1. Overview

1.1 Statement of Report

Flow cytometry is a laboratory analytical technique that can rapidly measure multiple parameters of individual cells or particles as they pass through a beam of light, typically a laser. Flow cytometers equipped with cell sorters can separate subpopulations of cells for further analysis for therapeutic use. These unique features allow immunophenotyping of leukocytes and lymphomas; detection of rare cells after chemotherapy (minimum residual disease); enumeration of CD4 T-cells in patients with HIV/AIDS; identification of biomarkers for monitoring cancer therapies; and identification and isolation of embryonic and adult stem cells in bone marrow and other tissues.
The global flow cytometry market remains one of the fastest-growing segments of life sciences and clinical diagnostics markets with a forecasted compound annual growth rate of [redacted]% through [redacted]. Highly attractive growth areas covered in this study include:

- Stem cell research.
- Biomarkers and companion diagnostics.
- CD4 testing.
- High throughput screening.
- Immunology and vaccine development.

This TriMark Publications report provides a detailed analysis of the global flow cytometry market, including size, growth, technology platforms, applications, new instrumentation, industry trends and the internal structure of the sector. In the current life sciences research, pharmaceutical drug discovery and development, and clinical diagnostics markets, flow cytometry offers some of the brightest promise for growth and innovation. The rapid development of this sector is driven by:

- Introduction of compact, affordable flow cytometry instruments with user-friendly software moving flow cytometry from core laboratories to individual laboratories.
- Multicolor flow cytometers with multiple lasers that can simultaneously detect up to 18 cell parameters, distinguishing subpopulations among millions of cells.
- Integration of flow cytometry with multiplex bead assays and imaging devices.
- Multiplex bead immunoassays, a powerful analytical technique enabling measurement of up to 100 analytes or proteins simultaneously.
- Availability of high speed clinical grade cell sorters for stem cell research and clinical development.
- Development of easier to use POC flow cytometers for CD4 Testing allowing testing in more sites for resource limited countries with a high prevalence of HIV/AIDS.
- Automated sample preparation and handling, enabling high throughput screening for drug discovery and development.

This review analyzes the size and growth of the global flow cytometry market, including the factors that influence the various market segments within it, the dollar volume of sales, both in the United States and worldwide. Examined are:

- Flow cytometry technology platforms.
- Applications of flow cytometry based testing.
- Companies participating in this sector.
- New instrumentation.
- Trends in the industry.

This report provides a detailed market analysis and forecasts through [redacted] for the global flow cytometry market in North America, Europe, Asia-Pacific, the BRICs countries (Brazil, Russia, India and China), and resource limited countries. For each region, detailed market analysis of the research, pharmaceutical and clinical diagnostics segments.

The global investment in stem cell research, and drivers and restrictors are discussed in detail. The rapidly growing field of biomarkers and companion diagnostics are analyzed from the perspective of reference laboratories offering prognostic and predictive biomarker assays with issues of validation discussed. Identification and discussion of drivers and restrictors for adoption of this technology by the pharmaceutical industry are presented.

Of particular interest, this report includes analysis of global health needs for CD4 testing, and the application of flow cytometry in the development of new treatments and vaccines for malaria, tuberculosis and tropical diseases. This has become a growing market segment with increasing funding by the U.S. PEPFAR program, the Global Fund, and foundations including the Bill and Melinda Gates Foundation and the Clinton Global Initiative. It provides a market forecast and discussion of market potential for CD4 Testing for HIV/AIDS. It includes market analysis, trends, and new technology for POC (Point of Care) flow cytometry CD4 testing. Competitors are analyzed in detail in the market dominated by BD Biosciences and Beckman Coulter, with more than 60 companies competing for share.

This report includes the following features:

- Review of current instrumentation technologies and a feature comparison of leading systems.
- Five-year reagent and instrument sales forecasts.
- Market shares of leading reagent and instrument suppliers.
- Review of current and emerging technologies and their market applications.
- Product development opportunities for new instruments, reagents and consumables
- Profiles of current and emerging suppliers, including their sales, product portfolios,
- Corporate strategies and collaborative arrangements, business opportunities and strategic recommendations for suppliers.

