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# MOLECULAR DIAGNOSTICS IN INFECTIOUS DISEASE TESTING

***(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 molecular diagnostics (MDx), with a specialization in the MDx tests for infectious disease. In the current medical diagnostics market, molecular diagnostics for infectious disease testing offers one of the brightest areas for growth and innovation. The confluence of breakthroughs in genomics, proteomics and the development of microarray devices to measure analytes in the blood and various body tissues, has led to this revolutionary market segment offering the power of advanced analytical techniques to the diagnosis and treatment of infectious disease.

Continuing new advancements in the ability to detect and diagnose infectious diseases are being made. Whereas before, detection and identification of many clinically important infectious agents was slow and expensive, and relied upon traditional culturing methods, and where there once were limited solutions offered by diagnostics, researchers and diagnostic companies are now at the cusp of overcoming such limitations by the use of nucleic acid mediated molecular diagnostics testing. Now, the area of molecular diagnostic medicine promises to revolutionize the ability to detect, diagnose and treat a wide variety of infectious diseases. The infectious disease space is the most dominant and profitable sector of molecular diagnostics, and is expected to be throughout the forecast period.

As such, the purpose of this report is to describe the emerging field of molecular diagnostics for infectious disease. The areas covered in this study include: available and emerging technologies in the field, the United States and global market size for molecular diagnostic products, and the profiles of companies that are focusing on the molecular diagnostic sector. This review analyzes the size and growth of the molecular diagnostics infectious disease market, including the factors that influence the various market segments within it, the dollar volume of sales, both in the U.S. and worldwide.

Also examined are:

- Polymerase chain reaction (PCR) technology platforms.
- Clinical applications of nucleic acid based testing.
- The market for molecular diagnostic tests associated with infectious disease diagnosis.
- Companies participating in this sector.
- New technology platforms and diagnostic test kits.
- Trends in the molecular diagnostics industry sector.
- The internal structure of the molecular diagnostics clinical testing sector.

This market report analyzes the size and growth of the molecular diagnostics 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 infectious disease market has been divided into the following parts for examination:

- Hepatitis infectious B and C disease molecular diagnostics markets.
- Human immunodeficiency virus (HIV) infectious disease molecular diagnostics market.
- Human papillomavirus (HPV) infectious disease molecular diagnostics market.
- Influenza infectious disease molecular diagnostics market.
- Tuberculosis (TB) infectious disease molecular diagnostics market.
- Sexually transmitted diseases (STDs) infectious disease molecular diagnostics market.
- Chlamydia and gonorrhea blood screening market.
- Methicillin-resistant *Staphylococcus aureus* (MRSA) market.
- Vancomycin-resistant *enterococci* (VRE) market.
- Other infectious disease molecular diagnostic market segments.

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

This report includes the following features for each major infectious disease market using molecular diagnostics techniques:

- It examines the generally accepted clinical analytical activities in use today in the MDx sector for diagnosis and management of infectious 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.

- It discusses the potential benefits of the molecular diagnostics technique for various sectors of the medical and scientific communities, and it assesses the market drivers and bottlenecks for MDx tests from the perspective of these communities.

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

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

- It examines 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.

- It discusses new collaborative business models that bring together diagnostics and therapeutics.

- It evaluates the role that infectious disease prognostic assays can play in partnership opportunities in personalized medicine.

