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HIV/AIDS TESTING MARKETS

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Trends, Industry Participants, Product Overviews and Market Drivers

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1. Overview

1.1 Statement of Report

There are an estimated ■■■ million people living with HIV (the virus which causes AIDS) worldwide and approximately ■■■ million people are newly infected each year. While the Asian and African regions account for more than ■■■% of the HIV-infected population (with the highest number in Sub-Saharan Africa), the U.S. and European regions make up greater than ■■■% of the HIV testing market. This TriMark Publications report provides a comprehensive examination of the HIV/AIDS testing market, a specific segment of the *in vitro* diagnostics (IVD) market as it relates to infectious diseases. It examines the available and emerging technologies being utilized by the HIV testing field, defines the dollar volume of sales—both in the U.S. and worldwide—and analyzes the factors that influence the size and growth of the market. The chief HIV testing assays, *i.e.*, predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic, are covered thoroughly, as are high-growth applications in different clinical diagnostic areas and expanding markets, such as employee screening, emergency medicine and satellite clinic testing. Additionally, this analysis covers the following areas in details: enzyme-linked immunosorbent assay (ELISA), antibody/p24 antigen test (fourth-generation test), Western blot assay, line immunoassays, indirect fluorescent antibody (IFA) assay, nucleic acid tests for infectious diseases and the emerging technologies related to diagnosis. This report provides a thorough analysis of the HIV testing market by:

- Identifying viable technology drivers through a comprehensive look at platform technologies for HIV testing.
- Providing a description of the instruments, reagents, and supplies marketed by major companies in the HIV testing market, from their basic principles to their clinical applications.
- Discovering feasible market opportunities by identifying high-growth applications in different analytical diagnostic and disease monitoring areas.
- Focusing on global industry development through an in-depth analysis of the major world markets for HIV testing technology, including growth forecasts.
- Presenting market figures regarding the current value of HIV testing, market projections, market share, key players and sector growth rates.
- Providing a detailed analysis of each of the major types of HIV tests, such as diagnostic immunoassays, nucleic acid HIV-monitoring assays and HIV confirmation assays.

This study contains:

- A detailed analysis of recent trends in the HIV testing marketplace.
- In-depth profiles of the leading companies with HIV testing tools and technologies.
- Perspectives of the HIV testing industry from leading industry experts.
- Analysis of potential new HIV testing applications in the clinical sector as they pertain to AIDS management.
- Market predictions and trends analysis concerning U.S. expenditures on HIV testing solutions.
- Projections of HIV testing market sizes for U.S., European and Asian markets.
- Projections for future applications of molecular diagnostic tests in monitoring HIV/AIDS.
- Analysis of commercial HIV testing business strategies.
- The latest news and mergers and acquisitions (M&As) developments in the HIV testing marketplace.
- A comprehensive overview and insight into HIV testing business strategies.
- Regulatory issues and legislation affecting use and marketing of HIV testing products.

Analysis includes charts and graphs measuring product growth and trends within the marketplace. Company-specific information, including sales figures, product pipeline status and research and development (R&D) trends, is provided. This review will also:

- Assess HIV testing market drivers and bottlenecks, from medical and scientific community perspectives.
- Discuss the potential benefits of HIV testing for various sectors of the medical and scientific community, as they relate to HIV/AIDS management.

- Establish the current total market size and future growth of the HIV testing 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.
- Assess current commercial uses of the HIV testing market.

The following questions will also be addressed in this analysis:

- What are the near-term business opportunities in the HIV testing market?
- What are the current and forecasted HIV testing market sizes in the U.S., European Union (E.U.) and Japan, as well as in other emerging markets such as India and the People's Republic of China (China)?
- What are the business models currently used by companies in the HIV testing market?
- How will manufacturers, researchers, physicians and patients influence this market?
- What are the drivers and bottlenecks influencing the HIV testing market?
- What are the technologies used in HIV testing?
- Who holds the proprietary rights to the HIV testing market technology platforms?
- In the U.S., Japan and the E.U., what regulatory processes apply to HIV testing technologies?
- How will new HIV testing technologies change diagnostic screening testing paradigms?
- How will new HIV testing technologies reduce healthcare expenditures and affect R&D spending?

1.2 About This Report

The main objectives of this analysis are to:

- Identify viable technology drivers through a comprehensive look at platform technologies for HIV testing, including point of care systems, alternative testing samples and the latest combination antigen/antibody tests.
- Obtain a complete understanding of the chief HIV testing assays— *i.e.*, predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic—from their basic principles to their applications.
- Discover feasible market opportunities by identifying high-growth applications in different clinical diagnostic areas and by focusing on expanding markets, such as employee screening, emergency medicine and satellite clinic testing.
- Focus on global industry development through an in-depth analysis of the major world markets for HIV testing, including growth forecasts.
- Assess the impact of HIV testing on laboratory growth plans.
- Identify HIV rapid tests that are the most likely candidates for migration to home testing platforms.
- Analyze the business issues associated with HIV testing.

