# GLOBAL HEMOSTASIS DIAGNOSTICS 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 Hemostasis 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

- 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

- 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

- 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

# <u>France</u>

- 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

# <u>Italy</u>

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

### <u>Japan</u>

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

#### <u>Spain</u>

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

### <u>UK</u>

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

### <u>USA</u>

- 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

### 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
- ADI/American Diagnostic
- Axis-Shield
- Alere/Biosite/Inverness
- Beckman Coulter/Danaher
- Becton Dickinson
- Bio/Data Corporation
- Chrono-Log
- Corgenix Medical
- Diagnostica Stago/Trinity Biotech
- Helena Laboratories

# <u>Table of Contents</u> (continued)

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

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 Hemostasis Tests By Country

Worldwide, All Market Segments, Total Hemostasis Test Volume By Country

Worldwide, All Market Segments, Total Hemostasis Reagent Market By Country

Worldwide, All Market Segments, Total Hemostasis Instrument Market By Country

Worldwide, All Market Segments, Total Hemostasis Diagnostics Market By Country

Executive Summary Table: France, Total Hemostasis Diagnostics Market By Market Segment and Product Category

France, Laboratories Performing Hemostasis Tests By Market Segment

France, Hospital Laboratories Performing Hemostasis Tests By Bed Size

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

France, Hospital Laboratories Average Daily Test Volume

France, Commercial/Private Laboratories Average Daily Test Volume

#### List of Tables (continued)

France, Total Hemostasis Test Volume By Market Segment

France, All Market Segments Hemostasis Test Volume

France, Hospital Laboratories Hemostasis Test Volume

France, Commercial/Private Laboratories Hemostasis Test Volume

France, Hemostasis Reagent Market By Market Segment

France, Major Suppliers of Hemostasis Reagents Estimated Sales And Market Shares

France, Hemostasis Instrument Market By Market Segment

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

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

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

France, Total Hemostasis Diagnostics Market By Product Category

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

Executive Summary Table: Germany, Total Hemostasis Diagnostics Market By Market Segment and Product Category

Germany, Laboratories Performing Hemostasis Tests By Market Segment

Germany, Hospital Laboratories Performing Hemostasis Tests By Bed Size

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

Germany, Hospital Laboratories Average Daily Test Volume

Germany, Commercial/Private Laboratories Average Daily Test Volume

Germany, Physician Offices/Group Practice Average Daily Test Volume

Germany, Total Hemostasis Test Volume By Market Segment

Germany, All Market Segments Hemostasis Test Volume

Germany, Hospital Laboratories Hemostasis Test Volume

Germany, Commercial/Private Laboratories Hemostasis Test Volume

Germany, Physician Offices/Group Practices Hemostasis Test Volume

Germany, Hemostasis Reagent Market By Market Segment

Germany, Major Suppliers of Hemostasis Reagents, Estimated Sales and Market Shares

Germany, Hemostasis Instrument Market By Market Segment

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

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

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

Germany, Total Hemostasis Diagnostics Market By Product Category

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

Executive Summary Table: Italy, Total Hemostasis Diagnostics Market By Market Segment and Product Category

Italy, Laboratories Performing Hemostasis Tests By Market Segment

Italy, Hospital Laboratories Performing Hemostasis Tests By Bed Size

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

Italy, Hospital Laboratories Average Daily Test Volume

Italy, Commercial/Private Laboratories Average Daily Test Volume

Italy, Total Hemostasis Test Volum By Market Segment

Italy, All Market Segments Hemostasis Test Volume

Italy, Hospital Laboratories Hemostasis Test Volume

Italy, Commercial/Private Laboratories Hemostasis Test Volume

Italy, Hemostasis Reagent Market By Market Segment

Italy, Major Suppliers of Hemostasis Reagents Estimated Sales And Market Shares

Italy, Hemostasis Instrument Market By Market Segment

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

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

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

Italy, Total Hemostasis Diagnostics Market By Product Category

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

Executive Summary Table: Japan, Total Hemostasis Diagnostics Market By Market Segment and Product Category

Japan, Laboratories Performing Hemostasis Tests By Market Segment

Japan, Hospital Laboratories Performing Hemostasis Tests By Bed Size

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

Japan, Hospital Laboratories Average Daily Test Volume

Japan, Commercial/Private Laboratories Average Daily Test Volume

Japan, Total Hemostasis Test Volume By Market Segment

Japan, All Market Segments Hemostasis Test Volume

Japan, Hospital Laboratories Hemostasis Test Volume

Japan, Commercial/Private Laboratories Hemostasis Test Volume

Japan, Hemostasis Reagent Market By Market Segment

Japan, Major Suppliers of Hemostasis Reagents Estimated Sales and Market Shares

Japan, Hemostasis Instrument Market By Market Segment,

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

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

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

Japan, Total Hemostasis Diagnostics Market By Product Category

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

Executive Summary Table: Spain, Total Hemostasis Diagnostics Market By Market Segment and Product Category

Spain, Laboratories Performing Hemostasis Tests By Market Segment

Spain, Hospital Laboratories Performing Hemostasis Tests By Bed Size

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

Spain, Hospital Laboratories Average Daily Test Volume

Spain, Ambulatory Care Centers Average Daily Test Volume

Spain, Commercial/Private Laboratories Average Daily Test Volume

Spain, Total Hemostasis Test Volume By Market Segment

Spain, All Market Segments Hemostasis Test Volume

Spain, Hospital Laboratories Hemostasis Test Volume

Spain, Ambulatory Care Centers Hemostasis Test Volume

Spain, Commercial/Private Laboratories Hemostasis Test Volume

Spain, Hemostasis Reagent Market By Market Segment

Spain, Major Suppliers of Hemostasis Reagents, Estimated Sales and Market Shares

Spain, Hemostasis Instrument Market By Market Segment

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

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

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

Spain, Total Hemostasis Diagnostics Market By Product Category

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

Executive Summary Table: U.K., Total Hemostasis Diagnostics Market By Market Segment and Product Category

U.K., Laboratories Performing Hemostasis Tests By Market Segment

U.K., Hospital Laboratories Performing Hemostasis Tests By Bed Size

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

#### List of Tables (continued)

- U.K., Hospital Laboratories Average Daily Test Volume
- U.K., Commercial/Private Laboratories Average Daily Test Volume
- U.K., Total Hemostasis Test Volume By Market Segment
- U.K., All Market Segments Hemostasis Test Volume
- U.K., Hospital Laboratories Hemostasis Test Volume
- U.K., Commercial/Private Laboratories Hemostasis Test Volume
- U.K., Hemostasis Reagent Market By Market Segment
- U.K., Major Suppliers of Hemostasis Reagents Estimated Sales And Market Shares
- U.K., Hemostasis Instrument Market By Market Segment
- U.K., Major Suppliers of Hemostasis Analyzers, Estimated Total Instrument Placements and Market Shares
- U.K., Major Suppliers of Hemostasis Analyzers, Estimated Placements and Installed Base By Supplier and Model
- U.K., Major Suppliers of Hemostasis Analyzers, Estimated Instrument Sales and Market Shares
- U.K., Total Hemostasis Diagnostics Market By Product Category
- U.K., Major Suppliers of Hemostasis Diagnostic Products, Estimated Sales and Market Shares

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

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

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

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

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

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 Hemostasis Test Volume By Market Segment

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

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

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

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

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

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

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

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

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

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

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

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