

COAGULATION DIAGNOSTIC TESTING MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

TABLE OF CONTENTS

1.	Overview	10	
1.1	Statement of Report	10	
1.2	About this Report	11	
1.3	Scope of the Report	11	
1.4	Objectives	12	
1.5	Methodology	12	
1.6	Executive Summary	13	
2.	Introduction to Hemostasis and Blood Coagulation	15	
2.1	Vascular Constriction	15	
2.2	Platelet Activation and Platelet Plug Formation	15	
2.3	Blood Coagulation	16	
2.3.1	Coagulation Cascade	16	
2.3.2	Current Cell-Based Model for Blood Coagulation	17	
2.3.2.1	Initiation of Blood Coagulation	17	
2.3.2.2	Amplification of Blood Coagulation	18	
2.3.2.3	Propagation of Blood Coagulation	19	
2.4	Fibrinolysis	19	
2.5	Regulation of Coagulation	20	
2.5.1	Tissue Factor Pathway Inhibitor	20	
2.5.2	Antithrombin	21	
2.5.3	Thrombomodulin and Protein C	22	
2.5.4	Protein Z and Protein Z-dependent Protease Inhibitor	22	
2.5.5	Prostacyclin	22	
2.6	Clinical Significance of Blood Coagulation and Anticoagulants	22	
2.6.1	Overview of Bleeding Disorders	23	
2.6.2	Overview of Hypercoagulable Disorders	24	
2.6.3	Anticoagulation Therapy in Cardiovascular Disease	25	
2.7	Overview of Commonly Used Drugs to Regulate Coagulation	27	
2.7.1	Heparin (Unfractionated)	28	
2.7.2	Low Molecular-Weight Heparin (LMWH)	28	
2.7.3	Fondaparinux	29	
2.7.4	Warfarin (Coumadin)	29	
2.7.5	Direct Factor Xa Inhibitors	29	
2.7.6	Direct Thrombin Inhibitors	30	
2.7.7	Thrombolytic Agents	31	
2.7.8	Antiplatelet Agents	31	
2.7.9	Differences Between Antiplatelets and Anticoagulants	33	
2.8	Situations Requiring Coagulation Testing	33	
2.8.1	Managing Anticoagulation Therapies	33	
2.8.1.1	Monitoring Unfractionated Heparin	34	
2.8.2.2	Monitoring Low-Molecular Weight Heparin	36	
2.8.1.3	Monitoring Warfarin	36	
2.8.1.4	Monitoring Direct Factor Xa Inhibitors	37	
2.8.1.5	Monitoring Direct Thrombin Inhibitors	38	
2.8.1.6	Monitoring Antiplatelet Therapies	39	
2.8.1.7	Perioperative Monitoring of Coagulation	40	
2.8.1.8	Monitoring of Coagulation During Hemodialysis	41	
2.8.2	Diagnosing and Managing Bleeding Disorders	41	
3.	Overview of Routine and Special Blood Coagulation Tests	44	
3.1	Activated Clotting Time (ACT)	44	
3.2	Activated Partial Thromboplastin Time	44	
3.3	Activated Protein C Resistance	45	

3.4	Alpha-2 Plasmin Inhibitor	46
3.5	Antiphospholipid Antibody	47
3.6	Antithrombin (Activity and Antigen)	48
3.7	Bleeding Time	49
3.8	D-Dimer	49
3.9	Ecarin Clotting Time	50
3.10	Euglobulin Lysis	51
3.11	Factor Activity Assays	51
3.11.1	Factor I (Fibrinogen) Assay	53
3.11.2	Factor II	54
3.11.3	Factor III (Tissue Factor)	54
3.11.4	Factor V	55
3.11.5	Factor V Leiden Mutation	55
3.11.6	Factor VII	56
3.11.7	Factor VIII	56
3.11.8	Factor IX	57
3.11.9	Factor X	58
3.11.10	Factor XI	58
3.11.11	Factor XII	59
3.11.12	Factor XIII	59
3.11.13	High Molecular Weight Kininogen	60
3.11.14	Prekallikrein	61
3.12	Factor Inhibitor Assays	61
3.13	Fibrin Degradation Product Assay	62
3.14	Fibrinogen	63
3.15	Heparin anti-Xa	64
3.16	Heparin Induced Thrombocytopenia	65
3.17	Plasminogen Activity	66
3.18	Plasminogen Activator Inhibitor	67
3.19	Platelet Function Tests	67
3.20	Protein C	68
3.21	Protein S	69
3.22	Prothrombin Time	70
3.23	Prothrombin G20210A Mutation	72
3.24	Reptilase Time	72
3.25	Thrombin Time	73
3.26	Viscoelastic Coagulation Tests	74
3.27	von Willebrand Factor	74
4.	Understanding the Technologies Used in Coagulation Testing	77
4.1	Mechanical	77
4.1.1	Viscoelastic Tests	77
4.1.1.1	TEG/Thromboelastography	78
4.1.1.2	ROTEM/Rotational Thromboelastometry	82
4.1.1.3	Sonoclot85	
4.1.1.4	Clinical Applications	88
4.1.2	Photo-Optical Detection	89
4.1.3	Electro-Mechanical and Electromagnetic Mechanical Detection	89
4.2	Immunologic	90
4.3	Chemical (Chromogenic) Assays	90
4.4	Molecular PCR Testing	90
4.5	Potential Interfering Variables Affecting Coagulation Testing	90
4.6	Influence of New Anticoagulants on Coagulation Testing Paradigms	91
4.7	Future Technologies in Coagulation and Antiplatelet Testing	93
5.	Market Analysis: Size, Growth, Share, and Competitors	94

