

# **United States Tissue Diagnostics Market By Technology & Product (Immunohistochemistry, In situ Hybridization, Primary & Special Staining, Digital Pathology & Workflow, Anatomic Pathology), By End Use (Hospitals, Research Laboratories, Pharmaceutical Organizations, CRO), By Application (Breast Cancer, Non-Small Cell Lung Cancer, Prostate Cancer, Gastric Cancer, Other Cancers), By Region, Competition, Forecast and Opportunities, 2020-2030F**

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## **Abstracts**

United States Tissue Diagnostics Market was valued at USD 2.74 Billion in 2024 and is expected to reach USD 4.50 Billion by 2030 with a CAGR of 8.56% during the forecast period. The United States Tissue Diagnostics Market is a rapidly growing segment within the broader healthcare and diagnostic industry, primarily driven by advancements in technology and the increasing prevalence of chronic diseases, particularly cancer. Tissue diagnostics involves the use of various tools and techniques to analyze tissue samples and assist in diagnosing diseases, such as cancer, autoimmune disorders, and infections. For instance, According to a CDC report, in 2021, the most recent year for which incidence data is available, the United States saw 1,777,566 new cancer cases. This equates to 439 new cancer cases for every 100,000 individuals. These diagnostics are essential for providing accurate and personalized treatment plans, which has contributed to the rise in demand for high-quality diagnostic solutions.

The market is characterized by the widespread adoption of advanced technologies such as immunohistochemistry (IHC), in situ hybridization (ISH), and digital pathology. These innovations allow for more precise and efficient tissue analysis, improving diagnostic

accuracy and reducing turnaround times. Additionally, the increasing prevalence of cancer and the aging population in the United States have led to greater demand for tissue-based testing, particularly in oncology. As early detection becomes critical for improving patient outcomes, tissue diagnostics plays a crucial role in identifying cancer biomarkers and enabling personalized medicine. The market is also benefitting from the growing focus on companion diagnostics, which involves using tissue testing to identify the most appropriate treatment options for individual patients. This trend, combined with a rising preference for minimally invasive biopsy procedures, further fuels the demand for tissue diagnostics.

## Key Market Drivers

### Technological Advancements in Diagnostic Tools

Technological advancements are a key factor driving the growth of the US Tissue Diagnostics Market. The introduction of digital pathology and high-resolution imaging systems has revolutionized the diagnostic process. Digital pathology, which involves the use of digital slides and image analysis software, allows for the remote viewing and sharing of tissue samples. This innovation has significantly improved diagnostic accuracy by providing detailed images that are easier to analyze than traditional glass slides. Furthermore, it allows pathologists to evaluate tissue samples faster, reducing the turnaround time for diagnoses.

Automation and artificial intelligence (AI) are also making significant contributions to tissue diagnostics. AI algorithms are now being integrated into tissue diagnostic platforms to analyze complex tissue samples with precision, detecting minute details that may be overlooked by the human eye. Machine learning algorithms can identify patterns in large datasets, enabling the prediction of disease progression or treatment response. These advancements lead to better clinical outcomes by facilitating quicker, more accurate diagnoses. Additionally, the integration of AI into diagnostic workflows reduces human error, increases efficiency, and enhances the consistency of results, which is crucial for personalized treatment planning. As these technologies continue to evolve, the demand for digital tools that enable faster, more accurate tissue analysis is expected to increase. Additionally, the shift toward digital platforms facilitates data storage and management, enhancing the ability to share patient information across healthcare institutions. This trend towards digitization is anticipated to play a critical role in improving collaboration among healthcare professionals, enhancing patient care, and boosting the US Tissue Diagnostics Market.

## Increasing Prevalence of Cancer and Chronic Diseases

The rising prevalence of cancer and other chronic diseases is a major driver of the US Tissue Diagnostics Market. As the population ages, the incidence of cancers—particularly breast, prostate, lung, and colorectal cancers—continues to rise, driving the demand for more sophisticated diagnostic tools. Tissue diagnostics, including biopsy analysis, plays a crucial role in detecting and diagnosing cancers at an early stage, when treatment options are more effective. Early detection through tissue diagnostics helps identify specific molecular markers associated with cancer, enabling clinicians to make informed decisions about the most appropriate treatment options.

