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Human Biospecimen Market - A Global and Regional Analysis: Focus on Specimen Type, Application, Procurement Type, End User, and Regional Analysis - Analysis and Forecast, 2025-2035

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Abstracts

Human biospecimens are biological materials such as tissues, blood, biofluids, and molecular derivatives collected from the human body for scientific and clinical investigation. They retain real-world disease characteristics and are essential for studying molecular pathways, validating diagnostics, and developing targeted therapies. With standardized collection, processing, and storage that preserve integrity and link clinical data, biospecimens enable accurate translational research and drive advancements in precision medicine.

Market Introduction

The global human biospecimen market is expected to witness significant growth, projected to reach $8,178.9 million by 2035, supported by the rising global burden of cancer, rare diseases, infectious diseases, and chronic conditions that require genomic and precision-based research. Human biospecimens, including tissues, plasma/serum, PBMCs, primary cells, and molecular derivatives such as DNA, RNA, and exosomes, now serve as mission-critical inputs for drug discovery, biomarker development, next-generation diagnostics, and translational medicine.

Market expansion has been driven by the shift toward high-quality, clinically annotated, and multi-omic-ready biospecimens, alongside advancements in pre-analytical standardization, biorepository automation, and digital sample-tracking platforms. Key developments such as ISO 20387 and CAP ISO 15189 accreditations across leading providers, and the launch of AI-enabled biospecimen data platforms, reflect increasing

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regulatory maturity and rising customer expectations for traceability, consent compliance, and reproducibility.

Strong momentum also stems from growing investments in national biobanks and population-genomics programs, including the U.K. Biobank and the U.S. All of Us Research Program, which collectively manage millions of biospecimens and enable pan-omics integration at scale. Pharmaceutical and biotechnology companies further accelerate demand as they expand pipelines in oncology, immunology, metabolic diseases, and rare genetic disorders, where deeply characterized patient samples are essential for target validation, companion diagnostics, and post-approval monitoring.

While North America and Europe currently lead in adoption due to mature biobanking networks and robust research funding, Asia-Pacific is rapidly emerging as a high-growth region with China holding the largest share and India projected to grow the fastest, driven by expanding clinical research ecosystems and access to large patient populations. Meanwhile, Latin America and the Middle East markets are increasingly focusing on biospecimen-linked precision-medicine initiatives, presenting new commercialization opportunities.

Despite strong progress, challenges persist, including pre-analytical variability, high-cost cryogenic infrastructure, cross-border data-transfer barriers, and limited access to high-quality samples in lower-resource settings. However, increased collaboration among industry, academia, and government bodies is steadily overcoming these gaps and enabling larger, more diverse, and ethically governed specimen networks.

Leading companies such as BioIVT, LLC, Crown Bioscience, Precision Medicine Group, LLC, Boca Biolistics, ABS Bio, and Reprocell are strengthening competitive positioning through global sourcing expansion, AI-powered clinical-data integration, and disease-specific cohort development. As precision medicine, multi-omics research, and advanced therapies accelerate, the human biospecimen market is positioned as a core enabler of future biomedical innovation, unlocking faster clinical translation and improved patient outcomes worldwide.

Industrial Impact

The human biospecimen industry is becoming an essential backbone of precision medicine by enabling access to high-quality, clinically contextualized biological materials needed for biomarker discovery, clinical trial enrollment, and diagnostic development. With cancer, metabolic disorders, CNS diseases, and rare diseases

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driving global R&D, demand for deeply annotated tissues, matched biofluids, and viable primary cells is rising sharply across pharmaceutical, biotech, and diagnostic segments.

Established providers such as Crown Bioscience, BioIVT LLC, Precision Medicine Group, LLC, and Grifols, S.A. are reshaping research workflows by delivering multi-matrix, longitudinal, and genomics-ready biospecimens with robust chain-of-custody documentation. These offerings reduce experimental variability, streamline assay validation, and accelerate drug development decision-making, particularly in oncology, where >55% of clinical trials are now biomarker-guided.