5.1	Worldwide Coagulation and Antiplatelet Testing Markets	94
5.1.1	U.S. Market	97
5.1.2	European Market	100
5.1.3	Japanese Market	101
5.1.4	ROW	102
5.2	Market Structure and Competitive Situation	104
5.2.1	Laboratory Testing	104
5.2.2	POC Coagulation Testing	106
5.2.3	Anticoagulation Clinics	108
5.2.4	Anticoagulation Self-Testing and Self-Management	108
5.3	Market Drivers and Restraints	112
5.3.1	Impact of New Oral Anticoagulant Drugs on the Coagulation Testing Market	113
5.4	Market and Technology Trends – A Look Towards the Future	114
5.5	Marketing Approaches	116
5.6	Strategic Recommendations	116
5.7	Recent Industry Activity	118
5.7.1	Roche and Diagnostica Stago Parting Ways in Laboratory Coagulation	118
5.7.2	Roche Acquires Verum Diagnostica GmbH and Expands Coagulation Testing Product Line	118
5.7.3	Universal Biosensors and Siemens Collaborate on Advanced POC Coagulation Platform	119
5.7.4	Instrumentation Laboratory and Beckman Coulter concluded their Cross-Distribution Agreement	119
5.7.5	CoaguChek® XS Personal Receives Reimbursement Approval for Self-Testing in Japan	119
5.7.6	Diagnostica Stago Launches Products for Measurement of Rivaroxaban	119
5.7.7	Diagnostic Stago Offers Three Factor VII Detection Methods	120
5.7.8	Diagnostic Stago Offers Three Procoagulant Microparticle Detection Methods	120
5.7.9	Trinity Biotech Sold its Worldwide Coagulation Business to the Stago Group	121
5.7.10	Inverness Medical Innovations Acquired HemoSense, Inc.	121
6.	Coagulation Instrumentation and Assays on the Market	122
6.1	Laboratory Coagulation Testing Instruments and Assays	122
6.1.1	American Labor/Lab A.C.M. Inc.	126
6.1.1.1	CD2000	127
6.1.1.2	CoaLab 6000	127
6.1.2	Beckman Coulter	127
6.1.3	Behnk Elektronik	127
6.1.3.1	Thrombolyzer Fully Automated Systems	127
6.1.3.2	Semi-Automated Instruments	128
6.1.4	Bio/Data	129
6.1.4.1	Platelet Aggregation Profiler, Model-PAP 8E	129
6.1.4.2	Aggregation Reagents and Standalone Assay Kits	129
6.1.4.3	Coagulation Reagents and Controls	129
6.1.5	Cepheid	130
6.1.5.1	Xpert® FII & FV	130
6.1.6	Chrono-Log Corp.	130
6.1.6.1	Whole Blood-Optical Lumi-Aggregation System, Models 700-2/700-4	130
6.1.7	Diagnostica Stago	130
6.1.7.1	STA Compact Hemostasis System	130
6.1.7.2	STA Compact CT	131
6.1.7.3	STA Satellite	131
6.1.7.4	STA-R Evolution Expert Series	132
6.1.7.5	STart 4 Hemostasis Analyzer	132
6.1.7.6	Calibrated Automated Thrombogram	132
6.1.8	Helena Laboratories	133
6.1.8.1	AggRAM	133
6.1.8.2	Cascade M and Cascade M-4	133
6.1.9	Hyphen BioMed	134
6.1.9.1	HEMOCLOT Clotting Assays	134

