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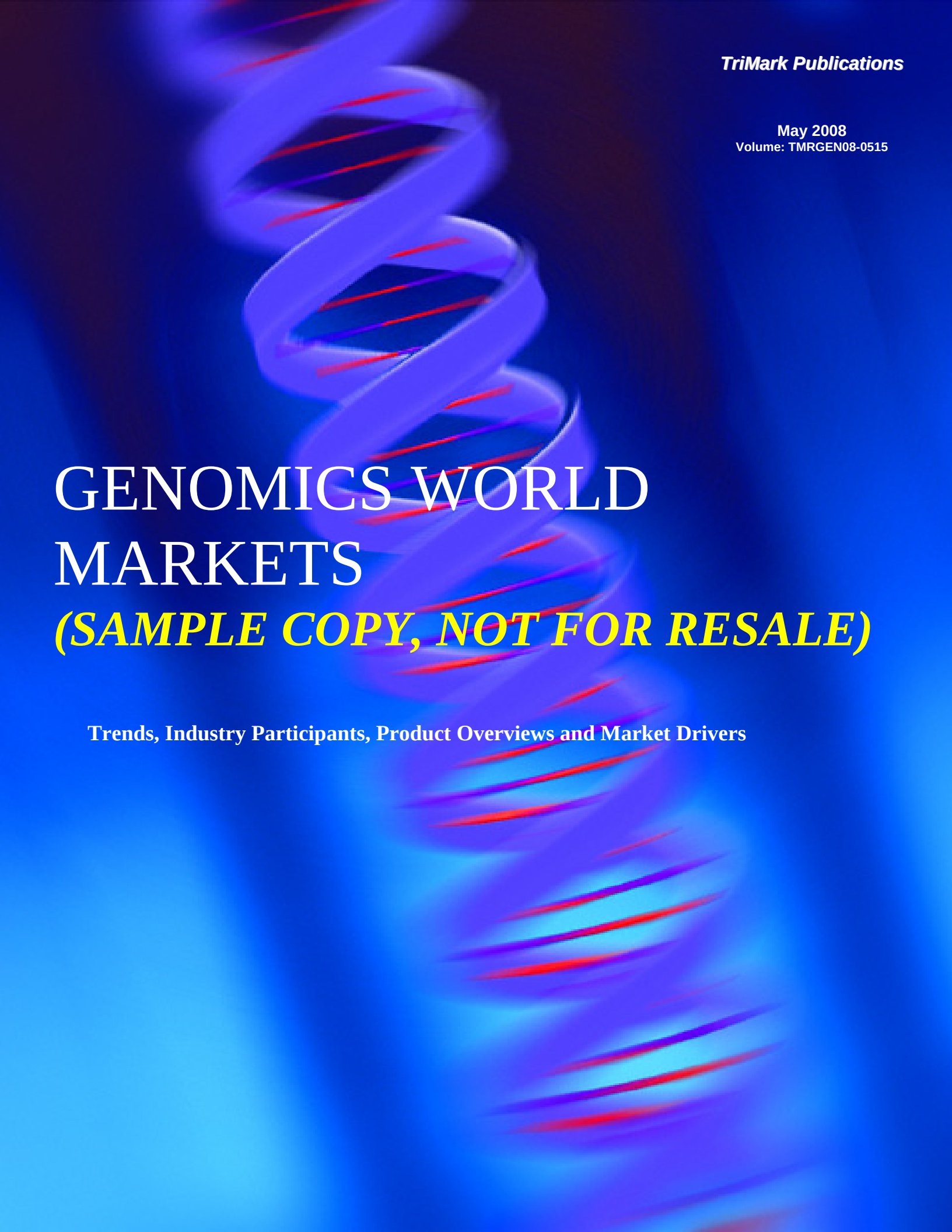

GENOMICS WORLD MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Introduction

1.1 Statement of Report

The purpose of this report is to describe the specific market segment of the biotechnology market sector called genomics. This sector includes all of the generally accepted activities that are currently used today for analyzing genetic codes in DNA and applying the resultant analyses to the formulation of new products in pharmaceuticals, agriculture, diagnostics and other areas marketing biological materials. This analysis presents an overview of the genomics market with the latest information regarding emerging new products and industry trends. It will not only quantify, but also qualify, the genomics segments as an area of research, product development and investment. Forecasts of the genomics market and an analysis of products in the worldwide biotechnology and pharmaceutical markets will provide a basis for understanding the significance of past developments and future possibilities within this exciting new market category.