## 1.3 Scope of the Report

The goal of this study is to review the market for molecular diagnostics infectious disease testing equipment and supplies using reagents and instruments for analysis of individual components in body tissues and fluids. Toward this goal, this review answers the following key questions:

- Which companies are utilizing new, cutting-edge technologies to develop, validate and market molecular diagnostics tests for clinical use in infectious disease management?
- What are the current impediments to incorporating promising molecular tests into clinical practice?
- Which new molecular diagnostics tests show the most promise for regulatory approval?
- What are the economic challenges to gaining approval? And what kind is best?
- How does regulatory oversight drive approval and adoption of new technologies?
- Which strategic alliances show the greatest synergy in bringing molecular diagnostics tests to market?
- Which shared technologies are driving the most encouraging development of new infectious disease testing methods?
- Estimate the current and future U.S. and global markets for molecular diagnostics for infectious disease.
- Examine market drivers that have resulted in the global race for new infectious disease diagnostics.
- Assess market opportunities and the potential market pertaining to the disease indications.
- Discuss product development challenges in relation to regulatory constraints, legislative constraints and technical challenges.
- Analyze the need for molecular diagnostics for the different infectious disease indications.
- Understand the impact of current products and the future of molecular diagnostics industry.
- Provide insight into the molecular diagnostics products in the pipeline and the companies that strive to bring these products to the market in the immediate future.



 

- Evaluate global activity in molecular diagnostics with specific contributions from the top-ranking five countries: U.S., Japan, Germany, U.K. and China.
- Analyze the segments in molecular diagnostics in major diseases like hepatitis, HIV and HPV.
- Gain insight into the current applications of molecular diagnostics in a wide variety of infectious diseases.
- Explore drug discovery efforts in relation to molecular diagnostics methods.
- Analyze the usual hurdles new MDx diagnostic methods are encountering to reach the market and the right path to the market for these products.
- Review the current licensing, investing and partnering activities in molecular diagnostics sector.
- Assess business models and requirements for a successful molecular diagnostics industry.
- Examine funding scenario for the molecular diagnostics sector.
- Identify the key players in the molecular diagnostics industry and their contribution to this emerging therapy.

Key questions answered in this study are:

- What are the products that come under the phrase “molecular diagnostics”?
- What disease conditions offer the greatest potential for molecular diagnostics technology platforms?
- What is the current global market for molecular diagnostics?
- How much of clinical development activities are taking place globally in molecular diagnostics sector?
- How many companies are involved in the development of molecular diagnostics products?
- How many patents have been issued for molecular diagnostics products in infectious disease?
- What market drivers are responsible for the global growth in diagnosis of infectious disease?
- What regulatory and technical challenges are being confronted by the molecular diagnostics industry?
- What are the current promising developments in molecular diagnostics infectious disease sector?
- What is the latest position of the clinical studies and product pipe line in molecular diagnostics infectious disease sector?
- How long it will take for the molecular diagnostics technology platforms to become the standard of clinical laboratory practice to replace old and slow culture techniques?
- How much of venture capital funding was invested into the molecular diagnostics sector?
- What is the potential population in the U.S. for infectious disease diagnosis?
- Do the developing countries offer growth for the molecular diagnostics products related to infectious disease?
- What are the top-ten molecular diagnostics infectious products available in the market place?
- What are the molecular diagnostics infectious products available in the market?
- How many companies are involved in the development of molecular diagnostics infectious products?
- How many firms concentrate on hepatitis products?
- Which firms are involved in the development of HIV products?
- Which companies are focused on the development of HPV products?
- Which companies are focusing on STD molecular diagnostics infectious products?
- Which companies are associated with developing molecular diagnostics infectious products for diagnosis of bacterial infections?
- What are the different business models suitable for the different types of molecular diagnostics products?
- What are the requirements for the commercial manufacturing of molecular diagnostics products?
- What are the different funding sources in the U.S. for the development of molecular diagnostics products?

This report contains:

- Current market opportunities for molecular diagnostics products for infectious disease.
- Product development challenges confronted by the molecular diagnostics industry.
- A brief discussion on the need for molecular diagnostics and the advantages over the conventional microbiology approaches.
- The future direction of the emerging molecular diagnostics infectious products.
- The overall picture of pipeline products in molecular diagnostics sector and the companies involved.



