

Bioanalytical Testing Services Market Poised for Strong 9.2% CAGR Growth, States Persistence Market Research

Bioanalytical testing market driven by rising biologics, gene therapies, and strict regulations, with growing demand for integrated hybrid assay platforms.

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/EINPresswire.com/ -- The global [bioanalytical testing services market](https://www.persistencemarketresearch.com/samples/35586) is witnessing robust growth, with a projected increase from US\$5.6 billion in 2025 to US\$10.4 billion by 2032, reflecting a compound annual growth rate (CAGR) of 9.2% over the forecast period. This expansion is primarily driven by advancements in therapeutic modalities, increased adoption of stringent drug development guidelines, and growing demand for precision medicine and complex biologics. The bioanalytical testing landscape is evolving rapidly as new therapies emerge, requiring specialized testing solutions for novel drug formulations and gene therapies.



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Key Industry Highlights

North America is poised to maintain a leading position, commanding an estimated 48.2% share of the bioanalytical testing services market in 2025. This dominance is attributed to the rapid adoption of advanced bioanalytical technologies and the substantial presence of pharmaceutical and biopharmaceutical companies focusing on biologics and gene therapies.

Europe, on the other hand, is expected to emerge as the fastest-growing region, buoyed by harmonized regulatory guidelines, particularly the International Council for Harmonisation's (ICH) M10, and rising demand for integrated bioanalytical services across various stages of clinical trials.

The bioavailability test segment is projected to hold a dominant share of 35.8% in 2025, as it offers direct insights into drug absorption and systemic exposure, making it a crucial component in regulatory drug approval processes.

Pharmaceutical and biopharmaceutical companies, representing nearly 54.8% of the market share, remain the leading end-users of bioanalytical testing services. Their increasing reliance on specialized assays to evaluate complex therapeutics fuels the demand for these services.

In terms of industry movements, SGS launched a suite of specialized bioanalytical testing services in August 2024 in North America to support discovery and clinical trials, particularly for biologics and gene therapies.

Market Dynamics

Driver: Rising Biologics and Gene Therapies Push Specialized Testing Demand

The increasing prevalence of biologics and gene therapies is significantly driving the demand for bioanalytical testing services. Biologics such as monoclonal antibodies, bispecific antibodies, and fusion proteins require hybrid assay platforms that combine various techniques, including LC-MS (Liquid Chromatography-Mass Spectrometry) and ligand-binding assays, to assess pharmacokinetics and drug immunogenicity. Additionally, gene therapies, which are inherently complex and require extensive monitoring, further fuel the demand for specialized testing solutions. These therapies necessitate the use of high-sensitivity molecular techniques, such as qPCR (quantitative Polymerase Chain Reaction) and digital PCR, to track vector shedding, biodistribution, and immune responses.

Restraint: Complex Regulatory Requirements Hamper Lab Efficiency

While the bioanalytical testing services market continues to grow, it faces significant challenges due to increasingly complex regulatory frameworks. Bioanalytical labs must adhere to strict guidelines, including ICH M10, GLP (Good Laboratory Practice), and GCP (Good Clinical Practice), as well as country-specific requirements. Compliance demands substantial documentation, validated testing methods, and routine audits, which can hinder the efficiency of smaller labs, particularly when dealing with high-complexity or multi-site studies. Moreover, specialized labs handling Advanced Therapy Medicinal Products (ATMPs) or viral vectors must meet additional regulatory standards, such as BSL-2 or BSL-3 containment requirements, which complicate operations.

Opportunity: Specialized Outsourcing Firms Expand Bioanalytical Capabilities

The rise of specialized outsourcing firms presents a significant opportunity for the bioanalytical testing market. These firms enable pharmaceutical and biotechnology companies to access

cutting-edge technologies without the need for in-house infrastructure or expertise. By offering integrated bioanalytical solutions, including hybrid assay platforms, high-resolution mass spectrometry, and automated sample preparation systems, outsourcing firms are enabling faster and more efficient clinical trials. Furthermore, these companies facilitate the expansion of global trial operations by helping sponsors meet varying regional regulatory requirements. Notable players such as Syneos Health and Eurofins have developed extensive multi-site networks, enabling them to offer consistent and compliant bioanalytical services across multiple regions.

Category-wise Analysis

Test Insights

The market is segmented based on various types of tests, including ADME (Absorption, Distribution, Metabolism, Excretion), pharmacokinetics (PK), pharmacodynamics (PD), bioavailability, bioequivalence, biomarker testing, cell-based assays, and virology testing. Among these, bioavailability testing is expected to dominate the market, accounting for 35.8% of the share in 2025. Bioavailability testing is critical in understanding how a drug is absorbed into the body and its systemic exposure, both of which are key factors for drug approval and therapeutic efficacy.

