TriMark Publications

January 2015
Volume: TMRIVD15-0101

IN VITRO DIAGNOSTIC TESTING WORLD MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

TABLE OF CONTENTS

INDEX OF FIGURES

INDEX OF TABLES

1. IVD Market Overview

1.1 Statement of Report

In vitro diagnostic (IVD) testing is experiencing a revival fueled by a combination of technological improvements, cost pressures, reimbursement changes, rapid growth in molecular diagnostics and increasing interest in the genomics testing. Recent advances in molecular diagnostics technologies—including sequencing, PCR and microarrays—are enabling greater sensitivity and precision in nucleic acid measurements, further expanding manufacturers' offerings. This TriMark Publications report is an overview of each major *in vitro* diagnostic testing segment, including: point-of-care testing (POCT), molecular diagnostics, chemistry, diabetes and glucose, immunoassay, hematology, coagulation, pathology, microbiology, histology and cytology, and blood banking. For each segment, this study examines the generally accepted clinical analytical activities in use today. Moreover, the analysis here discusses the potential benefits of the diagnostics techniques, as well as provides market size and future growth potential. Additionally, this report assesses the various business models, including CLIA-licensed specialty labs, general reference labs and reagent kit marketing. This study also examines hundreds of companies that are actively developing and marketing IVD testing products around the world. This report analyzes the size and growth of the important sectors of the diagnostics market, including the drivers and restraints that influence the various market segments, as well as the dollar volume of sales and market growth rates, both in the U.S. and worldwide.

1.2 About This Report

This report includes the following features for each major IVD market segment:

- It examines the generally accepted clinical analytical activities in use today in the diagnostics (IVD) sector for diagnosis and management of disease. It includes the prevalent clinical-measurement devices and the accompanying reagents and supplies as utilized in hospitals and large reference and specialty Clinical Laboratory Improvements Act (CLIA) licensed laboratories, as well as physicians' offices and point of care testing.

- It discusses the potential benefits of the diagnostics techniques for various sectors of the medical and scientific communities in serving patients and managing disease, and it assesses the market drivers and bottlenecks for IVD tests from the perspective of these communities.

- It establishes the current total IVD market size and future growth of the diagnostics market for disease management, and analyzes the current size and growth of key segments.

- It assesses various business models in diagnostics, including CLIA-licensed specialty labs, general reference labs and reagent kit marketing and provides strategic recommendations for near-term business opportunities.

- It examines the roles played by companies that have invested significantly in this market, and it provides current and forecasted market shares by these companies.

1.3 Scope of the Report

The goal of this study is to review the market for IVD diagnostics testing equipment and supplies using reagents and instruments for analysis of individual components in body tissues and fluids. Toward this goal, this review:

- Identifies the major segments in IVD markets.
- Estimates the current and future U.S. and global markets for *in vitro* diagnostics for various disease sectors.
- Examines market drivers that have resulted in the global race for new *in vitro* diagnostics.
- Reviews the impact of current products and the future of the diagnostics industry.
- Provides insight into the diagnostics products in the pipeline and the companies that strive to bring these products to the market in the immediate future.

- Evaluates global activity of IVD with specific contributions from the top-ranking five country markets: U.S., Japan, Europe, China and ROW.

Key questions answered in this study are:

- What products are included in the phrase "*in vitro* diagnostics"?
- What disease conditions offer the greatest potential for diagnostics technology platforms?
- What is the current global market for *in vitro* diagnostics?
- What regulatory and technical challenges are being confronted by the diagnostics industry?
- What are the current promising developments in each major diagnostics sector?

This examination surveys most of the biotech companies known to be currently marketing, manufacturing or developing instruments and reagents for the diagnostics market for disease diagnosis and management, in both the U.S. and the world. Each company is discussed in depth, with sections on its history, product line, business and marketing analysis, and a subjective commentary of the company's market position. Market size, growth rates and market components for instruments, reagents, controls and consumables used in this area are also analyzed.

1.4 Objectives

The reader should consult other TriMark Publications reports for detailed discussions of important individual market segments related to the molecular diagnostics market or routine testing. In addition to this report, TriMark Publications offers a complete suite of market reports aimed at the molecular diagnostic space including: *Molecular Diagnostics Markets*, *Molecular Diagnostics in Infectious Disease Testing, Molecular Diagnostics in Cancer Testing* and *Molecular Diagnostics in Genetic Testing*.

