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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. 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 on 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 author of this report is a Ph.D. in biochemistry from the University of Minnesota, with many decades of experience in scientific writing and as a medical industry analyst. He has been a senior director of several large regional and national healthcare laboratories. 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. Additionally, sources of information include the non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities like the U.S. Department of Health and Human Services (HHS) and U.S. federal agencies such as 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 we publish annually. We extract relevant data and analytics from TriMark's 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.

Market Forecasts and Modeling

The numerical data on market size, growth rates and sales forecasts are obtained from a well-examined model based upon quantitative market information obtained from the leading global companies in the sector, private seminar presentations by company experts and public SEC filings. Many industry experts are also consulted to confirm these market estimates. The numbers used are washed of discounts and returns, and represent the final sale numbers. In addition, global numbers are assessed by region components as well, taking into account differences in market conditions between the U.S., Europe and Asian markets in particular.

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.

1.3 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. Clinical hematology analyzer tests carried out within hospitals in the U.S. increased to ██████ in ██████. 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 \$█████ in sales in ██████, with the U.S., Europe and Japan comprising approximately █%, █% and █%, respectively. Five countries account for approximately █% of the IVD market worldwide. ██████ country markets account for █% of total IVD sales. The size and growth of the global clinical hematology analyzer market has increased █% per year with worldwide revenues for clinical hematology analyzer testing estimated to be \$█████.

█████ companies control approximately █% of the total \$█████ diagnostics industry. The worldwide IVD market is estimated to be growing at █% to █% per year. Although more than ██████ major companies are involved in the \$█████ global market for clinical diagnostics, only ██████ have sales of over \$█████, creating an environment that is still ripe for consolidation and partnering. Of the top seven companies, only Beckman Coulter is 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 █% of clinical diagnostic testing is currently conducted in hospital-based and commercial laboratories. Clinical hematology analyzer testing now represents █% of the \$█████ U.S. market for clinical diagnostic testing reagents, controls and equipment and is projected to grow at an annual rate of █% in the U.S. through ██████, to a total of \$█████. Surveys show that █% of hospitals with more than ██████ beds have adopted some form of clinical hematology analyzer testing, with over █% of the ██████ U.S. hospitals (█████-bed size and larger) having installed some form of clinical hematology analyzer instrumentation. The specific category of IVD devices, which encompasses the sales of automated clinical hematology analyzers, had sales of approximately \$█████ in the U.S. in ██████, and has increased to \$█████ in ██████. This portion of the market had sales in North America, Western Europe and Japan that increased to \$█████. The worldwide clinical hematology analyzer instrument, reagent and supply segment of the IVD market increased to \$█████ in ██████. This includes general hematology analyzers, electrolytes, enzymes, blood gases, lipids and urinalysis. In the U.S. this total market is \$█████.

2. IVD Clinical Hematology Analyzer Market

2.1 Introduction

Clinical hematology analyzer testing includes processes used to detect red and white blood cells, platelets, and other substances in the whole blood in order to determine general clinical conditions. Such testing is widely applied in identifying conditions like anemia, cancer and various blood disorders during clinical diagnoses and as a part of regular health checkups.

The most common hematology tests are performed by automated instruments as traditional routine clinical hematology analyzer tests that measure red and white cells and platelets, generally referred to as a complete blood count (CBC). Other hematology related IVD tests measure bodily functions, such as blood-clotting ability and oxygen-carrying functions, or measure the presence of infections or parasites.

The wide range and important nature of these tests have established CBC testing as an integral part of the managed-care environment, providing for accurate and timely patient diagnosis and treatment. Increasingly, CBC testing is being recognized as making a significant contribution to improving patient care and lowering total patient costs. CBC tests are performed in a number of different clinical settings, including:

- Hospitals.
- Reference laboratories.
- Physician's offices.
- Ambulatory care centers.
- Nursing homes.

CBC is used in virtually every part of the health delivery system and test providers generally fall into a number of categories:

- Reference laboratories that conduct batteries of tests for physicians and hospitals.
- Hospital central clinical laboratories.
- Operating rooms.
- Emergency rooms.
- Stat laboratories.
- Near-patient and patient bedside testing.
- Physician's offices.
- Walk-in clinics.
- Surgeries.
- Pharmacies and supermarkets that offer in-store testing.
- Individuals who purchase kits for self-testing (occult blood testing).

The number of clinical hematology analyzer tests carried out within hospitals, independent labs and POLs in the U.S. is estimated to grow to [REDACTED] tests per annum by [REDACTED], double the number performed in [REDACTED].