

**New Frontiers in the US Coagulation Testing Market:  
Business Challenges, Emerging Technologies, Competitive Landscape**

**Table of Contents**

**I. Introduction**

**II. Worldwide Market and Technology Overview**

**A. Major Routine and Special Coagulation Tests**

1. Introduction
2. Activated Partial Thromboplastin Time (APTT)
3. Alpha-2 Antiplasmin
4. Antithrombin III
5. Bleeding Time
6. D-Dimer
7. Ethanol Flocculation Test
8. Euglobulin Lysis
9. Factor Assays
  - a. Introduction
  - b. Factor II
  - c. Factor V/Factor V Leiden
  - d. Factor VII
  - e. Factor VIII
  - f. Factor IX
  - g. Factor IXa
  - h. Factor X (Stuart Factor)
  - i. Factor Xa
  - j. Factor XI
  - k. Factor XII
  - l. Factor XIII
10. Fibrin Degradation Products
11. Fibrinogen
12. Heparin
13. Hirudin
14. Hypercoagulability and Thrombosis
15. Lipoprotein a
16. Plasmin
17. Plasminogen
18. Plasminogen Activator Inhibitor (PAI)
19. Platelet Function Tests

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

- 20. Platelet Aggregation
- 21. Proteins C and S
- 22. Prothrombin Fragment 1.2
- 23. Prothrombin Time (PT)
- 24. Reptilase Time
- 25. Thrombin Time
- 26. Tissue-Type Plasminogen Activator (t-PA)
- 27. Von Willebrand's Factor

### **B. Instrumentation Review**

### **C. Major in Vitro Diagnostic Technologies and Their Potential Applications**

- 1. Molecular Diagnostics
  - a. Technology Overview
  - b. Amplification Methods
  - c. Sequencing
  - d. Microarrays/Biochips
- 2. Chromogenic Substrates
- 3. Monoclonal and Polyclonal Antibodies
- 4. Immunoassays
- 5. Microcomputers
- 6. Automation
- 7. Robotics
- 8. Artificial Intelligence
- 9. Dry Chemistry
- 10. Biosensors

### **III. U.S.**

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

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

### **IV. Major Product Development Opportunities**

### **V. Design Criteria For Decentralized Testing Products**

### **VI. 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

### **VII. 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

### **VIII. Competitive Assessments**

- Abbott
- ADI/American Diagnostica
- Alere/Biosite/Inverness
- Axis-Shield
- Beckman Coulter/Danaher
- Becton Dickinson

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

- Bio/Data
- Chrono-Log
- Corgenix Medical/Orgentec
- Diagnostica Stago/Trinity Biotech
- Grifols
- Helena Laboratories
- HYPEN BioMed
- Instrumentation Laboratory
- ITC/Nexus Dx
- Roche
- Siemens
- Sienco
- Sysmex
- Thermo Fischer
- ZyCare/Alere

## **List of Tables**

Major Companies Developing or Marketing Activated Clotting Time 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

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 Plasmin Tests

Major Companies Developing or Marketing Plasminogen Tests

Major Companies Developing or Marketing Plasminogen Activator  
Inhibitor Tests

Major Companies Developing or Marketing Platelet Aggregation Tests

Major Companies Developing or Marketing Protein C Tests

Major Companies Developing or Marketing Protein S Tests

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

Major Companies Developing or Marketing PT Tests

Major Companies Developing or Marketing Thrombin Time Tests

Major Companies Developing or Marketing TPA Tests

Major Companies Developing or Marketing Von Willebrand's  
Factor Tests

Executive Summary Table: U.S.A., Total Coagulation Diagnostics  
Market By Market Segment and Product Category

U.S.A., Laboratories Performing Coagulation Tests By Market Segment

U.S.A., Hospital Laboratories Performing Coagulation Tests  
By Bed Size

U.S.A., Commercial/Private Laboratories Performing Coagulation  
Tests By Annual Test Volume

U.S.A., Hospital Laboratories Average Daily Test Volume

U.S.A., Commercial/Private Laboratories Average Daily Test Volume

U.S.A., Physician Offices/Group Practices Average Daily Test Volume

U.S.A., Total Coagulation Test Volume By Market Segment

U.S.A., All Market Segments Coagulation Test Volume

U.S.A., Hospital Laboratories Coagulation Test Volume

U.S.A., Commercial/Private Laboratories Coagulation Test Volume

U.S.A., Physician Offices/Group Practices Coagulation Test Volume

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

U.S.A., Coagulation Reagent Market By Market Segment

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

U.S.A., Coagulation Instrument Market By Market Segment

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

U.S.A., Total Coagulation Diagnostics Market By Product Category

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