

**THE 2011 COAGULATION TESTING MARKET: US, EUROPE, JAPAN**  
**Emerging Business Opportunities and Market Expansion Strategies for Suppliers**

**Table of Contents**

**Introduction**

**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**

- Introduction
- Benk Hemolab
- Benk TRT Thrombotimer
- Bio/Data MCA 310
- Bio/Data MCA 210
- Bio/Data PAP-4C D/4D/4C
- Cardiovascular Diagnostics COAG
- Diagnostica Stago STA Compact
- Diagnostica Stago STA-R
- Diagnostica Stago Star 4/8
- Helena Laboratories Cascade 480
- Helena Laboratories Cascade M
- Helena Laboratories PACKS-4
- Helena THOR
- Instrumentation Laboratory ACL 100 and 1000 series
- Instrumentation Laboratory ACL6000
- Instrumentation Laboratory ACL7000
- Instrumentation Laboratory ACL9000
- Instrumentation Laboratory Electra 1000C
- Instrumentation Laboratory Electra 1400C
- Instrumentation Laboratory Electra 1600/C
- Instrumentation Laboratory Electra 1800C
- Instrumentation Laboratory Futura
- ITC Hemochron 8000
- Roche Diagnostics CoaguChek
- Siemens BCS
- Siemens BCT
- Siemens BF II/Fibrintimer Series
- Sysmex CA-50
- Sysmex CA-500
- Sysmex CA-1500

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

- Sysmex CA-5000/CA-1000
- Sysmex CA-6000
- Sysmex CA-7000
- Teco Coatron II/Jr./AccuStasis 5000
- Trinity Biotech Amax CS190
- Trinity Biotech Amax CS400
- Trinity Biotech Coag-A-Mate Max
- Trinity Biotech KC 40, 4A, 1A Series
- Trinity Biotech MDA 180
- Trinity Biotech Coag-A-Mate MTX
- Trinity Biotech Coag-A-Mate RA4
- Trinity Biotech Coag-A-Mate XC/Plus
- Trinity Biotech Coag-A-Mate XM

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

1. Chromogenic Substrates
2. Monoclonal and Polyclonal Antibodies
3. Immunoassays
  - a. Applications
  - b. Technological Principle
  - c. Enzyme Immunoassays (EIA)
    - Overview
    - ELISA
    - EMIT
    - Dot Immunobinding Assays
    - Capillary Immunoassays
    - Enzyme Amplification
    - Electrochemical Immunoassay
  - d. Fluorescent Immunoassays
    - Fluorescence Polarization
    - Time-Resolved Pulse Fluorescence
    - Fluorescence Lifetime
  - e. Latex Agglutination
  - f. Immunoprecipitation
4. Microcomputers
5. Automation
6. Robotics
7. DNA Probes
  - a. Overview
  - b. Amplification Methods

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

- PCR
- Ligase Chain Reaction
- Branched DNA
- Q-Beta Replicase
- NASBA
- SDA
- 3 SR
- HPA
- Two-Tiered System
- LAT

8. Artificial Intelligence

9. Dry Chemistry

10. Biosensors

### **D. Worldwide Market Overview**

1. Business Environment
2. Market Structure
3. Market Size and Growth
4. POC Testing Market

#### **France**

- A. Executive Summary
- B. Business Environment
- C. Market Structure
- D. Market Size, Growth and Major Suppliers

#### **Germany**

- A. Executive Summary
- B. Business Environment
- C. Market Structure
- D. Market Size, Growth and Major Suppliers

#### **Italy**

- A. Executive Summary
- B. Business Environment
- C. Market Structure
- D. Market Size, Growth and Major Suppliers

#### **Japan**

- A. Executive Summary
- B. Business Environment
- C. Market Structure
- D. Market Size, Growth and Major Suppliers

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

### **Spain**

- A. Executive Summary
- B. Business Environment
- C. Market Structure
- D. Market Size, Growth and Major Suppliers

### **UK**

- A. Executive Summary
- B. Business Environment
- C. Market Structure
- D. Market Size, Growth and Major Suppliers

### **USA**

- A. Executive Summary
- B. Business Environment
  - 1. Health Care Expenditures
  - 2. Cost Consciousness
  - 3. Industry Consolidation
  - 4. Managed Care
  - 5. Hospitals
  - 6. Admissions
  - 7. Length of Stay
  - 8. Industry Diversification
  - 9. Physician Demographics
  - 10. Population Aging
    - a. Chronic Illnesses
    - b. Disease Incidence
    - c. Susceptibility to Iatrogenesis
    - d. Multiple Illness Cases
  - 11. Laboratory Regulations
- C. Market Structure
  - 1. Centralized Testing
    - a. Hospitals
    - b. Commercial laboratories
  - 2. Decentralized Testing
    - a. Physician Offices/Group Practices
    - b. Point-of-Care Testing
    - c. Home/Self Testing
    - d. Other Decentralized Testing Locations
- D. Market Size, Growth And Major Suppliers