6.1.9.2	BIOPHEN Chromogenic Reagents	134
6.1.9.3	ZYMUTEST ELISA Assays	134
6.1.10	Instrumentation Laboratory	135
6.1.10.1	ACL TOP Family of Hemostasis Testing Systems	135
6.1.10.2	ACL ELITE Series	136
6.1.10.3	ACL AcuStar	136
6.1.11	LABiTec GmbH	136
6.1.11.1	CoaLab 1000	136
6.1.11.2	CoaData 2004/4004	137
6.1.12	Pentapharm	137
6.1.13	Roche	138
6.1.13.1	cobas t 411 and cobas t 611	138
6.1.14	Sekisui Diagnostics	138
6.1.15	Siemens	140
6.1.15.1	Sysmex CA-600 Systems	140
6.1.15.2	Sysmex CA-1500	141
6.1.15.3	Sysmex CA-7000	141
6.1.15.4	BFT II	142
6.1.15.5	BCS XP	143
6.1.16	Sysmex	144
6.1.17	Tcoag	144
6.1.17.1	Destiny Max	144
6.1.17.2	Destiny Plus	144
6.1.17.3	KC1 Delta / KC4 Delta	145
6.1.18	TECO GmbH	145
6.1.18.1	Coatron M1, M2, and M4	145
6.1.18.2	Coatron A4	146
6.1.18.3	Dimex and Dimex Jr.	146
6.2	POC Coagulation Testing Instruments and Assays: Professional and Self-Testing	147
6.2.1	Abbott	150
6.2.1.1	i-STAT 1	150
6.2.2	Alere	150
6.2.2.1	INRatio/INRatio2 PT INR Monitoring Systems	150
6.2.3	CoaguSense	151
6.2.3.1	Coag-Sense PT/INR Monitoring System	151
6.2.4	Helena Laboratories	151
6.2.4.1	Cascade POC	151
6.2.4.2	Actalyke XL and Actalyke Mini II	151
6.2.4.3	Abrazo	152
6.2.5	ITC	152
6.2.5.1	ProTime Microcoagulation System	152
6.2.5.2	Hemochron Signature Elite and Signature Plus	152
6.2.5.3	Hemochron Response	153
6.2.6	Medtronic	153
6.2.6.1	HMS Plus	153
6.2.6.2	ACT Plus	154
6.2.7	Roche	154
6.2.7.1	CoaguChek XS PT Test System	154
6.2.7.2	CoaguChek XS Plus PT Test System	155
6.2.7.3	CoaguChek XS Pro PT Test System	155
6.2.8	Spartan Bioscience	155
6.2.9	Universal Biosensors	155
6.3	Platelet Function Testing Instruments and Assays	155
6.3.1	Multiplate Analyzer	156
6.3.2	Platelet Function Analyzer-100 (PFA-100)	156
6.3.3	Plateletworks Assay	157

6.3.4	Platelet VASP test (PLT-VASP)	157
6.3.5	ROTEM158	
6.3.6	Sonoclot Analyzer	158
6.3.7	TEG 5000 Thrombelastograph Hemostasis Analyzer	159
6.3.8	VerifyNow	159
6.4	Home Monitoring Devices and Assays	159
6.5	New Product Launches and Products in Development	160
7.	Market Challenges	162
7.1	Cost Containment	162
7.2	Competition	162
7.3	Patent Protection	162
7.4	Regulatory Constraints	163
7.5	Discontinuation of Warfarin Therapy	163
7.6	Controversies in Guided Antiplatelet Therapy	163
7.6.1	Aspirin Resistance Testing	164
7.6.2	Clopidogrel Resistance Testing	164
7.7	Introduction of New Anticoagulants with No Monitoring Requirements	164
8.	Business Trends in Coagulation Testing	166
8.1	Drivers of Coagulation Testing	166
8.2	Industry Consolidation	166
8.3	Healthcare Expenditures and Cost Controls	167
8.4	Changes in Patient Management	167
8.4.1	Testing Recommendations Updates	167
8.4.2	Centers for Medicare and Medicaid Services Impose Penalty on Readmission Rates	167
8.5	Regionalization of Laboratory Care	168
8.6	Satellite Facilities	169
8.7	Point-of-Care Coagulation Testing	169
8.7.1	Key Issues in the POC Coagulation Testing Sector	170
8.7.1.1	POC Coagulation Testing is Safe and Effective	170
8.7.1.2	Different POC Techniques Provide Diverse Information Regarding Coagulation	170
8.7.1.3	Economic Savings Associated with POC Testing	170
8.7.1.4	Effect on Clinical Outcomes	171
8.7.1.5	Connectivity Issues	171
8.7.1.6	Cost Benefits	171
8.7.1.7	Quality Control Issues	172
8.7.1.8	Cross-Contamination	172
8.7.2	Current POC Coagulation Market Trends and Drivers	172
8.7.2.1	Market Drivers	173
8.7.2.2	Market Restraints	174
8.7.2.3	POC Coagulation Testing Assay Market Trends	174
8.7.2.4	POC Coagulation Testing Assay Technology Trends	174
8.7.2.5	POC Coagulation Testing Assay Strategic Recommendations	175
8.7.3	Advantages and Disadvantages of POC Coagulation Testing	175
8.7.3.1	Advantages of POC Coagulation Testing	175
8.7.3.2	Disadvantages to POC Coagulation Testing	176
8.7.4	Key Customer Segments	176
8.7.4.1	Laboratory Testing	176
8.7.4.2	POC Coagulation Testing	177
8.7.4.3	Anticoagulation Clinics	178
8.7.4.4	Anticoagulation Self-Testing and Self-Management	178
8.7.5	Design Criteria For Decentralized Testing Products	179
8.8	Drivers of OTC and Self-Testing Markets	180
9.	Regulatory Environment and Insurance Reimbursements	181