The reader should consult other TriMark Publications reports at http://www.trimarkpublications.com for detailed discussions of important individual market segments related to the flow cytometry market, such as hematology instrumentation and reagent markets, clinical chemistry testing, high-growth diagnostic tests markets, genomics and medical nanotechnology.

1.2 About This Report

This report includes the following features:

- Five-year volume and sales forecasts for major flow cytometry tests performed in U.S. hospitals and commercial laboratories.
- Annual placements and installed base of major flow cytometers.
- Review of current instrumentation technologies and a feature comparison of leading systems.
- Five-year reagent and instrument sales forecasts.
- Sales and market shares of leading reagent and instrument suppliers.
- Review of current and emerging diagnostic technologies, and their potential market applications.
- Product development opportunities for new instruments, consumables, and auxiliary products.
- Profiles of current and emerging suppliers, including their sales, product portfolios, marketing tactics, technological know-how, new products in R&D, collaborative arrangements, and corporate strategies.
- Business opportunities and strategic recommendations for suppliers.

The report examines all of the generally-accepted clinical analytical activities in use today in the flow cytometry sector. It includes the prevalent clinical measurement devices and the accompanying reagents and supplies as utilized in hospitals and large reference laboratories. It discusses the potential benefits of the flow cytometry market for various sectors of the medical and scientific communities, and it assesses the market drivers and bottlenecks from the perspective of these communities.

- It establishes the current total market size and future growth of the flow cytometry market and analyzes the current size and growth of various segments.

- It assesses various business models in flow cytometry and provides strategic recommendations for near-term business opportunities.
- It examines the products offered and roles played by companies that have invested significantly in this market, and it provides current and forecasted market shares by these companies.

1.3 Objectives

The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for flow cytometry.
- Obtaining a complete understanding of the chief flow cytometry tests from their basic principles to their applications.
- Discovering feasible market opportunities by identifying high-growth applications in different clinical diagnostic and life science areas.
- Focusing on global industry development through an in-depth analysis of the major world markets for flow cytometry, including growth forecasts.
- How can flow cytometry contribute to laboratory growth plans?
- Which test procedures are the most likely candidates for migration to flow cytometry platforms?
- How to understand the business issues that go into justifying flow cytometry?

This analysis defines the dollar volume of market sales in the U.S. and analyzes the factors that influence the size and the growth of the market segments. Key questions answered in this examination include:

- How can flow cytometry measuring tools and technologies facilitate improved patient care?
- What are the main types of flow cytometry testing technologies that are currently available?
- Who are the current key players in this marketplace?
- Which flow cytometry testing market areas have the greatest potential for growth?
- What is the current state of the flow cytometry testing market?
- Which diagnostic companies are investing in new flow cytometry testing technology platform solutions?
- What are the main business strategies adopted by leading flow cytometry testing companies?
- What are the benefits of various flow cytometry testing technology platforms?

Additionally, this study contains:

- Detailed analysis of recent trends in the flow cytometry testing marketplace.
- In-depth profiles of the leading companies with flow cytometry testing tools and technologies.
- Perspectives of the flow cytometry testing industry from leading industry experts.
- Analysis of potential new flow cytometry testing applications in the clinical sector as they pertain to HIV/AIDS management.
- Market predictions and trends analysis concerning U.S. expenditures on flow cytometry testing solutions.
- Projections of the U.S. flow cytometry testing market size through [redacted].
- Review of commercial flow cytometry testing business strategies such as co-branding.

Analysis includes charts and graphs measuring product growth and trends within the marketplace. Company-specific information—including sales figures, product pipeline status and R&D trends—is provided. Also, this review includes:

- Assessment of flow cytometry testing market drivers and bottlenecks, from medical and scientific community perspectives.
- Discussions on the potential benefits of flow cytometry testing for various sectors of the medical and scientific community, as they relate to diabetes management.

