

# **United States Bioanalytical Testing Services Market By Molecule (Small Molecule, Large Molecule), By Test (ADME, Pharmacokinetics (PK), Pharmacodynamics (PD), Bioavailability, Bioequivalence, Biomarker Testing, Cell-based Assay, Virology Testing, Others), By Workflow (Sample Collection and Preparation, Method Development and Validation, Sample Analysis, Other Processes), By End User (Pharma & BioPharma Companies, CDMO, CRO, Others), By Region, Competition, Forecast & Opportunities, 2020-2030F**

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## **Abstracts**

### **Market Overview**

The United States Bioanalytical Testing Services Market was valued at USD 2.03 billion in 2024 and is projected to reach USD 3.49 billion by 2030, expanding at a CAGR of 9.41% during the forecast period. This market is witnessing strong growth due to the expanding pipeline of biologics and biosimilars and the rising number of clinical trials. As pharmaceutical and biotechnology companies increasingly shift from small-molecule drugs to complex biologics, there is heightened demand for specialized testing services, including pharmacokinetics (PK), pharmacodynamics (PD), and bioequivalence studies. Outsourcing bioanalytical services helps streamline development timelines and ensures regulatory compliance, particularly with stringent U.S. FDA requirements. The emergence of personalized medicine and targeted therapies further boosts the need for tailored testing methodologies and advanced analytical technologies. Innovations such

as high-resolution mass spectrometry, automated platforms, and LIMS are improving testing precision and scalability. Moreover, the proliferation of GLP and GCLP-compliant labs, combined with real-time analytics and data-driven decision-making, is enhancing efficiency and supporting market expansion.

## Key Market Drivers

### Increasing Demand for Biologics and Biosimilars

The growing demand for biologics and biosimilars is a significant catalyst in the U.S. bioanalytical testing services market. The development of monoclonal antibodies, vaccines, gene therapies, and cell-based treatments requires robust and highly sensitive analytical methods, including ligand-binding assays and immunogenicity testing. Unlike traditional small-molecule drugs, biologics necessitate extensive PK/PD evaluations and rigorous validation to ensure quality and regulatory compliance. The FDA's approval of 19 biosimilars in 2024 alone—including those for ustekinumab and denosumab—highlights the accelerating pace of biosimilar integration. With 63 FDA-approved biosimilars across 17 reference products to date, the industry's focus on therapeutic equivalence, efficacy, and safety continues to drive demand for comprehensive and advanced testing services.

## Key Market Challenges

### High Operational Costs and Capital Investment Requirements

High operational expenses and capital investment needs pose major challenges to the growth of the U.S. bioanalytical testing services market. Laboratories must invest in advanced instruments like mass spectrometers and chromatographs, which are not only expensive to acquire but also costly to maintain and calibrate. Ensuring compliance with regulatory standards such as those enforced by the FDA and EMA demands further financial commitments for audits, certifications, and documentation. Adhering to GLP and GMP guidelines increases operational complexity and overhead. Small and mid-sized laboratories often struggle with limited access to capital and may lack the infrastructure to compete with larger, established players. These financial barriers can restrict market entry, slow innovation, and hinder expansion efforts, especially for emerging service providers.

## Key Market Trends

## Rising Emphasis on Biomarker Development and Companion Diagnostics

Biomarker development and companion diagnostics are emerging as pivotal trends in the U.S. bioanalytical testing services market. Biomarkers are essential for diagnosing diseases, predicting treatment responses, and tailoring personalized therapies.

Companion diagnostics help identify patients most likely to benefit from specific drugs, thereby aligning treatment strategies with individual genetic profiles. In oncology, tests like FoundationOne Liquid CDx, which detects mutations in solid tumors, exemplify how diagnostics are driving precision medicine. Regulatory backing and funding initiatives from agencies such as the NIH—through programs like PAR-25-024—are promoting biomarker validation and adoption in clinical trials. These efforts underscore the strategic shift toward more personalized and targeted healthcare solutions, increasing demand for specialized bioanalytical services to support drug development pipelines.

## Key Market Players

Thermo Fisher Scientific, Inc.

ICON plc

Charles River Laboratories International, Inc.

Laboratory Corporation of America Holdings

IQVIA Inc.

Syneos Health

SGS SA

Intertek Group Plc

Pace Analytical Services, LLC

Medpace Holdings, Inc.

## Report Scope:

In this report, the United States Bioanalytical Testing Services Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

United States Bioanalytical Testing Services Market, By Molecule:

Small Molecule

Large Molecule

United States Bioanalytical Testing Services Market, By Test:

ADME

Pharmacokinetics (PK)

Pharmacodynamics (PD)

Bioavailability

Bioequivalence

Biomarker Testing

Cell-based Assay

Virology Testing

Others

United States Bioanalytical Testing Services Market, By Workflow:

Sample Collection and Preparation

Method Development and Validation

Sample Analysis

Other Processes

## United States Bioanalytical Testing Services Market, By End User:

Pharma & BioPharma Companies

CDMO

CRO

Others

## United States Bioanalytical Testing Services Market, By Region:

North-East

Mid-West

West

South

## Competitive Landscape

**Company Profiles:** Detailed analysis of the major companies present in the United States Bioanalytical Testing Services Market.

## Available Customizations:

United States Bioanalytical Testing Services Market report with the given market data, TechSci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

## Company Information

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