD & BEVERAGE

ELECTRONICS

Clinical Chemistry and Immunodiagnostic Testing in US Hospital, Commercial Laboratories and Point-of-Care/POC Locations

Table of Contents

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

VPG Market Research Reports www.VPGMarketResearch.com

Partner Reports 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*

Table of Contents

I. Introduction

II. Major Product Development Opportunities

III. Design Criteria for Decentralized Testing Products

IV. 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

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

VI. 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, Total
- 8. Blood Gases
- 9. Blood Urea Nitrogen (BUN)
- 10. Calcium
- 11. Cardio CRP
- 12. Cholesterol
- 13. Cholinesterase
- 14. CRP
- 15. Creatinine
- 16. Electrolytes
 - a. Carbon Dioxide/Bicarbonate
 - b. Chloride
 - c. Potassium
 - d. Sodium
- 17. Ferritin
- 18. Fructosamine
- 19. Gamma-Glutamyl Transpeptidase (GGT)
- 20. Glucose
- 21. High Density Lipoprotein (HDL)
- 22. Homocysteine
- 23. Iron
- 24. Lactate Dehydrogenase (LDH)
- 25. Magnesium
- 26. Phosphorus
- 27. Protein
- 28. Triglycerides
- 29. Uric Acid
- 30. Troponin
- B. Therapeutic Drug Monitoring (TDM)
 - 1. Overview
 - 2. Carbamazepine
 - 3. Cyclosporin
 - 4. Digoxin
 - 5. Everolimus
 - 6. Gentamicin
 - 7. Lamotrigine/Lamictal
 - 8. Levetiracetam
 - 9. Lidocaine
 - 10. Lithium
 - 11. NAPA/Procainamide

- 12. Phenytoin
- 13. Quinidine
- 14. Sirolimus
- 15. Tacrolimus
- 16. Theophylline
- 17. Topirimate
- 18. Valproic Acid

C. Endocrine Function Tests

- 1. Cortisol
- 2. Estradiol
- 3. Follicle-Stimulating Hormone (FSH)
- 4. Gastrin
- 5. Growth Hormone/IGF-1
- 6. Human Chorionic Gonadotropin (HCG)
- 7. LH
- 8. Progesterone
- 9. PTH/IO PTH
- 10. Prolactin
- 11. T3
- 12. T3 Free
- 13. T3 Uptake
- 14. T4 (Thyroxine)
- 15. T4 Free
- 16. TBG
- 17. Testosterone
- 18. Thyroglobulin Ab
- 19. TPO Ab
- 20. TSH
- D. Tumor Markers And Special Chemistry Tests
 - 1. AFP
 - 2. CA 15-3
 - 3. CA 19-9
 - 4. CA 27-29
 - 5. Carcinoembrionic Antigen (CEA)
 - 6. Folate/Folic Acid
 - 7. HCG
 - 8. 25-Hydroxy Vitamin D2 and D3

- 9. Occult Blood
- 10. Prostate-Specific Antigen (PSA)
- 11. Thyroglobulin
- 12. Vitamin B-12
- E. Immunoprotein Tests
 - 1. Complement
 - a. C3
 - b. C4
 - 2. Free Light Chains
 - 3. Immunofixation
 - 4. Immunoglobulins (IgA, IgE, IgG, IgM)
 - 5. Haptoglobin
 - 6. Prealbumin
 - 7. Protein Electrophoresis
- F. Drugs of Abuse
 - 1. Overview
 - 2. Test Methodologies
 - 3. Amphetamines
 - 4. Barbiturates
 - 5. Benzodiazepines
 - 6. Cannabinoids/Marijuana
 - 7. Cocaine
 - 8. Lysergic Acid Diethylamide (LSD)
 - 9. Methadone
 - 10. Methaqualone
 - 11. Opiates
 - 12. Phencyclidine
 - 13. Tricyclic Antidepressants
- G. Instrumentation Review: Operating characteristics and features of high-, medium-, and low-volume/POC analyzers
- H. Major In Vitro Diagnostic Technologies And Their Potential Applications
 - 1. Monoclonal and Polyclonal Antibodies
 - 2. Immunoassays

