

# MASS SPECTROSCOPY FOR CLINICAL LABORATORY ANALYSIS *(SAMPLE COPY, NOT FOR RESALE)*

Trends, Industry Participants, Product Overviews and Market Drivers



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## 1. Overview

### 1.1 Statement of Report

Mass spectroscopy is a clinical laboratory analysis technique used in determining the basic composition and structure of a sample or molecule. The process involves bending a charged beam of vaporized material using an electric and/or magnetic field and then plotting a spectrum of how the sample's ions are deflected. Mass spectroscopy (MS) assays based on well-documented techniques such as time-of-flight, liquid chromatography/tandem, liquid chromatography, gas chromatography-quadrupole and others have gained wide acceptance in the clinical laboratory due to their accuracy, speed and sensitivity compared to traditional analytical drug detection techniques. The mass spectroscopy market remains the fastest-growing segment of the diagnostics analytical instruments market with a forecasted compound annual growth rate of 11% through 2016. Highly-attractive clinical growth areas covered in this study include:

- Disease markers.
- Molecular diagnostics.
- Infectious disease.
- Toxicology.
- Inborn errors in metabolism.
- Metabolomics.
- Proteins and peptides.
- Small molecule analytes (vitamins, steroids, thyroid, etc.).
- Tobacco exposure.
- Chemical warfare agents.
- Tissue analysis by MALDI.
- Clinical chemistry/toxicology.
- Microbiology/virology.
- Proteomic, metabolomic and tissue histology laboratories.
- High-end MS.
- Food testing.

This TriMark Publications report provides a detailed analysis of the mass spectroscopy drug testing market, including size, growth, technology platforms, clinical applications, new instrumentation, industry trends and the internal structure of the sector. In the current medical diagnostics market, mass spectroscopy offers some of the brightest promise for growth and innovation. The rapid development of this sector of the diagnostics industry has been driven by:

- The use of mass spectroscopy instrumentation for vitamin D determinations, testosterone analysis, and drug-screening confirmation.
- The development of a wide variety of MS and separation based technology platforms (*e.g.*, tandem mass spectroscopy, time-of-flight [TOF] methods, multiplex design).
- The rise of drug profiling.
- New developments in diagnosis and treatment of drug dependence.
- The need for screening both therapeutic and illicit drug content.
- Improved detection levels.
- The use of computer-assisted data analysis and multiplexing.

This review analyzes the size and growth of the mass spectroscopy market, including the factors that influence the various market segments within it, the dollar volume of sales, both in the United States and worldwide.

Also examined are:

- MS technology platforms.
- Clinical applications of mass spectroscopy based testing.
- The market for quantitative diagnostic drug tests.
- Companies participating in this sector.
- New instrumentation.
- Trends in the industry.
- The internal structure of the mass spectroscopy testing sector.

## 1.2 About This Report

This report includes the following features:

- It examines all of the generally-accepted clinical analytical activities in use today in the mass spectroscopy sector. It includes the prevalent clinical measurement devices and the accompanying reagents and supplies as utilized in hospitals and large reference laboratories.
- It discusses the potential benefits of the mass spectroscopy market for various sectors of the medical and scientific communities, and it assesses the market drivers and bottlenecks from the perspective of these communities.
- It establishes the current total market size and future growth of the mass spectroscopy market and analyzes the current size and growth of various segments.
- It assesses various business models in mass spectroscopy 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.

The main objectives of this analysis are:

- Identifying viable technology drivers through a comprehensive look at platform technologies for mass spectroscopy, including gas chromatography-quadrupole mass spectrometry, ion trap mass spectrometers, liquid chromatography/mass spectrometry, ion mobility and high definition mass spectrometry, liquid chromatography tandem mass spectrometry, time-of-flight mass spectrometry, inductively-coupled plasma mass spectrometry, matrix-assisted laser desorption/ionization (MALDI) time-of-flight mass spectrometry, and Orbitrap.
- Obtaining a complete understanding of the chief mass spectroscopy tests—*i.e.*, predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic—from their basic principles to their applications.
- Discovering feasible market opportunities by identifying high-growth applications in different clinical diagnostic areas and by focusing on expanding markets, such as communicable diseases, cardiology and oncology.
- Focusing on global industry development through an in-depth analysis of the major world markets for mass spectroscopy, including growth forecasts.
- How can mass spectrometry contribute to laboratory growth plans?
- Which tests are the most likely candidates for migration to MS platforms?
- How to understand the business issues that go into justifying mass spectrometry?