1.2 Objectives and Goals of Study

The aim of this study is to provide in-depth information on the developing market for genomics products and services. The report will include detailed market analyses and discussions of industry trends in order to assess the impact of genomics on the current and emerging pharmaceutical and diagnostic markets. Forecasts and trends were developed from interviews with industry sources, as well as from an assessment of available and emerging technologies. This review also focuses on the efforts of biotechnology companies and pharmaceutical firms to incorporate genomics technologies into their corporate strategies. Company profiles have been compiled from annual reports, investment analysis summaries and interviews with individuals from various companies and organizations involved with the industry. Profiled companies include Affymetrix, Agilent Technologies, Applied Biosystems, Clinical Data, Verenium and many others. This analysis includes:

- Accurate and up-to-date R&D information from the major biotech companies with an interest in the genomics market.
- Identification of the unmet need in current genomics development markets and the extent to which current technologies meet such needs.
- In-depth, comparative analysis of individual genomic products.
- Profiles of current research developments that will impact the genomics market and identification of the future direction of innovative research.
- Future sales potential of the genomics market.

1.3 Methodology

This study is based on interviews with sales and marketing professionals of companies in the genomics market. They 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, CEOs and vice presidents of some of the companies discussed in the report. Descriptions of the hospital laboratories and nearby patient facilities were derived from interviews with laboratory directors and medical technologists in these areas.

Sources of information for the study 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 were used as the basis of the data reported. Important data sources include the Health for All Database of the World Health Organization, data published by the statistical office of the European Commission (Eurostat), as well as various health data from the United Nations and the Organisation for Economic Co-operation and Development. Where possible and practicable, the most recent data available have been used.

The author of this report is a Ph.D. in biochemistry with decades of experience in science writing and as a medical industry analyst. He has been a senior director of several large regional and national clinical testing laboratories. The senior editor is a doctoral level clinical scientist. He has over thirty years of experience in laboratory testing and instrument and reagent development technology, as well as extensive experience in senior level positions in biotech

and medical service companies. The editor of the report has a Ph.D. in biophysics and has worked as a research assistant professor at the University of Missouri.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information set forth 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, 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 with regard to commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this study.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects and Sector Snapshots that we publish annually. We extract relevant data and analytics from TriMark's research of the past three years as part of this data collection. We also extract qualified data feeds from e-questionnaire responses and primary research responses for this compilation.

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 our 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. The report conclusions are verified through intensive interviewing of top-ranking companies in the industry.

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 a 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 these 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.

1.4 Executive Summary

Genomics is transforming the pharmaceutical industry. Companies are moving from drug discovery and development based on medicinal chemistry to the design of drugs based on information provided by genomics. Virtually all of the major pharmaceutical houses have either formed partnerships with genomics firms that began to emerge in the early 1990s or have created in-house genomics divisions.

The market for genetic data and technology is projected to be worth hundreds of billions of dollars within the next decade. Products provided by genomics firms include databases, specialized proprietary software that can be used to search the databases, DNA biochips (also called the DNA microarrays or DNA chips), which are typically a glass wafer containing nucleic acid samples used in genomic analysis, and many other novel kits and technologies for genetic analysis. The reason for this rapid interest in genomics is that genomics allows greater efficiency in identifying therapeutic targets by determining in a single analysis a plethora of candidate genes which may contribute to the onset of disease. By measuring the abundance of certain genes or sets of genes in response to a particular therapy or in a particular disease model, scientists can identify the mechanisms by which these genes are responsible for the creation and control of the disease process, and possible technologies that can be used to inhibit the genes.