The market is also driving improvements in how samples are collected, processed, and documented, with more companies following formal quality and regulatory standards such as CAP ISO 15189 and ISO 20387. This ensures that biospecimens are ethically sourced, high-quality, and suitable for use in diagnostics, clinical research, and advanced therapies. Strategic collaborations between commercial biobanks, academic medical centers, and government-funded population-genomics programs are expanding access to diverse patient cohorts, including high-value oncology and rare-disease samples. These partnerships strengthen global biospecimen pipelines, reduce access bottlenecks, and support decentralized CGT and translational-research ecosystems.

Overall, the human biospecimen market has been transforming the life-science tools landscape, making reliable, data-rich human samples a core determinant of therapeutic success. By deepening integration with regulated workflows and high-impact discovery platforms, the industry is directly improving clinical-development efficiency, advancing personalized-medicine strategies, and accelerating the translation of scientific innovation into real-world patient benefit.

Market Segmentation:

Segmentation 1: By Specimen Type

- Tissue Specimens
- Biofluids
- Cellular Material
- Nucleic Acids

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Others

Tissue specimens remain the leading segment by specimen type in the global human biospecimen market, holding 41.30% market share in 2024, with a projected CAGR of 7.48% during 2025–2035, driven by their essential role in oncology research, precision medicine, and the growth of digital pathology and spatial omics. High-value FFPE blocks, fresh-frozen tissues, and resection specimens continue to support biomarker discovery, companion diagnostics development, and tumor–normal sequencing, making tissues the highest revenue-generating category. Biofluids, including plasma, serum, PBMCs, and urine, are growing at a higher CAGR, supported by the rise of liquid biopsy testing, ctDNA-based diagnostics, and immuno-oncology programs. The growing preference for minimally invasive sampling and longitudinal patient monitoring is expected to strengthen the future contribution of biofluid-based biospecimens to market growth.

Segmentation 2: By Application

Biomedical Research

Diagnostics

Therapeutic Development

Clinical Trials

Based on application, the global human biospecimen market was led by the biomedical research segment, which accounted for 45.00% share in 2024. This dominance has been driven by sustained demand for high-quality tissues, biofluids, and primary cells across discovery biology, translational programs, and biomarker development. The growing adoption of multi-omics platforms, including genomics, proteomics, metabolomics, and spatial biology, further strengthens biomedical research as the primary consumer of annotated biospecimens.

Diagnostics and clinical development applications are expanding rapidly as liquid biopsy testing, CDx-linked drug approvals, and regulated assay validation increase globally. Biopharma sponsors rely on deeply characterized human samples for patient stratification, analytical performance evaluation, and real-world evidence generation. As

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precision-medicine adoption accelerates, biospecimen utilization in diagnostics, immuno-oncology, neurology, and rare-disease studies is expected to drive strong future growth and enhance this segment's contribution to overall market revenue through 2035.

Segmentation 3: By Procurement Type

Prospective Collection (On-Demand Collection)

Retrospective Samples

Based on procurement type, the global human biospecimen market was led by retrospective samples, which held a 55.00% share in 2024, supported by vast existing repositories of FFPE blocks, frozen tissues, plasma/serum, PBMCs, and other archived biofluids stored across hospital biobanks and national research networks. These samples offer rapid accessibility, high batch volumes, and coverage across multiple disease cohorts, including oncology, metabolic disorders, and infectious diseases, making them the primary source for discovery biology, translational studies, and early diagnostic development.

Prospective (on-demand) collections command a smaller share today but represent the fastest-growing segment. Their growth has been driven by precision research requirements, including strict inclusion/exclusion criteria, genetic profiling, fresh tissue acquisition, pediatric rare-disease sampling, and longitudinal collections linked with real-world clinical data. As biomarker-guided trials, multi-omics studies, and precision-medicine pipelines scale, the contribution of prospective collections is expected to expand significantly through 2035.

Segmentation 4: By End User

Pharmaceutical and Biotechnology Companies

Contract Research Organizations (CROs)

Academic and Research Institutes

Hospitals and Biobanks

Diagnostic Laboratories

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Government and Non-Profit Organizations

Based on end user, the global human biospecimen market was led by pharmaceutical and biotechnology companies, which held a 48.00% share in 2024, as they represent the largest and most consistent consumers of well-annotated human tissues, biofluids, and cellular materials across the drug development life cycle. These organizations drive premium-value demand for disease-specific cohorts, multi-matrix matched samples, and regulatory-ready biospecimens that support target discovery, translational programs, biomarker validation, companion diagnostic development, and clinical progression.

