

Gene Fusion Testing Market – Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented by Category (Research, Diagnostic), by Technology (Next-Generation Sequencing (NGS), Fluorescence In-Situ Hybridization (FISH), Polymerase Chain Reaction (PCR), Immunohistochemistry (IHC)), by Indication (Solid Tumors, Hematological Malignancies), by End User (Pharmaceutical and Biotechnology Companies, Hospitals and Diagnostic Laboratories, Academic and Research Centers), by region, and Competition

<https://marketpublishers.com/r/GB65A4D9D213EN.html>

Date: October 2023

Pages: 177

Price: US\$ 4,900.00 (Single User License)

ID: GB65A4D9D213EN

Abstracts

Global Gene Fusion Testing Market has valued at USD 244.30 million in 2022 and is anticipated to witness a robust growth in the forecast period with a CAGR of 10.51% through 2028. Gene fusion, also known as gene translocation or chromosomal translocation, is a genetic event that occurs when two separate genes from different regions of the genome become abnormally connected or fused together. This fusion can result in the creation of a hybrid gene, also known as a chimeric gene, which combines portions of both original genes. Gene fusion events can have significant implications for an organism's health, particularly when they occur in human cells and are associated with diseases, such as cancer. Gene fusion occurs when there is a rearrangement of genetic material, often through a process called chromosomal translocation. In chromosomal translocation, a piece of one chromosome breaks off and attaches to another chromosome, leading to the fusion of genes located on these chromosomes.

Identifying specific gene fusion events is of great diagnostic and therapeutic relevance, particularly in cancer. Gene fusion testing is used to detect these events and guide treatment decisions. In some cases, targeted therapies have been developed to inhibit the function of abnormal chimeric proteins. The development and adoption of targeted therapies for cancer treatment were driving the need for precise molecular profiling of tumors, including the detection of gene fusions. These therapies often rely on the identification of specific genetic alterations as therapeutic targets. Ongoing advancements in genomic technologies, particularly next-generation sequencing (NGS) and high-throughput molecular assays, were making gene fusion testing more accessible, cost-effective, and efficient. Research efforts were continually uncovering new gene fusion events and their relevance in various diseases, including cancer. This research drove interest in developing and commercializing gene fusion tests.

Key Market Drivers

Advancements in Genomic Technologies

Next-Generation Sequencing (NGS) technologies, such as Illumina and Ion Torrent, enable rapid and cost-effective sequencing of DNA and RNA. They have transformed genomics research and clinical diagnostics. NGS has been adapted for single-cell analysis, allowing researchers to study individual cells' genomes, transcriptomes, and epigenomes. This technology has broad applications in understanding cell heterogeneity and disease mechanisms. Technologies like Pacific Biosciences (PacBio) and Oxford Nanopore sequencing offer long-read sequencing, providing a more comprehensive view of the genome. They are particularly useful for detecting structural variants and complex genomic regions. The CRISPR-Cas9 system has revolutionized genome editing. It allows for precise and targeted modification of genes, making it a powerful tool for functional genomics, gene therapy, and genetic engineering. Advances in technologies like DNA methylation sequencing (bisulfite sequencing) and chromatin immunoprecipitation sequencing (ChIP-seq) have deepened our understanding of epigenetic modifications and their roles in gene regulation and disease. Techniques like single-molecule fluorescence in situ hybridization (smFISH) and single-molecule real-time (SMRT) sequencing offer insights into molecular processes at the individual molecule level.

Metagenomic sequencing allows for the study of microbial communities and their genetic diversity. This has applications in environmental microbiology, microbiome research, and infectious disease diagnostics. High-throughput methods, such as RNA-seq and CRISPR screens, have enabled large-scale investigations of gene function,

gene expression regulation, and protein interactions. Liquid biopsy techniques, including circulating tumor DNA (ctDNA) sequencing, have emerged for non-invasive cancer diagnosis and monitoring. They detect tumor-specific genetic alterations in blood samples. Technologies like Hi-C and 3C-based methods have provided insights into the three-dimensional organization of the genome, revealing how genes and regulatory elements interact in space. AI and machine learning are increasingly used for genomic data analysis. They help identify patterns, predict disease risk, and assist in drug discovery and personalized medicine. Advances in prenatal testing, such as non-invasive prenatal testing (NIPT), and neonatal genomic screening are improving the early detection of genetic disorders. The development of sophisticated bioinformatics tools and algorithms has become essential for managing, analyzing, and interpreting the vast amounts of genomic data generated by these technologies. This factor will help in the development of Global Gene Fusion Testing Market.