- The current total market size and future growth of the U.S. flow cytometry testing market and analysis of the current size and growth of individual segments.
- Current and forecasted market shares by companies.
- Discussions on profit and business opportunities by segments.
- Strategic recommendations for near-term business opportunities.
- Analysis of the current commercial uses of flow cytometry testing for diabetes management.

The following questions will also be addressed in this report:

- What are the near-term business opportunities in the U.S. flow cytometry testing market?
- What are the current and forecasted flow cytometry testing market sizes in the U.S.?
- What are the business models currently used by companies in the flow cytometry testing market?
- What are the drivers and bottlenecks influencing the flow cytometry testing market?
- What are the barriers to entry for the flow cytometry testing market?
- What are the key technologies used in flow cytometry testing?
- Who holds the proprietary rights to the flow cytometry testing market technology platforms?
- How is this technology currently being applied and utilized?
- What regulatory processes apply to flow cytometry testing technologies in the U.S.?
- How will new flow cytometry testing technologies change diagnostic screening/testing paradigms and reduce diagnostic false negatives and decrease costs of patient care?
- How will new flow cytometry testing technologies reduce healthcare expenditures and affect R&D spending?

1.4 Scope of the Report

The goal of this study is to review the market for Flow cytometry testing equipment and supplies using reagents and instruments for analysis of individual components in body tissues and fluids. Toward this goal, this review answers the following key questions:

- Which companies are utilizing cutting-edge technologies to develop, validate and market flow cytometry tests for clinical use?
- What are the current impediments to incorporating promising flow cytometry tests into clinical practice?
- Which new flow cytometry tests show the most promise for approval?
- What are the economic challenges to gaining approval?
- How can regulatory oversight drive approval and adoption of new technologies?
- Which alliances show the greatest synergy in bringing flow cytometry tests to market?
- Which shared technologies are driving the most encouraging development?

This examination surveys most of the instrument companies known to be currently marketing, manufacturing or developing instruments and reagents for the flow cytometry market, in both the U.S. and the world. Each leading company is discussed in depth, with sections on its history, product line, business and marketing analysis, and a subjective commentary of the company's market position.

Primary attention is paid to the hospital market segment and, separately, to the instruments, reagents and supplies marketed by the major companies in this segment. Market size, growth rates and market components for instruments, reagents, controls and consumables used in this area are also analyzed.

This analysis emphasizes the companies that are actively developing and marketing flow cytometry clinical laboratory instrumentation, reagents and supplies for performing flow cytometry tests. The emphasis in this report is on the clinical use of flow cytometry tests.

The reader should consult other TriMark Publications reports at http://www.trimarkpublications.com for detailed discussions of important individual market segments related to the flow cytometry market, such as Hematology

Instrumentation and Reagent Markets, clinical Chemistry Testing, High-Growth Diagnostic Tests Markets, Genomics and Medical Nanotechnology.

The purpose of this report is to describe the specific segments of the global flow cytometry market that are highly active in terms of innovation and growth. Specifically, this study examines the markets for high-end multicolor and compact flow cytometers, fluorescent dyes, multiplex bead assays, high throughput sample preparation and handling, and software.

The emphasis in this analysis is on those companies and products that are actively developing and marketing flow cytometry instruments and reagents for life sciences research, pharmaceutical drug discovery and development, and clinical diagnostics. This study examines the flow cytometry instrument and reagents industry in the U.S., Europe, Asia-Pacific, BRICs emerging markets and resource limited countries. These regional markets and their differences are examined in terms of investment in life sciences research, pharmaceutical drug development, and clinical diagnostics; and restrictors and drivers in these segments. Particular attention is paid to those regions in which the flow cytometry market is showing the greatest growth or most innovation. This report attempts to answer the following questions:

- Which companies are the key players?
- What are the opportunities for flow cytometry instrumentation and reagents?
- What are the development trends in flow cytometry?
- Where are the new market growth areas in flow cytometry instruments and reagents?
- Where is the flow cytometry technology taking us?
- How are complementary technologies blending with flow cytometry?

This examination defines the dollar volume of sales in each major regional and country market, and it analyzes the factors that influence the size and growth of the individual market segments. The report details the market sizes and growth rates for these regions.

