HIV/AIDS TESTING MARKETS
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Trends, Industry Participants, Product Overviews and Market Drivers
# HIV/AIDS Testing Markets

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## TABLE OF CONTENTS

1. **Overview** 8  
   1.1 Statement of Report 8  
   1.2 About This Report 9  
   1.3 Scope of the Report 9  
   1.4 Objectives 10  
   1.5 Methodology 10  
   1.6 Executive Summary 11  
2. **Overview of HIV and AIDS** 13  
   2.1 HIV Virus 13  
   2.1.1 Structure 13  
   2.1.2 Genetic Code 14  
   2.1.3 Subtypes 14  
   2.1.3.1 HIV-1 14  
   2.1.3.2 HIV-2 15  
   2.2 Viral Mechanism of Action (HIV Life Cycle) 16  
   2.2.1 Entry into the Cell 16  
   2.2.2 Replication and Transcription 17  
   2.2.3 Assembly and Release 17  
   2.3 HIV Transmission 17  
   2.4 Symptoms of HIV and AIDS 17  
   2.4.1 Acute (Primary) Infection 18  
   2.4.2 Clinically Asymptomatic Infection 18  
   2.4.3 Symptomatic HIV Infection 18  
   2.4.4 AIDS 18  
   2.5 Diagnosis of HIV and AIDS 19  
   2.6 Brief Summary of Current Therapies 22  
3. **Profile of HIV/AIDS: Statistics and Epidemiology** 25  
   3.1 Worldwide HIV/AIDS Incidence 25  
   3.1.1 Sub-Saharan Africa 27  
   3.1.2 Asia 28  
   3.1.3 Eastern Europe and Central Asia 28  
   3.1.4 Caribbean 28  
   3.1.5 Central and South America 28  
   3.1.6 Middle East and North Africa 28  
   3.1.7 North America and Western and Central Europe 28  
   3.1.8 Oceania 29  
   3.2 HIV/AIDS in the U.S. 30  
3.3 Economic Impact of HIV/AIDS 34  
4. **Overview of HIV Testing** 35  
   4.1 Main Objectives of HIV Testing 35  
   4.2 HIV Screening Tests 35  
   4.3 HIV Confirmation Tests 36  
   4.4 HIV Monitoring Tests 36  
   4.4.1 Measuring Viral Loads 36  
   4.4.2 Genotyping Assays 37  
   4.4.3 Phenotyping Assays 37  
   4.5 Proposed Changes to the HIV Testing Algorithm 37  
   4.6 U.S. Recommendations for HIV Testing 39  
   4.7 U.S. HIV Testing Statistics 41  
5. **Technological Platforms Used in HIV Testing** 44  
   5.1 Enzyme-Linked Immunosorbent Assay (ELISA) 44  
   5.1.1 Rapid HIV Tests 46  
   5.1.1.1 Immunocentration (Flow Through Assay) 49
7.2.4.1 Alere 84
7.2.4.2 bioLytical Laboratories, Inc. 84
7.2.4.3 Bio-Rad Laboratories 85
7.2.4.4 MedMira Laboratories, Inc. 85
7.2.4.5 OraSure Technologies 86
7.2.4.6 Trinity Biotech 87
7.2.4.7 Alere 87
7.2.4.8 bioMérieux 88
7.2.4.9 Bioner 88
7.2.4.10 Chembio Diagnostics 88
7.2.4.11 Core Diagnostics 88
7.2.4.12 EY Laboratories 88
7.2.4.13 Green Cross 89
7.2.4.14 InTec Products 89
7.2.4.15 J Mitra & Co. 89
7.2.4.16 Orgenics, Ltd. 89
7.2.4.17 Premier Medical Corporation 89
7.2.4.18 Qualpro Diagnostics 90
7.2.4.19 Savyon Diagnostics 90
7.2.4.20 Shanghai Kehua 90
7.2.4.21 Span Diagnostics 90
7.2.4.22 Standard Diagnostics, Inc. 91
7.2.4.23 Additional Companies Selling Non-FDA-Approved Rapid HIV Assays Outside of the U.S. 91
7.3 HIV Antibody/p24 Antigen Tests (Fourth-Generation Tests) 94
7.3.1 FDA-Approved Fourth-Generation HIV Assays 94
7.3.1.1 ARCHITECT HIV Ag/Ab Combo Assay (Abbott Laboratories) 94
7.3.1.2 GS HIV Ag/Ab Combo EIA (Bio-Rad Laboratories) 94
7.3.2 Fourth-Generation HIV Assays Commercially Available Outside of the U.S. 95
7.3.2.1 ABBOTT AxSYM HIV Ab/Ag Combo (Abbott Laboratories) 95
7.3.2.2 Determine™ HIV-1/2 Ag/Ab Combo (Alere) 95
7.3.2.3 Vironostika® HIV Uni-Form II Ag/Ab (bioMérieux) 95
7.3.2.4 GENEDIA® HIV Ag-Ab ELISA (Green Cross) 95
7.3.2.5 HIV TRI-DOT + Ag (J Mitra & Co.) 96
7.3.2.6 Fourth-Generation Microlisa HIV Ag and Ab (J Mitra & Co.) 96
7.3.2.7 ImmunoComb® II HIV-1&2 TriSpot Ag-Ab (Organics) 96
7.3.2.8 Enzygnost HIV Integral II (Siemens Healthcare Diagnostics) 96
7.3.2.9 Enzaids Duet (Span Diagnostics) 96
7.4 Anti-HIV Antibody Confirmation Tests 97
7.4.1 Western Blot 97
7.4.1.1 Cambridge Biotech HIV-1 Western Blot Kit (Maxim Biomedical) 97
7.4.1.2 GS HIV-1 Western Blot (Bio-Rad Laboratories) 97
7.4.1.3 OraSure HIV-1 Western Blot Kit (OraSure Technologies) 97
7.4.1.4 HIV Blot 2.2 (MP Diagnostics) 97
7.4.2 Line Immunoassays 98
7.4.3 Indirect Fluorescent Antibody 98
7.4.4 Line Immunoassays 98
7.5 Nucleic Acid Tests 98
7.5.1 Measuring Viral Loads and Resistance Testing 99
7.5.2 Instruments and Reagents 100
7.5.2.1 Abbott Molecular 100
7.5.2.2 Gen-Probe, Inc. 101
7.5.2.3 Roche Molecular Systems 102
7.5.2.4 Siemens Healthcare Diagnostics 104
7.5.2.5 bioMérieux 105
7.5.2.6 Qiagen 106
7.5.3 Diagnostic Testing Services 107
7.5.4 Comparisons of HIV Nucleic Acid Testing Platforms 108
7.5.5 HIV Molecular Diagnostic and NAT HIV Monitoring Market History 108
7.6 Home HIV Testing 109
7.6.1 Home HIV Testing Kits 109
7.6.1.1 Direct Access Diagnostics 109
7.6.1.2 Home Access Health Corp. 109
7.6.1.3 OraSure Technologies 110
7.6.2 Competitive Situation for Home HIV Testing Kits 110
7.6.3 Advantages and Disadvantages of Home HIV Testing 112
7.7 Emerging Technologies and Products 113
8. Market Analysis: Size, Growth, Share and Competitors 115
8.1 Worldwide HIV/AIDS Testing Market 115
8.1.1 U.S. Market 120
8.1.2 European Market 126
8.1.3 Asian Market 127
8.1.4 ROW Market 128
8.2 Market Drivers and Restraints 129
8.2.1 Market Drivers 129
8.2.2 Market Restraints 130
8.3 Market and Technology Trends 131
8.3.1 Market Trends 131
8.3.2 Socio-Cultural Trends 132
8.3.3 Technology Trends 133
8.4 Competitive Situation 134
8.5 HIV Market Challenges and Strategic Recommendations 136
8.6 Insurance Coverage and Reimbursement 137
8.7 Policies Affecting HIV Testing 137
8.8 Recent Industry Activity 138
9. Company Profiles 140