Segmentation 5: By Region

North America

U.S.

Canada

Europe

Germany

U.K.

France

Italy

Spain

Rest-of-Europe

Asia-Pacific

Japan

India

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China

Australia

South Korea

Rest-of-Asia-Pacific

Rest-of-the-World

The human biospecimen market in the Asia-Pacific region is expanding. China accounts for the highest market share, driven by large population size, high cancer and metabolic disease burden, strong investment in biobank infrastructure, and rapid growth in precision-medicine and multi-omics programs. India is the fastest-growing market, supported by expanding clinical-trial activity, increasing availability of surgical and pathology samples, and improving digital-health infrastructure that enables scalable sourcing from diverse patient cohorts.

Japan and South Korea contribute high-quality, deeply annotated biospecimens through advanced national biobank networks and genomics initiatives. Australia offers strong translational research capabilities and procedure-rich clinical environments, while Singapore and Malaysia serve as data-linked logistics hubs supporting global biospecimen exchange. Southeast Asian markets such as Indonesia, Vietnam, and the Philippines are gradually expanding but remain constrained by infrastructure, regulatory variability, and cold-chain limitations.

Collectively, APAC offers unmatched scale, disease diversity, and multi-ethnic representation, making it a priority region for globally sourced biospecimens supporting oncology, metabolic disorders, neurology, and rare diseases research.

Recent Developments in the Human Biospecimen Market

In October 2025, BioIVT acquired Spain-based BeCytes Biotechnologies to strengthen its European biobanking footprint and expand access to ethically sourced human biospecimens supporting new approach methodologies (NAMs).

In February 2025, Crown Bioscience merged with Indivumed Services,

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combining their biospecimen and multi-omics platforms to enhance oncology drug discovery through integrated human biospecimen solutions.

In June 2025, iProcess Global Research partnered with ViewsML to integrate AI-powered virtual IHC biomarker testing, enhancing biospecimen-based digital pathology and tissue-sparing biomarker analysis for research and diagnostics.

In September 2025, ABS Bio earned ISO 20387 accreditation for its biospecimen procurement and biobanking operations, reinforcing its commitment to high-quality, ethically sourced human biospecimens and global biorepository standards.

In August 2025, Logical Biological partnered with Bcell Design to develop engineered disease state plasma materials replicating native human biospecimens, ensuring sustainable and high-performance alternatives for diagnostic and research applications.

In January 2025, Reprocell launched ReproRegistry, a volunteer registry connecting individuals with healthy or diseased skin for research, enabling human skin sample procurement for dermatology and drug discovery.

In September 2024, Discovery Life Sciences integrated Lunaphore's COMET platform to expand multiplexed spatial biology capabilities for clinical biospecimen analysis.

Demand - Drivers, Challenges, and Opportunities

Market Demand Drivers: Rising Adoption of Annotated Human Biospecimens

The shift toward precision medicine is significantly increasing demand for high-quality, clinically annotated human biospecimens that accurately reflect real-world disease biology. Pharmaceutical and biotechnology companies now depend on tumor–normal matched tissues, ctDNA-ready plasma, sequencing-grade nucleic acids, and disease-specific immune cell subsets to enable biomarker-driven drug development, stratified clinical trial enrollment, and companion diagnostic validation. Oncology has been at the forefront of this transformation, with biomarker-guided trials rising from roughly 15% in 2000 to over 55% today, and more than 60 FDA-approved therapies now linked to a validated CDx assay.

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Beyond oncology, rare-disease research has amplified the need for deeply characterized, patient-matched biospecimens, including primary cells, fibroblasts, neuromuscular and pediatric tissues, and blood samples from small, genetically defined cohorts. National genomic-testing programs such as NHS England's ctDNA cancer screening initiative, projected to benefit around 15,000 patients annually, further highlight the growing link between precision healthcare delivery and robust biospecimen supply chains. These advancements require rigorous pre-analytics, longitudinal clinical annotation, and reliable traceability frameworks to ensure consistent data quality across multi-omics applications.

As pharmaceutical sponsors continue to prioritize targeted therapy programs and reduce late-stage clinical failures, access to clinically rich, standardized biospecimens has become a strategic necessity. This reliance is expected to intensify, making annotated human biospecimens a central enabler of next-generation drug discovery, translational science, and regulatory decision-making.

