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HEMATOLOGY ANALYZER INSTRUMENTATION AND REAGENT MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

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1.0 Overview

Clinical hematology analyzer analysis is one of the oldest and most important sectors of clinical laboratory analysis. The hematology instrument and reagent market is centered around a group of instruments called hematology analyzers. The term clinical hematology analyzer usually refers to an automated instrument for determining the presence, number and type of cellular elements in easily collected body fluids, such as blood. However, it is not necessarily limited to these determinations. The hematology analysis always includes determination of non-cellular parameters in blood, such as hemoglobin and hematocrit. Other closely related areas of clinical interest are coagulation and flow cytometry.

In fact, traditional specialization barriers, such as microbiology, hematology, blood banking, immunology and even anatomical pathology are rapidly fading both operationally and instrumentally. But for the sake of defining the subject to a reasonable size, the more traditional scope of clinical hematology analyzer will be the focus of this examination.

1.1 Objectives of the Report

The purpose of this report is to describe the specific segments of the global clinical hematology analyzer instrumentation and reagent marketplace. The review covers those segments that are highly active in terms of innovation and growth. Specifically, this study examines the markets for small-lab, as well as highly-automated large-lab, platforms and accessory equipment, such as reagents, supplies and add-on equipment from original equipment manufacturers.

The emphasis in this analysis is on those companies and products that are actively developing and marketing hematology analyzer products for the clinical setting, including hospitals, independent labs, physician's offices and miscellaneous clinics. This study examines the clinical hematology analyzer instrumentation and reagent industry market segment in the U.S. and around the world. The regional markets and their differences are examined, including Europe, Japan and the rest of the world. Particular attention is paid to those areas of the clinical hematology analyzer instrumentation sector that are showing the greatest growth or the most innovation. This review attempts to answer the following questions:

- Which companies are the key players?
- What are the opportunities in clinical hematology analyzer instrumentation?
- What are the development trends in hematology?
- Where are the new market growth areas in hematology instruments?
- What are the most favored technology platforms for hematology instruments?
- Where is the hematology analyzer instrument technology taking us?
- How is immunological technology blending with hematology analyzer?

This examination reviews the market for clinical hematology analyzer instrumentation used in clinical practice. It defines the dollar volume of sales in each major regional and country market, and it analyzes the factors that influence the size and the growth of the individual market segments. The report details market sizes and growth rates for the U.S. and world markets.

The study surveys some of the primary companies known to be marketing, manufacturing or developing products for the clinical hematology analyzer instrumentation market for those sectors covered here. Each company is discussed in depth with a section on the history of the company, the product line, business and marketing analysis, and a subjective commentary of the position of the company in its market.

The benefits of this report are:

- In-depth analysis of the major sectors of the clinical hematology analyzer instrumentation and reagent marketplace, their sizes, growth rates and major drivers.
- Presentation of some of the emerging technology platforms, elucidating the potential areas that could gain traction in this market.
- Analysis of the partnerships and alliances the various key sector players have forged, as well as describing financings of these market participants, giving insight into potential market collaborations.
- Examination of new technology platforms in the U.S., Japan and Europe that seek to dominate this mature market, and to identify lead positions and potential future growth areas.

1.2 Methodology

The information and analysis presented in this report are based on an extensive survey of the clinical hematology analyzer segment of the diagnostic instrument sector, as well as on a detailed examination of published literature and reports obtained from regulatory authorities, medical research institutions, trade associations, and national and world health organizations. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals with regard to commercial potential and market sizes. Senior managers from major diagnostic companies were interviewed for part of the information in this report.

The information in this report is based upon interviews with sales and marketing professionals of companies in the hematology instrument market. People from virtually every company mentioned in this report were queried, some several times, about their companies' products and marketing strategies, as well as their overall thoughts about their industry segment. Information was also obtained from interviews with founders, chief executive officers, and vice presidents of some of the companies discussed in the report. The structure of the hospital laboratories and commercial laboratory facilities was derived from interviews with laboratory directors and medical technologists working in these areas.

Other sources of information for this analysis were trade association publications and meetings, product brochures and catalogs, and company literature. Where the companies under discussion were publicly held, an examination of the annual reports, 10k filings and financial reports was used as the basis of the data reported. Some of the information obtained for the report was taken from Biotechnology Associates' proprietary databases and from the private data stores of TriMark Publications.

1.3 Scope of the Report

This report deals with the analysis of common constituents of blood in well and ill patients for specifically hematology related parameters. The two most important areas where such tests are measured are in the hospital and the independent clinical laboratories. The third place these tests are measured is in physician's office laboratories (POLs). Newer areas of testing interest for these analytes can be satellite labs and pharmacies and corporate clinics. This study touches on coagulation analysis primarily because it is historically included in hematology laboratory procedures. But no effort is made to give a comprehensive analysis of the coagulation testing market. Flow cytometry is briefly examined because of its increasing use in clinical hematology diagnosis. Again, no effort is made to examine this area extensively.

This examination does not include the areas of blood collection and processing for transfusion. Segments like apheresis, blood grouping, tests for groups A, B, AB, O; and Rh factor, blood screening, antibody screening, infectious disease testing, development of new techniques to ensure safer blood supply, blood conservation, and cord blood banking are reserved for other market reports. Most of the time in clinical practice, these areas are specifically separated from hematology and designated blood banking. The emphasis in this report is on those companies and products that are actively developing and marketing clinical laboratory instrumentation and reagents and supplies for performing clinical hematology analyzer tests in clinical diagnostics. The reader should consult other TriMark Publications reports at http://www.trimarkpublications.com for a detailed discussion of the important individual market segments that are related to the *in vitro* diagnostics (IVD) market, such as molecular diagnostic testing, high-growth diagnostic test markets, blood gas and electrolytes, over-the-counter diagnostic testing markets, clinical chemistry, immunochemistry, and point of care testing (POCT).