INDEX OF FIGURES

Figure 2.1: Diagram of HIV 14
Figure 2.2: HIV Replication Cycle 16
Figure 2.3: Ten Best-Selling AIDS Drugs in the U.S., 2011 23
Figure 3.1: Global Trend of HIV Infection, 1990-2009 26
Figure 3.2: Number of People Newly Infected with HIV, 1990-2009 26
Figure 3.3: Number of Deaths Due to AIDS, 1990-2009 27
Figure 3.4: Top Ten Countries with the Highest Adult HIV Prevalence Rate, 2009 27
Figure 3.5: Global View of Adult (Ages 15-49) HIV Infection, 2009 29
Figure 3.6: Ethnic Distribution of AIDS Patients in the U.S., 2011 31
Figure 3.7: U.S. Rates for New HIV Cases, 2011 31
Figure 3.8: New HIV Infections by Transmission Category, 2011 33
Figure 4.1: Proposed HIV Testing Algorithm 38
Figure 4.2: Percent of Persons (Ages 18-64) Who Reported Being Tested for HIV in the U.S., 2011 42
Figure 4.3: Percent of Persons (Ages 18-64) Who Reported Being Tested for HIV in the U.S. by Race/Ethnicity, 2011 42
Figure 5.1: Schematic of ELISA Tests 44
Figure 5.2: Concentration of Different HIV Markers in Plasma Following Initial Infection 46
Figure 5.3: Schematic of a Flow Through Assay 49
Figure 5.4: Schematic of a Lateral Flow Assay 50
Figure 5.5: Basic Components of a Lateral Flow Device 50
Figure 5.6: Schematic of a Dipstick Assay 52
Figure 5.7: Schematic of an Antibody/p24 Antigen (Fourth-Generation) Test 52
Figure 5.8: Western Blot Assay Preparation 53
Figure 5.9: Western Blot Banding Pattern 54
Figure 6.1: Understanding Positive Predictive Values 62
Figure 6.2: Window Period for Antibody-based HIV Tests 63
Figure 6.3: Concentration of Different HIV Markers in Plasma Following Initial Infection 64
Figure 6.4: Percentage of Emergency Departments Performing HIV Testing, 2011 69
Figure 6.5: Legislative Changes in State Laws to Increase Compatibility with CDC Recommendations, 2011 70
Figure 8.1: Global POCT Share of HIV Testing Market, 2011 118
Figure 8.2: HIV Test Kits Procured by WHO in 2009, by Region 120
Figure 8.3: Distribution of HIV Molecular Diagnostic Testing by Purpose 124
Figure 8.4: Market Share Viral Load HIV NAT Diagnostic Testing 124