1.5 Methodology

The principal author of this report holds a Ph.D. in biochemistry from the University of Minnesota, and had his post-doctoral studies at the University Of Connecticut School of Medicine. He has taught at Quinnipiac University, the Tufts School of Medicine and New York Institute of Technology. He has been a senior scientist at DuPont and Pfizer Pharmaceutical Laboratories in drug development and diagnostic testing. He was a leader in the formation and development of Dianon Laboratories, now part of LabCorp. He also has many decades of experience in science writing and as a medical industry analyst and consultant. He has over 40 years of experience in laboratory testing and instrument and reagent development technology as a licensed clinical laboratory director, as well as extensive experience in senior level management positions in biotech and medical service companies. The editor holds a Ph.D. in life sciences from Jawaharlal Nehru University, with post-doctoral training from the University of Manitoba and Saskatoon Cancer Centre, respectively. She has authored several peer-reviewed articles on signaling pathways involved in cancer progression, and has over six years' experience as a scientific editor.

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. Additional sources of information include non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities such as the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and the Centers for 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 full market reports, 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.

For projection for the future values and growth rates of specific markets our analysts use a proprietary forecast spreadsheet, which takes into account a wide variety of market indices such as inflation rates and anticipated increases and decreases in funding of specific markets. Then, other factors such as new market introductions, acquisitions, and other factors are manually incorporated into the spreadsheet.

1.6 Executive Summary

The total IVD market was $[redacted] in [redacted]. Growing at a CAGR of [redacted]%, it is on track to reach $[redacted] by [redacted]. North America accounted for an estimated [redacted]% of the IVD testing hospital market in [redacted], Europe for [redacted]%, Asia Pacific for [redacted]% and the rest of the world for [redacted]%. Total IVD revenues are growing at a rate of [redacted]% to [redacted]% per year worldwide, The U.S. and Western Europe are the largest IVD markets. Asia Pacific and Eastern Europe are projected to be the fastest growing. Revenue for the global the IVD market is forecasted to reach $[redacted] by [redacted].

The Asia Pacific area, which is led by the Chinese and Indian national markets (once Japan is excluded), is expected to be the fastest growing region for IVD market applications during the period [redacted] to [redacted] with a CAGR of [redacted]%. The market for IVD testing in Asia (including Japan) is estimated to be $[redacted] in [redacted]. The Asia Pacific region will account for [redacted]% of the world IVD market by [redacted]. IVD sales in China have grown more than [redacted]% per year for the past four to five years and now stand at more than $[redacted]. The IVD markets of China and India, two countries that account for approximately one-third of the world's population, have demonstrated remarkable growth in the past decade. The IVD markets in these two countries have seen steady growth rates of [redacted]% to [redacted]% per year over the past [redacted] years

TriMark estimates that the global POCT market was valued at $[redacted] in [redacted], equivalent to [redacted]% of the global IVD market. It is estimated that the global POCT market will exhibit a compound annual growth rate (CAGR) of [redacted]% between [redacted] and [redacted] to $[redacted]. Within the POCT markets, glucose testing remains the leading global segment, projected to account for [redacted]% of global near-patient testing by [redacted]. Excluding glucose testing, in the point-of-care (near-patient) segment, only rapid cardiac markers rises above $[redacted] in POCT testing by [redacted], accounting for an estimated [redacted]% of total testing by [redacted]. TriMark is publishing a report with more detail called *Point of Care Diagnostic Testing World Markets.*

Worldwide, approximately $[redacted] was spent on molecular diagnostics tools, assays and other products in [redacted], corresponding to a CAGR of more than [redacted]%. The CAGR is projected to be around [redacted]% through [redacted], reaching $[redacted] by that year. Of this amount, approximately [redacted]% was spent on assays used for testing infectious diseases. The remaining [redacted]% was spent for other products, such as those used in cancer markers and genetic testing.

A summary review of the global IVD high-growth markets as a percentage of revenues by geographic region is provided in the next table in the form of a five-year revenue forecast. Whilst the U.S. will obtain a higher proportion of the global market between [redacted] and [redacted], it is expected that it will decline between [redacted] and [redacted]. It is anticipated that this will be as a direct result of the increase share of the global market by the emerging markets and, in particular, the effect of the increase in the market for IVD products in the BRIC countries. The value of the IVD high-growth diagnostic testing market in the U.S. in [redacted] was $[redacted]. By the end of the forecast period in [redacted], it is predicted that the market will have increased in value to $[redacted] (CAGR [redacted]%). TriMark is publishing a report with more detail called *High-Growth Diagnostic Testing Markets.*

Many of the new high-growth IVD products and services are specifically targeted at markets outside of the traditional hospital or clinical laboratory such as the point of care setting or genetic screening. Competition in the development and marketing of high-growth diagnostic products is intense, and diagnostic technologies have been subject to rapid change. TriMark estimates that the competitive factors determining success in the diagnostic market include convenience, privacy, price and product performance as well as the distribution, advertising, promotion and brand name recognition of the marketer.