## Table of Contents (continued)

### 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

#### Competitive Assessments

- Abbott
- American Diagnostica
- Avocet Medical
- Axis-Shield
- Beckman Coulter
- Becton Dickinson
- Bio/Data Corporation
- Biosite
- Chrono-Log
- Corgenix Medical
- Diagnostica Stago
- Helena Laboratories

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

- HYPEN BioMed
- Instrumentation Laboratory
- ITC
- Nanogen
- Roche
- Siemens
- Sienco
- Sysmex
- Thermo Fischer
- Trinity Biotech
- ZyCare

## 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

Worldwide, All Market Segments, Laboratories Performing  
Coagulation Tests By Country, 2010

Worldwide, All Market Segments, Total Coagulation Test Volume  
By Country, 2010-2020

Worldwide, All Market Segments, Total Coagulation Reagent  
Market By Country, 2010-2020

Worldwide, All Market Segments, Total Coagulation Instrument  
Market By Country, 2010-2020

Worldwide, All Market Segments, Total Coagulation Diagnostics  
Market By Country, 2010-2020

Executive Summary Table: France, Total Coagulation Diagnostics  
Market By Market Segment and Product Category, 2010-2020

France, Laboratories Performing Coagulation Tests By Market  
Segment, 2010

France, Hospital Laboratories Performing Coagulation Tests By  
Bed Size, 2010

France, Commercial/Private Laboratories Performing Coagulation  
Tests By Annual Test Volume, 2010

France, Hospital Laboratories Average Daily Test Volume, 2010

France, Commercial/Private Laboratories Average Daily Test  
Volume, 2010

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

France, Total Coagulation Test Volume By Market Segment, 2010-2020

France, All Market Segments Coagulation Test Volume, 2010-2020

France, Hospital Laboratories Coagulation Test Volume, 2010-2020

France, Commercial/Private Laboratories Coagulation Test Volume, 2010-2020

France, Coagulation Reagent Market By Market Segment, 2010-2020

France, Major Suppliers of Coagulation Reagents Estimated Sales and Market Shares, 2010

France, Coagulation Instrument Market By Market Segment, 2010-2020

France, Major Suppliers of Coagulation Analyzers, Estimated Total Instrument Placements and Market Shares, 2010

France, Major Suppliers of Coagulation Analyzers, Estimated Placements and Installed Base By Supplier and Model, 2010

France, Major Suppliers of Coagulation Analyzers, Estimated Instrument Sales and Market Shares, 2010

France, Total Coagulation Diagnostics Market By Product Category, 2010-2020

France, Major Suppliers of Coagulation Diagnostic Products, Estimated Sales and Market Shares, 2010

Executive Summary Table: Germany, Total Coagulation Diagnostics Market By Market Segment and Product Category, 2010-2020

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

Germany, Laboratories Performing Coagulation Tests By Market Segment, 2010

Germany, Hospital Laboratories Performing Coagulation Tests By Bed Size, 2010

Germany, Commercial/Private Laboratories Performing Coagulation Tests By Annual Test Volume, 2010

Germany, Hospital Laboratories Average Daily Test Volume, 2010

Germany, Commercial/Private Laboratories Average Daily Test Volume, 2010

Germany, Physician Offices/Group Practice Average Daily Test Volume, 2010

Germany, Total Coagulation Test Volume By Market Segment, 2010-2020

Germany, All Market Segments Coagulation Test Volume, 2010-2020

Germany, Hospital Laboratories Coagulation Test Volume, 2010-2020

Germany, Commercial/Private Laboratories Coagulation Test Volume, 2010-2020

Germany, Physician Offices/Group Practices Coagulation Test Volume, 2010-2020

Germany, Coagulation Reagent Market By Market Segment, 2010-2020

Germany, Major Suppliers of Coagulation Reagents, Estimated Sales and Market Shares, 2010

Germany, Coagulation Instrument Market By Market Segment, 2010-2020

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

Germany, Major Suppliers of Coagulation Analyzers, Estimated Total Instrument Placements and Market Shares, 2010

Germany, Major Suppliers of Coagulation Analyzers, Estimated Placements and Installed Base By Supplier and Model, 2010

