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# MICROARRAY 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

Microarray technologies multiplex and miniaturize the analysis of tens of thousands of molecules (*e.g.*, DNA, protein, etc.) for a variety of assays including drug binding, molecular interactions, enzyme activity, and pathway identification. A microarray can contain tens of thousands of probes bound to a solid surface, which can be glass, silicon chip or microscopic bead. Microarray printing technology can deposit any kind of molecule onto a microarray, including DNA, proteins, antibodies, carbohydrates, tissue sections, cells, as well as various diagnostic elements and other compounds. Microarrays are excellent tools for gene expression profiling, biomarker profiling, and diagnostics. Pharmaceutical and biotechnology researchers use microarrays to streamline drug target identification, selection, validation and predictive testing. Rapid growth in the clinical research and diagnostic devices markets holds great potential for applications of microarray technology ranging from basic research to clinical trials and, ultimately, diagnostic devices.

An emerging technology that is accelerating growth in the microarray markets is the Lab-on-a-Chip, which encompasses an entire biochemical assay, in a miniaturized format, on a self-contained device. The ability to merge microarrays and Lab-on-a-Chip technologies is leading to the development of point of care devices with unmatched capabilities in terms of specificity, efficiency and portability. This report covers emerging microarray technologies with the highest potential for growth over the next five years; new technology platforms enable the production and analysis of a wide variety of microarrays including tissue, genome, proteome, or glycoproteome microarrays. Promising technological advancements in microfluidics and other emerging technologies are discussed, as are important drivers of growth, such as genomic and proteomic research initiatives, including emerging trends in diagnostics and drug discovery.

The purpose of this report is to describe the specific segment of the microarray market aimed at the analysis of proteins and DNA. It examines various microarray platforms and the technologies that are utilized in hospitals, clinics, commercial laboratories and research institutions to detect DNA and proteins for the purpose of drug discovery, diagnosis and the monitoring of disease. Those companies that are actively developing and marketing microarray instrumentation or microarray biochips for performing DNA and protein array tests are emphasized. The main objectives of this analysis are as follows:

- Identifying viable technology drivers through a comprehensive look at platform technologies for DNA and protein arrays, including probe-based nucleic acid assays, microarrays and sequencing.
- Obtaining a complete understanding of the primary DNA and protein array tests from their basic principles to their applications.
- Discovering feasible market opportunities by identifying high-growth applications in different analytical diagnostic areas, focusing on the biggest and expanding markets.
- Focusing on global industry development through an in-depth analysis of the major world markets for DNA and protein array technology, including growth forecasts.
- Presenting market figures regarding the current value of the microarray market, projections and growth rates. The source of this information is the most current data derived from the global diagnostic industry.

By purchasing this report, the reader will have:

- An understanding of the most exciting microarray market segments, current and future.
- The latest information on leading products and research and development (R&D) initiatives.
- Familiarity with recent developments and their effects on selected markets.
- Knowledge of the microarray market as an area of growth, research and investment.

Key questions answered in this study:

- How can microarray tools and technologies facilitate drug discovery, design and development?
- What are the main types of array technologies that are currently available?
- Who are the current key players in this marketplace?



- Which microarray market areas have the greatest potential for growth?
- What is the current state of the microarray market?
- Which biotechnology and pharmaceutical companies are investing in microarray solutions?
- What are the main microarray business strategies adopted by leading companies?
- What are the benefits of microarray technology platforms?

This report contains:

- Detailed analysis of recent trends in the microarray marketplace.
- In-depth profiles of the leading companies with microarray tools and technologies.
- Views and principles on the microarray industry from leading industry experts.
- Analysis of potential microarray applications in the life science sector.
- Market predictions and trends analysis concerning expenditure on array solutions.
- Projections for future applications of microarrays in drug discovery, from the industry's R&D perspective.
- Analysis of commercial microarray business strategies.
- The latest news and developments in the microarray marketplace.
- A comprehensive overview and insight into microarray business strategies.

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. This review will also:

- Assess microarray market drivers and bottlenecks from medical and scientific community perspectives.
- Discuss the potential benefits of microarray for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the microarray market and analyze the current size and growth of individual segments.
- Provide current and forecasted market shares by segment.
- Discuss profit and business opportunities by segment.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the microarray market.

