

Global Genomic Reference Materials and Controls Systems Market: Focus on Product Type, Application, End User, and Country-Level Analysis - Analysis and Forecast, 2025-2035

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Abstracts

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This report will be delivered in 7-10 working days. Introduction to Genomic Reference Materials and Controls Systems Market

Genomic reference materials and control systems are standardized biological samples used to ensure the accuracy, precision, and reliability of genomic testing. These materials help calibrate and validate laboratory assays, providing consistent benchmarks for performance. They are crucial in quality control for DNA sequencing, PCR, and other molecular diagnostic technologies.

The global genomic reference materials and control systems market is set to experience substantial growth between 2024 and 2035, driven by innovations in genomic technologies, the rise of precision medicine, and increasing demand for quality control in molecular diagnostics. The need for reliable reference materials in clinical diagnostics and molecular assay validation will be a major market driver in 2024, particularly to ensure the accuracy of next-generation sequencing (NGS) and polymerase chain reaction (PCR) tests. The market will expand as hospitals, diagnostic labs, pharmaceutical companies, and research institutions increasingly utilize genomic reference materials. The growing regulatory focus on standardized genomic testing protocols will further fuel this demand. By 2035, advancements in synthetic and whole-genome reference materials will support new applications, including gene therapy, CRISPR-based diagnostics, and personalized medicine. Additionally, developments in

digital PCR, single-cell genomics, and liquid biopsy assays, along with the integration of AI-driven bioinformatics, will propel the growth of the market.

The growing application of genomic testing in precision medicine is a key driver for the Genomic Reference Materials and Control Systems Market. Advances in cancer genomics, rare disease diagnostics, and pharmacogenomics are increasing the need for high-quality reference materials to ensure accuracy and reproducibility in tests. In addition, government initiatives such as the U.S.'s All of Us Research Program and Genomics England are pushing for standardized genomic reference materials, further fueling market demand. For instance, established by the UK Department of Health and Social Care, Genomics England has successfully completed the 100,000 Genomes Project, sequencing genomes from NHS patients with rare diseases and cancers. In 2024, they launched a pioneering scheme to screen 100,000 newborns for over 200 genetic conditions using whole genome sequencing. This large-scale genomic data collection underscores the demand for high-quality reference materials to support accurate diagnostics and research.

Moreover, pharmaceutical companies are also incorporating genomic biomarkers into drug development, which necessitates rigorous quality control measures. The rise of liquid biopsy and minimal residual disease (MRD) testing, particularly in circulating tumor DNA (ctDNA) and cell-free DNA (cfDNA) assays, further drives the need for validated genomic reference standards. As precision medicine continues to expand, so too will the demand for robust genomic control systems to meet these evolving needs.

A significant growth opportunity in the Genomic Reference Materials and Control Systems Market lies in their expanding use in liquid biopsy and minimal residual disease (MRD) testing. As the oncology field shifts towards non-invasive cancer diagnostics, the demand for high-quality circulating tumor DNA (ctDNA) and cell-free DNA (cfDNA) reference materials is increasing. Liquid biopsies enable early cancer detection and treatment monitoring, but their accuracy relies heavily on well-characterized reference standards for assay validation. Similarly, MRD testing for hematological malignancies requires highly sensitive genomic controls to ensure reliable results. Moreover, the growing adoption of AI-powered bioinformatics solutions for genomic data interpretation further strengthens this opportunity, making precise, high-quality reference materials crucial for the advancement of next-generation diagnostics.

However, the high cost and limited availability of high-quality reference materials is a major challenge for market growth. Producing accurate and reliable genomic controls

requires extensive validation, quality testing, and regulatory approvals, making the development process expensive. Many laboratories and small research institutions struggle with affordability and accessibility, especially in emerging economies where funding for genomics research is limited. Additionally, sourcing high-quality whole-genome reference materials is challenging due to biological variability and standardization issues. Moreover, the regulatory landscape for genomic reference materials remains complex, with varying compliance requirements across regions, further hindering market expansion. To address this, companies are investing in synthetic and digital reference materials that offer cost-effective and scalable alternatives.

Key players in the Genomic Reference Materials and Control Systems market are focusing on advancing their product offerings, expanding applications, and collaborating with research institutions and pharmaceutical companies to meet the rising demand. For instance, in 2023, Horizon launched its SeraCare Genomic Reference Materials to support next-generation sequencing (NGS) and other molecular diagnostics platforms. These products are used for assay validation and to ensure accuracy in ctDNA and cfDNA assays, which are essential for liquid biopsy applications. Similarly, in 2023, Bio-Rad introduced its AccuPlex SARS-CoV-2 reference materials and other genomic reference standards for viral and genetic analysis. These products ensure consistency in test results, especially as liquid biopsy and precision oncology testing are gaining prominence. The Droplet Digital PCR technology plays a vital role in the MRD testing of hematological malignancies. Such activities are expected to impel the market growth over a forecast period.