Bioequivalence testing is also experiencing growth as it provides a cost-effective and time-efficient route for regulatory approval of generic drugs. By confirming that a generic product performs similarly to the brand-name drug, bioequivalence testing helps speed up the launch of generics into the market, offering an alternative to expensive and time-consuming clinical trials.

End-user Insights

The primary end-users of bioanalytical testing services include pharmaceutical and biopharmaceutical companies, contract development and manufacturing organizations (CDMOs), contract research organizations (CROs), and others. Pharmaceutical and biopharmaceutical companies dominate the market, contributing around 54.8% of the total share in 2025. These companies rely on bioanalytical data to support drug development processes, including preclinical and clinical testing, and require precise testing for complex biologics and gene therapies.

Contract Research Organizations (CROs) are also critical players in the market, providing bioanalytical testing services to pharma and biotech companies. CROs facilitate large-scale clinical trials and are responsible for ensuring that testing adheres to regulatory standards across different regions.

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Regional Insights

North America

North America is expected to maintain a dominant share in the global bioanalytical testing services market, with a forecasted market share of 48.2% in 2025. This is primarily due to the region's strong regulatory framework and the increasing prevalence of biologics and gene therapies. The FDA's finalization of the ICH M10 guidance in June 2024 has streamlined bioanalytical testing practices, promoting harmonization of standards across regions. Additionally, the U.S. market is seeing an uptick in gene and cell therapy programs, which are driving demand for integrated testing solutions.

Europe

Europe is the fastest-growing region in the bioanalytical testing services market, supported by harmonized regulations under ICH M10 and increasing investment in hybrid laboratories. The adoption of integrated testing platforms and novel assays for gene therapies is fueling market growth. Moreover, the European Medicines Agency's (EMA) updated guidance on Advanced Therapy Medicinal Products (ATMPs) and cell therapies is encouraging service providers to develop specialized bioanalytical services.

Asia Pacific

Asia Pacific is a diverse and evolving market, with key growth drivers in countries like China, Japan, India, and Singapore. The region is rapidly adopting advanced bioanalytical testing platforms, particularly in countries like Singapore, which serves as a hub for cell and gene therapy analytics. The growing demand for hybrid testing solutions, coupled with the region's cost-effective trial execution, is attracting significant investment from global CROs looking to expand their operations in Asia.

Competitive Landscape

The bioanalytical testing services market is characterized by the presence of several dominant players, with large-scale CROs leading the market. These companies offer end-to-end solutions that span all stages of drug development, from preclinical testing to clinical trials. Their extensive reach and ability to handle multinational trials make them the preferred choice for sponsors.

Key Players:

Thermo Fisher Scientific Inc.

Charles River Laboratories International

ICON Plc

Syneos Health

IQVIA Inc.
Pace Analytical Services LLC
Intertek Group Plc
SGS SA
Wuxi AppTec
Labcorp

In addition to these large players, mid-tier CROs are also making significant strides by focusing on niche services, such as immunogenicity testing and micro-volume workflows, which cater to the growing demand for specialized bioanalytical services.

Key Industry Developments

The bioanalytical testing market is evolving with several recent developments. In May 2025, Celerion launched an upgraded version of its Labnotes software, designed to improve data handling and analysis for sponsors. Meanwhile, Avance Biosciences opened a Next-Generation Sequencing (NGS) Center of Excellence in June 2025, aimed at enhancing its sequencing capabilities throughout the drug development process.

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Market Segmentation

By Molecule:

Small Molecule
Large Molecule

By Test:

ADME
Pharmacokinetics (PK)
Pharmacodynamics (PD)
Bioavailability
Bioequivalence
Biomarker Testing
Cell-based Assay
Virology Testing
Other Tests

By Workflow:

Sample Collection and Preparation

Method Development and Validation
Sample Analysis
Other Processes

By End-user:

Pharma and Biopharma Companies
CDMO
CRO
Others

By Region:

North America
Europe
East Asia
South Asia & Oceania
Latin America
Middle East & Africa

Future Outlook

The bioanalytical testing services market is poised for continued growth driven by the increasing complexity of drug development, particularly in biologics and gene therapies. With ongoing advancements in testing technologies, such as hybrid assay platforms and high-resolution mass spectrometry, the market is set to become more integrated and efficient. As regulatory guidelines evolve, the demand for specialized outsourcing services is expected to rise, creating new opportunities for companies to expand their offerings and cater to the needs of global drug development programs.

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