The following questions are also addressed in this report:

- What are the near-term business opportunities in the microarray market?
- What are the current and forecasted microarray market sizes?
- What are the business models currently used by companies in the microarray market?
- How will manufacturers, researchers, physicians and patients influence this market?
- What are the drivers and bottlenecks influencing the microarray market?
- What are the technologies used in microarray?
- Who holds the proprietary rights to the microarray market technology platforms?
- How is this technology currently being applied and utilized?
- What regulatory processes apply to microarray technologies?
- What are the emerging technologies, trends, and drivers in the current microarray arena?
- How will new microarray technologies change drug development paradigms?
- How will microarray technologies reduce adverse clinical reactions and decrease costs of patient care?
- How will microarray technologies reduce healthcare expenditures?
- How will microarray technologies decrease R&D costs?
- How will microarray technologies grow and adapt to the markets *vis à vis* competing technologies such as Next-Generation Sequencing?

The study contains:

- A comprehensive overview of the several categories of microarray technology platforms that are, or will be, revolutionizing the treatment of diseases.
- A chapter on each of the important microarray categories and applications.
- Full descriptions of the technologies involved and how these differ from existing and emerging technologies.
- Analysis of the technological approaches undertaken by various competitors, as well as industry and end-user response to these products.
- Regulatory issues and legislation affecting use and marketing of microarray products.

## 1.2 Scope of the Report

Companies that are actively developing and marketing laboratory instrumentation, reagents and supplies for performing DNA and protein array tests are emphasized in this report. The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the protein analysis market, such as clinical chemistry testing, high-growth diagnostic test markets, blood gas and electrolytes, over-the-counter diagnostic testing markets, and point of care testing. TriMark provides a separate market report called *DNA Sequencing and PCR Markets*, which emphasizes the analytical methods and PCR technology platforms used in clinical diagnostics.

Special attention is paid to the research market segment and, separately, to the instruments, reagents and supplies marketed by 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 report's scope includes emerging microarray technologies with the highest potential for growth over the next five years. Promising technological advancements including microfluidics and nanotechnology are discussed, as are important drivers of growth, such as genomic and proteomic research initiatives, cancer diagnostic and treatment trends, and drug discovery and development needs.

Specialty array testing is examined because it is often part of the overall analytical focus of companies that market general laboratory automation equipment. However, no effort is made to quantify this broader market. In addition, this report does not cover disposable plastic supplies for the laboratory. These subjects are discussed in other TriMark Publications reports. An analysis of business trends, technology trends, and developing areas of DNA and protein array testing is provided, along with a review of the market for protein array testing equipment and supplies in the clinical and research market segments, using screening reagents and instruments for analysis of individual components in blood, serum or plasma.

The U.S. and global market dollar sales volume and factors that influence the size and growth of market segments are defined. Activity and trends in research markets, including the numbers of institutions that use protein array testing and the factors that influence purchasing, are addressed in this report. Also discussed are trends that have stimulated this market and patterns of information processing in array testing instruments.

## 1.3 Objectives

The goal of this report is to review the market for DNA and protein array testing equipment and supplies that use screening reagents and instruments for the analysis of individual components in blood, serum or plasma. The dollar volume of sales is defined, both worldwide and in the U.S., and the factors that influence the size and the growth of the market segments are analyzed. Additionally, the numbers of institutions using this type of testing and the factors that influence purchases are discussed. The report surveys almost all of the companies known to be marketing, manufacturing or developing instruments and reagents for the protein array market in the U.S. Each company is discussed in depth with a section on its history, product line, business and marketing analysis, and a subjective commentary of the company's market position.

## 1.4 Methodology

The author 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. The editor holds a Ph.D. in life sciences from Jawaharlal Nehru University, with post-doctoral training from the University of Manitoba and Saskatoon Cancer Centre in Winnipeg and Saskatoon, respectively. She has authored several peer-reviewed articles on the molecular mechanisms and signaling pathways involved in cancer progression, and has over five years' experience as a scientific editor.

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. Although believed to be reliable, the information in this study is not guaranteed as accurate, adequate or complete. We do not take responsibility 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 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 databases, proprietary databases, direct meetings, and personal interviews with key personnel.
- Formulating a study outline with the assigned writer, including the following important items:
  - 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.
- Launching a combination of primary research activities including two levels of questionnaires, executive-direct focused, company-specific, and region-specific communications to qualified and experienced senior executives worldwide.
- Completing a confirmatory primary research assessment of the report's findings with the assistance of Expert Panel Partners from the industry being analyzed.

