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Alzheimers Disease Biomarkers Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, Segmented By Type (CSF Biomarkers, Amyloid Beta, Tau Protein, Genetic Biomarkers, Apolipoprotein E, Blood Biomarkers, Others), By Detection Technique (Molecular Diagnostics, Immunoassays), By End user (Hospitals & Clinics, Diagnostic Laboratories, Others), By Region & Competition, 2021-2031F

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Abstracts

The Global Alzheimer’s Disease Biomarkers Market is projected to expand from USD 0.91 Billion in 2025 to USD 1.43 Billion by 2031, reflecting a compound annual growth rate of 7.82%. These biomarkers function as quantifiable biological indicators found in cerebrospinal fluid, blood plasma, or through imaging techniques, serving to detect pathological alterations such as amyloid beta plaques and tau protein tangles. This growth trajectory is chiefly driven by the increasing global elderly population and the urgent clinical need for early diagnosis to maximize the effectiveness of new therapeutic options. Additionally, the rapid advancement of noninvasive blood-based diagnostic solutions is broadening market reach by reducing the patient burden and procedural invasiveness typical of conventional lumbar punctures.

However, the market faces substantial hurdles regarding the high expense of developing diagnostic assays and the lack of consistent reimbursement coverage, which limits availability in price-sensitive areas. This economic barrier is especially concerning given the rising prevalence of the disease, which demands scalable diagnostic interventions. According to the Alzheimer's Association, an estimated 7.2

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million Americans aged 65 and older are expected to be living with Alzheimer's dementia in 2025. This increasing incidence highlights a critical industry need for cost-effective and accessible biomarker platforms to ensure timely patient care and management.

Market Driver

The proliferation of disease-modifying therapies (DMTs) is fundamentally transforming the market by requiring precise companion diagnostics to determine patient eligibility and monitor treatment. As regulatory agencies approve new monoclonal antibodies that target amyloid-beta, clinical protocols are swiftly incorporating biomarker testing to verify amyloid pathology before starting therapy. This connection elevates diagnostics from simple screening tools to essential gatekeepers for pharmaceutical access, directly increasing the volume of FDA-cleared assays. To illustrate the clinical efficacy propelling this demand, Eli Lilly and Company reported in a July 2024 'FDA Approval Press Release' that the Phase 3 TRAILBLAZER-ALZ 2 study, critical for Kisunla's approval, showed the treatment slowed clinical decline by 35% in participants with confirmed amyloid and intermediate tau pathology, necessitating diagnostic platforms capable of detecting these specific markers.

Concurrently, the swift development and commercial release of minimally invasive blood-based biomarkers are removing accessibility obstacles linked to traditional PET scans and cerebrospinal fluid analysis. The adoption of high-performance plasma assays, particularly those detecting phosphorylated tau (p-tau), facilitates affordable prescreening within primary care, effectively triaging patients for further confirmation. This technological evolution is supported by recent data; an article published in 'JAMA Neurology' by the American Medical Association in January 2024 reported that a commercial p-tau217 blood assay achieved 96% diagnostic accuracy in detecting elevated brain amyloid. Such precision encourages widespread adoption, which is crucial given the high financial impact of the condition; the Alzheimer's Association projected that the total national cost for caring for individuals with Alzheimer's and other dementias would reach $360 billion in 2024.

Market Challenge

The growth of the market is primarily hindered by the substantial costs associated with developing diagnostic assays combined with inconsistent reimbursement policies. Manufacturers must invest heavily to validate and manufacture these tests, leading to premium pricing that limits access for numerous healthcare providers and patients.

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When insurance payers do not offer standardized or sufficient coverage, the financial responsibility falls on the individual or the medical facility. This economic uncertainty creates reluctance within healthcare systems to establish biomarker testing as a routine standard of care, thereby restricting testing volumes and stalling revenue growth for market participants.

This financial strain is especially significant within the broader economic landscape of dementia care, where resources are predominantly directed toward long-term management rather than diagnostics. The struggle for limited healthcare funding complicates the adoption of expensive diagnostic tools in the absence of guaranteed payment structures. According to the Alzheimer's Association, total estimated payments for health care, long-term care, and hospice services for people aged 65 and older with dementia were $360 billion in 2024. This immense existing expenditure on care delivery consumes available budgets, leaving little room for adopting new diagnostic technologies and directly limiting the scalability of the biomarkers market.