As more and more targeted drugs come onto the market in the next decade, there will be a growing need for diagnostics that can help predict and match patients with drugs which will serve them best. With a broad portfolio of genetic and proteomic analysis platforms, large diagnostic companies will be able to give a pharmaceutical company a flexible, cost-effective means to manage the evolution of the companion diagnostic assay through the drug development process. Leading clinical diagnostics companies, with the tools and technologies to help define the future of patient care, are looking forward to opportunities for collaborating with pharmaceutical companies and extending their position in specialty areas to take advantage of opportunities, particularly for early disease diagnosis and improved treatment regimens in the emerging companion diagnostic market.

Over the past few years, there has been a dramatic shift in diagnostic testing which is steadily moving away from the centralized laboratory setting to the operating room, bedside, clinic and home points of care. Factors such as rapid technological advancements, expanded test menus, user-friendly instrumentation, and improved connectivity and data management, are the main drivers of growth in the IVD markets. IVD in near-patient settings serve to improve patient outcomes and lower overall healthcare costs by reducing diagnosis times, resulting in shorter timeframes to therapeutic intervention. Accelerated adoption of POCT devices is evident in the global shift toward POCT from centralized laboratory testing. Forces shaping the landscape include evolution of innovative technologies, an aging population, increased incidence of chronic disease such as diabetes, development of personalized medicine and promising new opportunities in emerging markets.

The major drivers of the IVD markets include molecular methodologies such as nucleic acid amplification (in particular PCR), sequencing, microarrays and *in situ* hybridization (ISH). IVD manufacturers are constantly improving on and expanding their product offerings to keep pace with ever-evolving end-user needs. While major players in the IVD industry attempt to increase market share by intensifying product development efforts in POCT—for example, Abbott and Alere—the industry remains highly fragmented, and there is room for smaller players to enter and compete with innovative platforms and expansive test menus. As the IVD markets continue to grow and evolve—shaped by growing demand for IVD products and services—the industry is also experiencing escalating deal activity in many sectors. Within these rapidly growing areas of the diagnostics market, strategic acquisitions allow companies to expand existing portfolios with complementary products and capabilities.

Market drivers:

- Tests based upon molecular diagnostic (nucleic acid) technology platforms.
- Move toward marketing rapid point of care test kits.
- Tests developed as CLIA-waived tests.
- Cost per test less of an issue with high demand diagnostic tests.
- Coupling the diagnostic test with high profile diseases, *e.g.*, ovarian or breast cancer.
- Move toward bringing complicated tests into a single expert lab.
- Move for CLIA regulatory oversight using expert labs, rather than FDA using diagnostic kits.
- Move away from central lab "big iron" chemistry analyzers.
- Focus on improving patient outcomes with diagnostic tests using so called personalized medicine.
- Move to reduce expertise needed to run tests because of shortage of trained personnel.
- More diagnostic start-ups to develop tests with high growth potential.
- Increased M&As as larger players acquire exciting new test technology.
- Improving profit margins through improved product pricing and operational efficiencies.
- Securing a stronger new product pipeline from internal research and development.
- Pursuing licensing and acquisitions opportunities, when financially and strategically attractive.
- Launching diagnostic test business under a brand by leveraging marketing and distributing strength in the U.S., maximizing worldwide sales through current and newly identified sales channels in Europe and the rest of world.
- Launching a new and improved CLIA-waived test worldwide.
- Launching rapid diagnostic tests on a worldwide basis in conjunction with a development partner such as a pharmaceutical company, *i.e.*, companion diagnostic testing.
- Expanding development and marketing collaborations with large pharmaceutical and other healthcare companies.
- Identifying business development opportunities in the form of product or company acquisitions to enhance product portfolio and further leverage distribution channels worldwide.
- Expanding international sales through external alliances, collaborations and sales focus.
- Consolidation remains an attractive option in the IVD industry, which has been experiencing high rates of M&A activity over the past few years, and TriMark expects this trend to continue.