 

- A note on the projected time-line for molecular diagnostics infectious products.
- A market projection for global molecular diagnostics products.
- A short note on the potential number of U.S. patients requiring molecular diagnostics infectious products.
- Listing and explaining the most popular molecular diagnostics infectious products in the market.
- Presentation of the global picture of the molecular diagnostics infectious products market with particular reference to the leading countries, such as U.S., Japan, Germany, U.K. and China.
- Number of firms engaged in molecular diagnostics infectious products.

This examination surveys most of the biotech companies known to be currently marketing, manufacturing or developing instruments and reagents for the molecular diagnostics market for infectious disease 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. The U.S. is the focus of this report. Primary attention is paid to the specialty 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 molecular diagnostics in infectious disease management, including probe-based nucleic acid assays, microarrays and sequencing.
- Obtaining a complete understanding of the chief characteristics of molecular diagnostics tests as they are used in infectious disease testing (*i.e.*, 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 an in-depth analysis of the major world markets for molecular diagnostics for infectious disease management, including growth forecasts.

The emphasis in this report is on the clinical use of molecular diagnostics tests for infectious disease diagnosis and management. The reader should consult other TriMark Publications reports at www.trimarkpublications.com 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 Cancer Testing* and *Molecular Diagnostics in Genetic Testing*.

### 1.5 Methodology

The author of this report holds a Ph.D. in biochemistry from the University of Minnesota, and has had 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 of this report has a Masters in Immunology from the University of Colorado with many years of experience in science writing and as a medical industry analyst.

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.

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, anticipated increases/decreases in funding of specific markets. Then other factors such as new market introductions, acquisitions, etc. are manually incorporated into the spreadsheet.



 

## 1.6 Executive Summary

Molecular diagnostics is a rapidly-advancing area of research and medicine, with new technologies and applications being continually added. A large part of molecular diagnostics technology has been devoted to detection of infectious disease. Over the past several years, this rapidly evolving field has seen several fascinating developments, including:

- Impact on epidemiology of infectious diseases.
- Integration of molecular testing techniques into routine clinical practice.
- Specific identification of viral disease sub-types susceptible to drug therapy.
- Development of companion diagnostics for drug development.
- Use quantitative PCR for assessment of viral load in HIV, hepatitis C virus (HCV), HPV and other disease agents.
- Widespread installed base of automated instruments for molecular testing.
- Multiplexed testing.
- Development of personalized medicine.
- Rapidly expanding opportunities for molecular testing in BRIC country markets.
- Rapid expansion of molecular diagnostic test menus.

The technologies that are described as molecular diagnostics include:

- First-generation amplification, DNA probes, fluorescent *in situ* hybridization (FISH).
- Second-generation biochips and microfluidics.
- Next generation signal detection, biosensors and molecular labels, and gene expression profiling using microarrays.

These technologies are improving important in the diagnosis and screening of patients with infectious disease, and enhancing the optimization of drug therapy. Several major diagnostic companies, such as Abbott Laboratories, bioMérieux, Becton Dickinson (BD) and Roche Diagnostics, have substantial market shares in each category of the molecular diagnostics market, including infectious disease testing. Other smaller companies like Qiagen and Hologic are now the major competitors in most areas of molecular testing. Still others like Cepheid are charging forward and introducing instruments and new tests into selected infectious disease areas.

Small- and medium-sized companies with innovative products and technology platforms have great opportunities for success in the field of molecular diagnostics as applied to infectious disease. The exciting thing here is that this market segment is characterized by unprecedented growth rates, which stand in contrast with the low or even negative growth rates of mature laboratory-testing segments in fields such as hematology, chemistry and microbiology. Research in genomics has led to a new healthcare paradigm, where a disease is understood at the molecular level, allowing patients to be diagnosed based on genetic their own unique information and then treated with drugs designed to work on specific molecular targets.