Market Trends

The integration of Artificial Intelligence (AI) into biomarker discovery is revolutionizing the market by facilitating the detection of new pathological signatures from intricate, multi-modal datasets. In contrast to traditional single-assay validation, AI algorithms possess the capacity to analyze immense collections of genomic, proteomic, and imaging data to identify subtle, non-linear patterns that exist before clinical symptoms appear. This ability hastens the creation of precision diagnostics by revealing latent biological factors correlated with disease progression, which improves patient stratification for clinical trials. Underscoring the promise of this technological convergence, Premier Science reported in January 2025, within the article 'Revolutionizing Alzheimer’s Diagnostics: AI Tool Shows Superior Accuracy Over Traditional Methods', that a novel AI model attained nearly 90% prediction accuracy on independent datasets by recognizing latent metabolic and physiological factors linked to cognitive decline.

At the same time, the rise of digital biomarkers for remote monitoring is establishing a new standard for scalable and accessible patient assessment. This trend shifts diagnostic data capture from invasive clinical settings to continuous, non-intrusive collection utilizing consumer-grade sensors and specialized peripherals to monitor oculomotor, vocal, and behavioral metrics. These digital instruments are especially beneficial for detecting preclinical neurodegenerative changes often missed by episodic clinical examinations, presenting a cost-efficient method for mass population screening.

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Highlighting the precision of these non-invasive approaches, the University of Strathclyde announced in October 2025 regarding the 'ViewMind Atlas' system that the platform's integration of eye-tracking technology with machine learning analysis achieved a 96% accuracy rate in detecting asymptomatic carriers of a genetic mutation associated with Alzheimer’s disease.

Key Market Players

Enzo Life Sciences Inc.

Thermo Fisher Scientific Inc.

AnaSpec Inc.

Merck KGaA

Cell Signaling Technology Inc.

Fujirebio Diagnostics Inc

23andMe Inc.

NanoSomiX Inc.

QIAGEN NV

Quest Diagnostics

Report Scope

In this report, the Global Alzheimer's Disease Biomarkers Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Alzheimer's Disease Biomarkers Market, By Type

CSF Biomarkers

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Amyloid Beta

Tau Protein

Genetic Biomarkers

Apolipoprotein E

Blood Biomarkers

Others

Alzheimer's Disease Biomarkers Market, By Detection Technique

Molecular Diagnostics

Immunoassays

Alzheimer's Disease Biomarkers Market, By End user

Hospitals & Clinics

Diagnostic Laboratories

Others

Alzheimer's Disease Biomarkers Market, By Region

North America

United States

Canada

Mexico

Europe

France

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United Kingdom

Italy

Germany

Spain

Asia Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

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Company Profiles: Detailed analysis of the major companies present in the Global Alzheimer's Disease Biomarkers Market.

Available Customizations:

Global Alzheimer's Disease Biomarkers 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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Contents

1. PRODUCT OVERVIEW

1.1. Market Definition
1.2. Scope of the Market
  1.2.1. Markets Covered
  1.2.2. Years Considered for Study
  1.2.3. Key Market Segmentations

2. RESEARCH METHODOLOGY

2.1. Objective of the Study
2.2. Baseline Methodology
2.3. Key Industry Partners
2.4. Major Association and Secondary Sources
2.5. Forecasting Methodology
2.6. Data Triangulation & Validation
2.7. Assumptions and Limitations

3. EXECUTIVE SUMMARY

3.1. Overview of the Market
3.2. Overview of Key Market Segmentations
3.3. Overview of Key Market Players
3.4. Overview of Key Regions/Countries
3.5. Overview of Market Drivers, Challenges, Trends

4. VOICE OF CUSTOMER

5. GLOBAL ALZHEIMER'S DISEASE BIOMARKERS MARKET OUTLOOK

5.1. Market Size & Forecast
  5.1.1. By Value
5.2. Market Share & Forecast
  5.2.1. By Type (CSF Biomarkers, Amyloid Beta, Tau Protein, Genetic Biomarkers, Apolipoprotein E, Blood Biomarkers, Others)
  5.2.2. By Detection Technique (Molecular Diagnostics, Immunoassays)
  5.2.3. By End user (Hospitals & Clinics, Diagnostic Laboratories, Others)

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5.2.4. By Region
5.2.5. By Company (2025)
5.3. Market Map