### 1.5 Executive Summary

A microarray is an arrangement of miniaturized test sites or “spots” on a surface. Microarrays are often also known as “biochips”. The microarray format allows many tests or experiments to be performed simultaneously, in parallel, leading to the generation of huge amounts of biological information with the application of only a tiny amount of sample. This large-scale quantitative approach has changed biological research by allowing the analysis of whole genomes. Microarray technology enables scientists to attain ambitious goals by identifying genetic variations associated with disease to discovering new drug targets. This technology also simplifies, accelerates and reduces the cost of understanding this genetic information. Microarrays are now being used in more applications to validate results from sequencing or to take the outputs from sequencing SNPs, and apply them on a more cost-effective and higher-throughput platform, such as genotyping in humans and agricultural biotechnology applications.

Affymetrix, founded in 1992, was the first company to commercialize the microarray with the launch of its GeneChip<sup>®</sup>. Affymetrix still dominates the gene chip market, offering both DNA and protein microarrays to the pharma and biotech industries, and academic and government research labs. There is a trend towards significant consolidation in this sector over the next three years. With the top three firms having an early market presence and large R&D, sales and marketing budgets, it will be difficult for smaller companies and start-ups to gain significant market share in the gene expression segment. The top three microarray companies include Affymetrix, Illumina and Agilent. Primary applications for microarrays include gene expression profiling, biomarker profiling, and more recently cancer diagnostics. Growth in the microarray market is expected to come from the personalized medicine as well as advances in lab-on-a-chip (LOAC) technology.

New technology platforms, such as aptamer nanopores, are driving breakthrough innovations in microarrays. The technology has moved downstream to direct clinical and diagnostic applications. Another high-growth driver in microarray markets is the lab-on-a-chip (LOAC), which is based on the principle that a complete chemical or biochemical assay, from sample to result, can be engineered into a single, miniaturized device. Microarray and LOAC technologies leverage semiconductor-based photolithographic fabrication and microfluidic techniques, which enables the manufacturer to synthesize a large variety of analytical features simultaneously in predetermined locations on an independent, miniaturized, assay device. Lab-on-a-chip technology is poised for growth as a new tool for diagnostics. One promising area of growth features the combination of the multiplexing capabilities of microarrays with the efficiency of LOAC.

The Asian market is a major factor in future biochip market growth with fast developing economies such as India and China. Many of the biochip companies, including Affymetrix, Illumina and Fluidigm Corporation have moved their manufacturing bases to Singapore to take advantage of the benefits the country offers.

The rapid growth of the clinical research and the diagnostic devices markets holds the potential for microarray technology applications ranging from basic research to clinical trials and, ultimately, diagnostic devices. As a result, microarray companies are working with leaders in molecular diagnostics to provide custom made probe arrays to

their specifications. Their partners subsequently package the chips into kits, seek regulatory approval for their diagnostic use, and sell them into the diagnostic markets using their sales channels. The microarray companies are leveraging their partners' strengths in research, development, regulatory practices and distribution while leveraging their strengths in array technology. In point of care diagnostics, microarray-based tests and screens provide an attractive way of obtaining rapid results for panels of genes and proteins involved in cancer, heart disease and other chronic diseases. The prospect of obtaining maximum data from minimal sample is also important in the clinical context.

Technology displacement—the next generation sequencing platform RNAseq—is widely considered to be replacing arrays as the platform of choice for many gene expression-based studies. While dropping prices and maturing technology are causing NGS to make headway in becoming the technology of choice for a wide range of applications, the transition away from microarrays is a long and varied one. Investigators continue to use arrays for a number of reasons, including ease of use, installed instruments, and legacy data. Different applications have different requirements, so researchers need to carefully weigh their options when making the choice to switch to a new technology or platform. Regardless of which technology they choose, genomic researchers have never had more options.

There are two major applications for DNA microarray technology including the following:

- Identification of sequence variations.
- Determination of gene expression levels.

Other applications for microarray technologies include array comparative genomic hybridization (aCGH), copy number variation (CNV), DNA methylation, ChIP-Chip, RNA splice variants, microRNA and resequencing. New technology platforms enable the production and analysis of a variety of microarrays including proteome microarrays. Target molecules are printed into microarrays using a spotting device, nanoprinter or other microarray imprinters and attached using a variety of surfaces depending on the application and detection method.

Protein microarray applications include the following:

- Expression profiling.
- Serum-based diagnostics.
- Protein-protein binding assays.
- Drug-target binding.
- Receptor-epitope binding.
- Diagnostics.
- High-throughput screening.