- a. Technological Principle
- b. Chemiluminescence
- c. Enzyme Immunoassays (EIA)
 - ° Overview
 - ° ELISA
 - ° EMIT
 - ° Electrochemical
- d. Radioimmunoassays (RIA)
- e. Immunoprecipitation
- f. Affinity Chromatography
- 3. Tandem Mass Spec
- 4. IT and Automation
- 5. Dry Chemistry
- 6. Biosensors

VII. U.S.A.

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

VIII. Competitive Strategies

- Abbott Laboratories
- AdnaGen
- Agilent Technologies

- Beckman Coulter/Danaher
- Biomedical Diagnostics
- BioMerieux
- Bio-Rad
- DiaSorin
- Eiken
- Fujirebio
- Grifols
- Instrumentation Laboratory
- Kyowa Medex
- Matritech/Alere
- Ortho-Clinical Diagnostics
- Quest Diagnostics
- Roche
- Siemens
- Sysmex
- Thermo Fisher
- Tosoh
- Wako
- Wallac/PE

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 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 TDM Tests

Major Companies Developing or Marketing Digoxin Tests

Major Companies Developing or Marketing Lithium Tests

Major Companies Developing or Marketing Phenytoin/Dilantin Tests

Major Companies Developing or Marketing Theophylline Tests

Major Companies Developing or Marketing Valproic Acid 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 AFP Tests

Major Companies Developing or Marketing CEA Tests

Major Companies Developing or Marketing Ferritin Tests

Major Companies Developing or Marketing Occult Blood Tests

Major Companies Developing or Marketing Prostatic Acid Phosphatase Tests

Major Companies Developing or Marketing PSA Tests

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

Major Companies Developing or Marketing CRP Tests

Major Companies Developing or Marketing Drugs of Abuse Tests

Major Companies Developing or Marketing Biosensors for Immunological Testing

Executive Summary Table: U.S.A., Clinical Chemistry and Immunoassay Test Volume and Diagnostics Sales Forecast By Test Category

U.S.A., Laboratories Performing Chemistry and Immunoassay Testing By Market Segment

U.S.A., Hospital Laboratories Performing Chemistry and Immunoassay Tests By Bed Size

U.S.A., Commercial/Private Laboratories Performing Chemistry and Immunoassay Tests By Annual Test Volume

U.S.A., Total Chemistry and Immunoassay Specimen Volume Forecast

U.S.A., All Market Segments, Specimen Volume Forecast By Test Category

U.S.A., Total Clinical Chemistry and Immunoassay Test Volume Forecast By Test Category

U.S.A., Routine Chemistry Test Volume Forecast By Market Segment

U.S.A., TDM Test Volume Forecast By Market Segment

U.S.A., Endocrine Function Test Volume Forecast By Market Segment

U.S.A., Drugs of Abuse Test Volume Forecast By Market Segment

U.S.A., Tumor Markers and Special Chemistry Test Volume Forecast By Market Segment

U.S.A., Immunoprotein Test Volume Forecast By Market Segment

U.S.A., All Market Segments, Profiles, Panels and Individual Tests Forecast

U.S.A., Hospital Laboratories, Profiles, Panels and Individual Tests Forecast

U.S.A., Commercial/Private Laboratories, Profiles, Panels and Individual Tests Forecast

U.S.A., Physician Offices/Group Practices, Profiles, Panels and Individual Tests Forecast

U.S.A., All Market Segments, Routine Chemistry Test Volume Forecast by Assay

U.S.A., Hospital Laboratories, Routine Chemistry Test Volume Forecast by Assay

U.S.A., Commercial/Private Laboratories, Routine Chemistry Test Volume Forecast by Assay

U.S.A., Physician Offices/Group Practices, Routine Chemistry Test Volume Forecast by Assay

