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CYTOLOGY AND HPV TESTING WORLD 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

Cytology is the examination of cells using optical microscopy methods. The purpose of this report is to describe the specific segment of the diagnostic market aimed at analysis of cytology specimens derived from the human female reproductive tract. It examines the measurement devices and their reagents and supplies used in hospitals, clinics, commercial laboratories and research institutions to detect cells and proteins for the diagnosis and monitoring of disease.

1.2 About this Report

The study describes the analytical methods used to separate, isolate, characterize and quantitate cells, DNA and proteins complex in biological systems related to the diagnosis and treatment of disease of the female reproductive tract, such as the cervix and vagina. The emphasis is on those companies and products that are actively developing and marketing laboratory instrumentation, reagents and supplies for performing cytology and related molecular diagnostic tests, such as human papillomavirus (HPV) and other inflammatory and sexually-transmitted diseases. The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for cytology and HPV testing, including thin-film cytology techniques and Hybrid Capture technology for HPV detection.
- Obtaining a complete understanding of the chief cytology tests from their basic principles to their applications.
- Discovering feasible market opportunities by identifying high-growth applications in different analytical diagnostic areas, concentrating on the biggest and expanding markets.
- Focusing on global industry development through an in-depth analysis of the major world markets for cytology technology, including growth forecasts.
- Presenting market figures regarding the current value of the cytology and HPV market, projections and growth rates. The source of this information is the most current data derived from the global diagnostic industry with cytology market forecasts.

By purchasing this study, the reader will have:

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

Key questions answered in this review:

- How can cytology tools and technologies facilitate other diagnostic tests like HPV?
- What are the main types of cytology technologies that are currently available?
- Who are the current key players in this marketplace?
- Which cytology market areas have the greatest potential for growth?
- What is the current state of the cytology market?
- Which biotechnology and diagnostic companies are investing in cytology solutions?
- What are the main cytology business strategies adopted by leading companies?
- What are the benefits of cytology technology platforms?

This report contains:

- Detailed analysis of recent trends in the cytology marketplace.
- In-depth profiles of the leading companies with cytology tools and technologies.
- A five-year forecast for the cytology market in the biotechnology and diagnostic industries.
- Views and principles on the cytology industry from leading industry experts.
- Analysis of potential cytology applications in the life science sector.
- Market predictions and trends analysis concerning U.S. expenditure on cytology solutions.
- Projections for future applications of molecular diagnostic tests in cytology-related screening.
- Analysis of commercial cytology business strategies.
- The latest news and developments in the cytology marketplace.
- A comprehensive overview and insight into cytology 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. Also, this report will:

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

The following questions will also be addressed in this analysis:

- What are the near-term business opportunities in the cytology market?
- What are the current and forecasted cytology market sizes in the U.S., E.U. and Japan, as well as in other key country markets?
- What are the business models currently used by companies in the cytology market?
- How will manufacturers, researchers, physicians and patients influence this market?
- What are the drivers and bottlenecks influencing the cytology market?
- What are the technologies used in cytology?
- Who holds the proprietary rights to the cytology-market technology platforms?
- How is this technology currently being applied and utilized?
- In the U.S., Japan and the E.U., what regulatory processes apply to cytology technologies?
- How will new cytology technologies change diagnostic screening testing paradigms?
- How will new cytology technologies reduce diagnostic false negatives and decrease costs of patient care?
- How will new cytology technologies reduce healthcare expenditures?
- How will new cytology technologies affect R&D spending?

1.3 Scope of the Report

This analysis emphasizes companies that are actively developing and marketing laboratory instrumentation, reagents and supplies for performing cytology tests. The reader can 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 polymerase chain reaction (PCR) technology platforms used in clinical diagnostics.

The U.S., Japan and Europe—the world's three largest analytical markets—are the focus of this report. Primary attention is paid to the clinical 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. Specialty molecular diagnostic testing, such as HPV is examined, since it is often a part of the overall analytical focus of companies that market cytology laboratory-automation equipment. 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 cytology and HPV testing is provided, along with a review of the market for cytology 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. This report defines U.S. and global market dollar-sales volume and analyzes factors that influence the size and growth of market segments. Market size and growth rates—with projections (where sensible) for the U.S. and global markets—are examined. Activity and trends in research markets, including the number of institutions that use cytology 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.