9.1	FDA Labeling Requirements	181
9.2	U.S. Government Regulation of Medical Devices	181
9.3	Clinical Laboratory Improvement Act (CLIA)	182
9.3.1	Certification for POC Coagulation Devices	184
9.4	Coagulation Self-Testing Insurance Coverage and Reimbursement	185
9.5	Trends in U.S. Laboratory Testing Reimbursement Practices	185
9.6	Proposed Changes to the European Regulatory Environment	186
10.	Company Profiles	188
10.1	Abbott	188
10.2	Accumetrics	191
10.3	Alere	191
10.4	American Labor/Lab A.C.M. Inc.	192
10.5	Beckman Coulter	192
10.6	Bio/Data	196
10.7	BioCytex	197
10.8	Cepheid	197
10.9	Chrono-Log Corp.	198
10.10	CoaguSense	199
10.11	Diagnostica Stago	199
10.12	Haemonetics	199
10.13	Helena Laboratories	199
10.14	HYPEN BioMed	200
10.15	Instrumentation Laboratory	200
10.16	Inverness Medical Innovations	200
10.17	ITC	200
10.18	Behnk Elektronik GmbH & Co. (Kommanditgesellschaft)	201
10.19	LABiTec GmbH	201
10.20	Medtronic	201
10.21	Pentapharm Ltd. (Now Owned by DSM Nutritional Products AG)	202
10.22	Roche	203
10.23	Sekisui Diagnostics (Formerly American Diagnostica, Inc.)	204
10.24	Siemens	205
10.25	Sienco, Inc.	205
10.26	Spartan Bioscience	205
10.27	Symex	206
10.28	Tcoag	206
10.29	Technoclone GmbH	206
10.30	Trinity Biotech, Plc.	206
10.31	Universal Biosensors	207

INDEX OF TABLES

Table 2.1:	Coagulation Factors	17
Table 2.2:	Proteins Involved in Regulating Coagulation	20
Table 2.3:	Acquired Hypercoagulable Disorders	24
Table 2.4:	Inherited Hypercoagulable Disorders	25
Table 2.5:	Common Conditions Requiring Anticoagulation Therapy	25
Table 2.6:	Limitations of Traditional Anticoagulants	28
Table 2.7:	Desired Characteristics for New Anticoagulants	28
Table 2.8:	Properties of FDA-Approved Direct Thrombin Inhibitors	31
Table 2.9:	Advantages of Using Anti-Factor Xa Assay to Monitor Unfractionated Heparin	35
Table 2.10:	Disadvantages of Using Anti-Factor Xa Assay to Monitor Unfractionated Heparin	35
Table 2.11:	Recommended Laboratory Evaluations for Suspected Underlying Hypercoagulable States	42
Table 2.12:	Laboratory Results in Various Platelet and Coagulation Disorders	43