Market Challenges: Pre-Analytical Variability and Biospecimen Quality Gaps

Pre-analytical variability remains one of the most critical restraints in the human biospecimen market because even minor deviations during collection, processing, transport, or storage can cause irreversible molecular degradation. Differences in handling timelines, tube types, anticoagulants, centrifugation parameters, freeze–thaw cycles, and storage temperatures (?20°C vs. ?80°C) significantly alter DNA, RNA, protein, and metabolite profiles, directly impacting suitability for NGS, proteomics, metabolomics, and spatial omics. Large-scale quality assessments such as SPIDIA-RNA have demonstrated that fewer than half of participating laboratories consistently meet RNA integrity requirements, and up to 28% show multiple parameters "out of control," highlighting widespread inconsistency across the market.

Compounding this issue is inadequate metadata reporting. Many archived samples lack essential pre-analytical details such as time-to-processing, hemolysis indices, and freeze–thaw history, making them unusable for regulatory-aligned biomarker research or multi-omics studies requiring high sensitivity and reproducibility. As a result, significant portions of legacy biobank inventory, particularly older, poorly documented collections, cannot support precision-medicine applications.

To remain competitive, biospecimen providers must now adopt SPREC-based documentation, harmonized SOPs, and stringent, real-time quality monitoring

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throughout the biospecimen lifecycle. This push toward standardization increases operational costs and raises capability thresholds, favoring large-scale and quality-mature vendors while limiting participation from small, unstandardized suppliers.

Market Opportunities: Commercialization of Disease-Specific Rare-Disease Cohorts

With more than 10,000 known rare and ultra-rare diseases and very few approved therapies, there is a critical unmet need for high-quality, disease-matched biospecimens to support diagnostic innovation, biomarker discovery, and therapeutic development. Many rare conditions lack established sample repositories, and patient populations are geographically dispersed, making access to relevant cohorts extremely limited. Pharmaceutical sponsors increasingly require specialized biospecimens such as fibroblasts, neuromuscular and pediatric tissues, CSF samples, and matched longitudinal aliquots to characterize disease progression and validate genetic targets, particularly in metabolic, neuromuscular, and inherited disorders.

Regulatory momentum further reinforces this opportunity. Rising orphan-drug designations and accelerated approval pathways have intensified R&D focus on uncommon indications, but the scarcity of reliable biospecimens remains a major bottleneck. National initiatives like the NIH Rare Disease Cures Accelerator highlight the demand for multi-timepoint datasets and deeply annotated samples capable of linking biological changes with clinical outcomes.

This creates a strong commercial opportunity for specialized biospecimen providers that can establish disease-specific registries, deploy targeted recruitment strategies, and build consent-ready, data-rich repositories that include phenotypic profiles, genomic data, and follow-up timelines. As rare-disease pipelines continue expanding, the ability to deliver these high-value materials will become a key differentiator, positioning capable vendors as essential partners in accelerating precision therapy development for the underserved patient population.

Market Trends: Increasing Product Launches and Regulatory Approvals

Product innovation and regulatory alignment are reshaping the human biospecimen market from a transactional sample-supply model into a structured ecosystem of higher-value, compliance-driven offerings. Vendors are accelerating launches of specialty products such as indication-specific tissue panels, multi-matrix biospecimen kits, disease-state PBMCs, GMP-grade cell materials, and donor-driven registries like dermatology-focused ReproRegistry. Digital enablement is also advancing rapidly, with

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AI-powered data platforms now integrating biospecimen metadata, clinical outcomes, and genomic profiles to improve traceability, sample selection, and research relevance.

Simultaneously, more providers are obtaining accreditations such as CAP ISO 15189:2022 and ISO 20387, signaling a move toward standardized pre-analytics, validated workflows, and regulatory-compatible biorepository operations. This evolution is enabling biospecimens to support regulated workflows, including diagnostic validation, companion-diagnostic alignment, and clinical trial execution, expanding demand across pharma, biotech, and IVD developers.

However, this shift is also raising the competitive bar; high-quality documentation, chain-of-custody integrity, and compliance infrastructure are now baseline requirements rather than value-added differentiators. Scale players and specialized platforms with strong quality governance stand to benefit most, while traditional suppliers without regulatory maturity risk being limited to lower-margin, commoditized market segments.