### 1.3 Scope of the Report

The goal of this study is to review the market for mass spectroscopy 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 cutting-edge technologies to develop, validate and market mass spectroscopy tests for clinical use?
- What are the current impediments to incorporating promising mass spectroscopy tests into clinical practice?
- Which new mass spectroscopy tests 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 alliances show the greatest synergy in bringing mass spectroscopy tests to market?
- Which shared technologies are driving the most encouraging development?

This examination surveys most of the instrument companies known to be currently marketing, manufacturing or developing instruments and reagents for the mass spectroscopy market, in both the U.S. and the world. Each leading 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., Europe and Japan—the world's three largest mass spectroscopy markets—are the focus of this report. Primary attention is paid to the hospital market segment and, separately, to the instruments, reagents and supplies marketed by the major companies in this segment. Market size, growth rates and market components for instruments, reagents, controls and consumables used in this area are also analyzed.

This analysis emphasizes the companies that are actively developing and marketing mass spectrometry clinical laboratory instrumentation, reagents and supplies for performing mass spectroscopy tests. The emphasis in this report is on the clinical use of mass spectroscopy tests.

The reader should consult other TriMark Publications reports at <http://www.trimarkpublications.com> for detailed discussions of important individual market segments related to the mass spectroscopy market, such as clinical chemistry testing, high-growth diagnostic tests markets, genomics and medical nanotechnology. Diagnostics drug tests marketed primarily as qualitative or quantitative reagents are generally not included in this report, although there is inevitably some overlap. TriMark provides a separate market report called *DNA Sequencing and PCR Markets*, which emphasizes the analytical methods and polymerase chain reaction (PCR) technology platforms sometimes used in mass spectroscopy.

### 1.4 Objectives

The emphasis in this report is on the clinical use of mass spectroscopy tests and their development into the instrument mixture of clinical laboratory space. One goal of this study is to review the market for mass spectroscopy testing equipment and supplies using reagents and instruments for analysis of individual components in blood, serum or plasma. The report also defines the dollar volume of sales, both worldwide and in the U.S., and analyzes the factors that influence the size and the growth of the market segments. The subsections of the mass spectroscopy market segment are examined in detail, including: Quadrupoles, Quadrupole Ion Trap, Linear Ion Trap, Quadrupole Time-of-Flight Tandem MS (TOF), MALDI with Time-of-Flight Analysis (MALDI-TOF), Quadrupole Time-of-Flight MS, Fourier Transform Mass Spectrometry (FTMS). The use of MS in commercial, hospital and specialty laboratories are examined. Additionally, the factors that influence purchases are also discussed.

In this report, we:

- Assess the mass spectroscopy market drivers and bottlenecks from the perspective of the medical and scientific communities.
- Discuss the potential benefits of the mass spectroscopy market for various sectors of the medical and scientific community.

- Establish the current total market size and future growth of the mass spectroscopy market and analyze the current size and growth of various segments.
- Provide current and forecasted market shares by the company.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the mass spectroscopy market.
- Review the mass spectroscopy business models.

On a more technical level, we:

- Discuss the problems of using indirect methods such as immunoassays for analyzing complex biological fluids when making diagnostic decisions and their replacement with MS technology platforms.
- Review the strategies available for sample preparation to optimized mass spectrometry analysis
- Contrast the optimal methods for quantitation when employing liquid chromatography/mass spectrometry (LC/MS) techniques.
- Differentiate the strategies of toxicology analysis to best fit the clinical requirements.
- Appraise the use of mass spectrometry for applications of molecular diagnostics.
- Discuss the future of mass spectrometry in clinical chemistry, microbiology, hematology, tissue mapping, newborn screening.
- Examine the application of mass spectrometry for the development of metabolomic disorders.
- Evaluate the applications of new technologies such as proteomics and metabolomics to the clinical laboratory using MS techniques.
- Review the dynamic regulatory environment (FDA) and assess how mass spectrometry may play a role in the clinical laboratory.

This review answers the following key questions:

- Which companies are utilizing cutting-edge technologies to develop, validate and implement molecular tests for clinical use?
- What impediments still exist to incorporating promising molecular tests into clinical practice?
- Which new mass spectroscopy tests show the most promise for approval?
- What are the economic challenges to approval?
- How can regulatory oversight drive approval and adoption of new technologies?
- Which alliances show the greatest synergy in bringing mass spectroscopy tests to market?
- Which shared technologies are driving the most encouraging development?
- How are businesses entering the clinical lab testing space by leveraging mass spectroscopy.