6. NORTH AMERICA ALZHEIMER'S DISEASE BIOMARKERS MARKET OUTLOOK

6.1. Market Size & Forecast
6.1.1. By Value
6.2. Market Share & Forecast
6.2.1. By Type
6.2.2. By Detection Technique
6.2.3. By End user
6.2.4. By Country
6.3. North America: Country Analysis
6.3.1. United States Alzheimer's Disease Biomarkers Market Outlook
6.3.1.1. Market Size & Forecast
6.3.1.1.1. By Value
6.3.1.2. Market Share & Forecast
6.3.1.2.1. By Type
6.3.1.2.2. By Detection Technique
6.3.1.2.3. By End user
6.3.2. Canada Alzheimer's Disease Biomarkers Market Outlook
6.3.2.1. Market Size & Forecast
6.3.2.1.1. By Value
6.3.2.2. Market Share & Forecast
6.3.2.2.1. By Type
6.3.2.2.2. By Detection Technique
6.3.2.2.3. By End user
6.3.3. Mexico Alzheimer's Disease Biomarkers Market Outlook
6.3.3.1. Market Size & Forecast
6.3.3.1.1. By Value
6.3.3.2. Market Share & Forecast
6.3.3.2.1. By Type
6.3.3.2.2. By Detection Technique
6.3.3.2.3. By End user

7. EUROPE ALZHEIMER'S DISEASE BIOMARKERS MARKET OUTLOOK

7.1. Market Size & Forecast

+357 96 030922
info@marketpublishers.com

7.1.1. By Value
7.2. Market Share & Forecast
7.2.1. By Type
7.2.2. By Detection Technique
7.2.3. By End user
7.2.4. By Country
7.3. Europe: Country Analysis
7.3.1. Germany Alzheimer's Disease Biomarkers Market Outlook
7.3.1.1. Market Size & Forecast
7.3.1.1.1. By Value
7.3.1.2. Market Share & Forecast
7.3.1.2.1. By Type
7.3.1.2.2. By Detection Technique
7.3.1.2.3. By End user
7.3.2. France Alzheimer's Disease Biomarkers Market Outlook
7.3.2.1. Market Size & Forecast
7.3.2.1.1. By Value
7.3.2.2. Market Share & Forecast
7.3.2.2.1. By Type
7.3.2.2.2. By Detection Technique
7.3.2.2.3. By End user
7.3.3. United Kingdom Alzheimer's Disease Biomarkers Market Outlook
7.3.3.1. Market Size & Forecast
7.3.3.1.1. By Value
7.3.3.2. Market Share & Forecast
7.3.3.2.1. By Type
7.3.3.2.2. By Detection Technique
7.3.3.2.3. By End user
7.3.4. Italy Alzheimer's Disease Biomarkers Market Outlook
7.3.4.1. Market Size & Forecast
7.3.4.1.1. By Value
7.3.4.2. Market Share & Forecast
7.3.4.2.1. By Type
7.3.4.2.2. By Detection Technique
7.3.4.2.3. By End user
7.3.5. Spain Alzheimer's Disease Biomarkers Market Outlook
7.3.5.1. Market Size & Forecast
7.3.5.1.1. By Value
7.3.5.2. Market Share & Forecast

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info@marketpublishers.com

7.3.5.2.1. By Type
7.3.5.2.2. By Detection Technique
7.3.5.2.3. By End user

8. ASIA PACIFIC ALZHEIMER'S DISEASE BIOMARKERS MARKET OUTLOOK

8.1. Market Size & Forecast
8.1.1. By Value
8.2. Market Share & Forecast
8.2.1. By Type
8.2.2. By Detection Technique
8.2.3. By End user
8.2.4. By Country
8.3. Asia Pacific: Country Analysis
8.3.1. China Alzheimer's Disease Biomarkers Market Outlook
8.3.1.1. Market Size & Forecast
8.3.1.1.1. By Value
8.3.1.2. Market Share & Forecast
8.3.1.2.1. By Type
8.3.1.2.2. By Detection Technique
8.3.1.2.3. By End user
8.3.2. India Alzheimer's Disease Biomarkers Market Outlook
8.3.2.1. Market Size & Forecast
8.3.2.1.1. By Value
8.3.2.2. Market Share & Forecast
8.3.2.2.1. By Type
8.3.2.2.2. By Detection Technique
8.3.2.2.3. By End user
8.3.3. Japan Alzheimer's Disease Biomarkers Market Outlook
8.3.3.1. Market Size & Forecast
8.3.3.1.1. By Value
8.3.3.2. Market Share & Forecast
8.3.3.2.1. By Type
8.3.3.2.2. By Detection Technique
8.3.3.2.3. By End user
8.3.4. South Korea Alzheimer's Disease Biomarkers Market Outlook
8.3.4.1. Market Size & Forecast
8.3.4.1.1. By Value
8.3.4.2. Market Share & Forecast