Key players in the market are LGC Group, Thermo Fisher Scientific Inc., Microbiologics, PerkinElmer Inc. F. Hoffmann-La Roche Ltd, Merck KGaA, QIAGEN N.V, Promega Corporation, Bio-Rad Laboratories, Inc., Illumina, Inc., etc.

Market Segmentation:

Segmentation 1: by Product

- Reference Materials

 - DNA-based reference materials

 - RNA-based reference materials

Whole genome reference materials

Synthetic reference materials

Cell line-based reference materials

Control Systems

Positive Controls

Negative Controls

Others

Reference Materials to Lead the Global Genomic Reference Materials and Control Systems Market (by Product)

Reference materials are expected to dominate the Genomic Reference Materials and Controls Systems Market due to their critical role in molecular diagnostics, precision medicine, and NGS assay validation. These materials provide high stability, reproducibility, and accuracy, making them essential for clinical and research applications. As genomic sequencing technologies advance, the demand for well-characterized DNA reference materials continues to grow. These materials help laboratories validate sequencing assays, assess accuracy, and ensure quality control in clinical genomics, oncology, and rare disease diagnostics. Additionally, regulatory agencies such as the FDA and EMA emphasize the need for standardized reference materials to improve diagnostic reliability. The growing adoption of liquid biopsy assays in oncology, which rely on circulating tumor DNA (ctDNA) detection, further strengthens the demand for high-quality DNA-based reference materials. With increasing investments in genomic research and precision medicine, this sub-segment is expected to experience sustained growth over the forecast period.

Segmentation 2: by Application

Clinical Diagnostics

Clinical Research

Molecular Assay Validation

Clinical Diagnostics to Lead the Global Genomic Reference Materials and Control Systems Market (by Application)

The clinical diagnostics segment is the largest application for genomic reference materials, driven by the growing role of genomics in diagnosing cancer, infectious diseases, and genetic disorders. With next-generation sequencing (NGS) and PCR-based diagnostics becoming standard in clinical settings, the demand for high-quality genomic reference materials is on the rise. Oncology diagnostics, in particular, is a major driver, as liquid biopsy and circulating tumor DNA (ctDNA) assays gain popularity for early cancer detection and treatment monitoring. Additionally, pharmacogenomics, which customizes drug therapies based on an individual's genetic makeup, relies heavily on validated genomic reference materials. Governments and regulatory bodies worldwide are heavily investing in genomic-driven healthcare initiatives. As precision medicine continues to expand, the need for reliable reference materials in clinical diagnostics will grow, ensuring accuracy, reproducibility, and regulatory compliance.

Segmentation 3: by End User

Hospitals and Diagnostic Laboratories

Research and Academic Institutions

Pharmaceutical and Biotechnology Companies

Contract Research Organizations (CROs)

Pharmaceutical and Biotechnology Companies to Lead the Global Genomic Reference Materials and Control Systems Market (by End User)

Pharmaceutical and biotechnology companies are the primary end-users of genomic reference materials, utilizing them extensively in drug development, biomarker validation, and genomic quality control. These companies depend on reference materials to standardize genomic assays, ensuring that targeted therapies and personalized medicine approaches are based on accurate genetic data. As precision medicine continues to evolve, pharmaceutical firms are incorporating genomic

biomarkers into clinical trials to stratify patient populations and enhance drug efficacy. The increasing use of gene editing technologies like CRISPR in drug development has also amplified the need for reference standards to verify genetic modifications. Furthermore, regulatory bodies such as the FDA and EMA require the use of quality-controlled genomic materials in clinical trials, further driving demand in this sector.

Segmentation 4: by Region

North America

Europe

Asia-Pacific

Latin America

Rest-of-the-World

North America to Lead the Global Genomic Reference Materials and Control Systems Market (by Region)

North America is expected to maintain its dominance in the Genomic Reference Materials and Controls Systems Market throughout the forecast period due to several key factors. The U.S. and Canada are home to leading research institutions, biotech companies, and genomic testing firms that drive innovation in the sector. Organizations such as the FDA, CDC, and NIH actively promote the standardization of genomic reference materials, ensuring their widespread adoption across clinical and research applications. The rising demand for precision medicine, particularly in oncology, rare disease diagnostics, and pharmacogenomics, is further fueling the need for high-quality control systems. For example, the U.S. National Cancer Institute's Cancer Moonshot initiative aims to accelerate cancer research and has increased the need for robust genomic reference materials. Additionally, the U.S. is home to top biotech firms like Illumina, Thermo Fisher Scientific, and Horizon Discovery, which are advancing NGS and PCR-based technologies, driving demand for genomic reference materials in clinical diagnostics and molecular assays. As these companies continue to innovate, the North American market for genomic reference materials and controls is poised for sustained growth.

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