## 1.5 Methodology

The senior author of this report holds 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 over 40 years of experience as a director in laboratory testing and instrument and reagent development technology, as well as extensive experience in senior level positions in biotech and medical service companies. The contributing analyst has a Ph.D. in chemistry from the University of Illinois, with more than 30 years of experience as a clinical laboratory director, as well as editing and writing articles in science and technology. He is currently laboratory director of a large urban hospital whose lab specializes in mass spectroscopy and drug analysis.

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. Information on mass spectrometry instruments and clinical methods were obtained in part from interviews with representatives of the major companies in the sector.

### ***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**

Mass spectrometry based test platforms are now an integral part of operations in a growing number of clinical labs. The ubiquitous immunoassay-based approaches for hormone analysis used in clinical labs are often plagued by interferences, preventing them from obtaining accurate measurements. Thus, the mass spectrometry technology will enable greater sensitivity and accurate quantitation of low-abundant hormones.

Mass spectrometry has many uses related to the clinical lab and the life science space. It now amounts to a regular laundry list. The maturity of mass spectrometry (it is more than [REDACTED] years old), and yet vigorous new technology platform innovations, have made this analytical technique well known in the pharma and life science sectors, and now is overseeing a solid growth in the clinical and medical spaces.

Large reference laboratories and major medical centers have demonstrated that the use of mass spectrometry leads to more accurate testing, which results in actionable results, improved patient care and reduced costs. Innovative mass spectrometric technologies—alone and combined with molecular methods—have led to improved diagnostic testing approaches.

Mass spectrometry assays based on well documented techniques such as time-of-flight mass spectrometry, liquid chromatography/tandem mass spectrometry, liquid chromatography/mass spectrometry, gas chromatography-quadrupole mass spectrometry, and others, have gained wide acceptance in the clinical laboratory due to the benefits of accuracy, speed, and sensitivity that these methods offer compared to traditional analytical drug detection techniques. The mass spectrometry market is estimated to constitute the fastest-growing segment of the diagnostics analytical instruments market. Industry experts estimate the market at more than \$ [REDACTED] in [REDACTED].

It is in the area of Clinical Laboratory monitoring of drugs and hormones that mass spectrometry diagnostic assays have found extensive use. Currently, the use mass spectrometry instrumentation for vitamin D determinations, testosterone analysis, and drug-screening confirmation using a wide variety of MS, immunosuppressants monitoring, and separation based technology platforms (e.g., tandem mass spec, TOF methods, multiplex design) is well accepted and growing in importance.

Over the past several years, this rapidly evolving field has seen several fascinating developments in Clinical Laboratory management, including:

- Impact on pharmacogenomics and epidemiology.
- Integration of specialty labs and drug profiling into clinical practice.
- Integration into therapeutic choices for Clinical Laboratory management.
- The use of diagnostics for predicting drug and therapeutic compliance in HIV patients.
- Development of companion diagnostics for drug development.
- Use of drug profiling for determining the efficacy of therapeutic drugs for HIV.
- Obtaining a complete understanding of the use of mass spectrometry tests for predictive, screening, prognostic, monitoring, pharmacogenomic and theranostic applications.

More than ten companies market products in mass spectrometry. Most of these are large international instrument companies, with annual sales more than \$ [REDACTED]. Many major instrument companies, such as Thermo Fisher Scientific, Shimadzu, Danaher, Waters, bioMérieux and PerkinElmer, have substantial market play in the category of clinical laboratory for the mass spectrometry market. This market segment is characterized by unprecedented growth rates, which stand in contrast with the low rates of mature laboratory-testing segments in traditional fields such as hematology and microbiology.

### ***Therapeutic Drug Monitoring***

Compared to 20 years ago, most therapeutic drug monitoring for clinical practice is still performed using automated immunoassay analyzers. However, therapeutic drugs that have a narrow therapeutic index or exhibit significant inter-individual variability are candidates for routine measurement by mass spectrometry. Examples of drug classes whose blood concentrations are regularly monitored in clinical laboratories by mass spectrometry include antibiotics (e.g., aminoglycosides, antiarrhythmics, anticonvulsants, antineoplastic drugs and immunosuppressants).