1.3 Scope of the Report

This examination surveys most of the companies known to be currently marketing, manufacturing or developing instruments and reagents for the HIV testing market in both the U.S. and the world. Although emphasis is placed upon the U.S. market, analyses of the other regional markets are also included. The report covers diagnostic screening assays, confirmatory assays and HIV monitoring assays. The focus in this report is on assays that detect the presence of the HIV virus, either directly (*e.g.*, NAT assays) or indirectly (*e.g.*, detecting anti-HIV antibodies). Other assays that are used for AIDS management but that do not assess the presence of the HIV virus, such as CD4 T-cell measurements, are not included in this report. The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the HIV testing market, such as *Molecular Diagnostics in Infectious Disease Testing* and *Anti-Infective Drugs Markets*.

1.4 Objectives

The goal of this study is to review the market for HIV testing equipment and supplies. Toward this goal, this report answers the following key questions:

- Which companies are utilizing cutting-edge technologies to develop, validate and market HIV testing assays?
- What are the current impediments to incorporating promising HIV tests into clinical practice?
- Which new HIV assays show the most promise for approval?
- What are the economic challenges to gaining approval?
- How can regulatory oversight drive approval and adoption of new technologies?
- Which new home HIV tests show the most promise for approval?
- What impediments still exist to incorporating home HIV testing into clinical practice?
- What are the economic challenges to approval?

1.5 Methodology

The author of this report holds a Master's in immunology and has substantial experience in science writing and as a medical industry analyst. She also has many years of laboratory experience and has conducted laboratory testing and instrument and reagent development for biotech companies. The senior editor of this report holds a Ph.D. in biochemistry from the University of Minnesota and has had post-doctoral experience at the University of Connecticut School of Medicine. He has taught at Quinnipiac University and the Tufts School of Medicine, and has been a senior scientist at Pfizer Pharmaceutical Laboratories in drug development. He also has many decades of experience in science writing and as a medical industry analyst. He has over 30 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.

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 a 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

Worldwide, there are an estimated █ million people living with HIV, and approximately █ million people are newly infected each year. The global market forecast for HIV testing, which includes screening assays, confirmatory assays and HIV-monitoring assays, is growing at a compounded annual growth rate (CAGR) of █%, and is projected to grow from \$█ billion in █ to \$█ billion by █. Worldwide HIV diagnostic tests, which encompass screening and confirmatory tests, are expected to increase from \$█ billion to \$█ billion in █.

The Asian and African regions account for more than █% of the HIV-infected population, with the highest number (█ million) in Sub-Saharan Africa. However, the U.S. and European regions make up greater than █% of the HIV testing market. Although HIV testing is a key component for the prevention and treatment of HIV infection, many developing nations have limited resources in procuring and administering such tests. One expanding area of the worldwide HIV market is the increasing use of rapid point of care (POCT) HIV assays in these developing countries. The Asian HIV testing market will likely experience the largest growth rates, with rapid HIV assays generating the greatest number of sales.

The global market for the POCT HIV tests is more than \$█ million and is predicted to grow at a rapid rate for the next decade. TriMark estimates that this market niche will grow worldwide to over \$█ million within the next █ years, particularly as rapid oral fluid-based and urine-based tests become available to the large third-world markets and as cheaper therapeutic agents become available to poor populations.

Diagnostic HIV assays are dominated by immunoassays, but HIV monitoring assays generally rely on molecular diagnostic platforms. These nucleic acid tests (NATs) being performed for genotyping and viral load measurements are significant parts of the overall U.S. HIV testing market. In 2011, the U.S. market for NAT HIV monitoring assays was nearly \$■ million, but is expected to increase to \$■ million by ■. Because NAT HIV assays are much more costly and complex to perform, the U.S. and Europe account for greater than ■% of this global market.

The HIV testing market is highly competitive with several medical diagnostic, pharmaceutical and biotechnology companies vying for market share. Major players profiled in the report include Abbott Laboratories, Inc., Alere, Avioq, bioMérieux SA, Bio-Rad Laboratories, Inc., Gen-Probe, Inc., Innogenetics NV, MedMira Laboratories, Inc., Maxim Biomedical, OraSure Technologies, Inc., Ortho-Clinical Diagnostics, Inc., Roche Diagnostics and Siemens Healthcare Diagnostics, Inc.

Fourth-generation antibody/antigen (Ab/Ag) assays are the most recent technological advancement in HIV ELISA testing. These combination assays are capable of detecting HIV infection even earlier than previous types of assays because p24 antigens are present in plasma almost one week earlier than anti-HIV antibodies. Ab/Ag assays are also more accurate and have been shown to detect nearly ■% of infected individuals who had been missed by the standard antibody screening test. The two companies who currently have FDA-approved fourth-generation assays on the market are Abbott and Bio-Rad Laboratories.