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info@marketpublishers.com

8.3.4.2.1. By Type
8.3.4.2.2. By Detection Technique
8.3.4.2.3. By End user
8.3.5. Australia Alzheimer's Disease Biomarkers Market Outlook
8.3.5.1. Market Size & Forecast
8.3.5.1.1. By Value
8.3.5.2. Market Share & Forecast
8.3.5.2.1. By Type
8.3.5.2.2. By Detection Technique
8.3.5.2.3. By End user

9. MIDDLE EAST & AFRICA ALZHEIMER'S DISEASE BIOMARKERS MARKET OUTLOOK

9.1. Market Size & Forecast
9.1.1. By Value
9.2. Market Share & Forecast
9.2.1. By Type
9.2.2. By Detection Technique
9.2.3. By End user
9.2.4. By Country
9.3. Middle East & Africa: Country Analysis
9.3.1. Saudi Arabia Alzheimer's Disease Biomarkers Market Outlook
9.3.1.1. Market Size & Forecast
9.3.1.1.1. By Value
9.3.1.2. Market Share & Forecast
9.3.1.2.1. By Type
9.3.1.2.2. By Detection Technique
9.3.1.2.3. By End user
9.3.2. UAE Alzheimer's Disease Biomarkers Market Outlook
9.3.2.1. Market Size & Forecast
9.3.2.1.1. By Value
9.3.2.2. Market Share & Forecast
9.3.2.2.1. By Type
9.3.2.2.2. By Detection Technique
9.3.2.2.3. By End user
9.3.3. South Africa Alzheimer's Disease Biomarkers Market Outlook
9.3.3.1. Market Size & Forecast
9.3.3.1.1. By Value

+357 96 030922
info@marketpublishers.com

9.3.3.2. Market Share & Forecast
9.3.3.2.1. By Type
9.3.3.2.2. By Detection Technique
9.3.3.2.3. By End user

10. SOUTH AMERICA ALZHEIMER'S DISEASE BIOMARKERS MARKET OUTLOOK

10.1. Market Size & Forecast
10.1.1. By Value
10.2. Market Share & Forecast
10.2.1. By Type
10.2.2. By Detection Technique
10.2.3. By End user
10.2.4. By Country
10.3. South America: Country Analysis
10.3.1. Brazil Alzheimer's Disease Biomarkers Market Outlook
10.3.1.1. Market Size & Forecast
10.3.1.1.1. By Value
10.3.1.2. Market Share & Forecast
10.3.1.2.1. By Type
10.3.1.2.2. By Detection Technique
10.3.1.2.3. By End user
10.3.2. Colombia Alzheimer's Disease Biomarkers Market Outlook
10.3.2.1. Market Size & Forecast
10.3.2.1.1. By Value
10.3.2.2. Market Share & Forecast
10.3.2.2.1. By Type
10.3.2.2.2. By Detection Technique
10.3.2.2.3. By End user
10.3.3. Argentina Alzheimer's Disease Biomarkers Market Outlook
10.3.3.1. Market Size & Forecast
10.3.3.1.1. By Value
10.3.3.2. Market Share & Forecast
10.3.3.2.1. By Type
10.3.3.2.2. By Detection Technique
10.3.3.2.3. By End user

11. MARKET DYNAMICS

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11.1. Drivers
11.2. Challenges

12. MARKET TRENDS & DEVELOPMENTS

12.1. Merger & Acquisition (If Any)
12.2. Product Launches (If Any)
12.3. Recent Developments

13. GLOBAL ALZHEIMER'S DISEASE BIOMARKERS MARKET: SWOT ANALYSIS

14. PORTER'S FIVE FORCES ANALYSIS

14.1. Competition in the Industry
14.2. Potential of New Entrants
14.3. Power of Suppliers
14.4. Power of Customers
14.5. Threat of Substitute Products

15. COMPETITIVE LANDSCAPE

15.1. Enzo Life Sciences Inc.
  15.1.1. Business Overview
  15.1.2. Products & Services
  15.1.3. Recent Developments
  15.1.4. Key Personnel
  15.1.5. SWOT Analysis
15.2. Thermo Fisher Scientific Inc.
15.3. AnaSpec Inc.
15.4. Merck KGaA
15.5. Cell Signaling Technology Inc.
15.6. Fujirebio Diagnostics Inc
15.7. 23andMe Inc.
15.8. NanoSomiX Inc.
15.9. QIAGEN NV
15.10. Quest Diagnostics

16. STRATEGIC RECOMMENDATIONS

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