Increasing Utilization of Gene Fusion Testing in the Development of Targeted Therapies

Gene fusion testing helps identify specific genetic alterations, including fusion events, that drive the development and progression of diseases, especially cancer. These fusion events often create unique and targetable proteins or protein domains. Targeted therapies can be designed to inhibit these proteins, disrupting the disease's underlying mechanisms. Gene fusion testing allows for the stratification of patients based on their genetic profiles. Patients who harbor specific fusion events that are targetable by a particular therapy can be selected for treatment. This personalized approach maximizes the chances of treatment success while minimizing side effects for patients who are unlikely to benefit from the therapy. Pharmaceutical companies use gene fusion testing data to inform the development of targeted therapies. Once a fusion event is identified as a potential drug target, researchers can design and test therapeutic agents, such as small molecule inhibitors or monoclonal antibodies, to specifically target the fusion protein. Gene fusion testing plays a pivotal role in patient selection for clinical trials of targeted therapies. These trials are designed to assess the safety and efficacy of new drugs in specific patient populations. Patients with the relevant fusion event are enrolled, ensuring that the therapy is tested on those most likely to benefit.

In some cases, gene fusion testing is used to develop companion diagnostic tests. These tests are designed to identify patients who are most likely to respond to a specific targeted therapy. Regulatory agencies, such as the U.S. Food and Drug Administration (FDA), often require companion diagnostics for certain targeted therapies. Gene fusion testing is also used to monitor a patient's response to targeted therapy. Changes in the fusion event or its associated markers can provide insights into treatment efficacy. If a

therapy is not working, adjustments can be made quickly to explore alternative treatment options. Gene fusion testing can help researchers understand mechanisms of drug resistance. As patients may develop resistance to targeted therapies over time, continued testing and analysis of fusion events can guide the development of next-generation therapies that overcome resistance mechanisms. Gene fusion testing can reveal rare or previously undruggable targets. Even in cases where fusion events are relatively rare, they can be highly relevant for the small subset of patients who carry them. Identifying these targets opens new avenues for drug development. Targeted therapies developed through gene fusion testing tend to have fewer side effects compared to traditional chemotherapy because they selectively target cancer cells while sparing healthy ones. By tailoring treatment based on gene fusion testing results, patients have a higher chance of responding positively to therapy, leading to improved clinical outcomes and potentially longer survival rates. This factor will pace up the demand of Global Gene Fusion Testing Market.

Rising Incidence of Cancer

The global population is growing, and as people live longer, the risk of developing cancer increases with age. Aging is a significant risk factor for many types of cancer. Unhealthy lifestyle choices, such as smoking, excessive alcohol consumption, poor diet, lack of physical activity, and exposure to environmental carcinogens, contribute to the development of many cancers. The increasing prevalence of obesity is linked to a higher risk of several cancers, including breast, colorectal, and endometrial cancer. Environmental factors, including air pollution, exposure to hazardous chemicals, and radiation, can contribute to cancer risk. Occupational exposures to carcinogens are also a concern.

Certain infectious agents, such as human papillomavirus (HPV), hepatitis B and C viruses, and *Helicobacter pylori*, can cause cancers. Efforts to prevent these infections can reduce cancer incidence. Inherited genetic mutations can increase the risk of specific cancers. While these mutations are relatively rare, they contribute to some cancer cases. Improved cancer screening and early detection programs have led to the identification of cancers at earlier stages when treatment is more likely to be successful. This can result in higher reported incidence rates. Increased awareness of cancer and better access to healthcare services have led to more people seeking medical attention for symptoms, resulting in earlier cancer diagnoses. Changes in lifestyle and dietary habits, along with increased exposure to carcinogens, have occurred due to globalization and urbanization. Advances in cancer treatment have increased survival rates. However, cancer survivors remain at risk of developing secondary cancers,

contributing to overall incidence rates. Although there have been significant efforts to reduce tobacco use, it remains a leading cause of cancer. In regions where tobacco control measures are not as stringent, the incidence of smoking-related cancers remains high. In some regions, improved access to healthcare has resulted in earlier cancer diagnoses, leading to higher reported incidence rates. This factor will accelerate the demand of Global Gene Fusion Testing Market.