Table 4.1: TEG, ROTEM and Sonoclot Assessments of Coagulation Variables	77
Table 4.2: Advantages of Viscoelastic Assays	78
Table 4.3: Disadvantages of Viscoelastic Assays	78
Table 4.4: TEG Reference Ranges for Kaolin-Activated Citrated Whole Blood	80
Table 4.5: TEG Assay Menu	81
Table 4.6: ROTEM Reference Ranges for Citrated Whole Blood Using the In-TEM Assay	84
Table 4.7: ROTEM Assay Menu	84
Table 4.8: Reference Ranges for Native Whole Blood Using Sonoclot Assays	86
Table 4.9: Sonoclot Assay Menu	87
Table 4.10: Pre-Analytical Variables Affecting Coagulation Testing	90
Table 4.11: Analytical Variables Affecting Coagulation Testing	91
Table 4.12: Influence of Anticoagulants on Routine Coagulation Assays	92
Table 4.13: Influence of Anticoagulants on Thrombophilia Assays	92
Table 5.1: POCT Frequency in Hospitals	106
Table 5.2: Benefits of Anticoagulation Self-Testing	109
Table 5.3: Barriers to Anticoagulation Self-Testing and Self-Management	111
Table 5.4: Key Market Drivers for Coagulation Testing	112
Table 5.5: Market Drivers for Point-of-Care Anticoagulation Testing Market	112
Table 5.6: Key Market Restraints for Coagulation Testing	113
Table 5.7: Market Restraints for Point-of-Care Anticoagulation Testing Market	113
Table 6.1: Coagulation Analyzers – Laboratory	122
Table 6.2: Comparison of IL's ACL TOP Family of Hemostasis Analyzers	135
Table 6.3: Sysmex CA-600 System Assays	140
Table 6.4: Sysmex CA-1500 System Assays	141
Table 6.5: Sysmex CA-7000 System Assays	142
Table 6.6: BFT II System Assays	143
Table 6.7: BCS XP System Assays	143
Table 6.8: Coagulation Analyzers – POC and Self-Testing Devices	147
Table 6.9: Multiplate Analyzer Assays	156
Table 7.1: Documents for Protecting Intellectual Property Rights	163
Table 8.1: SWOT Analysis: Summary of Strengths, Weaknesses, Opportunities and Threats in the Coagulation POC Market	175
Table 9.1: Financial Comparison for Moderate and Waived CLIA Labs	183

INDEX OF FIGURES

Figure 2.1: Coagulation Cascade	16
Figure 2.2: Initiation and Amplification of Blood Coagulation	18
Figure 2.3: Fibrinolysis	19
Figure 2.4: Role of Tissue Factor Pathway Inhibitor	21
Figure 2.5: Role of Antithrombin	21
Figure 2.6: Role of Thrombomodulin and Protein C	22
Figure 4.1: Schematic of TEG Result Parameters	79
Figure 4.2: TEG Analysis Tree – Kaolin Sample Type	80
Figure 4.3: TEG 5000 Thrombelastograph® Hemostasis Analyzer System	81
Figure 4.4: Schematic of ROTEM Result Parameters	83
Figure 4.5: ROTEM delta	84
Figure 4.6: Schematic of ROTEM Result Parameters	86
Figure 4.7: Sonoclot Coagulation & Platelet Function Analyzer	87
Figure 4.8: Photo-Optical Detection System	89
Figure 5.1: Global Revenue Forecasts for Laboratory and POC Coagulation Testing, 2010-2018	94
Figure 5.2: Global Revenue Forecasts for POC Rapid Coagulation Analyzer Systems, 2010-2018	94
Figure 5.3: Market Share for Coagulation POCT Diagnostic Testing Companies Worldwide, 2013	95
Figure 5.4: Overall Global Market for Anticoagulant Drugs, 2012-2019	96
Figure 5.5: Estimated Market for Diagnostic Assays of Platelet Function, 2013-2018	96

Figure 5.6: U.S. Revenue Forecasts for Laboratory and POC Coagulation Testing, 2010-2018	97
Figure 5.7: U.S. Laboratory Coagulation Testing Customers by Size	98
Figure 5.8: U.S. Market Share of Laboratory Coagulation Testing by Dollar Volume	98
Figure 5.9: U.S. Revenue Forecasts for POC Rapid Coagulation Analyzer Systems, 2010-2018	99
Figure 5.10: U.S. Market for Anticoagulant Drugs, 2012-2019	99
Figure 5.11: European Revenue Forecasts for Laboratory and POC Coagulation Testing, 2010-2018	100
Figure 5.12: European Revenue Forecasts for POC Rapid Coagulation Analyzer Systems, 2010-2018	101
Figure 5.13: Japanese Revenue Forecasts for Laboratory and POC Coagulation Testing, 2010-2018	101
Figure 5.14: Japanese Revenue Forecasts for POC Rapid Coagulation Analyzer Systems, 2010-2018	102
Figure 5.15: ROW Revenue Forecasts for Laboratory and POC Coagulation Testing, 2010-2018	103
Figure 5.16: ROW Revenue Forecasts for POC Rapid Coagulation Analyzer Systems, 2010-2018	103
Figure 5.17: Indian Coagulation Reagents Market – Test Contribution	104