This report surveys all companies known to be marketing, manufacturing or developing instruments and reagents for the cytology and HPV market in both the U.S. and the world. Leading companies are discussed in-depth, with sections on the company's history, product line, business and marketing analysis and a subjective commentary on the company's market position. Several subjects related to the major elements of cytology testing, such as histology and cellular staining, are discussed only briefly in this report, because they are considered entirely different fields or markets. Fuller explorations of these areas of interest can be found in other TriMark Publications reports, such as *Clinical Chemistry Analyzers* and *Point of Care Diagnostic Testing World Markets*.

1.4 Objectives

The goal of this report is to review the market for cytology and HPV testing equipment and supplies using screening reagents and instruments for analysis of individual components in tissue samples, blood, serum or plasma. It defines the dollar volume of sales, both worldwide and in the U.S., and analyzes the factors that influence the size and the growth of the market segments. The subsections of each market segment are also examined including the research labs, hospital labs and commercial laboratories. Additionally, the number of institutions using this type of cytology 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 cytology market in the U.S. Each company is discussed in extensive depth with a section on its history, product line, business and marketing analysis and a subjective commentary of the company's market position.

1.5 Methodology

This study is based upon interviews with sales and marketing professionals of companies in the cytology testing 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. Descriptions of the hospital laboratories and nearby patient facilities were derived from interviews with laboratory directors and medical technologists in these areas.

Other sources of information included trade association publications and meetings, product brochures and catalogs, and company literature. We have also gathered statistical information from the U.S. government, the World Health Organization (WHO), and private foundations. Annual reports, 10k filings, and financial reports were used as the basis for data reported on publicly held companies. The author of this report is a PhD in biochemistry with years 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 well as extensive experience in senior level positions in biotech and medical service companies.

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 report.

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 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. 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 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 important items:
 - Market and product segment grouping and evaluating their relative significance.
 - Key competitor's 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.

2. Introduction to Cancer Biology and the Diagnostic Industry

2.1 Cancer

2.1.1 The Disease

Cancer is a group of diseases characterized by uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. Cancer is caused by both external (chemicals, radiation and viruses) and internal (hormones, immune conditions and inherited mutations) factors. Causal factors may act together or in sequence to initiate or promote carcinogenesis. Ten or more years often pass between exposures or mutations and detectable cancer. Cancer is treated by surgery, radiation, chemotherapy, hormones and immunotherapy.

Since the occurrence of cancer increases as individual's age, most cases affect adults who are middle-aged or older. About 70% of all cancers are diagnosed in persons 65 and older. Cancer researchers use the word "risk" in different ways, most commonly expressing risk as lifetime risk or relative risk. Lifetime risk refers to the probability that an individual, over the course of a lifetime, will develop cancer or die from it. In the U.S., men have a one-in-two lifetime risk of developing cancer and for women, the risk is a little more than one-in-three.

"Relative risk" is a measure of the strength of the relationship between risk factors and the particular cancer. It compares the risk of developing cancer in persons with a certain exposure or trait to the risk in persons who do not have this exposure or trait. For example, male smokers are 23 times more likely to develop lung cancer than non-smokers, which means their relative risk is 23. Most relative risks are not this large. For example, women who have a first-degree (mother, sister or daughter) family history of breast cancer have about a 2-fold increased risk of developing breast cancer compared with women who do not have a family history.

2.1.2 Metastasis

One of the great limitations of tumor markers in clinical diagnosis is by the time the tumor is large enough to place detectable levels of marker into the circulation, it most probably has reached such a size as to already be in metastasis. By the time, the patient has detected sufficient symptoms to seek medical attention; the tumor has already begun to spread to other parts of the body.

The probability of such metastases ranges from about 10% in colon cancer to virtually 100% in cancer of the pancreas. Cancer cure rates would improve if the diagnostic tumor marker tests yielded positive results before the spread of the cancer to other parts of the body. Unfortunately, few diagnostic tumor marker tests are observed to be positive before the metastatic spread of cancer. This is most unfortunate since many cancers, such as ovarian, have a very high cure rate, if caught early as "Stage 1."

In lung cancer, the probability of metastases is 10% at the time a primary tumor is less than 1 centimeter in diameter. In breast cancer, metastasis occurs in 10% of tumors as small as one centimeter—about the threshold of detection of a good mammogram. In some cases, metastases may occur in tumors consisting of as few as 100 cells. It is highly unlikely that such small tumors would be detectable either by clinical examination or would release enough tumor specific proteins into the blood stream to be detectable by currently available marker tests. It has been estimated that the cell turnover is a variable of the cell type of the cancer: 10% in adenocarcinomas, 10% in sarcomas, 10% in squamous cell carcinomas and 10% in embryonal tumor types. In the latter, markers, such as AFP and hCG, are effective in early detection.