Key Market Challenges

Tissue Availability

In some cases, obtaining enough tissue for gene fusion testing can be challenging, especially when dealing with small biopsies or fine-needle aspirates. Insufficient tissue can result in inadequate test results. The quality of tissue samples is crucial for accurate gene fusion testing. Factors such as tissue preservation, fixation, and handling can impact the integrity of the genetic material and affect the reliability of test results. Tumors are often heterogeneous, meaning that different regions of the tumor may have distinct genetic profiles, including gene fusion events. Obtaining a single tissue sample may not fully represent the genetic diversity within the tumor. In some cases, tumors may be in anatomically challenging or inaccessible areas, making it difficult to obtain tissue samples for testing. Invasive procedures like biopsies carry inherent risks, including bleeding, infection, and damage to surrounding tissues. These risks can influence the decision to perform a biopsy and impact tissue availability. For rare or uncommon tumor types, obtaining sufficient tissue samples for gene fusion testing can be particularly challenging due to the limited number of cases available for study. Properly preserving and storing tissue samples for future testing is essential. Inadequate preservation or long-term storage conditions can compromise the quality of the samples. Obtaining informed consent for tissue collection is crucial, and ethical considerations may affect the availability of tissue samples, especially in cases involving minors or vulnerable populations.

Complexity of Gene Fusion Events

Gene fusion events can involve a wide range of fusion partner genes, and these partners can vary between individuals and even within the same type of cancer. Identifying all potential fusion partners and designing tests that cover this diversity can be challenging. Some gene fusions are rare or entirely novel, making them difficult to detect using conventional testing methods. Detecting these rare events requires highly sensitive and comprehensive techniques. Gene fusion events can have multiple

variants, including different breakpoints and fusion junctions. Each variant may have distinct clinical implications, complicated interpretation, and treatment decisions. Tumors are often heterogeneous, meaning that different regions of a tumor may have different fusion events. This heterogeneity can impact the accuracy of gene fusion testing if only a small portion of the tumor is sampled. Gene fusions may co-occur with other genetic mutations or alterations in the same tumor. Understanding the interplay between different genetic alterations and their combined impact on disease is complex. Some gene fusion events involve complex chromosomal rearrangements, such as translocations or inversions, which can be challenging to detect and characterize. The accuracy and sensitivity of gene fusion detection assays can vary depending on the specific assay used, potentially leading to differences in results between laboratories and platforms. Certain gene fusion events may be specific to tissue types or diseases. Designing tests that cover a broad spectrum of fusion events across different diseases can be complex.

Key Market Trends

Personalized Medicine

Gene fusion testing plays a crucial role in identifying specific genetic alterations that drive diseases, particularly in cancer. With the advent of personalized medicine, oncologists and other healthcare providers can use the results of gene fusion tests to select targeted therapies that are most likely to be effective for individual patients. This approach maximizes treatment efficacy while minimizing side effects. Gene fusion testing is used to stratify patients into different subgroups based on their genetic profiles. Patients with similar gene fusion events may respond differently to treatments. Personalized medicine enables the selection of the most appropriate treatment regimen for each patient based on their specific genetic alterations. Gene fusion tests are often developed alongside targeted therapies as companion diagnostics. These tests help identify patients who are most likely to benefit from a particular drug. Regulatory agencies like the U.S. Food and Drug Administration (FDA) often require companion diagnostics as part of the drug approval process. Personalized medicine extends beyond initial treatment selection. It also involves ongoing monitoring of a patient's response to therapy. Gene fusion testing can be used to assess whether a targeted therapy is effectively suppressing the fusion event and whether treatment adjustments are needed.

Segmental Insights

Category Insights

In 2022, the Global Gene Fusion Testing Market dominated by research segment and is predicted to continue expanding over the coming years. The research segment plays a central role in the initial discovery and characterization of gene fusion events.

Researchers in academic institutions, pharmaceutical companies, and biotechnology firms are continually investigating gene fusions to understand their role in diseases, especially cancer. Gene fusion research is essential for biomarker discovery. Identifying specific fusion events associated with diseases can lead to the development of diagnostic tests, prognostic markers, and potential therapeutic targets. Pharmaceutical and biotechnology companies rely on gene fusion research to identify potential drug targets. Gene fusion events can drive cancer and other diseases, and understanding these events is crucial for developing targeted therapies. Before a potential drug can enter clinical trials, extensive preclinical studies are required. Researchers in the research segment use gene fusion testing to validate drug targets, study the mechanisms of action, and assess the efficacy of candidate therapies in cellular and animal models.

