New Frontiers in US Critical Care (ER, OR, ICU) Diagnostic Testing: Business Challenges, Emerging Technologies, Competitive Landscape

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Worldwide Market and Technology Overview

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. Ferratin
- 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

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

- 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. Carcinoembrionic 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

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

- 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
- bioMeriuex
- 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

- 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

Worldwide Business Environment

U.S.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

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

Major Suppliers' Instrument Placements, Installed Base, Consumable Sales and Market Shares

Major Product Development Opportunities

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

<u>Design Criteria for Decentralized Testing Products</u>

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
- ADI/America Diagnostica
- Agilent Technologies
- Axis-Shield
- Beckman Coulter/Danaher
- Becton Dickinson
- Bio/Data
- Biomerieux
- Bio-Rad
- Biosite/Inverness/Alere
- Cepheid
- Chrono-Log
- Corgenix
- Decode
- Diadexus
- Diagnocure
- Diagnostica Stago/Trinity Biotech
- Diamedix
- Diasorin
- Eiken Chemical
- EKF Diagnostics
- Fujirebio/Innogenetics
- Grifols
- Helena Laboratories
- Hologic/Gen-Probe
- Horiba
- Instrumentation Laboratory
- International Technidyne/Nexus DX
- Kreatech
- Kyowa Medex
- Lonza
- Mackay Life Sciences
- Matritech
- Nihon Kohden
- Ortho-Clinical Diagnostics
- Polartechnics

- Polymedco
- Qiagen
- Roche
- SDIX
- Sequenom
- Siemens
- Sienco
- Sysmex
- Takara Bio
- ThermoFisher/Life Technologies
- Tosoh
- Wako
- Zycare/Alere

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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

Major Companies Developing or Marketing AIDS Tests

Major Companies Developing or Marketing Adenovirus Tests

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

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

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

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Major Companies Developing or Marketing Fibrinogen Tests

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Major Companies Developing or Marketing Protein C Tests

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

Ancillary Hospital Locations Estimated Number

Ancillary Hospital Locations
Annual Utilization

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Hospital Emergency Departments Reagent Sales Forecast by Market Segment

Hospital Emergency Departments Instrument Sales Forecast by Market Segment

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Hospital Emergency Departments
Drugs of Abuse Test Volume Forecast

Hospital Emergency Departments Routine Hematology Test Volume Forecast

Hospital Emergency Departments Coagulation Test Volume Forecast

Hospital Emergency Departments Selected Infectious Disease Test Volume Forecast

Hospital Emergency Departments Routine and Special Chemistry Reagent Market Forecast by Test

Hospital Emergency Departments
Drugs of Abuse Reagent Market Forecast
by Test

Hospital Emergency Departments Hematology Reagent Market Forecast

Hospital Emergency Departments
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Hospital Emergency Departments Selected Infectious Disease Reagent Market Forecast by Test

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Reagent Sales Forecast by Market Segment

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Hospital ICUs/CCUs Routine Hematology Test Volume Forecast

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Hospital ICUs/CCUs
Hematology Reagent Market Forecast

Hospital ICUs/CCUs
Coagulation Reagent Market Forecast

Major Suppliers of Clinical Chemistry Diagnostic 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

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CMV Testing Market Estimated Market Shares of Major Suppliers

Gonorrhea Testing Market Estimated Market Shares of Major Suppliers

Helicobacter Pylori Testing Market Estimated Market Shares of Major Suppliers

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CA 19-9 Testing Market by Major Supplier

CEA Testing Market by Major Supplier

PAP Testing Market by Major Supplier

PSA Testing Market by Major Supplier

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 Instrument Market Estimated Market Shares of Major Suppliers

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