## 2013 Analysis of the Point-of-Care Clinical Chemistry Market: US, Germany, Spain Physician Offices, Emergency Rooms, Operating/Recovery Suites, ICUs/CCUs, Cancer Clinics, Ambulatory Care Centers, Surgery Centers, Nursing Homes, Birth Centers

# Table of Contents

## **Introduction**

## **Executive Summary**

## **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

## **Review of Clinical 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. Follate/Folic Acid
- 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

## Instrumentation: Chemistry Analyzers Manufactured by:

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

## **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

# <u>U.S.A.</u>

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 latrogenesis
- ? Multiple Illnesses Cases
- I. Laboratory Regulations
- 2. Market Structure
  - a. Hospitals
  - b. Commercial/Private Laboratories
- B. Physician Offices/Group Practices
  - 1. Market Summary
  - 2. Market Structure
  - 3. Test Volume and Sales Forecasts
- C. Ancillary Hospital Locations
  - 1. Introduction
    - a. Emergency Departments
    - b. Operating Suites
    - c. Intensive Care Units
  - 2. Emergency Departments
    - a. Market Summary
    - b. Test volume and Sales Forecasts
  - 3. Operating and Recovery Suites
    - a. Market Summary
    - b. Test Volume and Sales Forecasts
  - 4. ICUs/CCUs
    - a. Market Summary
    - b. Test Volume and Sales Forecasts
- D. Cancer Clinics
  - 1. Introduction
  - 2. Market Summary
  - 3. Test Volume and Sales Forecasts
- E. Ambulatory Care Centers
  - 1. Introduction
  - 2. Market Summary
  - 3. Market Structure
  - 4. Test Volume and Sales Forecasts
- F. Surgery Centers
  - 1. Introduction
  - 2. Market Summary

- 3. Market Structure
- 4. Test Volume and Sales Forecasts
- G. Nursing Homes
  - 1. Introduction
  - 2. Market Summary
  - 3. Market Structure
  - 4. Test Volume and Sales Forecasts
- H. Birth Centers
  - 1. Introduction
  - 2. Market Summary
  - 3. Market Structure
  - 4. Test Volume and Sales Forecasts
- I. Major Suppliers' Sales and Market Shares

## <u>Germany</u>

- A. Market Overview
- B. Market Structure
- C. Market Summary
- D. Test Volume and Sales Forecasts
- E. Major Suppliers' Sales and Market Shares

## <u>Spain</u>

- A. Business Environment
- B. Market Structure
- C. Market Summary
- D. Test Volume and Sales Forecasts
- E. Major Suppliers' Sales and Market Shares

### Major Product Development Opportunities

## **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

## 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 Laboratories
- AdnaGen
- Agilent Technologies
- Beckman Coulter/Danaher
- Biomedical Diagnostics
- BioMerieux
- Bio-Rad
- DiaSorin
- Eiken
- Fujirebio/Innogenetics
- 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 Ferritin 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 Vitamin B-12/Folate Tests

U.S.A., Physician Office/Group Practice Laboratories Forecast by Practice Size

U.S.A., Physician Offices/Group Practices Forecast by Type

U.S.A., Office-Based Physicians Forecast by Practice Type

U.S.A., Physician Offices/Group Practices Routine and Special Chemistry Test Volume Forecast

U.S.A., Physician Offices/Group Practices Routine and Special Chemistry Test Volume Forecast by Practice Type

U.S.A., Physician Offices/Group Practices Routine and Special Chemistry Reagent Market Forecast By Test

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 Diagnostic Products Estimated Market Shares

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

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

U.S.A., Major Suppliers of Immunodiagnostic Products, Estimated Market Shares

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

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

Germany, Laboratory Performing Diagnostic Tests by Market Segment

Germany, Physician Offices/Group Practices Routine and Special Chemistry Test Volume Forecast

Germany, Physician Offices/Group Practices Routine and Special Chemistry Reagent Market Forecast by Test

Germany, Major Suppliers of Clinical Chemistry Diagnostic Products Estimated Market Shares

Germany, Major Suppliers of Clinical Chemistry Reagent Estimated Market Shares

Germany, Major Suppliers of Clinical Chemistry Analyzers Estimated Market Shares

Germany, Major Suppliers of Immunodiagnostic Products Estimated Market Shares

Germany, Major Suppliers of Immunodiagnostic Reagent Estimated Market Shares

Germany, Major Suppliers of Immunoassay Analyzers Estimated Market Shares

Spain, Laboratory Performing Chemistry And Immunoassay Tests by Market Segment

Spain, Ambulatory Care Centers Routine And Special Chemistry Test Volume Forecast

Spain, Ambulatory Care Centers Routine And Special Chemistry Reagent Market Forecast by Test

Spain, Major Suppliers of Clinical Chemistry Diagnostic Products Estimated Market Shares

Spain, Major Suppliers of Immunodiagnostics Products Estimated Market Shares