1.4.1 Market Drivers

- Increased pressure for pharmaceutical pipeline development.
- Need for reduced cost for pharmaceutical discovery.
- Need to reduce the time required for drug discovery and development due to the significant number of upcoming patent expirations.
- Expansion of knowledge from the human genome.
- New products for agriculture.
- New products for the biotechnology industry.
- Proliferation of targets has shifted the drug discovery bottleneck from the identification of new points of disease intervention to the discovery and development of safe and effective drugs.

1.4.2 Market Restraints

- Low rates of drug discovery success.
- Competition between genomic companies and pharmaceutical companies.
- Lack of public acceptance of genetically-engineered consumer products.
- Many traditional biotechnology companies are shifting some of their focus downstream from genomics to drug discovery.

1.4.3 Market Size and Growth Projections

Major new technologies will be developed over the next few years, and recently-developed technologies will be more universally and successfully applied. These developments constitute the discovery phase, which is only the first phase of evolution in this field. Those companies that most quickly use functional studies to establish possession of critical genomics-related targets and therapeutics will have an important advantage in the next phase, the development phase.

The information and analyses presented here provide an important asset in decision making for managers involved in business development, marketing, market research, product development, mergers and acquisitions, licensing, business management, investment banking and deal creation, as well as for consultants to the pharmaceutical and biotechnology industry. The study provides a comprehensive analysis of the current markets for genomics-based products, services and applications.

Overview of Genomics

Within the genomics industry, companies and research can be divided into three areas:

- Sequencing the genome.
- Functional genomics, which is focused on finding the functions of the genes.
- Information systems, which develops the software tools necessary for managing and summarizing the tremendous amount of data associated with genomic analysis.

For each area, different technology is generated and, thus, a different intellectual property strategy is deployed. Often, companies participate in one or more of these areas, and should pursue a hybrid strategy.

The Impact of Genomics

The R&D process has experienced a fundamental change fueled by the revolution in genomics and the sequencing of the human genome. Genomics has resulted in the identification of many new potential disease targets, against which chemical compounds can be evaluated. This breakthrough effectively shifts the drug discovery bottleneck from biology to chemistry, as the need for effective target identification and validation has been eclipsed by the challenge of discovering and developing viable preclinical and clinical candidates. The discovery of new potential drug targets fuels the demand for collaborative relationships between companies with lead generation technology and the companies with medicinal chemistry expertise to develop promising leads into solid therapeutic candidates.

1.5 What Is a Gene?

A genome is the entire set of hereditary instructions for building, running and maintaining an organism, and passing life on to the next generation. The genome is comprised of DNA (deoxyribonucleic acid), which encodes genes. Genes coordinately determine specific characteristics of the organism. Each species has its own distinctive genome, whether it is a plant or animal, bacteria or virus, mammal or reptile (*e.g.*, the dog genome, the wheat genome, the rat genome, the herpes virus genome, the *Escherichia coli* (*E. coli*) genome, the budding yeast genome and so on). The genome contains all of the information necessary to produce a specific organism. Genomes belong to species, but they also belong to individuals. Only identical twins and other clones have the exact same genome.

The genes of an organism—whether an animal, plant or microbe—determine its physical and chemical characteristics. Genes consist of organized units of DNA; these units of DNA are comprised of four different chemical bases called nucleotides. In the double helical structure of DNA, each nucleotide unit pairs with its complementary nucleotide forming a base pair. Only certain pairs of nucleotide bases can form these bonds: cytosine (C) always pairs with guanine (G) and adenine (A) always pairs with thymine (T). When two DNA strands are complementary, they can bind together to form a double helix in a process called hybridization. DNA, and specifically the sequence of the C, G, A and T nucleotides along the DNA strand in each gene, lays out the blueprint or “instruction program” for biological organisms.

In addition to genes, there are much smaller regulatory sequences (usually ten to 20 letters long) that may be associated with each gene and are used by cells to control when and how much of the gene should be produced. The genomes of more evolved organisms may contain a large amount of junk DNA that is left over from the process of evolution.