How can this report add value to an organization?

Product/Innovation Strategy: The report offers in-depth insights into the latest technological advancements in human biospecimens, enabling organizations to drive innovation and develop cutting-edge products tailored to market needs.

Growth/Marketing Strategy: By providing comprehensive market analysis and identifying key growth opportunities, the report equips organizations with the knowledge to craft targeted marketing strategies and expand their market presence effectively.

Competitive Strategy: The report includes a thorough competitive landscape analysis, helping organizations understand their competitors' strengths and weaknesses and allowing them to strategize effectively to gain a competitive edge in the market.

Regulatory and Compliance Strategy: It provides updates on evolving regulatory frameworks, approvals, and industry guidelines, ensuring organizations stay compliant and accelerate market entry for new human biospecimens.

Investment and Business Expansion Strategy: By analyzing market trends, funding patterns, and partnership opportunities, the report assists organizations in making informed investment decisions and identifying potential M&A opportunities for business growth.

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Methodology

Key Considerations and Assumptions in Market Engineering and Validation

The base year considered for the calculation of the market size is 2024. A historical year analysis has been done for the period FY2023. The market size has been estimated for FY2024 and projected for the period FY2025-FY2035.

The scope of this report has been carefully derived from extensive interactions with experts and stakeholders across leading biospecimen companies, clinical research institutions, and biobanking networks worldwide. This report provides a comprehensive market analysis of the human biospecimen ecosystem, covering specimen types, procurement models, end-user demand dynamics, regulatory and ethical frameworks, and emerging technology integrations such as multi-omics data enablement and digitalized biobanking operations.

Revenues of the companies have been referenced from their annual reports for FY2023 and FY2024. For private companies, revenues have been estimated based on factors such as inputs obtained from primary research, funding history, market collaborations, and operational history.

The market has been mapped based on the available human biospecimen products. All the key companies with significant offerings in this field have been considered and profiled in this report.

Primary Research

The primary sources involve industry experts in human biospecimen, including the market players offering products and services. Resources such as CEOs, vice presidents, marketing directors, and technology and innovation directors have been interviewed to obtain and verify both qualitative and quantitative aspects of this research study.

The key data points taken from the primary sources include:

Validation and triangulation of all the numbers and graphs

Validation of the report’s segmentation and key qualitative findings

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- Understanding the competitive landscape and business model
- Current and proposed production values of a product by market players
- Validation of the numbers of the different segments of the market in focus
- Percentage split of individual markets for regional analysis

Secondary Research

Open Sources

- Certified publications, articles from recognized authors, white papers, directories, and major databases, among others
- Annual reports, SEC filings, and investors' presentations of the leading market players
- Company websites and a detailed study of their product portfolio
- Gold standard magazines, journals, white papers, press releases, and news articles
- Paid databases

The key data points taken from the secondary sources include:

- Segmentations and percentage shares
- Data for market value
- Key industry trends of the top players in the market
- Qualitative insights into various aspects of the market, key trends, and emerging areas of innovation

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Quantitative data for mathematical and statistical calculations

Key Market Players and Competition Synopsis

Profiled companies have been selected based on primary insights, portfolio coverage, regulatory accreditations, and global biospecimen sourcing capabilities.

Established providers such as Crown Bioscience, Grifols S.A., BioIVT LLC, and Precision Medicine Group, LLC hold strong market positions with large, ethically sourced biospecimen inventories, CAP/ISO-certified biobanking operations, and long-standing partnerships with pharmaceutical, biotechnology, and diagnostics companies. Their expanding multi-omic-ready sample collections and data-rich offerings support advanced translational and precision-medicine research.

Emerging players, including Logical Biological and Labtoo, are gaining traction through flexible procurement models, disease-specific sample solutions, and digital sourcing platforms that simplify researchers' access to global biospecimens, especially within Europe and Asia-Pacific.

Together, these companies are strengthening global biospecimen supply chains, enhancing sample diversity, and improving traceability and regulatory compliance, driving the market toward higher-quality, clinically annotated resources that support drug discovery and diagnostic development.

Some prominent names established in this market are:

BioIVT LLC.

Crown Bioscience

Precision Medicine Group, LLC

Grifols, S.A.

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