SAMPLE

1. Overview

1.1 Statement of Report

The purpose of this report is to provide a comprehensive examination of the specific segment of the *in vitro* diagnostics (IVD) market known as the coagulation and antiplatelet testing market. It examines the available and emerging technologies being utilized in this space, and describes the current product lines of all of the companies known to be marketing, manufacturing, or developing instruments and reagents for coagulation and antiplatelet testing. Moreover, the study defines the dollar volume of sales—both worldwide and in the U.S.—and analyzes the factors that influence the size and the growth of the market.

This report provides a thorough analysis of the coagulation and antiplatelet testing market by:

- Identifying viable technology drivers through a comprehensive look at platform technologies for coagulation and antiplatelet testing.
- Providing a description of the instruments, reagents, and supplies marketed by major companies in the coagulation and antiplatelet testing market, from their basic principles to their clinical applications.
- Discovering feasible market opportunities by identifying high-growth applications in different analytical diagnostic and disease monitoring areas.
- Focusing on global industry development through an in-depth analysis of the major world markets for coagulation and antiplatelet testing, including growth forecasts.
- Presenting market figures regarding the current value of coagulation and antiplatelet testing, market projections, market share, key players and sector growth rates.
- Providing a detailed analysis of each of the major types of coagulation and antiplatelet tests, such as automated laboratory assays and point-of-care (POC) testing.

This study contains:

- A detailed analysis of recent trends in the coagulation and antiplatelet testing marketplace.
- In-depth profiles of the leading companies with coagulation and antiplatelet testing tools and technologies.
- Perspectives of the coagulation and antiplatelet testing industry from leading industry experts.
- Analysis of potential new coagulation and antiplatelet testing applications in clinical management.
- Market predictions and trends analysis concerning U.S. expenditures on coagulation and antiplatelet testing solutions.
- Projections of coagulation and antiplatelet testing market sizes for U.S., European, and Asian markets.
- Analysis of commercial coagulation and antiplatelet testing business strategies.
- The latest news and mergers and acquisitions (M&As) developments in the coagulation and antiplatelet testing marketplace.
- A comprehensive overview and insight into coagulation and antiplatelet testing business strategies.
- Regulatory issues and legislation affecting use and marketing of coagulation and antiplatelet testing products.

Analysis includes charts and graphs measuring product growth and trends within the marketplace. Company-specific information, including sales figures, product pipeline status and research and development (R&D) trends, is provided. This review will also:

- Assess coagulation and antiplatelet testing market drivers and bottlenecks, from medical and scientific community perspectives.
- Discuss the potential benefits of coagulation and antiplatelet testing for various sectors of the medical and scientific community, as they relate to managing a variety of clinical conditions.
- Establish the current total market size and future growth of the coagulation and antiplatelet testing market and analyze the current size and growth of individual segments.
- Provide current and forecasted market shares by company.
- Discuss profit and business opportunities by segment.

- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the coagulation and antiplatelet testing market.

The following questions will also be addressed in this analysis:

- What are the near-term business opportunities in the coagulation and antiplatelet testing market?
- What are the current and forecasted coagulation and antiplatelet testing market sizes in the U.S., European Union (E.U.) and Japan, as well as in other emerging markets such as India and China?
- What are the business models currently used by companies in the coagulation and antiplatelet testing market?
- How will manufacturers, researchers, physicians and patients influence this market?
- What are the drivers and bottlenecks influencing the coagulation and antiplatelet testing market?
- What are the technologies used in coagulation and antiplatelet testing?
- Who holds the proprietary rights to the coagulation and antiplatelet testing market technology platforms?
- In the U.S., Japan and the E.U., what regulatory processes apply to coagulation and antiplatelet testing technologies?
- How will new coagulation and antiplatelet testing technologies change testing paradigms?
- How will new coagulation and antiplatelet testing technologies reduce healthcare expenditures and affect R&D spending?