Germany, Major Suppliers of Coagulation Analyzers, Estimated Instrument Sales and Market Shares, 2010

Germany, Total Coagulation Diagnostics Market By Product Category, 2010-2020

Germany, Major Suppliers of Coagulation Diagnostic Products, Estimated Sales and Market Shares, 2010

Executive Summary Table: Italy, Total Coagulation Diagnostics Market By Market Segment and Product Category, 2010-2020

Italy, Laboratories Performing Coagulation Tests By Market Segment, 2010

Italy, Hospital Laboratories Performing Coagulation Tests By Bed Size, 2010

Italy, Commercial/Private Laboratories Performing Coagulation Tests By Annual Test Volume, 2010

Italy, Hospital Laboratories Average Daily Test Volume, 2010

Italy, Commercial/Private Laboratories Average Daily Test Volume, 2010

Italy, Total Coagulation Test Volume By Market Segment, 2010-2020

Italy, All Market Segments Coagulation Test Volume, 2010-2020

Italy, Hospital Laboratories Coagulation Test Volume, 2010-2020

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

Italy, Commercial/Private Laboratories Coagulation Test Volume, 2010-2020

Italy, Coagulation Reagent Market By Market Segment, 2010-2020

Italy, Major Suppliers of Coagulation Reagents Estimated Sales and Market Shares, 2010

Italy, Coagulation Instrument Market By Market Segment, 2010-2020

Italy, Major Suppliers of Coagulation Analyzers, Estimated Total Instrument Placements and Market Shares, 2010

Italy, Major Suppliers of Coagulation Analyzers, Estimated Placements and Installed Base By Supplier and Model, 2010

Italy, Major Suppliers of Coagulation Analyzers, Estimated Instrument Sales and Market Shares, 2010

Italy, Total Coagulation Diagnostics Market By Product Category, 2010-2020

Italy, Major Suppliers of Coagulation Diagnostic Products, Estimated Sales and Market Shares, 2010

Executive Summary Table: Japan, Total Coagulation Diagnostics Market By Market Segment and Product Category, 2010-2020

Japan, Laboratories Performing Coagulation Tests By Market Segment, 2010

Japan, Hospital Laboratories Performing Coagulation Tests By Bed Size, 2010

Japan, Commercial/Private Laboratories Performing Coagulation Tests By Annual Test Volume, 2010

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

Japan, Hospital Laboratories Average Daily Test Volume, 2010

Japan, Commercial/Private Laboratories Average Daily Test Volume, 2010

Japan, Total Coagulation Test Volume By Market Segment, 2010-2020

Japan, All Market Segments Coagulation Test Volume, 2010-2020

Japan, Hospital Laboratories Coagulation Test Volume, 2010-2020

Japan, Commercial/Private Laboratories Coagulation Test Volume, 2010-2020

Japan, Coagulation Reagent Market By Market Segment, 2010-2020

Japan, Major Suppliers of Coagulation Reagents Estimated Sales and Market Shares, 2010

Japan, Coagulation Instrument Market By Market Segment, 2010-2020

Japan, Major Suppliers of Coagulation Analyzers, Estimated Total Instrument Placements and Market Shares, 2010

Japan, Major Suppliers of Coagulation Analyzers, Estimated Placements and Installed Base By Supplier and Model, 2010

Japan, Major Suppliers of Coagulation Analyzers, Estimated Instrument Sales and Market Shares, 2010

Japan, Total Coagulation Diagnostics Market By Product Category, 2010-2020

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

Japan, Major Suppliers of Coagulation Diagnostic Products,  
Estimated Sales and Market Shares, 2010

Executive Summary Table: Spain, Total Coagulation Diagnostics  
Market By Market Segment and Product Category, 2010-2020

Spain, Laboratories Performing Coagulation Tests By Market  
Segment, 2010

Spain, Hospital Laboratories Performing Coagulation Tests By  
Bed Size, 2010

Spain, Commercial/Private Laboratories Performing Coagulation  
Tests By Annual Test Volume, 2010

Spain, Hospital Laboratories Average Daily Test Volume, 2010

Spain, Ambulatory Care Centers Average Daily Test Volume, 2010

Spain, Commercial/Private Laboratories Average Daily Test  
Volume, 2010

Spain, Total Coagulation Test Volume By Market Segment,  
2010-2020

Spain, All Market Segments Coagulation Test Volume,  
2010-2020

Spain, Hospital Laboratories Coagulation Test Volume,  
2010-2020

Spain, Ambulatory Care Centers Coagulation Test Volume,  
2010-2020

Spain, Commercial/Private Laboratories Coagulation Test  
Volume, 2010-2020

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

Spain, Coagulation Reagent Market By Market Segment, 2010-2020

Spain, Major Suppliers of Coagulation Reagents, Estimated Sales and Market Shares, 2010

