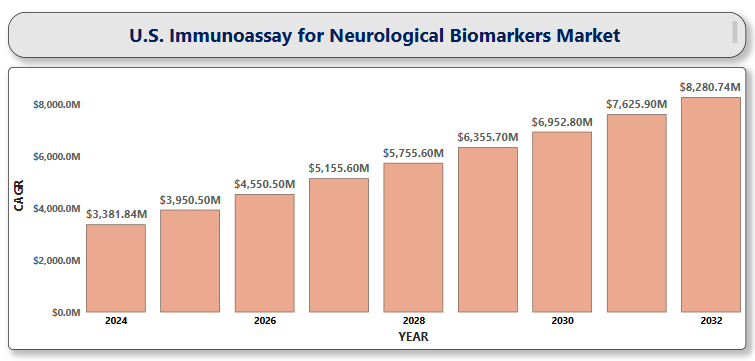
A close-up of hands holding a tablet and a pen

Description automatically generated**U.S. Immunoassay for Neurological Biomarkers Market**

According to Intelli, the U.S. Immunoassay for Neurological Biomarkers Market size was valued at USD 3,381.84 Million in 2024 and is projected to reach USD 8,280.74 Million by 2032, growing at a compound annual growth rate (CAGR) of 12.34%, during the forecast period of 2024 to 2032.



The rising global burden of neurological disorders such as Alzheimer's disease, Parkinson's disease, multiple sclerosis, and traumatic brain injuries has driven an urgent need for accurate, early, and non-invasive diagnostic tools. Among the most promising innovations in this domain is the immunoassay for neurological biomarkers, a powerful biochemical technique that enables the detection and quantification of disease-specific proteins in biological samples like blood, cerebrospinal fluid (CSF), or urine. Immunoassays leverage the exceptional specificity and sensitivity of antigen–antibody interactions to detect extremely low concentrations of neurological biomarkers, often long before the manifestation of clinical symptoms. These biomarkers, including beta-amyloid (Aβ), tau protein (total and phosphorylated), alpha-synuclein, and neurofilament light chain (NfL), serve as molecular indicators of pathological processes occurring in the brain. Their early identification offers profound insights into neurodegenerative changes at a cellular level, enabling clinicians and researchers to not only diagnose conditions like Alzheimer’s, Parkinson’s, and multiple sclerosis with greater accuracy but also to track disease progression over time and evaluate patients’ responses to targeted therapies. This evolving technology is fundamentally transforming the landscape of neurological diagnostics. By supporting precision medicine paradigms, immunoassays allow for the personalization of treatment strategies based on an individual’s unique biomarker profile. Perhaps most notably, recent advancements in blood-based immunoassays are driving a paradigm shift away from invasive and resource-intensive procedures such as CSF collection via lumbar puncture and advanced neuroimaging. These minimally invasive alternatives promise to expand accessibility, streamline diagnosis, and facilitate early intervention, ultimately enhancing patient outcomes and reducing the burden on healthcare systems.

**U.S. Immunoassay for Neurological Biomarkers Market Definition**

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Description automatically generatedThe U.S. Immunoassay for Neurological Biomarkers Market refers to the segment of the in-vitro diagnostics industry focused on the development, production, and commercialization of immunoassay-based technologies used to detect and quantify biomarkers associated with neurological disorders. This market encompasses a range of products and services, including reagents and assay kits, immunoassay analyzers, software for data analysis, and testing services offered by clinical laboratories. Applications span from clinical diagnostics and disease monitoring to drug development and academic research.