U.S.A., All Market Segments, TDM Test Volume Forecast by Assay

U.S.A., Hospital Laboratories, TDM Test Volume Forecast by Assay

U.S.A., Commercial/Private Laboratories, TDM Test Volume Forecast by Assay

U.S.A., Physician Offices/Group Practices, TDM Test Volume Forecast by Assay

U.S.A., All Market Segments, Endocrine Function Test Volume Forecast by Assay

U.S.A., Hospital Laboratories, Endocrine Function Test Volume Forecast by Assay

U.S.A., Commercial/Private Laboratories, Endocrine Function Test Volume Forecast by Assay

U.S.A., Physician Offices/Group Practices, Endocrine Function Test Volume Forecast by Assay

U.S.A., All Market Segments, Drugs of Abuse Test Volume Forecast by Assay

U.S.A., Hospital Laboratories, Drugs of Abuse Test Volume Forecast by Assay

U.S.A., Commercial/Private Laboratories, Drugs of Abuse Test Volume Forecast by Assay

U.S.A., Physician Offices/Group Practices, Drugs of Abuse Test Volume Forecast by Assay

U.S.A., All Market Segments, Tumor Markers and Special Chemistry Test Volume Forecast by Assay

U.S.A., Hospital Laboratories, Tumor Markers and Special Chemistry Test Volume Forecast by Assay

U.S.A., Commercial/Private Laboratories, Tumor Markers and Special Chemistry Test Volume Forecast by Assay

U.S.A., Physician Offices/Group Practices, Tumor Markers and Special Chemistry Test Volume Forecast by Assay

U.S.A., All Market Segments, Immunoprotein Test Volume Forecast by Assay

U.S.A., Hospital Laboratories, Immunoprotein Test Volume Forecast by Assay

U.S.A., Commercial/Private Laboratories, Immunoprotein Test Volume Forecast by Assay

U.S.A., Physician Offices/Group Practices, Immunoprotein Test Volume Forecast by Assay

U.S.A., Total Clinical Chemistry and Immunoassay Reagent Market Forecast By Test Category

U.S.A., Clinical Chemistry and Immunoassay Calibrator and Control Market Forecast By Test Category

U.S.A., Routine Chemistry Reagent Market Forecast By Market Segment

U.S.A., TDM Reagent Market Forecast By Market Segment

U.S.A., Drugs of Abuse Reagent Market Forecast By Market Segment

U.S.A., Tumor Markers and Special Chemistry Reagent Market Forecast By Market Segment

U.S.A., Endocrine Function Reagent Market Forecast By Market Segment

U.S.A., All Market Segments, Routine Chemistry Reagent Market Forecast by Assay

U.S.A., Hospital Laboratories, Routine Chemistry Reagent Market Forecast by Assay

U.S.A., Commercial/Private Laboratories, Routine Chemistry Reagent Market Forecast by Assay

U.S.A., Physician Offices/Group Practices, Routine Chemistry Reagent Market Forecast by Assay

U.S.A., All Market Segments, TDM Reagent Market Forecast by Assay

U.S.A., Hospital Laboratories, TDM Reagent Market Forecast by Assay

U.S.A., Commercial/Private Laboratories, TDM Reagent Market Forecast by Assay

U.S.A., Physician Office/Group Practices, TDM Reagent Market Forecast by Assay

U.S.A., All Market Segments, Drugs of Abuse Reagent Market Forecast by Assay

U.S.A., Hospital Laboratories, Drugs of Abuse Reagent Market Forecast by Assay

U.S.A., Commercial/Private Laboratories, Drugs of Abuse Reagent Market Forecast by Assay

U.S.A., Physician Offices/Group Practices, Drugs of Abuse Reagent Market Forecast by Assay

U.S.A., All Market Segments, Endocrine Function Reagent Market Forecast by Assay

U.S.A., Hospital Laboratories, Endocrine Function Reagent Market Forecast by Assay

U.S.A., Commercial/Private Laboratories, Endocrine Function Reagent Market Forecast by Assay