Gene expression profiling will continue to increase as companies in the pharmaceutical industry work with diagnostic companies to accelerate their drug discovery and development efforts in infectious disease therapeutics by using companion diagnostic tests in clinical trials, and later as guides to optimum efficaciousness during therapy through targeted drugs. These efforts are expected to create a demand for increasingly effective diagnostic tests for infectious disease.

Most industry experts believe that over the next few decades, the use of molecular diagnostics will grow rapidly, in the order of [redacted]% to [redacted]% per year, and will have a revolutionary impact on the way clinical medicine is practiced. Factors that drive the molecular diagnostics business are:

- Personalization of diagnosis and therapy by identifying genes associated with complex diseases, optimizing the drug response, and reducing side effects and failure rates (pharmacogenetics).
- Need for faster methods of diagnosing disease states and medical disorders earlier, and for a powerful, reliable tool for therapy decisions.



 

- Need for an automated analysis and data evaluation.
- Need to contain or decrease healthcare costs without compromising accuracy or reliability.

The global market for advanced infectious disease molecular diagnostic testing will increase from $[redacted] in [redacted] to $[redacted] by [redacted].

***Business Factors Influencing Advanced Infectious Disease DNA Testing Services***

- Demographic shifts to an older (>60-year-old) population.
- An increased incidence of HIV within a younger population, and co-infection with HIV in many cases.
- New HIV therapies and the need to evaluate viral load in patients undergoing drug therapy.
- An expanding test menu for rapid detection of infectious disease using DNA methodology.
- Recent trends indicate that treatment decisions are likely to involve the assessment of a complex panel of protein and gene based testing, rather than a single test.
- Diagnostic and predictive testing for infectious disease will likely become increasingly complex, and there will be increased demand for sophisticated tests.
- Advanced molecular tests will also require additional expertise to interpret test results and/or assist pathologists in such interpretations.
- Pharmaceutical companies' demand for high potential targeted therapies will continue to grow under pressure from the FDA for more effective drugs and guides by companion diagnostics.
- Hospitals and healthcare networks that are striving to reduce the costs of hospital associated infections (HAIs) constitute a large readymade market.
- Biopharmaceutical companies developing new drugs and partnering with large pharmaceutical companies for targeted therapies.
- Emergence of CLIA certified specialty labs for advanced testing services.

Pharmaceutical companies have invested billions of dollars in the development of high-potential therapeutics for infectious diseases like HIV and hepatitis. These new drugs are one of the fastest growing segments of drug development. Many of these therapies will require a specific test (referred to as a "theranostic" or "companion diagnostic") to assist physicians in selecting the right drug for the right patient. The field of theranostics is likely to accelerate the process for drug approval and market introduction by guiding selection of the most appropriate patients for the clinical trials. The Food and Drug Administration's Critical Path Initiative is facilitating a national effort to modernize the scientific process through which a potential human drug, biological product, or medical device is transformed from a discovery or "proof of concept" into a medical product.

**Table 1.1: Market Trends in Infectious Disease DNA Testing**

- Rapidly growing market segment in infectious disease testing.
- Expansion of Pharma DX collaborations.
- Strong growth of esoteric testing for less prevalent diseases.
- Expansion of molecular diagnostics to drive therapy decisions.
- Minimal pressure on reimbursements.
- Lack of capital will increase opportunities to license markers.
- Emerging opportunity for molecular pathology space in hospital and commercial labs.
- Focus on delivering companion diagnostic information for new drug therapies.
- Increased M&A activity.

***Source:*** Biotechnology Associates



 

### Table 1.2: Molecular Diagnostics Infectious Disease Market: Market Drivers Ranked in Order of Impact

- Core infectious disease DNA testing industry growth.
- Increased sensitivity for detection of HIV and hepatitis.
- Faster detection and analysis times (increased TAT).
- Higher accuracy of detection, particularly in complex mixtures.
- Ease of use for previously esoteric assays (*e.g.*, HPV).
- Ability for the molecular diagnostic nucleic acid technology platforms to be developed for assay of new analytes.
- Applicability of molecular diagnostic techniques to pharmaceutical industry development needs, *e.g.*, companion diagnostics for drug development.
- The rapid expansion of genomics and genetic testing.
- The clarification of much proteomic research and development through improvements in data handling.
- Continuing breakthroughs in HIV diagnosis and therapy.
- New analysis needs for biosafety and homeland security.
- Trend to increased penetration through more tests ordered per requisition for lab orders.
- Increased M&A activity.
- Partnering with large diagnostic companies (Abbott, Roche, etc.).