**U.S. Immunoassay for Neurological Biomarkers Market Overview**

The U.S. Immunoassay for Neurological Biomarkers Market is driven by a combination of clinical, technological, and demographic factors that are reshaping the neurological diagnostics landscape. A major driver is the rising prevalence of neurodegenerative disorders such as Alzheimer’s disease, Parkinson’s disease, and multiple sclerosis, fueled by an aging population and increased life expectancy. This growing burden of neurological diseases has intensified the need for early, accurate, and non-invasive diagnostic tools that can support timely clinical decision-making. Innovations in immunoassay technology, especially the development of high-sensitivity and multiplex platforms, have significantly improved the detection of low-concentration biomarkers in easily accessible samples such as blood, enhancing both diagnostic accuracy and patient convenience. The market is further propelled by the rising emphasis on precision medicine, as pharmaceutical and biotechnology companies increasingly depend on biomarker-based diagnostics for personalized therapy selection, clinical trial stratification, and treatment monitoring. Moreover, supportive government initiatives, increased funding for neuroscience research, the expansion of clinical studies, and favorable reimbursement frameworks are creating a conducive environment for broader adoption of immunoassay-based neurological testing across healthcare and research institutions in the U.S.

**U.S. Immunoassay for Neurological Biomarkers Market Segmentation**

The U.S. Immunoassay for Neurological Biomarkers Market can be segmented across several key dimensions.

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Description automatically generated**U.S. Immunoassay for Neurological Biomarkers Market, By Product Type**

* **Reagents & Kits**
* **ELISA kits**
* **Buffers and diluents**
* **Antibodies**
* **Instruments**
* **Immunoassay analyzers**
* **Readers and detectors**
* **Software & Services**

In the U.S. Immunoassay for Neurological Biomarkers Market, reagents and kits dominate the product segment, accounting for the largest market share due to their high consumption rate in routine diagnostics, research applications, and drug development processes. Within this category, ELISA kits are particularly prominent, owing to their proven reliability, affordability, and widespread adoption in clinical laboratories. Supporting components such as buffers, diluents, and antibodies are essential for assay accuracy and repeatability, further strengthening this segment’s position. The instruments segment, comprising immunoassay analyzers and detection systems like readers, is also experiencing steady growth, driven by increasing automation in laboratories and the need for high-throughput screening platforms. Additionally, the software and services segment is gaining momentum, fueled by the growing need for integrated data analysis tools and outsourced testing services that enhance workflow efficiency and support clinical decision-making.

**U.S. Immunoassay for Neurological Biomarkers Market, By Biomarker Type**

* **Alzheimer’s Disease Biomarkers**
* **Parkinson’s Disease Biomarkers**
* **Traumatic Brain Injury (TBI) Biomarkers**
* **Multiple Sclerosis Biomarkers**
* **Others**

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Description automatically generatedThe U.S. Immunoassay for Neurological Biomarkers Market, segmented by biomarker type, is led by Alzheimer’s disease biomarkers, which hold the largest market share due to the high prevalence of the disease and the urgent need for early and reliable diagnostic tools. Key biomarkers such as beta-amyloid (Aβ42/Aβ40) and tau proteins are widely used in both clinical diagnostics and research, supported by ongoing advancements in blood-based testing. Parkinson’s disease biomarkers, particularly alpha-synuclein, are gaining traction with increasing R&D focused on early detection and disease progression monitoring. For traumatic brain injuries (TBI), the demand for biomarkers is growing quickly due to the increasing number of head injuries caused by sports and accidents. In these cases, blood tests that detect proteins like GFAP and UCH-L1 are being used more often in emergency rooms to quickly assess brain damage. Meanwhile, for multiple sclerosis (MS), biomarkers such as neurofilament light chain (NfL) are proving useful in tracking disease activity and seeing how well treatments are working. Overall, these biomarkers are helping doctors make faster, more accurate decisions across different brain conditions. The “others” category includes emerging biomarkers for conditions such as ALS and Huntington’s disease, reflecting the broader potential of immunoassay platforms in addressing a wide spectrum of neurological disorders.

