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AUTOMATED MICROBIAL TESTING 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

This report describes the specific segment of the *in vitro* diagnostics (IVD) market known as the diagnostic microbiology and focuses primarily on the automated microbial testing systems. Within medical diagnostics, automated microbial testing for infectious disease-causing organisms offers one of the brightest areas for growth and innovation. The confluence of breakthroughs in genomics and proteomics—as well as the development of microarray devices—have led the microbiology market to accept the power of advanced analytical techniques for the diagnosis and treatment of infectious disease. As such, this study analyzes the size and growth of the automated microbial testing market in its applications for infectious disease detection and therapy, examining the factors that influence the various market segments and the dollar volume of sales, both in the U.S. and worldwide. The automated microbial testing market has been divided into the following segments for this examination:

- Microbial detection.
- Microbial enumeration.
- Microbial identification.
- Detection of antibiotic resistance.

This segregation is based upon the available technology platform advances and the number of companies interested in that segment of the infectious disease market.

1.2 About this Report

The goal of this study is to provide in-depth analysis of the trends affecting automated microbial testing methods, from technological advances to the rising demands of the various business segments. This report:

- Examines the generally-accepted clinical analytical activities in use today in the microbiology space for automated microbial testing. It includes the prevalent clinical-measurement devices and the accompanying reagents and supplies as utilized in hospitals and large reference and specialty Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories.
- Discusses the potential benefits of automated microbial techniques for various sectors of the medical and scientific communities, and it assesses the market drivers and bottlenecks for automated microbial testing from the perspective of these communities.
- Establishes the current total automated microbial testing market size and future five-year projected growth of this market for infectious disease management, and analyzes the current size and growth of various commercial and industrial segments.
- Assesses various business models in automated microbial testing, including those used in licensed hospital and specialty labs, general reference labs and reagent kit marketing, and provides strategic recommendations for near-term business opportunities.
- Reviews the products offered and roles played by companies that have invested significantly in this market, and it provides current and forecasted market shares by these companies.
- Discusses new collaborative business models that bring together diagnostics and therapeutics.
- Evaluates the role that automated microbial assays can play in partnership opportunities with personalized medicine.

1.3 Scope of the Report

This study examines *in vitro* diagnostic systems that detect microorganisms. It includes direct detection methods such as those designed to detect microbial cellular components or growth and division. However, systems that measure the body's response to infection (*e.g.*, antibody production) are not covered in this report. Although a greater emphasis is placed on bacterial detection platforms, technologies used in the automated detection of viruses and fungi are briefly discussed. The goal of this examination is to review the market for automated microbial testing equipment and supplies using reagents and instruments for analysis. Toward this goal, this review answers the following key questions:

- Which companies are utilizing new, cutting-edge technologies to develop, validate and market automated microbial tests for clinical use in infectious disease management?
- What are the current impediments to incorporating promising automated microbial tests into clinical practice?
- Which new automated microbial tests show the most promise for regulatory approval?
- What are the economic challenges to gaining approval?
- How does regulatory oversight drive approval and adoption of new technologies?
- Which strategic alliances show the greatest synergy in bringing automated microbial tests to market?
- Which shared technologies are driving the most encouraging development of new automated microbial testing methods?

This examination surveys most of the diagnostic companies known to be currently marketing, manufacturing or developing instruments and reagents for the automated microbial testing market in both the U.S. and worldwide. 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. Primary attention is paid to the specialty, hospital and reference lab market segment and, separately, to the instruments, reagents and supplies marketed by the leading companies in this segment. Market size, growth rates and market components for instruments, reagents, controls and consumables used in this area are also analyzed.

1.4 Objectives

The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for automated microbial testing.
- Obtaining a complete understanding of the chief characteristics of automated microbial testing methods as they are used in infectious disease testing—*e.g.*, predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic tests—from their basic principles to their applications.
- Discovering feasible market opportunities by identifying high-growth applications in different clinical infectious disease diagnostic areas.
- Focusing on global industry development through a comprehensive analysis of the major world markets for automated microbial testing, including growth forecasts.