***Source:*** Biotechnology Associates

### Table 1.3: Molecular Diagnostics Infectious Disease Market: Market Restraints Ranked in Order of Impact

- Increased cost of assays.
- Changes in analysis paradigm, particularly in the movement of tests to specialized CLIA labs.
- Inaccessibility of many molecular diagnostic tests to standard laboratory instrumentation, and therefore the need for labs to acquire additional hardware for high throughput automated analysis.
- High cost of test results and lack of third-party reimbursement.
- Lack of understanding of molecular tests by oncologists and other physician groups.
- Stringent licensing requirements by CLIA and state governments.
- Complex mix of third-party payors.
- Competition from hospitals and community pathologists.

***Source:*** Biotechnology Associates

### Table 1.4: Strategic Recommendations on Molecular Diagnostic Sector Business Functions

- Infectious disease testing will become a significant growth area during the forecast period.
- Small diagnostic companies will only succeed in partnership with large diagnostic companies with significant marketing reach; general clinical labs are overdue for consolidation.
- Funding for promising technology platform start ups will become increasing more difficult to obtain and licensing will dominate to entry of new test procedures.
- Funding for on-going small companies who have used up their initial funding will be extremely problematic.
- The infectious disease testing sector of molecular diagnostics will see a significant increase in the number of active players in the mixed specialty and pure play testing labs.
- Companion diagnostics for new pharmaceutical drugs will be a grow area for molecular diagnostics as it is driven by increasingly strict FDA requirements for marketing approval.
- Niche areas for diagnostic tests on less-tested infectious diseases (*e.g.*, *C. trichomonas*) and women health determinations will become an important place for small companies to survive and grow.
- Biosecurity testing will become an important source of funding in response to government funding for Homeland Security.

***Source:*** Biotechnology Associates

TriMark has determined that the global market for all molecular diagnostics tools, assays and other products in [redacted] was estimated at $[redacted]. It is predicted that by the end of the forecast period, the market will be valued at $[redacted] (CAGR [redacted] of [redacted]%).



 

Of this amount, over [redacted]% was spent on assays used for testing infectious diseases such as HIV and HCV, *et.al*. The remaining percentage was spent for other products, such as those used in cancer markers and genetic testing. As the molecular diagnostics market continues to grow, TriMark expects human genetic testing, pharmacogenomics and cancer testing to represent an increasingly larger percentage of this annual amount in the near future, even as the infectious disease space continues to grow.

The entire molecular diagnostics testing market in the U.S. is the largest and most highly developed in the world. This market segment growth will significantly outperform the overall *in vitro* diagnostics market in the U.S., with sales in the U.S. molecular diagnostic reagent and instrument market growing from $[redacted] in [redacted] to $[redacted] in [redacted] (a CAGR of [redacted]%). European molecular diagnostics market revenues are forecast to increase from $[redacted] in [redacted] to $[redacted] in [redacted], with a growth rate of [redacted]%. The Japanese molecular diagnostics market is estimated to be valued at $[redacted] in [redacted]. The projected compound annual growth rate (CAGR) is [redacted]% per year through [redacted], to reach $[redacted].

Fifteen companies control more than [redacted]% of the molecular diagnostics market. These include:

- Roche Diagnostics, division of Roche Holdings.
- Hologic, Inc.
- Qiagen NV.
- Becton Dickinson
- Myriad Genetics
- bioMérieux.
- Grifols.
- Abbott Diagnostics.
- Cepheid.
- Illumina.
- Genomic Health.
- Siemens.
- Alere.
- Meridian Bioscience.
- Thermo Fisher Scientific.