The aging US population also contributes to the increase in chronic diseases, including cardiovascular diseases, autoimmune disorders, and infectious diseases, all of which require tissue diagnostics for proper management. According to the CDC's United States Cancer Statistics, in 2021, the most recent year for which incidence data is available, 141,902 new cases of colon and rectum cancer were reported in the United States. This equates to 36 new cases of colon and rectum cancer for every 100,000 individuals. Chronic diseases often require long-term monitoring and frequent tissue testing, leading to a sustained demand for diagnostic solutions. Tissue-based testing helps healthcare providers track disease progression, detect complications, and monitor patient responses to treatment. For example, in cancer care, tissue diagnostics plays a pivotal role in identifying specific cancer subtypes, which enables the use of targeted therapies. As healthcare providers increasingly focus on early detection and preventive care, tissue diagnostics becomes even more essential. The growing need for personalized medicine, which tailors treatment to the patient's unique genetic and molecular profile, is further increasing the reliance on tissue diagnostics. The rising incidence of cancer and chronic diseases highlights the critical role of tissue diagnostics in improving patient outcomes, positioning the market for continued growth in the coming years.

## Rising Adoption of Personalized Medicine

Personalized medicine, which focuses on tailoring medical treatments to the individual characteristics of each patient, is an increasingly important driver of the US Tissue Diagnostics Market. Tissue diagnostics is integral to the personalized medicine approach because it helps identify specific biomarkers in tissue samples that are indicative of how a patient will respond to treatment. By analyzing these biomarkers, healthcare providers can develop targeted treatment plans, avoiding the one-size-fits-all approach and ensuring that patients receive the most effective therapy for their

condition.

The rising prevalence of cancer has further accelerated the adoption of personalized medicine, as specific genetic mutations and molecular markers in tumors influence the choice of treatment. For example, in oncology, tissue diagnostics is essential for determining which patients are eligible for targeted therapies or immunotherapy. These therapies are designed to target specific molecular changes in cancer cells, which improves treatment efficacy and reduces side effects compared to traditional chemotherapy. As more personalized therapies are developed, tissue diagnostics becomes an indispensable tool in determining the appropriate course of treatment. Additionally, the growing emphasis on precision medicine is expanding beyond oncology to other therapeutic areas, such as cardiovascular disease, neurology, and rare genetic disorders. As the demand for personalized treatments grows, the role of tissue diagnostics in identifying relevant biomarkers and molecular targets becomes even more critical. The integration of personalized medicine into routine clinical practice, facilitated by advanced tissue diagnostic tools, is expected to boost the market's growth as healthcare providers increasingly turn to tailored, patient-specific treatment options for better outcomes.

## Key Market Challenges

### High Cost of Diagnostic Tools and Procedures

One of the primary challenges facing the US Tissue Diagnostics Market is the high cost associated with diagnostic tools and procedures. The development and maintenance of advanced diagnostic technologies, such as digital pathology systems, high-resolution imaging tools, and artificial intelligence (AI)-integrated diagnostic platforms, require significant investments in research and development. These high initial costs often translate into higher prices for end-users, such as hospitals, clinics, and diagnostic labs. Additionally, the ongoing costs associated with training healthcare professionals to use advanced technologies, as well as maintaining and updating these tools, further increase the financial burden on healthcare institutions. Moreover, the high cost of diagnostic tools can impact the overall adoption rate of newer technologies in the market. For instance, despite the potential benefits of digital pathology and AI integration, many healthcare facilities may hesitate to make the necessary investment due to concerns about the return on investment (ROI). This slow adoption of innovative technologies can limit the market's growth and restrict the widespread availability of state-of-the-art diagnostic solutions.

In addition to direct costs, reimbursement policies play a significant role in this challenge. Inconsistent reimbursement rates for tissue diagnostic procedures, particularly for newer technologies, can deter healthcare providers from implementing them. The lack of clear reimbursement guidelines and delays in establishing coverage for new diagnostic tests further exacerbate the financial challenges faced by the healthcare sector. As a result, reducing the cost burden of tissue diagnostic technologies and improving reimbursement policies are crucial for enabling broader adoption and access to these tools across the United States.