**U.S. Immunoassay for Neurological Biomarkers Market, By Technology**

* **Enzyme-Linked Immunosorbent Assay (ELISA)**
* **Chemiluminescence Immunoassay (CLIA)**
* **Radioimmunoassay (RIA)**
* **Fluorescent Immunoassay (FIA)**
* **Others**

In the U.S. Immunoassay for Neurological Biomarkers Market, Enzyme-Linked Immunosorbent Assay (ELISA) holds the largest share due to its widespread use, cost-effectiveness, and high sensitivity in detecting neurological biomarkers like beta-amyloid and tau proteins. Chemiluminescence Immunoassay (CLIA) is rapidly gaining ground, driven by its enhanced sensitivity, faster turnaround times, and suitability for automated platforms, making it ideal for clinical laboratories handling large sample volumes. Radioimmunoassay (RIA), though declining in popularity due to safety and disposal concerns related to radioactive materials, is still used in specialized research applications A close-up of hands holding a tablet and a pen

Description automatically generatedfor its precision. Fluorescent Immunoassay (FIA) is also growing in adoption, particularly for multiplex testing, which allows simultaneous detection of multiple biomarkers, an emerging need in neurology. The "Others" category includes novel and evolving technologies such as electrochemiluminescence and nanoparticle-based immunoassays, which offer promising future potential as the market continues to prioritize speed, sensitivity, and multiplexing capabilities.

**U.S. Immunoassay for Neurological Biomarkers Market, By End-User**

* **Hospitals & Clinics**
* **Diagnostic Laboratories**
* **Academic & Research Institutes**

In the U.S. Immunoassay for Neurological Biomarkers Market, hospitals and clinics represent the largest end-user segment, driven by the increasing demand for diagnostic testing in clinical settings, particularly for early detection. The diagnostic laboratories segment is also experiencing significant growth, as these labs provide specialized testing services for a wide range of biomarkers, offering critical support for clinicians in diagnosing and managing neurological disorders. Academic and research institutes are another important end-user group, where immunoassays are integral to the ongoing research efforts aimed at discovering new biomarkers, advancing drug development, and understanding the underlying mechanisms of neurological diseases.

**Key Players**

The “U.S. Immunoassay for Neurological Biomarkers Market" study report will provide valuable insight emphasizing the U.S. market. The major players in the market Thermo Fisher Scientific, Abbott Laboratories, Roche Diagnostics, Siemens Healthineers, Bio-Rad Laboratories, Merck & Co., Danaher Corporation, Labcorp, PerkinElmer, BioMérieux, Quidel Corporation, Abcam, Stryker Corporation, Johnson & Johnson, Myriad Genetics among others. Our market analysis also entails a section solely dedicated to such major players wherein our analysts provide an insight into the financial statements of all the major players, along with product benchmarking and SWOT analysis.

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Description automatically generated**Key Developments**

* In 2025, Beckman Coulter Diagnostics introduced its Access p-Tau217/ β-Amyloid 1-42 plasma ratio blood test, which received FDA Breakthrough Device Designation.
* In 2024, Roche’s Elecsys® pTau217 plasma assay received FDA Breakthrough Device Designation. Developed with Eli Lilly, this blood test helps identify amyloid pathology, a key indicator of Alzheimer’s disease, enabling earlier and more accurate diagnoses.
* In 2024, Biogen, Beckman Coulter, and Fujirebio formed a partnership to develop blood-based biomarkers and tests for tau pathology in Alzheimer's disease. This collaboration combines their expertise in biomarker research and treatment development to improve diagnostic solutions for the disease.

**Market Attractiveness**

The image of market attractiveness provided further helps to get information about the region leading in the U.S. Immunoassay for Neurological Biomarkers Market. We cover the major impacting factors driving the industry growth in the given region.

**Porter’s Five Forces**

The image provided would further help to get information about Porter's five forces framework providing a blueprint for understanding the behavior of competitors and a player's strategic positioning in the respective industry. Porter's five forces model can be used to assess the competitive landscape U.S. Immunoassay for Neurological Biomarkers Market, gauge the attractiveness of a particular sector, and assess investment possibilities.

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