Roche is the undisputed market leader with more than [redacted]% share and a product portfolio that includes molecular diagnostic tests for oncology, virology, microbiology and blood screening.

This market segment is characterized by strong growth rates (~[redacted]%), which stand in contrast with the low rates of mature laboratory-testing segments in traditional fields such as hematology and microbiology. Qiagen's growth rate has outpaced competitors over the past three years. Emerging from primarily a sample-preparation technology and PCR reagent vendor, the company has aggressively expanded its business by the acquisition of Life Technologies and is now well positioned in the market niche to the extent that now approximately half of its sales come from molecular diagnostics. Similarly, Hologic's growth rate has outpaced the industry average given the company's global market leadership in Chlamydia and gonorrhea (CT/NG) testing. Revenue from reagents and instruments used in molecular diagnostic tests for infectious diseases generate greater than [redacted]% of overall molecular diagnostics market sales with its Panther and Tiger Systems. These include tests for HIV, HPV, hepatitis B and C (HBV/HCV) and CT/NG. With the exception of the HPV molecular diagnostics market, many of these testing spaces are mature, with growth rates settling around [redacted]%.

TriMark has determined that the global market for molecular diagnostic tests for infectious diseases in [redacted] was $[redacted]. By [redacted], the global market for molecular diagnostic tests for infectious diseases increased in value to an estimated $[redacted], and by the end of the forecast period, the market is predicted to grow to $[redacted] (CAGR [redacted]-[redacted] of [redacted]%).

Geographically, the U.S. represents the largest individual market with the market for molecular diagnostic tests for infectious diseases valued at $[redacted] in [redacted] and predicted to grow to $[redacted] by the end of the forecast period (CAGR [redacted]%). The European market is the second largest geographic region and collectively these individual



 

markets have been estimated to be valued at $[redacted] in [redacted] and predicted to grow to $[redacted] by the end of the forecast period (CAGR [redacted]%). The emerging markets in Asia a are expected to exhibit the fastest CAGRs and will take in ever increasing share of the global market.

In addition to the more established molecular diagnostic testing for HIV, HPV, HBV/HCV and CT/NG, companies are steadily introducing molecular diagnostic tests for many other infectious disease indications. Molecular diagnostics for West Nile Virus, *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), respiratory syncytial virus, influenza, pneumonia, *Trichomonas vaginalis*, genital mycoplasma, herpes simplex virus, norovirus, rotavirus, tuberculosis and meningitis are now all available on the market.

Among these, the two tests for diagnosing nosocomial infections, or healthcare-acquired infections (HAIs)—*C. diff* and MRSA—have witnessed the greatest level of adoption. With direct medical costs attributable to HAI totaling as much as $[redacted] in the U.S., molecular diagnostic-based screens are proving to be necessary for risk mitigation. The increase in emerging infectious diseases such as Ebola, Zika virus, and dengue fever are also driving companies to develop new molecular methods to detect these pathogens.

Infectious disease molecular diagnostic segments:

***HIV***

- Key players: Roche, Hologic, Abbott, Grifols.
- Market [redacted] size: $[redacted] (global); $[redacted] (U.S.).
- Market [redacted] forecast size: $[redacted] (global); $[redacted] (U.S.).

***HBV***

- Key players: Roche, Abbott.
- Market [redacted] size: $[redacted] (global); $[redacted] (U.S.).
- Market [redacted] forecast size: $[redacted] (global); $[redacted] (U.S.).

***HCV***

- Key players: Roche, Abbott.
- Market [redacted] size: $[redacted] (global); $[redacted] (U.S.).
- Market [redacted] forecast size: $[redacted] (global); $[redacted] (U.S.).