The analysis touches on the specialty testing areas in clinical hematology analyzer diagnostic testing, such as coagulation, CBC profiling and special markers, since these segments are frequently a part of the overall analytical focus of companies marketing general laboratory automation equipment. However, no effort is made to quantify the size of the broader market involving blood typing, blood banking and blood product collections. The report does not cover what is generally characterized as immunochemistry analyzer instruments and reagents, nor chemistry or coagulation markets, or other diagnostic device markets, although many of the instruments, reagents and techniques in the clinical hematology analyzer diagnostics market segment are intimately associated with these broader areas. Moreover, this examination does not cover disposable plastic supplies for the clinical laboratory or blood gases and electrolytes. All of these subjects are treated thoroughly in other TriMark Publications reports.

1.4 Executive Summary

Clinical hematology analyzer testing includes processes used to detect levels of enzyme, sugars, proteins and other substances in the blood in order to determine such clinical conditions as nutritional state, liver function, kidney function and others. Such testing is widely applied in identifying conditions like diabetes, hyperlipidemia and arteriosclerosis during clinical diagnoses and as a part of regular health checkups. During [redacted], approximately [redacted] clinical hematology analyzer tests were carried out within hospitals in the U.S. This figure is forecast to grow to [redacted] tests per annum by [redacted]. Most of these tests were performed as screening, or multi-channel tests, performed on automated hematology analyzer analyzers specifically designed for that purpose. Automated multi-channel testing addresses those tests that can be and are frequently done as groups and combinations on automated clinical hematology analyzer equipment.

The global IVD market for all test types reached $[redacted] in net manufacturers' revenues in [redacted], with the U.S., Europe and Japan comprising approximately [redacted]%, [redacted]% and [redacted]%, respectively. [redacted] countries account for approximately [redacted]% of the IVD market worldwide. [redacted] country markets account for [redacted]% of total IVD sales. In [redacted], clinical hematology analyzer had global revenues of approximately $[redacted], which grew to $[redacted] in [redacted], and it is forecast to be the slow- to moderate-growing segment of the pathology market. The size and anticipated growth of the global clinical hematology analyzer market is projected to increase at [redacted]% per year to [redacted], with worldwide revenues for clinical hematology analyzer testing estimated to be north of $[redacted].

[redacted] companies control approximately [redacted]% of the total $[redacted] diagnostics industry. The worldwide IVD market is estimated to be growing at [redacted]% to [redacted]% per year. Although more than [redacted] major companies are involved in the $[redacted] global market for clinical diagnostics, only [redacted] have sales of over $[redacted], creating an environment that is still ripe for consolidation and partnering. Of the top [redacted] companies, only Beckman Coulter and Dade Behring are not part of a larger corporate structure that includes a pharmaceutical division.

TriMark believes that the global IVD market will continue to grow due to a number of key favorable industry trends:

- Demographic shifts resulting from the aging of the population and socio-economic improvements are expected to increase the overall level of demand for diagnostic testing.
- Increased focus on lowering total healthcare expenditures will likely increase demand for diagnostic testing as an effective tool to improve patient outcomes and reduce the costs of misdiagnosis through earlier and more accurate diagnosis and patient monitoring.
- Emerging markets will provide additional demand as economic improvements in these countries lead to increases in healthcare expenditures.
- Technological improvements in new tests, pathogens and markers will result in the increased use of diagnostics to aid in the diagnosis of diseases.
- Improvements in lower-cost POC/near-patient testing capabilities are expected to expand the application of diagnostic testing capabilities into non-laboratory settings (*e.g.*, operating room, emergency room, acute care centers).
- Increased automation of diagnostic instruments is expected to lower the overall cost of diagnostic testing and thereby increase accessibility and demand.

In the U.S., approximately [redacted]% of clinical diagnostic testing is currently conducted in hospital-based and commercial laboratories. Clinical hematology analyzer testing now represents [redacted]% of the $[redacted] U.S. market for clinical diagnostic testing reagents, controls and equipment, or $[redacted] in [redacted], and is projected to grow at an annual rate of [redacted]% in the U.S. through [redacted], to a total of $[redacted]. Surveys show that [redacted]% of hospitals with more than [redacted] beds have adopted some form of clinical hematology analyzer testing, with over [redacted]% of the [redacted] U.S. hospitals ([redacted]-bed size and larger) having installed some form of clinical hematology analyzer instrumentation over the [redacted] months to the end of [redacted].

The specific category of IVD devices, which encompasses the sales of automated clinical hematology analyzer analyzers, had sales of approximately $[redacted] in the U.S. in [redacted], and that market is expected to increase to $[redacted] by [redacted]. By [redacted], the portion of the market presenting sales in North America, Western Europe and Japan is expected to increase to $[redacted] if economic conditions remain relatively stable. TriMark projects a U.S. growth rate of [redacted]% through [redacted].

The worldwide clinical hematology analyzer instrument, reagent and supply segment of the IVD market is estimated by TriMark to be approximately $[redacted] in [redacted]. The sales of this market segment are projected by TriMark to grow to only $[redacted] by [redacted]. This includes general hematology analyzer, electrolytes, enzymes, blood gases, lipids and urinalysis. In the U.S., this total market is $[redacted].