### Lack of Standardization and Regulation

Another challenge for the US Tissue Diagnostics Market is the lack of standardization and regulation in tissue diagnostic procedures. While the US Food and Drug Administration (FDA) has made strides in regulating tissue diagnostics technologies, the rapid pace of innovation in the field has made it difficult to keep regulatory standards up to date. As a result, new diagnostic tools, such as AI-driven platforms or advanced tissue biomarker tests, may face delays in receiving regulatory approval, hindering their ability to reach the market in a timely manner. The lack of standardized diagnostic protocols also creates challenges in terms of ensuring the reliability and consistency of results. Different laboratories and healthcare facilities may use varying diagnostic techniques or equipment, leading to potential discrepancies in results. This lack of consistency can undermine the confidence of healthcare providers in the accuracy and effectiveness of tissue diagnostics, ultimately impacting patient care.

Furthermore, the complexity of tissue diagnostics, particularly in oncology and other complex diseases, often leads to variations in interpretation. For example, pathologists may interpret tissue samples differently depending on their experience, the technology used, or the protocols followed. This variability in interpretation can affect the accuracy of diagnoses, leading to misdiagnoses or delayed treatment decisions. Inaccurate or inconsistent results can ultimately impact patient outcomes, reducing the effectiveness of personalized medicine approaches.

### Key Market Trends

#### Advancements in Companion Diagnostics

Companion diagnostics, a rapidly emerging field, is playing a pivotal role in the growth of the US Tissue Diagnostics Market. Companion diagnostics are tests that help identify the most suitable treatments for patients by detecting specific biomarkers in their tissue

samples. These tests are typically used in conjunction with specific drugs or therapies, providing healthcare providers with the necessary information to tailor treatments to individual patients. Companion diagnostics are particularly important in oncology, where they enable the identification of cancer subtypes and the selection of targeted therapies that are most likely to be effective. For instance, companion diagnostics are used to assess whether a cancer patient has specific genetic mutations that make them eligible for targeted therapies such as tyrosine kinase inhibitors or immunotherapies. Tissue diagnostic tools, including immunohistochemistry (IHC) and in situ hybridization (ISH), are commonly used to detect these biomarkers. This trend toward companion diagnostics is not only improving patient outcomes by enabling personalized treatment plans, but it is also reducing healthcare costs by minimizing ineffective treatments and side effects. In October 2023, NeoGenomics, Inc. expanded its innovative cancer diagnostic portfolio with the launch of two new tests. The early-stage Non-Small Cell Lung Cancer (NSCLC) Panel is designed to support treatment selection for patients with early-stage NSCLC. Additionally, the Neo Comprehensive-Heme Cancers panel provides a comprehensive genomic profile of hematopoietic malignancies using Next-Generation Sequencing (NGS).

As the development of biologics and immunotherapies continues to expand, the need for companion diagnostics will increase. The integration of tissue diagnostics into companion diagnostic strategies is also being facilitated by partnerships between pharmaceutical companies, diagnostic providers, and healthcare institutions. This growing collaboration aims to improve the efficiency and effectiveness of cancer treatments, making companion diagnostics a key trend in the US Tissue Diagnostics Market. The increasing number of approved companion diagnostic tests and their integration into clinical practice will drive further market growth and innovation.

### Growing Demand for Minimally Invasive Biopsy Techniques

The growing demand for minimally invasive biopsy techniques is another significant driver of the US Tissue Diagnostics Market. Traditional biopsy procedures, such as surgical biopsies, often require general anesthesia, long recovery times, and increased risks of complications. In contrast, minimally invasive biopsy techniques, such as core needle biopsies, fine-needle aspiration (FNA), and liquid biopsies, offer a more patient-friendly alternative. These procedures are typically performed under local anesthesia, reducing the risk of complications and improving recovery times. Core needle biopsy, for example, involves using a hollow needle to remove a small tissue sample, which is then analyzed for diagnostic purposes. FNA involves using a thin needle to extract cells from a tissue mass. Liquid biopsy, which analyzes blood or other body fluids for cancer-

related biomarkers, is a non-invasive method that is gaining popularity for early cancer detection. These minimally invasive techniques are particularly beneficial for patients who are unable to undergo traditional surgical procedures due to their health conditions or the location of the tumor.

The increasing popularity of these techniques has driven the demand for diagnostic tools that can support them, such as advanced staining techniques, imaging technologies, and automated diagnostic systems. As more healthcare providers adopt minimally invasive biopsy procedures, the need for efficient and accurate tissue diagnostics grows. This trend is expected to contribute significantly to the expansion of the tissue diagnostics market in the US, as it offers a more comfortable and less invasive way to obtain tissue samples for analysis.