INDEX OF TABLES

Table 2.1: AIDS-Defining Conditions 19
Table 2.2: Different Types of HIV Screening and Diagnostic Tests 20
Table 2.3: Comparison of CDC and WHO Case Definitions 21
Table 2.4: CDC Case Definition for HIV Infection Among Adults and Adolescents (Aged ≥13 years), 2008 21
Table 2.5: WHO Case Definition for HIV Infection, 2007 21
Table 2.6: WHO Case Definition for Advanced HIV (Including AIDS), 2007 22
Table 2.7: WHO Immunological Classification for Established HIV Infection, 2007 22
Table 2.8: Classes of Antiretroviral HIV Drugs 22
Table 2.9: New Antiretroviral Drugs 24
Table 3.1: Global Summary of the HIV/AIDS Epidemic, 2009 25
Table 3.2: Global HIV Statistics, 2009 29
Table 3.3: Countries with the Greatest Number of People Living with HIV, 2009 30
Table 3.4: Top Ten States by Cumulative AIDS Diagnosis, 2011 33
Table 3.5: Top Ten States by AIDS Diagnosis Rate, 2011 33
Table 3.6: Tests Used to Detect Acute HIV Infection 36
Table 4.1: Tests to Detect Acute HIV Infection 36
Table 4.2: HIV Antiviral Drug Resistance Testing Recommendations 41
Table 4.3: Common HIV Testing Sites 43
Table 4.4: Public Health HIV Testing Sites 43
Table 5.1: Advantages and Disadvantages of ELISA HIV Tests 45
Table 5.2: Rapid HIV Testing Outlets 47
Table 5.3: Desirable Characteristics of Rapid Tests 48
Table 5.4: Advantages of Rapid HIV Tests 48
Table 5.5: Disadvantages of Rapid HIV Tests 48
Table 5.6: Advantages and Disadvantages of Fourth-Generation Tests 53
Table 5.7: Advantages and Disadvantages of Nucleic Acid HIV Assays 58
Table 6.1: FDA-Approved Assays for Dried Blood Spot Samples 59
Table 6.2: Challenges Associated with HIV Testing 66
Table 6.3: Factors Influencing Assay Selection 67
Table 6.4: Compatibility of Consent and Counseling Laws with 2006 CDC Recommendations, 2011 70
Table 6.5: Financial Comparison for Moderate and Waived CLIA Labs 71
Table 7.1: ELISA Assays Detecting Anti-HIV Antibodies 74
Table 7.2: HIV Assays Using Oral Fluid Specimens 78
Table 7.3: Rapid HIV Immunoassay Tests 81
Table 7.4: FDA-Approved Rapid HIV Antibody Screening Tests 83
Table 7.5: USAID List of Approved HIV/AIDS Rapid Test Kits, June 2011 92
Table 7.6: HIV Antibody/p24 Antigen (Fourth-Generation) Tests 93
Table 7.7: FDA-Approved Confirmation Tests 97
Table 7.8: Nucleic Acid HIV Tests 98
Table 7.9: Summary of Assays for HIV Viral Load Testing 106
1. Overview

1.1 Statement of Report

There are an estimated 33.3 million people living with HIV (the virus which causes AIDS) worldwide and approximately 2.6 million people are newly infected each year. While the Asian and African regions account for more than 90% of the HIV-infected population (with the highest number in Sub-Saharan Africa), the U.S. and European regions make up greater than 60% of the HIV testing market. This TriMark Publications report provides a comprehensive examination of the HIV/AIDS testing market, a specific segment of the \textit{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, \textit{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 33.3 million people living with HIV, and approximately 2.6 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 21%, and is projected to grow from $1.7 billion in 2011 to $4.4 billion by 2016. Worldwide HIV diagnostic tests, which encompass screening and confirmatory tests, are expected to increase from $1.3 billion to $3.6 billion in 2016.

The Asian and African regions account for more than 90% of the HIV-infected population, with the highest number (22.5 million) in Sub-Saharan Africa. However, the U.S. and European regions make up greater than 60% 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 $300 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 $500 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 $275 million, but is expected to increase to $500 million by 2016. Because NAT HIV assays are much more costly and complex to perform, the U.S. and Europe account for greater than 75% of this global market.


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 90% 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.