***HPV***

- Key players: Abbott, Roche.
- Market [redacted] size: $[redacted] (global); $[redacted] (U.S.).
- Market [redacted] forecast size: $[redacted] (global); $[redacted] (U.S.).

***Influenza***

- Key players: Roche, Hologic, Quest, Cepheid, bioMérieux, Qiagen, Quidel, Nanosphere.
- Market [redacted] size: $[redacted] (global); $[redacted] (U.S.).
- Market [redacted] forecast size: $[redacted] (global); $[redacted] (U.S.).

***Chlamydia/Gonorrhea***

- Key players: Roche, Cepheid, Hologic, Siemens, Becton Dickinson.
- Market [redacted] size: $[redacted] (global); $[redacted] (U.S.).
- Market [redacted] forecast size: $[redacted] (global); $[redacted] (U.S.).



 

***Tuberculosis***

- Key players: Cepheid, Seegene, Veregene, Abbott.
- Market [redacted] size: $[redacted] (global); $[redacted] (U.S.).
- Market [redacted] forecast size: $[redacted] (global); $[redacted] (U.S.).

***MRSA***

- Key players: Roche, Cepheid, Becton Dickinson.
- Market [redacted] size: $[redacted] (global); $[redacted] (U.S.).
- Market [redacted] forecast size: $[redacted] (global); $[redacted] (U.S.).

Molecular diagnostic techniques for establishing presence or absence of clonality have been shown to be effective in following the spread of nosocomial infections and streamlining the activities of infection control programs. This is particularly relevant in terms of MRSA infections. Molecular typing can shorten or prevent an epidemic and reduce the number and cost of nosocomial infections.

Molecular diagnostic testing for new infectious disease strains has been challenging due to the high level of genetic heterogeneity and high cost of traditional sequencing technologies. Next-generation sequencing allows one to maximize the number of genes in a pathogen that can be tested simultaneously while reducing the cost and turnaround time. Medical sequencing will revolutionize diagnostics as the foundation of personalized medicine. However, the clinical practice of medicine lags far behind the technology and business communities in preparing for this change.

Three key industry segments—diagnostics, pharmaceuticals and biotechnology—are likely to shift towards more collaborative business models that focus on co-developed products. Collaborative and strategic partnerships with molecular diagnostic companies yield substantial return on investment for pharmaceutical clients by providing high value opportunities in key areas of high impact on clinical trials.

Sales of molecular diagnostic products depend in part on the availability of reimbursement to the consumer from third-party payors, including Medicare, Medicaid and private health insurance plans. Because a large percentage of revenue this is derived from older patients who are eligible under the Medicare program, the coverage and reimbursement rules of Medicare are of particular importance to molecular diagnostic oriented clinical laboratory operations. Medicare-participating laboratories bill the Medicare program's local state contractor and are therefore subject to that contractor's local coverage and reimbursement policies.

Diagnostic testing reagents are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act and regulations, including regulations governing the development, marketing, labeling, promotion, manufacturing and export of molecular diagnostic technologies. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil penalties, injunctions and criminal prosecution. The clinical laboratory testing industry is highly regulated. A colossal tangle of rules can affect the ability of a diagnostic company to conduct business.

***Molecular Diagnostics Testing Going Forward***

Molecular diagnostic tests are being developed for additional types of infectious disease at an increasing rate. Many of these tests are relatively new to the market:

- West Nile virus.
- *Clostridium difficile*.
- Methicillin-resistant *Staphylococcus aureus* (MRSA).
- Respiratory syncytial virus.
- Influenza.
- Pneumonia.



 

- *Trichomonas vaginalis.*
- Genital mycoplasma.
- Herpes simplex virus.
- Norovirus.
- Rotavirus.
- Tuberculosis.
- Meningitis.
- Ebola.
- Zika Virus.
- Dengue Fever.