The study surveys some of the primary companies known to be marketing, manufacturing or developing products for the flow cytometry market for those sectors covered here. Each company is discussed in depth with 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 flow cytometry 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.
- Examination of leading applications and market segments in the U.S., Europe, Asia-Pacific, the emerging BRICs countries and resource limited countries. Identification of lead positions and potential future growth areas.

1.5 Methodology

The principal analyst is a senior marketing and laboratory professional with multi-faceted experience in life sciences and clinical laboratory science, specializing in strategic planning, evaluating business opportunities and product portfolios, market research, technical training and clinical laboratory management.

The contributing author of this report holds a Ph.D. in biochemistry from the University of Minnesota, with many decades of experience in science writing and as a medical industry analyst. He has over 40 years of experience as a director in laboratory testing and instrument and reagent development technology, as well as extensive experience in senior level 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. Information on flow cytometry instruments and clinical methods were obtained in part from interviews with representatives of the major companies in the sector.

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, Asian and emerging 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.

1.6 Executive Summary

Flow cytometry is a tool that has been used in cell biology research for over 40 years. Fluorescence Activated Cell Sorting or FACS, commercialized in [redacted] by Becton Dickinson, changed the way scientists could study multiple subtypes of cells. The use of flow cytometry was instrumental in identifying the biological process of the HIV virus in the depletion of the immune system and subsequent onset of AIDS by detecting and counting CD4 T-cells in blood samples of those infected with the HIV virus. Innovative new developments in flow cytometry instrumentation, reagents and software have enabled new discoveries in cell biology leading to the diagnosis, treatment and prevention of diseases in the growing fields of regenerative medicine and oncology. Flow cytometry is now an important tool in the study and separation of stem cells for transplantation and regenerative therapies. Flow cytometry biomarker assays are used to identify hematopoietic cancers and tumors and for determination of the outcome of therapeutic regimens to treat cancer. This field of predictive and prognostic indicators has the potential for significantly reducing the cost of new drug development. High speed flow cytometry is used to detect rare tumor cells (minimum residual disease) to determine if chemotherapy has destroyed cancerous cells.

Flow cytometry instruments, reagents and software are used by scientists in life science research laboratories, in pharmaceutical companies and CROs (Contract Research Organizations) for drug discovery and clinical development, and major reference laboratories for specialized tests. Flow cytometry has been a used in niche markets of marine biology, plant biology, microbiology and industrial quality assurance testing. The highest number of users, [redacted]% are found in the life sciences research segment, with [redacted]% in the clinical diagnostics segment, [redacted]% in the pharmaceutical segment and [redacted]% in the niche markets.

The global flow cytometry market is $[redacted] revenue and forecast to grow at a compound annual rate of [redacted]% to $[redacted] in [redacted]. The U.S., Europe and Japan account for [redacted]% of the global market. The emerging BRICs countries (Brazil, Russia, India, China) account for [redacted]% but are rapidly growing at a CAGR of [redacted]%. Resource limited countries are [redacted]% of the market, growing at an annual rate of [redacted]% and have the highest potential for CD4 testing. Reagents are [redacted]% of total revenue, generated from sales of new instruments and recurring revenue from existing instruments. Instruments are [redacted]% of the revenue and software is [redacted]%. The market is dominated by two competitors, BD Biosciences division of Becton Dickinson and Beckman Coulter, owned by Danaher. These two key players own [redacted]% of the market with over [redacted] companies, are competing for a share of the market.

TriMark believes that the global flow cytometry market will continue to grow due to a number of key favorable industry trends.

- Reduction of drug development costs by personalized therapies and drugs driven by discoveries in new predictive and prognositic biomarkers
- Continued government funding of life sciences research as an investment in the future.
- Emerging markets driving demand as economic improvements lead to investment in research and pharmaceutical drug discovery, development and manufacture of biopharmaceuticals.
- Introduction of new POC (Point of Care) flow cytometry based technologies making testing for CD4 feasible in remote regions of resource limited countries.
- Reduction in the cost of healthcare driven by new discoveries leading earlier and improved diagnosis, treatment and prevention of diseases.