The emphasis in this review is on the clinical use of automated microbial testing for infectious disease diagnosis and management. The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the automated microbial testing market. For example, TriMark has separate reports on infectious disease diagnostic testing, clinical chemistry testing, high-growth diagnostic tests markets, blood gas and electrolytes, over-the-counter (OTC) diagnostic testing markets, molecular diagnostics, and point-of-care diagnostic testing. TriMark also provides a market report titled *DNA Sequencing and PCR Markets*, which discusses the analytical methods and polymerase chain reaction (PCR) technology platforms used in molecular diagnostics.

1.5 Methodology

The author of this report holds a master's in immunology from the University of Colorado Health Sciences Center and has many years of experience in science writing. She has also coordinated laboratory testing and instrument and reagent development for automated microbiology systems. The editor 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.

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 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.

1.6 Executive Summary

Microbial detection and characterization is an essential component of numerous industries spanning several market segments. The microbiology market is generally divided into the industrial sector, with a value of \$ [REDACTED] in [REDACTED], and the clinical sector, with a value of \$ [REDACTED] in [REDACTED]. Combined, the total microbiology market was approximately \$ [REDACTED] in [REDACTED] and is expected to reach \$ [REDACTED] by [REDACTED]. The U.S. represented [REDACTED]% of the global microbiology market in [REDACTED]. Europe and Japan, with [REDACTED]% and [REDACTED]% of the market, respectively, were next largest market regions. Microbiological assays accounted for approximately [REDACTED]% of the total IVD market, with \$ [REDACTED] in sales during [REDACTED], and the global clinical microbiology market is expected to increase [REDACTED]% annually to \$ [REDACTED] in [REDACTED]. In the U.S., an estimated [REDACTED] labs conducted [REDACTED] clinical microbiology lab tests per year.

A common denominator among all the industries that is driving the automation movement is their desire for quicker and more accurate results. In both clinical and industrial microbiology sectors, the rapid turn around time translates into rewards in terms of improving human health and increasing financial assets. Within the U.S., the medical automation market was roughly \$ [REDACTED] in [REDACTED] and is expected to reach \$ [REDACTED] in [REDACTED]. The diagnostic and monitoring applications sector, which includes automated microbiology IVD testing, is estimated to grow at a compound annual growth rate (CAGR) of [REDACTED]% from \$ [REDACTED] in [REDACTED] to nearly \$ [REDACTED] in [REDACTED].

The industrial microbiology segment has also seen a compelling movement towards rapid testing methods. As of [REDACTED], [REDACTED]% of the total industrial microbiology tests were performed using rapid technology. By [REDACTED], this figure is expected to increase to [REDACTED]%. The number of rapid tests performed in [REDACTED] is estimated to surpass [REDACTED], which is approximately a [REDACTED]% increase from the [REDACTED] tests performed in [REDACTED].

Molecular diagnostics represents the latest integration of new technology into the microbiology testing arena. The market value of molecular diagnostic assays, [REDACTED]% of which are used to identify infectious agents, was \$ [REDACTED] in [REDACTED] and is expected to increase at a rapid pace of greater than [REDACTED]% per year. There were approximately [REDACTED] molecular diagnostics tests detecting infectious diseases were conducted worldwide in [REDACTED].

Approximately [REDACTED]% of the clinical microbiology laboratories in the U.S. incorporated molecular diagnostic methods for the detection of infectious agents into their repertoire of tests in [REDACTED]. Almost [REDACTED]% of the molecular tests performed were for the detection of human papilloma virus (HPV), human immunodeficiency virus (HIV) and hepatitis C virus (HCV), viral loads and of the bacteria causing chlamydia and gonorrhea. Infectious disease testing continues to be at the forefront of the molecular market in part due to relative ease of obtaining unique identifiers from bacterial and viral genes.