COAGULATION DIAGNOSTIC TESTING MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers
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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 [2013] is valued at $[2013] and is expected to grow at a CAGR of [2013] to $[2018] by [2018]. Laboratory coagulation testing is estimated to be in the top ten professional diagnostics markets worldwide and POC testing continues have a strong presence in the coagulation testing market. In fact, POC coagulation testing accounts for approximately [2018]% of the total coagulation testing market dollar volume, and is expected to increase to about [2018]% of the coagulation testing market by [2018].

The U.S. coagulation testing market, which encompasses central laboratory, doctor’s office and POC testing, in [2013] is valued at $[2013] and is expected to grow at a CAGR of [2013] to $[2018] by [2018]. 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 [2013] and [2013] 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 $[2013] in [2013] to $[2018] by [2018] with a CAGR of [2018]% The U.S. anti-coagulant 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 [2010] and Xarelto (rivaroxaban) in [2011] has changed the market dynamics. Two other drugs waiting for approvals are Eliquis (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.