Coagulation Testing in US
Hospitals, Commercial Laboratories and Point-of-Care/POC Locations

Table of Contents
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. Chromogenic Substrates  
2. Monoclonal and Polyclonal Antibodies  
3. Immunoassays  
4. Molecular Diagnostics  
5. Microcomputers  
6. Automation  
7. Robotics  
8. Artificial Intelligence  
9. Dry Chemistry  
10. Biosensors

III. 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
Table of Contents (continued)

7. Quality of Care  
8. Defensive Medicine  
9. Quality Control Issues

E. Market Size, Growth and Major Instrument and Reagent Suppliers’ Sales and Market Shares

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 Strategies

- Abbott
- ADI/American Diagnostica
- Axis-Shield
- Alere/Biosite/Inverness
- Beckman Coulter/Danaher
- Becton Dickinson
- Bio/Data Corporation
- Chrono-Log
- Corgenix Medical
- Diagnostica Stago/Trinity Biotech
- Grifols
- Helena Laboratories
- HYPEN BioMed
- Instrumentation Laboratory
- ITC
- 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

U.S.A., Coagulation Reagent Market By Market Segment
List of Tables (continued)

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

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

U.S.A., Hospital Emergency Departments
Coagulation Test Volume Forecast

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

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

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

U.S.A., Hospital ICUs/CCUs
Coagulation Test Volume Forecast

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

U.S.A., Cancer Clinics Major
Coagulation 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
Coagulation Test Volume Forecast

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

U.S.A., Surgery Centers Most
Frequently Performed Procedures
List of Tables (continued)

U.S.A., Surgery Centers
Coagulation 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
Coagulation Test Volume Forecast

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

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

U.S.A., Birth Centers
Coagulation Test Volume Forecast

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

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