1.2 About this Report

The main objectives of this analysis are to:

- Identify viable technology drivers through a comprehensive look at platform technologies for coagulation and antiplatelet testing, including point of care systems and self-testing.
- Discover feasible market opportunities by identifying high-growth applications in different clinical diagnostic settings, and by focusing on expanding markets such as point of care testing, emergency medicine and satellite clinic testing.
- Focus on global industry development through an in-depth analysis of the major world markets for coagulation and antiplatelet testing, including growth forecasts.
- Assess the impact of coagulation and antiplatelet testing on central laboratory growth plans.
- Identify coagulation and antiplatelet rapid tests that are the most likely candidates for migration to self-testing platforms.
- Analyze the business issues associated with coagulation and antiplatelet testing.
- Assess the growing home testing market for International Normalized Ratio (INR).

1.3 Scope of the Report

This examination surveys most of the companies known to be currently marketing, manufacturing or developing instruments and reagents for the coagulation and antiplatelet testing market in both the U.S. and the world. Although emphasis is placed upon the U.S. market, analyses of the other regional markets are also included. The report covers diagnostic assays to detect clotting deficiencies and monitoring assays to assess the effect of anticoagulant and antiplatelet therapies. The focus in this report is on both routine and specialty assays that assess clotting mechanisms of hemostasis.

The reader should consult other TriMark Publications reports on the TriMark publications website for detailed discussions of important individual market segments related to the coagulation and antiplatelet testing market, such as *Point of Care Diagnostic Testing World Markets* and *New Oral Anticoagulant Markets*.

1.4 Objectives

The goal of this study is to review the market for coagulation and antiplatelet diagnostic testing equipment and supplies. Toward this goal, this report answers the following key questions:

- Which companies are utilizing cutting-edge technologies to develop, validate and market coagulation and antiplatelet diagnostic testing assays?
- Which new coagulation and antiplatelet diagnostic testing assays show the most promise for approval?
- What are the economic challenges in the coagulation and antiplatelet diagnostic testing market?
- How can regulatory oversight drive approval and adoption of new technologies?
- What impediments still exist to for home coagulation and antiplatelet testing?

1.5 Methodology

The author of this report holds a Master's in immunology and has substantial experience in science writing and as a medical industry analyst. She also has many years of laboratory experience and has conducted laboratory testing and instrument and reagent development for biotech companies. The senior editor of this report holds a Ph.D. in biochemistry from the University of Minnesota and has had post-doctoral experience at the University of Connecticut School of Medicine. He has taught at Quinnipiac University and the Tufts School of Medicine, and has been a senior scientist at Pfizer Pharmaceutical Laboratories in drug development. He also has many decades of experience in science writing and as a medical industry analyst. He has over 30 years of experience in laboratory testing and instrument and reagent development technology as a licensed clinical laboratory director, as well as extensive experience in senior level management positions in biotech and medical service companies.

Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites, as well as annual reports for publicly-held firms. Additional sources of information include non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities such as the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information or omission or for the results obtained by the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects, as well as Sector Snapshots that it publishes annually. TriMark extracts relevant data and analytics from its research as part of this data collection.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations.

TriMark Publications Report, Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report in TriMark Publications includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly-available data and proprietary databases.
- Formulating a study outline with the assigned writer, including important items, as follows:
 - Market and product segment grouping, and evaluating their relative significance.
 - Key competitors' evaluations, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
 - End-user research to evaluate analytical significance in market estimation.
 - Supply chain research and analysis to identify any factors affecting the market.
 - New technology platforms and cutting-edge applications.
- Identifying the key technology and market trends that drive or affect these markets.
- Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of expert panel partners from the industry being analyzed.

1.6 Executive Summary

Coagulation assays will continue to be one of the most commonly ordered assays in the IVD market for the foreseeable future. Many of the new models of laboratory coagulation testing devices and reagents, which are dominated by prothrombin time (PT) and aPTT, will include upgrades such as greater automation and the integration of more esoteric coagulation tests (e.g., D-dimer and antiphospholipid assays). Companies are also aiming to produce assays with more specific and sensitive markers of hemostasis.

Laboratory tests are often performed to assess the functions of the different steps involved in the coagulation process. These tests are crucial for:

- Diagnosing bleeding disorders.
- Monitoring the effectiveness of anticoagulant therapies.
- Establishing a baseline coagulation status for patients who may need future anticoagulation therapies.
- Screening patients' blood clotting status prior to surgery.
- Assessment of liver function.
- Monitoring coagulation function in patients with diseases known to interfere with coagulation.

