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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

Experts believe that █% of the █ people diagnosed with cancer worldwide each year could avert the killer disease by protecting themselves against infections and changing their lifestyles. A █ report by the Geneva-based Union for International Cancer Control (UICC) highlighted nine infections that can lead to cancer, with human papillomavirus (HPV) at the top of the list. On February 4, 2010—denoted “World Cancer Day” by the UICC—the International Agency for Research on Cancer (IARC), the Cervical Cancer Action (CCA) coalition and the UICC called for the implementation of comprehensive strategies to reduce cervical cancer—one of the leading causes of cancer among women in developing countries, and the second most common cancer in women worldwide. Most recent estimates suggest that each year there are more than a █ deaths from cervical cancer and over █ new cases, most of which could be prevented. The World Health Organization (WHO) projects that without immediate action the global number of deaths from this disease will increase by nearly █% by █, mostly in low- and middle-income countries.

Cervical cancer can now be prevented through vaccination with one of two newly-available vaccines against HPV, which is the main cause of cervical cancer. Both vaccines are highly efficacious in preventing infection with virus types 16 and 18, which are together responsible for approximately █% of cervical cancer cases globally. Furthermore, HPV testing enables diagnosis and treatment to be put in place before cervical cancer can develop. With the aid of preventative screening and vaccines such as these, we now have the knowledge to prevent █% of cancers, but the tragedy is we're not using it. This report provides an overview of HPV testing and the key players involved in this market, with specific emphasis on each company's sales focus, product portfolio and research and development (R&D) pipeline. It also discusses the specific segment of the diagnostic market aimed at analysis of cytology specimens derived from the female reproductive tract.

### 1.2 About this Report

This study describes the analytical methods used to separate, isolate, characterize and quantitate cells, DNA and protein complexes in biological systems related to the diagnosis and treatment of diseases of the female reproductive tract, such as the cervix, vagina, uterus and ovaries. The emphasis is on those companies that are actively developing and marketing products such as laboratory instrumentation and reagents, and supplies for performing cytology and related molecular diagnostic tests for HPV and 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 gain:

- An understanding of the most promising 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 are:

- How can cytology tools and technologies facilitate other diagnostic tests like those for HPV?
- What are the main types of cytology technologies that are currently available and used?
- 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.
- Forecasts 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.
- A comprehensive analysis, overview and insight into commercial 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 study will:

- Analyze 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 in the cytology market.
- Assess current commercial uses of the cytology market.

The following questions will also be addressed in this analysis:

- What are the current and forecasted cytology market sizes in the U.S., European Union (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?
- 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?

### 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, over-the-counter diagnostic testing markets and point of care testing.

The U.S., Japan and Europe—the world's three largest analytical markets—are the focus of this study. 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 that for HPV, is examined, since it is often a part of the overall analytical focus of companies that market cytology laboratory-automation equipment. This study 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 review 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.

### 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

The author of this report has 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 cancer testing laboratories. 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. The editor of the report has a Ph.D. in biochemistry from the University of Toronto and has over 15 years of experience in the fields of molecular biology, immunology and oncology. She has worked as a research assistant professor and scientist at the University of Pittsburgh's Cancer Institute.

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 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 Cancer Institute (NCI), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the American Cancer Society (ACS) and the Centers for Disease Control and Prevention (CDC). Where possible and practicable, the most recent data available have been used.

Some 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 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 U.S. Securities and Exchange Commission (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 prior to the publication of a report includes the following items:

- 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.
- 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.

## 2. Introduction to Cancer Biology and the Diagnostic Industry

### 2.1 Cancer

#### 2.1.1 The Disease

Cancer is a generic term for a large group of diseases that can affect any part of the body, characterized by uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. All cancers involve the malfunction of genes that control cell growth, division and death. However, over █% of the genetic abnormalities that affect cancer risk are not hereditary, resulting instead from damage to genes (mutations or polymorphisms) that occur throughout one's lifetime. A combination of both external factors (chemicals, radiation, sunlight, tobacco and viruses) and internal factors (hormones, immune conditions, genetic mutations and the metabolism of nutrients within cells) account for such acquired genetic damage. These types of non-hereditary mutations are collectively known as somatic mutations.

Causal factors may act together or in sequence to initiate or promote the development of cancer, or carcinogenesis. The molecular profiling of cancer has significantly advanced since the turn of the millennium due to the development of sophisticated technologies such as gene expression arrays, which permit simultaneous measurement of thousands of genes to create a "molecular portrait" of the tumor. Following a triggering event, the pathogenesis of cancer can be very prolonged. Ten or more years often pass between exposures or mutations and detectable cancer. Cancer is currently treated by surgery, radiation, biologic, chemo-, gene-, hormonal, immuno- and vaccine therapies.

Since the occurrence of cancer increases as individuals age, most cases affect adults that are middle-aged or older. Cancer researchers use the word "risk" in different ways. 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 █ lifetime risk of developing cancer and for women the risk is 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, smokers are ten times more likely to develop lung cancer compared with non-smokers. Most relative risks are not this large. For example, women who have a first-degree (mother, sister or daughter) family history of breast cancer are about twice as likely to develop breast cancer, compared with women who do not have a family history of breast cancer.

#### 2.1.2 Metastasis

One of the great limitations of tumor biomarkers in clinical diagnosis is the fact that by the time the tumor is large enough to place detectable levels of marker into the circulation, it has probably reached a size at which it has already metastasized to other organs. 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 █% in colon cancer to virtually █% 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 discouraging since many cancers, such as ovarian, have a very high cure rate if caught early, as in stage I.

In lung cancer, the probability of metastasis is █% when a primary tumor is less than 2 cm in diameter. In breast cancer, metastasis occurs in █% of tumors as small as 1 cm—about the threshold of detection of a good mammogram. In some cases, metastases may occur in tumors consisting of as few as █ 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 bloodstream 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: █% in adenocarcinomas; █% in sarcomas; █% in squamous cell carcinomas; and █% in embryonal tumor types. In the latter, markers such as alpha-fetoprotein (AFP) and human chorionic gonadotropin (hCG) are effective in early detection.

