

# 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 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 senior 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.

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 the 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 National Institutes of Health (NIH), Food and Drug Administration (FDA) and the Centers of 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. 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 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 in TriMark Publications 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 data and proprietary databases.
- 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.
  - 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 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. was 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 [REDACTED]% of the total number of facilities, but account for [REDACTED]% of test volume and [REDACTED]% of revenues.

In 2009, the U.S. Preventive Services Task Force (USPSTF) issued a dramatic change in the mammography guidelines for women between the ages of 40 and 49. In short, the USPSTF recommended that women begin having mammograms at age 50, instead of the previous 40-years-of-age starting point. This shift in government guidelines was met with swift negative reaction by several cancer and women's organizations. More will be discussed on this controversy later in the report.

The National Cancer Institute (NCI) appreciates the USPSTF's careful review and analysis of the evidence regarding breast cancer screening for women at average risk. The take-away message is that each woman needs to consider her individual benefits and risks and discuss them with her health care provider before making a decision on when to start screening mammography and how often to get one. The Task Force report concludes that screening mammography remains an important, effective tool for early detection of breast cancer. It also indicates, however, that the evidence of benefit might vary, according to age and individual risk factors.

NCI has had screening mammography recommendations for many years, and will need to evaluate them in light of the Task Force's recommendations -- for all women, not only for those of average risk. It's too early for NCI to make any decisions right now. NCI's primary role as a biomedical research agency is to generate scientific knowledge that can be used by the Task Force and other organizations in their deliberations and recommendations.

According to the NCI website there are many benefits to screening mammography. Several large studies conducted around the world show that breast cancer screening with mammograms reduces the number of deaths from breast cancer for women ages 40 to 69, especially for those over age 50. Studies conducted to date have not shown a benefit from regular screening mammograms, or from a baseline screening mammogram (a mammogram used for comparison), in women under age 40.

According to the U.S. Census Bureau, the number of women over age 40 is estimated to be [REDACTED]. The U.S. leads in its annual volume of mammography screening procedures. Over [REDACTED] women age 40 or above annually undergo breast examinations, resulting in as many as [REDACTED] mammograms to be interpreted annually. Abnormality is evident in [REDACTED]% of these mammograms, with most cases undergoing a second test and about [REDACTED]% undergoing biopsies. The total digital mammography market in the U.S. is projected to exceed \$[REDACTED] in [REDACTED]. 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. It is projected that the digital mammography market in the U.S. will reach \$[REDACTED] in [REDACTED], growing at a compounded rate of approximately [REDACTED]% between [REDACTED] and [REDACTED].

The total worldwide market for mammography, both film-based and digital, was \$[REDACTED] in [REDACTED], and is expected to reach \$[REDACTED] in [REDACTED]. 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 [REDACTED]% of total worldwide placements of mammography instruments and is expected to have a growth rate of more than [REDACTED]% by [REDACTED]. Sales of film-based mammography systems grew at rates from [REDACTED]% to [REDACTED]% through [REDACTED], reaching \$[REDACTED] compared to \$[REDACTED] in [REDACTED]. In [REDACTED], film-based systems were \$[REDACTED].

In the U.S., the mammography market increased to \$[REDACTED] in [REDACTED], and is expected to reach \$[REDACTED] in [REDACTED]. Sales for the European mammography film-based instrument market are estimated to have grown from \$[REDACTED] in [REDACTED], to an estimated \$[REDACTED] in [REDACTED]. TriMark anticipates a solid growth rate based upon continued brisk sales of new, first time mammography units as well as replacements. A sale for the Japanese mammography digital instrument market was \$[REDACTED] in [REDACTED], and expected to increase to \$[REDACTED] in [REDACTED].

## 2.0 Introduction - Sector Overview

### 2.1 Global Diagnostic Products Industry

By any measure, whether it is new product approvals, therapeutic outcomes, clinical acceptance, pipeline quality or market performance, the over-the-counter diagnostic products industry has come into its own. Looking ahead, women’s health diagnostic product segments are poised for a major new phase of growth fueled by the availability of new technology. This technology has arisen 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. In this report, TriMark takes stock of the current situation and future prospects of several high growth market segments in the industry. TriMark conducts this evaluation by detailing the salient developments and trends in the following areas:

- Financing alliances, mergers and acquisitions.
- Therapeutic markets intellectual property.
- Regulatory issues, economics and cost containment.
- Technologies for discovery.
- Development of public perception.

The emerging picture of the industry is sharpened by a rigorous analysis of sector-leading companies, detailing their unique strengths, R&D strategies, key patents and their relationship to pipeline elements, collaborations, commercial and developmental products, and direct competition for key products. As a representative group, these companies track the overall health and direction of the industry. The wealth of strategic and product-specific information contained in these profiles serves to validate our broader analysis of the industry.

**Table 2.1: Worldwide Market Share *In Vitro* Diagnostic Companies**

Company	Worldwide Market Share (%)
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]

Source: Roche

**Table 2.2: Worldwide *In Vitro* Diagnostics Market Size, 2001-2012**

Year	Worldwide Sales (\$ Billions)
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]

Source: Biotechnology Associates