Spain, Coagulation Instrument Market By Market Segment, 2010

Spain, Major Suppliers of Coagulation Analyzers, Estimated Total Instrument Placements and Market Shares, 2010

Spain, Major Suppliers of Coagulation Analyzers, Estimated Placements and Installed Base By Supplier and Model, 2010

Spain, Major Suppliers of Coagulation Analyzers, Estimated Instrument Sales and Market Shares, 2010

Spain, Total Coagulation Diagnostics Market By Product Category, 2010-2020

Spain, Major Suppliers of Coagulation Diagnostic Products, Estimates Sales and Market Shares, 2010

Executive Summary Table: U.K., Total Coagulation Diagnostics Market By Market Segment and Product Category, 2010-2020

U.K., Laboratories Performing Coagulation Tests By Market Segment, 2010

U.K., Hospital Laboratories Performing Coagulation Tests By Bed Size, 2010

U.K., Commercial/Private Laboratories Performing Coagulation Tests By Annual Test Volume, 2010

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

U.K., Hospital Laboratories Average Daily Test Volume, 2010

U.K., Commercial/Private Laboratories Average Daily Test Volume, 2010

U.K., Total Coagulation Test Volume By Market Segment, 2010-2020

U.K., All Market Segments Coagulation Test Volume, 2010-2020

U.K., Hospital Laboratories Coagulation Test Volume, 2010-2020

U.K., Commercial/Private Laboratories Coagulation Test Volume, 2010-2020

U.K., Coagulation Reagent Market By Market Segment, 2010-2020

U.K., Major Suppliers of Coagulation Reagents Estimated Sales and Market Shares, 2010

U.K., Coagulation Instrument Market By Market Segment, 2010

U.K., Major Suppliers of Coagulation Analyzers, Estimated Total Instrument Placements and Market Shares, 2010

U.K., Major Suppliers of Coagulation Analyzers, Estimated Placements and Installed Base By Supplier and Model, 2010

U.K., Major Suppliers of Coagulation Analyzers, Estimated Instrument Sales and Market Shares, 2010

U.K., Total Coagulation Diagnostics Market By Product Category, 2010-2020

U.K., Major Suppliers of Coagulation Diagnostic Products, Estimated Sales and Market Shares, 2010

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

Executive Summary Table: U.S.A., Total Coagulation Diagnostics Market By Market Segment and Product Category, 2010-2020

U.S.A., Laboratories Performing Coagulation Tests By Market Segment, 2010

U.S.A., Hospital Laboratories Performing Coagulation Tests By Bed Size, 2010

U.S.A., Commercial/Private Laboratories Performing Coagulation Tests By Annual Test Volume, 2010

U.S.A., Physician Offices/Group Practices Performing Coagulation Tests By Practice Size, 2010

U.S.A., Hospital Laboratories Average Daily Test Volume, 2010

U.S.A., Commercial/Private Laboratories Average Daily Test Volume, 2010

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

U.S.A., Total Coagulation Test Volume By Market Segment, 2010-2020

U.S.A., All Market Segments Coagulation Test Volume, 2010-2020

U.S.A., Hospital Laboratories Coagulation Test Volume, 2010-2020

U.S.A., Physician Offices/Group Practices Coagulation Test Volume, 2010-2020

U.S.A., Commercial/Private Laboratories Coagulation Test Volume, 2010-2020

**List of Tables (continued)**

U.S.A., Coagulation Reagent Market By Market Segment,  
2010-2020

U.S.A., Major Suppliers of Coagulation Reagents Estimated  
Sales and Market Shares, 2010

U.S.A., Coagulation Instrument Market By Market Segment,  
2010-2020

U.S.A., Major Suppliers of Coagulation Analyzers, Estimated  
Total Instrument Placements and Market Shares, 2010

U.S.A., Major Suppliers of Coagulation Analyzers, Estimated  
Placements and Installed Base By Supplier and Model, 2010

U.S.A., Major Suppliers of Coagulation Analyzers, Estimated  
Instrument Sales and Market Shares, 2010

U.S.A., Total Coagulation Diagnostics Market By Product  
Category, 2010-2020

U.S.A., Major Suppliers of Coagulation Diagnostic Products,  
Estimated Sales and Market Shares, 2010