Healthcare-associated infections (HAI) in the U.S. have generated direct medical costs of as much as $[redacted]. As a result, two tests for healthcare-associated infections (HAI), *C. difficile* and MRSA, have been among the top tests to have been quickly and widely adopted.

***Impediments to Incorporating Promising Molecular Tests into Clinical Practice***

- Cost.
- Lack of appropriate technology platform.
- Lack of broad test menu.
- Lack of support by early adapters.
- Lack of proper reimbursement structure.
- Need to take valuable technologist time for training.
- Narrow clinical utility.
- Lack of large placements of technology platform.
- In a technology-driven market, failure to exploit the new technology platform as a corporate strategic asset.
- Any question of failure to produce useful clinical results for patients, or rejection by the medical thought leaders, will quickly dry up test requests and an incipient revenue stream.
- Any breakdown in the protection of the featured licensed proprietary technology, or any determination that this licensed proprietary technology infringes on the rights of others, could negatively affect business.
- Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a marketing strategy.
- Competitive pressures from large national labs like Quest and LabCorp are substantial.
- Failure to obtain FDA or CE mark regulatory approval.
- Some advanced tests provide quantitative information not currently provided by pathologists and are performed at a remote lab facility rather than by the pathologist in a local laboratory, so pathologists may be reluctant to support such a test and this may make it difficult to convince medical practitioners to order advanced genomic tests for their patients with infectious disease.



 

- Even if medical practitioners recommend that their patients use a test, patients may still decide not to use these expensive and arcane tests, either because they do not want to be made aware of the details of their disease or they wish to pursue a particular course of therapy regardless of test results.

- A key driver for success is the need for acceptance by community based pathologists, who constitute a significant portion of the $[redacted] infectious disease diagnostic market. This very independent "show me" group must be convinced that the clinical lab can provide a highly professional, academic level resource for their pathology practices, while not threatening their professional position in the local medical community, or interfering with their income stream.

- Pathologists are notorious in their constant demands on labs. Part of the problem is that they know too much. Primary care and other providers like oncologists are not very knowledgeable about the operational details of diagnostic tests. They are willing to "go along" with the providing lab. Pathologists, on the other hand, are under pressure from their community hospitals and their own group dynamics to look professional and competent, and are usually quite knowledgeable about the arcane details of molecular tests. Because of these factors, they are much more likely to become dissatisfied with test results.

- The current turmoil in the global credit markets adds to such uncertainty due to the more limited availability of operating funds for clinical labs. These conditions could also impair the ability of customers, suppliers and clinical labs to satisfy their obligations. If adequate funds are not available, or are not available on commercially acceptable terms, the labs might be required to delay, scale back or eliminate some or all of their development activities or new business initiatives, or to license to third parties the right to commercialize products or technologies that they would otherwise seek to use themselves.

- The introduction of diagnostic tests using new technologies and the emergence of new industry standards can render existing tests and technology platforms obsolete and unmarketable in very short periods of time.

- Competitors will continue to introduce new products and services and enhancements to their existing products and services. The future success of diagnostic development companies will depend upon their ability to enhance their current tests, and to develop new tests, in a manner that keeps pace with emerging industry standards and achieves market acceptance. The inability to accomplish any of these endeavors will have a substantial negative effect on their business, operating results, cash flows and financial condition.

- Many important assays and reagents are not based on an absolutely clear-cut portfolio of patents and other intellectual property, so competitors are not blocked from coming out with their own versions. It is unlikely that any particular assay will contribute substantially to the revenues or earnings of a reagent company like Qiagen. However, this company also shows that development and marketing of many advanced assays—and the consumables and instruments it takes to run them—can appreciably benefit top and bottom lines.

Key sector overview takeaways:

- Many new molecular diagnostics tests for infectious disease are showing the promise for timely approval.
- Alliances with great synergy are bringing new molecular diagnostics tests to market.
- Shared technologies are driving the most encouraging molecular diagnostic testing development.



 