Technology Insights

In 2022, the Global Gene Fusion Testing Market dominated by Next-Generation Sequencing (NGS) segment and is predicted to continue expanding over the coming years. NGS technology allows for the comprehensive analysis of a patient's entire genome or specific genomic regions, making it a powerful tool for detecting gene fusion events. This capability is especially valuable in oncology and rare diseases where gene fusions can be diverse and complex. NGS is known for its high sensitivity and specificity in detecting genetic alterations, including gene fusions. This accuracy is crucial for identifying clinically relevant fusion events that may be missed by other testing methods. NGS can identify a wide range of fusion types, including known and novel gene fusions. This versatility is important for both research and clinical applications, as gene fusions can vary significantly between individuals and diseases.

Indication Insights

In 2022, the Global Gene Fusion Testing Market dominated by solid tumours segment and is predicted to continue expanding over the coming years. Solid tumours, such as those found in the breast, lung, prostate, and colon, are among the most common types of cancers worldwide. They account for a significant portion of cancer cases and cancer-related deaths. Due to their high prevalence, there is a strong demand for accurate

diagnostic and prognostic tools, including gene fusion testing. Gene fusion events are known to play a critical role in the development and progression of various solid tumours. Identifying specific fusion events can provide valuable information for treatment decisions, prognosis, and patient management. Solid tumour cancers often have well-defined genetic alterations, including gene fusions, that can be targeted with precision medicine approaches. Gene fusion testing is essential for identifying patients who may benefit from targeted therapies, such as tyrosine kinase inhibitors or immunotherapies.

End User Insights

In 2022, the Global Gene Fusion Testing Market largest share was held by pharmaceutical and biotechnology companies' segment in the forecast period and is predicted to continue expanding over the coming years. Pharmaceutical and biotechnology companies are major players in drug development. They invest heavily in research and development (R&D) to discover and develop new therapies, especially targeted therapies. Gene fusion testing plays a critical role in identifying specific genetic alterations that can serve as drug targets. These companies use gene fusion testing to select patient populations for clinical trials and to develop therapies tailored to individuals with gene fusion events. before a new drug can be approved for commercial use it must go through rigorous clinical trials. Gene fusion testing is essential in-patient stratification for these trials. Pharmaceutical and biotechnology companies use gene fusion testing to select the most appropriate patients for their clinical studies, improving the chances of demonstrating the drug's effectiveness.

Regional Insights

The North America region dominates the Global Gene Fusion Testing Market in 2022. North America, particularly the United States and Canada, boasts advanced healthcare infrastructure and a well-developed healthcare system. This includes access to cutting-edge medical technologies and well-established clinical research capabilities, which are crucial for the development and adoption of advanced diagnostic tests like gene fusion testing. The region is home to some of the world's leading academic and research institutions, pharmaceutical companies, and biotechnology firms. These organizations are at the forefront of research and innovation in the field of genomics and molecular diagnostics, including gene fusion testing. North America has a robust pharmaceutical industry, with a significant focus on precision medicine and targeted therapies. Gene fusion testing plays a vital role in identifying potential targets for personalized therapies, making it a key component of drug development pipelines.

Key Market Players

Amoy Diagnostics Co., Ltd.

ArcherDX (Integrated DNA Technologies, Inc.)

Biocartis

Biocare Medical, LLC

F. Hoffmann-La Roche Ltd.

Guardant Health, Inc

Illumina, Inc.

Myriad Genetics, Inc.

Natera, Inc.

NeoGenomics, Inc.

QIAGEN N.V.

Thermo Fisher Scientific Inc

Report Scope:

In this report, the Global Gene Fusion Testing Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Gene Fusion Testing Market, By Category:

Research

Diagnostic

Gene Fusion Testing Market, By Technology:

Next-Generation Sequencing (NGS)

Fluorescence In-Situ Hybridization (FISH)

Polymerase Chain Reaction (PCR)

Immunohistochemistry (IHC)

Gene Fusion Testing Market, By Indication:

Solid Tumors

Hematological Malignancies

Gene Fusion Testing Market, By End User:

Pharmaceutical and Biotechnology Companies

Hospitals and Diagnostic Laboratories

Academic and Research Centers

Global Gene Fusion Testing Market, By region:

North America

United States

Canada

Mexico

Asia-Pacific

China

India

South Korea

Australia

Japan

Europe

Germany

France

United Kingdom

Spain

Italy

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Gene

Gene Fusion Testing Market – Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segment...

Fusion Testing Market.

Available Customizations:

Global Gene Fusion Testing Market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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17. STRATEGIC RECOMMENDATIONS

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