U.S.A., Physician Offices/Group Practices, Endocrine Function Reagent Market Forecast by Assay

U.S.A., All Market Segments, Tumor Markers and Special Chemistry Reagent Market Forecast by Assay

U.S.A., Hospital Laboratories, Tumor Markers and Special Chemistry Reagent Market Forecast by Assay

U.S.A., Commercial/Private Laboratories, Tumor Markers and Special Chemistry Reagent Market Forecast by Assay

U.S.A., Physician Offices/Group Practices, Tumor Markers and Special Chemistry Reagent Market Forecast by Assay

U.S.A., All Market Segments, Immunoprotein Reagent Market Forecast

U.S.A., Hospital Laboratories, Immunoprotein Reagent Market Forecast Immunoprotein

U.S.A., Commercial/Private Laboratories, Immunoprotein Reagent Market Forecast

U.S.A., Physician Offices/Group Practices, Immunoprotein Reagent Market Forecast by Assay

U.S.A., Ancillary Hospital Locations Estimated Number

U.S.A., Ancillary Hospital Locations Annual Utilization

U.S.A., Hospital Emergency Departments Routine And Special Chemistry Test Volume Forecast

U.S.A., Hospital Emergency Departments Profiles, Panels and Individual Tests

U.S.A., Hospital Emergency Departments Routine and Special Chemistry Reagent Market Forecast by Test

U.S.A., Hospital Operating and Recovery Suites Routine and Special Chemistry Test Volume Forecast

U.S.A., Hospital Operating and Recovery Suites Routine and Special Chemistry Reagent Market Forecast by Test

U.S.A., Hospital ICUs/CCUs Routine And Special Chemistry Test Volume Forecast

U.S.A., Hospital ICUs/CCUs Routine And Special Reagent Market Forecast by Test

U.S.A., Cancer Clinics Routine And Special Chemistry Test Volume Forecast

U.S.A., Cancer Clinics Routine and Special Chemistry Reagent Market Forecast by Test

U.S.A., Ambulatory Care Centers Estimated Number of Facilities and Patient Visits

U.S.A., Ambulatory Care Centers Most Frequent Diagnoses

U.S.A., Ambulatory Care Centers Routine And Special Chemistry Test Volume Forecast

U.S.A., Ambulatory Care Centers Routine And Special Chemistry Reagent Market Forecast by Test

U.S.A., Surgery Centers Most Frequently Performed Procedures

U.S.A., Surgery Centers Routine And Special Chemistry Test Volume Forecast

U.S.A., Surgery Centers Routine And Special Chemistry Reagent Market Forecast by Test

U.S.A., Nursing Homes Estimated Number of Facilities, Beds and Occupancy Rate

U.S.A., Nursing Homes Routine And Special Chemistry Test Volume Forecast

U.S.A., Nursing Homes Routine And Special Chemistry Reagent Market Forecast by Test

U.S.A., Birth Centers Facilities, Patient Visits, and Births

U.S.A., Birth Centers Routine And Special Chemistry Test Volume Forecast

U.S.A., Birth Centers Profiles, Panels and Individual Tests

U.S.A., Birth Centers Routine And Special Chemistry Reagent Market Forecast by Test

U.S.A., Major Suppliers of Clinical Chemistry Reagents, Estimated Sales and Market Shares

U.S.A., Major Suppliers of Clinical Chemistry Analyzers, Estimated Instrument Sales and Market Shares

U.S.A., Major Suppliers of Clinical Chemistry Diagnostics Products, Estimated Sales and Market Shares

U.S.A., Major Suppliers of Immunoassay Reagents, Estimated Sales and Market Shares

U.S.A., Major Suppliers of Immunoassay Analyzers, Estimated Instrument Sales and Market Shares

U.S.A., Major Suppliers of Immunoassay Diagnostics Products, Estimated Sales And Market Shares

U.S.A., Clinical Chemistry and Immunoassay Instrument Market Forecast By Analyzer Type