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# WOMEN'S HEALTH DIAGNOSTIC TESTING MARKETS *(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers

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## 1.0 Overview

### 1.1 Statement of Report

The purpose of this report is to describe the specific segment of the *in vitro* diagnostics (IVDs) market called women's health testing. This study includes contemporary and generally accepted clinical and analytical activities. This analysis examines clinical measurement devices, as well as their reagents and supplies, as utilized in hospitals, clinics and doctor's offices. Some diagnostic tests, which are marketed primarily as over-the-counter products, are included in this review. This report also includes other important tests such as mammography, (*i.e.*, tests which are not generally associated with *in vitro* diagnostic tests, but which are an important component of the overall women's health market).

### 1.2 Scope of this Report

This examination deals with analysis related to the common chemical constituents of blood, plasma or serum which is of concern to patient testing in the field of women's health. Hospitals and clinics are the two most important areas where such tests are measured, with physician's office laboratories (POLs) being the third. Newer areas of interest where testing for these analytes is taking place are satellite laboratories and home testing locations.

The emphasis of this analysis is on those companies and products that are actively developing and marketing clinical laboratory instrumentation, reagents and supplies for performing diagnostic tests related to women's health. The reader should consult other TriMark Publications reports for a detailed discussion of the important individual market segments which are related to the women's health testing market such as clinical chemistry testing, hematology and coagulation, blood gas and electrolytes, immunochemistry, over-the-counter (OTC) testing, and point of care (POC) testing. All of these subjects receive thorough treatment in other reports by TriMark Publications and are available at <http://www.trimarkpublications.com>.

Concentration is placed on the women's health testing market segment in important worldwide markets such as the U.S., Japan and Europe. This focus is primarily on the hospital market and commercial laboratory segment and, separately, on a description of the instruments, reagents and supplies marketed by major companies in this segment.

The study does not cover markets generally associated with immunochemistry instruments and reagents. Hematology, coagulation and chemistry markets are not addressed, although many of the instruments, reagents and techniques in the women's health testing market segment are intimately associated with these broader areas. Analysis touches upon the specialty areas in women's health testing since these segments are frequently a part of the overall analytical focus of companies that are marketing general laboratory equipment. However, no effort is made to quantify the size of this broader market. The examination does mention companies who market and sell instruments and equipment as part of a much larger clinical laboratory product line produced by other companies. This is the case, for example, with Hitachi and its relationship with Roche Diagnostics Corporation, or JEOL and its manufacturing products for Bayer. However, these companies are only reported en passant since they are not a direct focus of the women's health testing market. This study further focuses on mergers and acquisitions in the sector, new product launches, and any important legal issues that are recent and have some bearing on the growth of the women's health testing sector.

There is a strong emphasis on the hospital and commercial laboratory segment of the women's health testing market and description of women's health testing devices in the physician's office and clinic setting. Home testing is not directly covered in this report, except where women's health testing products and companies are also active in the hospital and physician's office segments.

Although there's discussion on recombinant proteins in passing, as well as techniques such as measuring the serum concentrations of therapeutic drugs and drugs of abuse, no extensive or in depth treatment of this subject is presented here. Such a discussion is outside the scope of this analysis. The clinical women's health testing reagents and equipment market in the U.S. and worldwide are examined thoroughly. This field can be divided into three broad areas: the hospital market, the doctor's office market and, to a much lesser extent, the home care market.

Certain areas are only touched upon since they are related to the major elements of this report, but are for all practical purposes in an entirely different field or market. Examples of this are both the blood gas and electrolyte market and the clinical chemistry testing instruments. These are very interesting and substantive areas, which form much of the foundation for women's health testing analysis; however, in the interest of brevity and efficient research, these areas were not analyzed in depth. Finally, the mammography industry is examined herein with details of the relative merits and market sizes of digital and film-based mammography.

### 1.3 Methodology

The information in this examination is based upon interviews with sales and marketing professionals of companies in the women's health testing market. People from virtually every company mentioned in this report were queried, some several times, about their companies' products and marketing strategies, as well as their overall thoughts regarding relevant industry segments. Information was also obtained from interviews with founders, CEOs and vice presidents of some of the companies discussed here. Information concerning the structure of hospital laboratories and near patient facilities was derived from interviews with relevant laboratory directors and medical technologists.

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 (WHO), data published by the statistical office of the European Communities (Eurostat), as well as various health data from the United Nations (UN) and the Organization for Economic Cooperation and Development (OECD). Where possible and practicable, the most recent data available have been used.

The author of this report is 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 been a senior director of several large regional and national healthcare laboratories. The editor is a Ph.D. in physiology from the University of Toronto and is a post doctoral research fellow in the Department of Cell and Systems Biology at the University of Toronto.

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.

The information in this study is also based upon direct experience with sales and marketing professionals of companies in the instruments and reagents market. People from many companies mentioned in this report were considered thoughtfully about their companies' products and marketing strategies, as well as their overall thoughts about their industry segment. The structure of the laboratory facilities was derived from familiarity with scientists and technologists working in these areas.

