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

Worldwide Market and Technology Overview

- 1. Introduction
- 2. Activated Partial Thromboplastin Time (APTT)
- 3. Prothrombin Time (PT)

Instrumentation: 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

<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' Instrument Placements,

Installed Base, Consumables 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' Instrument Placements, Installed Base, Consumables 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' 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

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 Accriva Axis-Shield Beckman Coulter/Danaher Becton Dickinson Bio/Data Chrono-Log Corgenix Diagnostica Stago/Trinity Biotech Grifols Helena Laboratories HYPHEN BioMed Instrumentation Laboratory/Werfen Roche Sekisui Diagnostics Siemens Healthineers Sienco Sysmex Thermo Fisher

List of Tables

Major Companies Developing or Marketing APTT Tests

Major Companies Developing or Marketing PT 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 PT and APTT Test Volume Forecast

U.S.A., Physician Offices/Group Practices Coagulation Reagent and Instrument Sales Forecast

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

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

U.S.A., Hospital Emergency Departments PT and APTT Test Volume Forecast

U.S.A., Hospital Emergency Departments Coagulation Reagent and Instrument Sales Forecast

U.S.A., Hospital Operating and Recovery Suites PT and APTT Test Volume Forecast

U.S.A., Hospital Operating and Recovery Suites Coagulation Reagent and Instrument Sales Forecast

U.S.A., Hospital ICUs/CCUs PT and APTT Test Volume Forecast

List of Tables (continued)

U.S.A., Hospital ICUs/CCUs Coagulation Reagent and Instrument Sales Forecast

U.S.A., Cancer Clinics Major PT and APTT Test Volume Forecast

U.S.A., Cancer Clinics Coagulation Reagent and Instrument Sales Forecast

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 PT and APTT Test Volume Forecast

U.S.A., Ambulatory Care Centers Coagulation Reagent and Instrument Sales Forecast

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

U.S.A., Surgery Centers PT and APTT Test Volume Forecast

U.S.A., Surgery Centers Coagulation Reagent and Instrument Sales Forecast

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

U.S.A., Nursing Homes PT and APTT Test Volume Forecast

U.S.A., Nursing Homes Coagulation Reagent and Instrument Sales Forecast

List of Tables (continued)

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

U.S.A., Birth Centers PT and APTT Test Volume Forecast

U.S.A., Birth Centers Coagulation Reagent and Instrument Sales Forecast

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

Germany, Laboratory Performing Diagnostic Tests by Market Segment

Germany, Physician Offices/Group Practices PT and APTT Test Volume Forecast

Germany, Physician Offices/Group Practices Coagulation Reagent and Instrument Sales Forecast

Germany, Major Suppliers of Coagulation Diagnostic Products Estimated Market Shares

Spain, Laboratory Performing PT and APTT Tests by Market Segment

Spain, Ambulatory Care Centers PT and APTT Test Volume Forecast

Spain, Ambulatory Care Centers Coagulation Reagent and Instrument Sales Forecast

Spain, Major Suppliers of Coagulation Diagnostic Products Estimated Market Shares