### ***Metabolic Diseases***

Various forms of mass spectrometry have been used to detect metabolic diseases such as those seen in newborn infants with inborn errors of metabolism. Another application of mass spectrometry has been in the analysis of the

active metabolites of vitamin D (25-hydroxyvitamin D). Deficiencies of this metabolite have been linked to cancer, cardiovascular disease, depression, bone disease and many other chronic diseases.

### ***Endocrinology***

Current immunoassays do not have the analytic sensitivity to detect testosterone in women and children. Analog free thyroid hormone immunoassays are influenced by the concentration of thyroid hormone binding proteins such as albumin. Assays based on mass spectrometry have been deemed to be the “gold standard” for many hormone analyses. For the thyroid hormones, a pre-analytic step of equilibrium dialysis is necessary prior to MS analysis, increasing the labor and prolonging the turnaround time for results. These and the cost for LC/MS instrument have been deterrents to implementation of MS technology into routine practice.

### ***Clinical Toxicology***

Currently, drug testing in clinical and forensic practice is a two-step process: the initial testing for immunoassay followed by confirmatory analysis by mass spectrometry. Confirmatory assays are necessary because some immunoassays suffer from false positive results.

Mass spectrometry can also be used as a screening assay for unknown drugs and intoxicants. A computerized search algorithm is used to match unknown peaks from a chromatogram to library spectra. Comprehensive libraries have been assembled using electron impact ionization for GC/MS.

### ***Proteomics***

The role of mass spectrometry-based proteomics is an indispensable tool for molecular and cellular biology and for the emerging field of systems biology. These include the study of protein-protein interactions via affinity-based isolations on a small and proteome-wide scale, the mapping of numerous organelles, the concurrent description of the malaria parasite genome and proteome, and the generation of quantitative protein profiles from diverse species.

### ***Biomarkers***

Mass spectroscopy provides an ideal method for studying multiplexed biomarkers in a clinical setting. The use of mass spectrometry, particularly MALDI-TOF in conjunction with liquid chromatography is a critical tool for discovery of novel biomarkers.

### ***Opportunities in Mass Spectroscopy and Clinical Diagnostics***

Mass spectroscopy diagnostic testing has become important in many areas of clinical medicine including drug testing, forensic, hormone and vitamin D analysis. These tests have made the greatest market gains in the area of testing using mass spectroscopy; and drug tests still make up the largest segment of this market. TriMark expects the mass spectroscopy testing sector to maintain its leading market growth position for the forecast period to 2018, in part owing to advances in vitamin and hormone testing.

The \$1.5 billion mass spectroscopy market is a sub-set of the overall \$10 billion life science and pharma instrument market. Most industry experts believe that over the next few decades, the use of mass spectroscopy will grow rapidly, in the order of 10% to 15% per year, and will have a critical impact on the way clinical medicine is practiced. At a compound annual growth rate (CAGR) of more than 10%, this sector is forecast to grow to \$3.5 billion by the end of 2018.

Much of this growth will come in the area of clinical laboratory detection and management. In 2011, an estimated 1.5 million mass spectroscopy tests were performed at U.S. hospitals, clinics and laboratories, a figure that is projected to reach 2.5 million in 2018 at a CAGR of 10%. The clinical laboratory testing segment, while not the dominant sector of MS, will still experience high growth with the continued emergence of pharmacogenetic, gene profiling and companion diagnostic tests for use in patient stratification and therapy selection. These tests are also likely to command premium pricing because of their high clinical value. So it's not a volume driven situation, like most

clinical testing, but one that offers high value and high pricing in a premium market. The global market estimates for mass spectroscopy IVD tests were more than \$ [REDACTED] in [REDACTED], and is projected to increase to \$ [REDACTED] by [REDACTED], with a compound annual growth rate (CAGR) of [REDACTED]%. This high growth market is the underlying driver for the rising demand for new MS methods and instruments for clinical lab detection and identification.

### *Strategic Recommendations*

- Expansion of MS testing into the universe of [REDACTED] U.S. hospitals and [REDACTED] references labs.
- More emphasis should be placed on MS assays for early detection of drug abuse.
- Focus MS diagnostic development on the significant and largely untapped global market that exists for more effective tests to diagnose infectious disease.
- Collaborate with pharmaceutical development companies to develop MS companion tests and genetic tests for viral variants for clinical laboratory management.
- Move toward companion diagnostic tests with partners such as Pfizer, Merck, BMS, Astra Zeneca, Lilly, etc.

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