## Segmental Insights

### Technology & Product Insights

Based on the Technology & Product, Immunohistochemistry (IHC) was the dominant segment in the United States Tissue Diagnostics Market. This technique plays a crucial role in the detection and diagnosis of various diseases, especially cancers, by identifying specific antigens in tissue samples. IHC allows pathologists to determine the presence of biomarkers and gain insights into the molecular characteristics of tumors, which is essential for personalized medicine and treatment planning. The growing demand for precision medicine, along with advances in cancer diagnostics, has driven the adoption of IHC. It enables high specificity and sensitivity in detecting markers associated with different types of cancers, such as breast, lung, and colorectal cancers. The ability to perform multiplex testing and identify multiple biomarkers simultaneously enhances the diagnostic capabilities of IHC, making it indispensable in clinical pathology.

Moreover, IHC's role in prognostic and predictive testing, particularly in oncology, further solidifies its dominance. The ability to guide treatment decisions, including immunotherapy, has positioned IHC as a cornerstone of tissue diagnostics. It is also widely used in research settings to explore disease mechanisms and drug responses, adding to its prominence in the market.

## End Use Insights

Based on End Use, Hospitals was the dominant segment in the United States Tissue

Diagnostics Market. Hospitals, particularly those with specialized oncology or pathology departments, are at the forefront of adopting advanced tissue diagnostic techniques to aid in patient care. These facilities perform a large volume of diagnostic tests, including immunohistochemistry (IHC), in situ hybridization, and digital pathology, for both routine and specialized diagnostics. The primary drivers for hospitals dominating the market are the increasing demand for early and accurate disease detection, particularly in cancer diagnostics. Tissue diagnostics play a pivotal role in identifying tumor markers, guiding treatment decisions, and enabling personalized therapies. As hospitals are the primary healthcare providers for a broad range of patients, they see the highest volume of tissue samples for diagnostic testing.

Additionally, hospitals benefit from integrated healthcare systems that streamline diagnostics, ensuring a high level of precision and efficiency in patient care. Hospitals also have the infrastructure and expertise to adopt cutting-edge technologies such as digital pathology, which enhances the accuracy of tissue sample analysis through advanced imaging and AI-driven algorithms.

## Regional Insights

The Northeast region was dominating the United States Tissue Diagnostics Market. This region includes major healthcare hubs such as New York, Boston, and Philadelphia, where there is a high concentration of advanced medical centers, research institutions, and hospitals. These institutions are at the forefront of adopting cutting-edge tissue diagnostic technologies, particularly for oncology applications like breast, lung, and prostate cancer. The Northeast also benefits from a robust healthcare infrastructure, with well-established networks of hospitals and laboratories that conduct a significant volume of tissue diagnostic tests. This contributes to the region's dominant position in the market. Additionally, the proximity to leading pharmaceutical companies and research organizations drives innovation and collaboration in tissue diagnostics, further fueling growth in this area.

The region's dominance is also supported by a high level of awareness about early disease detection, especially cancer, and the widespread use of advanced diagnostic technologies such as immunohistochemistry (IHC), digital pathology, and molecular diagnostics. The presence of prominent academic and medical research centers ensures that the latest developments in tissue diagnostics are quickly integrated into clinical practices.

## Key Market Players

Merck KGaA.

Thermo Fisher Scientific Inc.

F. Hoffmann-La Roche Ltd.

Abbott Laboratories Inc

Siemens Healthineers AG

Danaher Corporation

bioMérieux SA

Qiagen NV

Agilent Technologies, Inc.

Becton, Dickinson & Company (BD)

#### Report Scope:

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

United States Tissue Diagnostics Market, By Technology & Product:

Immunohistochemistry

In situ Hybridization

Primary & Special Staining

Digital Pathology & Workflow

Anatomic Pathology

## United States Tissue Diagnostics Market, By End Use:

Hospitals

Research Laboratories

Pharmaceutical Organizations

CRO

## United States Tissue Diagnostics Market, By Application:

Breast Cancer

Non-Small Cell Lung Cancer

Prostate Cancer

Gastric Cancer

Other Cancers

## United States Tissue Diagnostics Market, By Region:

Northeast Region

Midwest Region

West Region

South Region

## Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the United States Tissue Diagnostics Market.

## Available Customizations:

*United States Tissue Diagnostics Market By Technology & Product (Immunohistochemistry, In situ Hybridization,...*

United States Tissue Diagnostics 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

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

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