*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 study's 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 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**

There is a steady increase in demand for home healthcare services along with pressures to lower the cost of home care and improve the quality of healthcare delivered in the home. The women's health diagnostic product segments are poised for a major new phase of growth fueled by the availability of new technology coming out of the point of care segment and the higher interest of individual patients and general healthcare consumers to take charge of their own health status. Continuous improvements in technology are resulting in a growing number of new *in vitro* diagnostic tests that combine high levels of accuracy with rapid, easy-to-use product formats. Digital mammography is also driving more screening programs.

Many women's health *in vitro* diagnostic products and mammography services are specifically targeted at markets outside of the traditional hospital or clinical laboratory. Competition in the development and marketing of women's health diagnostic products is intense and diagnostic technologies have been subject to rapid change. TriMark Publications estimates that the competitive factors in the women's diagnostic market include convenience, privacy, price and product performance, as well as the distribution, advertising, promotion and brand name recognition of the marketer. There are a few (perhaps ten) dominant global players in this market segment; these are matched by hundreds of small companies with one or more products aiming at niche markets. This is the case, for example, with Medix Biomedica and its tests for fetal development and early labor. In contrast, the mammography market is dominated by two or three very large players, such as General Electric.

The market for women's diagnostic health tests in the U.S. increased from \$ [REDACTED] in [REDACTED] to over \$ [REDACTED] in [REDACTED], representing a [REDACTED]% compounded annual growth rate. In [REDACTED], the U.S. women's diagnostic *in vitro* test market segment rose to an estimated \$ [REDACTED]. The growth rate for the U.S. market is estimated to be [REDACTED]% per year through [REDACTED]; the U.S. market is set to reach over \$ [REDACTED] in [REDACTED]. Two test categories—pregnancy and mammography dominate this market and account for approximately [REDACTED]% and [REDACTED]% of the total women's health *in vitro* market, respectively. Markets for women's health products, like pregnancy testing, are dominated by large

pharmacy chains retailing pregnancy testing kits over the counter directly to women. In the U.S., pharmacy chains represent less than █% of the total number of facilities, but account for █% of test volume and █% of revenues.

Outside the U.S., there are significant opportunities for growth in the women's health diagnostic testing business. During █, the European Union spent a larger share of its healthcare expenditures on diagnostic testing (█%) than the U.S. (█%), but less than Japan (█%). The European women's care diagnostics market has grown at a rate of █% to █% through █, somewhat higher than the general laboratory reagent market. The total value of the women's care market was estimated at \$█ in █. Mammography testing is particularly strong throughout Europe.

As for individual markets, over █ pregnancy tests for human chorionic gonadotropin (hCG) are performed each year in doctor's offices, clinics and emergency rooms generating a market estimated at \$█ annually in █. Net sales of metabolic bone markers by Quidel represent approximately █% of the company's total sales at \$█ and approximately █% of the total market segment.

According to the U.S. Centers for Disease Control and Prevention (CDC), █% of women over age █ received a mammogram in █. According to the U.S. Census Bureau, the number of women over age █ in the U.S. in █ was █ and the projected U.S. population in █ for women aged █ and above is █. The American Cancer Society has adopted a goal that █% of women over age █ comply with screening guidelines by █.

According to the U.S. Food and Drug Administration (FDA), the U.S. volume of mammography procedures as of █ is around █. TriMark estimates that in █ there were more than █ screening mammograms performed in Europe. It is estimated that the annual growth is about █%. Assuming this growth rate, a continued push to cover more eligible women and the introduction of digital techniques, TriMark estimates that the volume of mammography procedures in Europe in █ was around █. It is estimated that Japan's annual growth is about █% for the frequency of these procedures. Assuming this growth rate and a continued push to cover more eligible women, TriMark estimates that the volume of mammography procedures in Japan in █ was approximately █. The continued downward reimbursement structure in Japan will act as a brake on the market expansion of mammography.

The U.S. leads in its annual volume of mammography screening procedures. Over █ women age █ or above annually undergo breast examinations, resulting in as many as █ mammograms to be interpreted annually. Abnormality is evident in █% of these mammograms, with most cases undergoing a second test and about █% undergoing biopsies. With sales of \$█ in █, the film-based mammography market has almost doubled to \$█ in █, driven primarily by the growth of screening mammography markets. The total digital mammography market in the U.S. was projected to exceed \$█ in █ according to a █ Market Report from the Millennium Research Group ("MRG"). Digital mammography is currently a young and small market but will grow well despite higher costs because it provides opportunity for increased resolution and simpler image manipulation. Projections are that the digital mammography market in the U.S. will reach \$█ in █, growing at a compounded rate of approximately █% between █ and █.

The total worldwide market for mammography, both film-based and digital, has grown from \$█ in █ to over \$█ in █. TriMark anticipates that the digital mammography segment will be nearly half of the total sales for the mammography sector. The estimate is that the digital segment had less than █% of the total worldwide placements of mammography instruments in █, with a growth rate of more than █% by █. Sales of film-based mammography systems grew at rates from █% to █% through █, reaching \$█ from the market size of \$█ in █. In █, film-based systems comprised about half of the total mammography system sales worldwide. Sales for the European market were estimated to grow from \$█ in █ to an estimated \$█ in █. TriMark anticipates a good solid growth rate based upon continued brisk sales of new, first time mammography units as well as replacements. Sales for the Japanese market grew from \$█ in █ to an estimated \$█ in █.