The precise sequence of the nucleotides in a gene dictates the physical and chemical properties of the protein the gene encodes. The activity of these proteins causes the cell to perform biological functions that influence the physical traits of the organism. Each cell of an organism contains at least one complete copy of the organism’s genes, but each cell type expresses only those genes that are necessary for that particular cell to perform its role. When a gene is expressed, it acts alone or in combination with other expressed genes to synthesize structural proteins and enzymes. A modification in a gene sequence may lead to the overproduction or underproduction of a protein, modifying the normal biological function of the cell, and potentially affecting the physical and chemical characteristics of the entire organism.

1.6 Gene Expression

Cells carry out their normal biological functions through the genetic instructions encoded in their DNA. This genetic process, known as gene expression, involves several steps. In the first step, nucleotides in a gene are copied into a related nucleic acid molecule called ribonucleic acid (RNA), specifically, messenger RNA (mRNA). Cells translate RNA into proteins, and proteins are the biological end products that regulate or perform most of the physiological functions of the body. Because the order, or sequence, of nucleotides in each gene is different, each gene directs the production of a different protein.

Increased awareness of the role of genes in regulating the functions of living organisms has generated a worldwide effort to identify and sequence genes and genomes of many organisms. This effort was led by the Human Genome Project (HGP) and also involved academic, government and industry research projects, and was essentially completed in 2003 with the sequencing of 99% of the human genome. Ongoing sequencing and analysis indicated in 2004 that there are 25,000 to 30,000 protein-coding genes in the human genome. In 2006, the complete sequence of the last human chromosome was published. It is anticipated that many years of additional research will be required to understand the specific functions and roles in disease of each of these genes and their patterns of interaction. This research is expected to lead to a new healthcare paradigm, in which a disease is understood at the molecular level, allowing patients to be diagnosed according to their genetic profile and treated accordingly with drugs designed to work on specific molecular targets. In addition to diagnosis and treatment, genetic information may ultimately lead to novel therapies for preventing or curing disease.

1.7 Genetic Variability

The diversity of living organisms results from variability in their genomes. Variability stems from differences in the sequences of genes and from differences in levels of gene expression, partly because of interaction of the organism and its genes with the environment. In order to understand how genetic variation causes disease, scientists must compare both sequence variation and expression patterns of genes from healthy and diseased individuals. Chip-array technology has simplified, accelerated and reduced the cost of analyzing genetic variability, and has lead to new opportunities in disease management.

Sequence Variability

Changes in the sequences of genes may be introduced by environmental factors or other determinants, such as errors in gene replication. These sequence changes are known as polymorphisms and can be passed from generation to generation. In some cases, polymorphisms have no detectable effect on the biology of the organism. However, in other cases, polymorphisms can result in the altered function or expression of the protein encoded by the gene. Such polymorphisms are normally referred to as mutations. Mutations in single genes have been associated with diseases such as cystic fibrosis and sickle cell anemia, while mutations in multiple genes have been associated with diseases such as cancer and diabetes.

By screening for polymorphisms, researchers seek to correlate variability in the sequence of genes with a specific disease. By sequencing genes of interest from a large number of healthy and diseased persons, researchers are able to correlate specific gene polymorphisms with the disease. However, a typical polymorphism association project on one disease might require sequencing 100 genes of 3,000 nucleotide bases each in up to 500 patients, or a total of 150 million bases. Previously, such high-volume polymorphism screening was performed with gel-based sequencing, which was labor intensive and costly. Currently, chip-array technology is used and has many advantages over conventional, gel-based techniques for performing large studies in genetic correlation. Chips enable high-throughput polymorphism discovery and database projects, as well as product development initiatives to allow researchers to identify correlations between disease and genomic changes.

Expression Variability

Differences in the timing and levels of gene expression in a given cell are another basis for genetic variability. Although most cells contain an organism's full set of genes, each cell expresses only a small fraction of this set in different quantities and at different times. The expression of genes at the wrong time, the expression of a gene mutation, or the overexpression or underexpression of normal genes have all been associated with human diseases