Those who administer anticoagulants must traverse a fine line between clot prevention and the risk of unwanted, potentially fatal bleeding. Managing this balance represents a challenge for practicing physicians today. Thus, coagulation testing is imperative for effective monitoring of hemostasis and to ensure proper anticoagulant drug treatment. Understanding the risk of clotting enables health care professionals to avoid under-treating patients, which may lead to potential blood clots that can travel from the leg to the lungs or from the heart to the brain. Conversely, the other unwanted scenario would be when patients receive too much blood thinning medication, putting them at risk for serious bleeding complications.

After 60 years with warfarin and heparins as the only commonly used anticoagulants, the past 20 years have generated an impressive array of new agents. The introduction of low-molecular-weight heparins resulted in the first major change for coagulation testing by enabling outpatient care of many patients with venous thromboembolism.

The next significant shift in the testing paradigm is in progress as the need for routine laboratory monitoring and frequent dose adjustments of warfarin is diminished by the introduction of the new oral anticoagulants.

The introduction of novel anticoagulation therapies has also prompted companies to identify new customer needs associated with detecting and monitoring these drugs. New approaches to coagulation testing will emerge to address the changing landscape of anticoagulation and antiplatelet drugs. Although these new oral antithrombotic agents do not require routine monitoring, detection assays would be extremely helpful for investigating unexplained bleeding episodes, checking patient compliance, or addressing concerns about dosages for patients with conditions outside the norm such as situations where patients' pharmacokinetics and pharmacodynamics of the drug are altered (*e.g.*, impaired liver and kidney functions or pregnancy).

The advent of new anticoagulation and antiplatelet drugs is also driving the need for greater standardization across the many different coagulation assay protocols. Since the U.S. coagulation testing market tends to follow a whole system approach, companies are incorporating reagents for multiple assays to be run on the same device. Thus, the market for quality control products and services will also benefit from the diversification of on-board assays.

In spite of the introduction of novel oral anticoagulants, traditional agents such as warfarin are expected to continue to play a role in a significant subset of patients. For those patients, future models of care will entail patient-centered self-testing and self-management. The incorporation of technology (*i.e.*, Web-based expert systems) is also expected to further improve outcomes.

The contraction of the hospital system and technological advances will facilitate decentralization of the coagulation testing, thus creating POC opportunities and challenges for suppliers. Like their central laboratory counterparts, there is now a trend to incorporate esoteric anticoagulant assays into the POC instruments. Portability, connectivity, and ease of use still top the list of desired POC device characteristics. New technologies that will likely impact the field of POC coagulation testing in the decade include lab-on-a-chip type devices and non-invasive blood coagulation monitors.

The worldwide coagulation testing market, which encompasses both laboratory and POC testing, in 2012 is valued at \$1.2 billion and is expected to grow at a CAGR of 5.5% to \$1.6 billion by 2017. Laboratory coagulation testing is estimated to be in the top ten professional diagnostics markets worldwide and POC testing continues to have a strong presence in the coagulation testing market. In fact, POC coagulation testing accounts for approximately 15% of the total coagulation testing market dollar volume, and is expected to increase to about 25% of the coagulation testing market by 2017.

The U.S. coagulation testing market, which encompasses central laboratory, doctor's office and POC testing, in 2012 is valued at \$800 million and is expected to grow at a CAGR of 5.5% to \$1.1 billion by 2017. The most frequently performed coagulation tests in U.S. laboratories are the prothrombin time (PT) and the activated partial thromboplastin time (aPTT) assays, with an estimated annual test volume of 1.2 billion and 1.1 billion, respectively. Bleeding times, fibrinogen assays and D-dimer assays round out the top five most common tests in U.S. laboratories. Not surprisingly, larger hospital laboratories perform a greater number of coagulation tests in house as compared to smaller institutions.

The U.S. coagulation testing market is closely linked with the U.S. anticoagulation drug market, which is slated to increase from \$1.2 billion in 2012 to \$1.6 billion by 2017 with a CAGR of 5.5%. The U.S. anticoagulant market is subtly undergoing a visible shift in clinical practice. It is shifting from a market monopolized by a single injectable anticoagulant to the simple once-daily oral anticoagulants. Although warfarin remains the market leader, the entry of Pradaxa (dabigatran) in 2011 and Xarelto (rivaroxaban) in 2012 has changed the market dynamics. Two other drugs waiting for approvals are Elikvis (apixaban) and edoxaban. These two drugs are expected to dominate the partially untapped market of stroke prevention in atrial fibrillation (AF). Further, these two drugs are expected to seize a large market share from the parenteral anticoagulants used in joint replacement surgeries. Notably, neither of these drugs is monitored by the ever present INR (prothrombin ratio), which is used to follow patients on warfarin.