KingMYlab
A Core Member of KingMed
Since 2008

Alzheimer's Disease

—Central Laboratory Solutions for Clinical Trials

Your Best Central Lab Partner for Clinical Trials in China

The Challenge

Alzheimer's disease (AD) is the most common neurodegenerative disorder, marked by insidious onset and early diagnostic challenges. Key hallmarks include amyloid-β(Aβ) deposition and hyperphosphorylated tau(p-tau) aggregation. Symptoms lag behind pathology by up to 10–20 years-allowing significant Aβ burden to accumulate before cognitive decline appears.

China has the world's largest AD patient population

~38.8 million adults aged 60+ have MCI

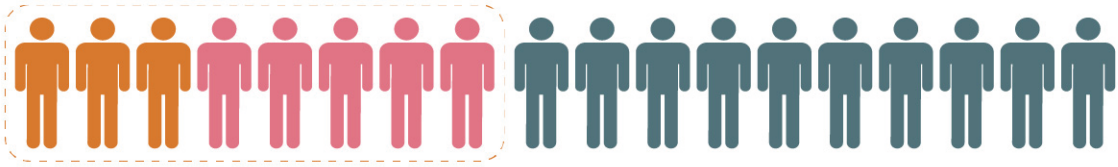
3877

~15.1 million have dementia

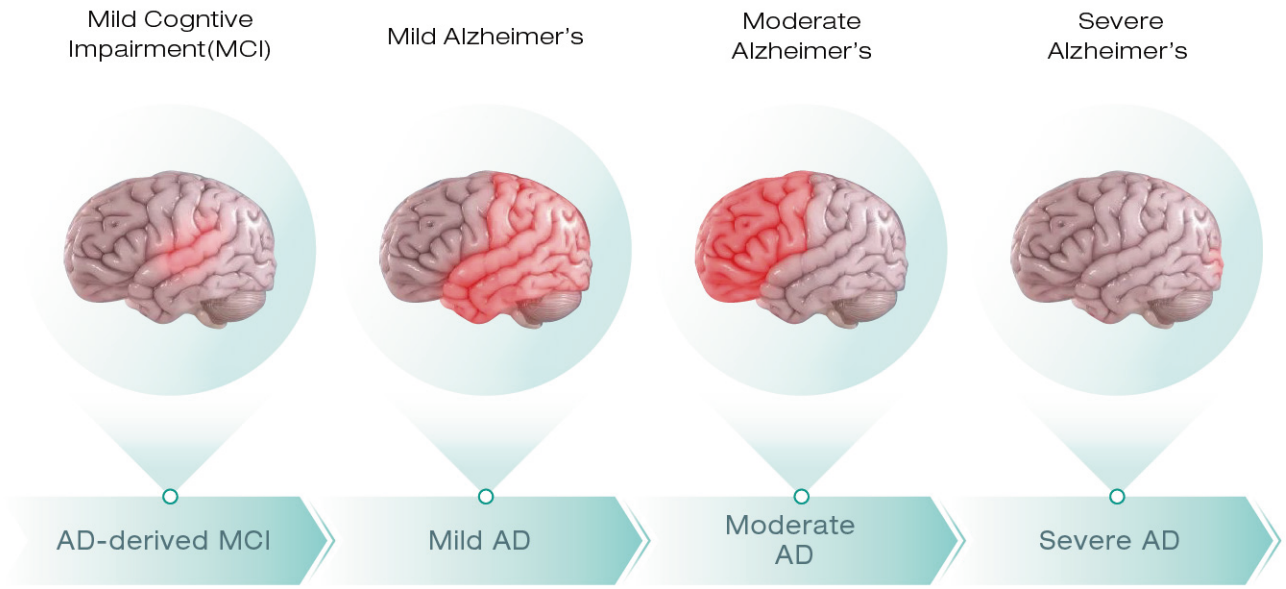
1507

~9.8 million are diagnosed with AD

983



Data source: Chinese Expert Consensus on the Diagnosis and Treatment of Mild Cognitive Impairment Due to Alzheimer's Disease (2024)



Early identification and diagnostic intervention

With disease-modifying therapies (DMT) targeting Aβ—including lecanemab and donanemab—now receiving approvals, early detection of AD neuropathological changes is more crucial than ever. The clinical success of these therapies depends on identifying patients in the earliest stages, creating an urgent need for scalable, accurate screening solutions.

The Shift to Blood-Based Biomarkers

Current diagnostic methods—amyloid positron emission tomography (PET) imaging and invasive cerebrospinal fluid (CSF) assays—are limited by high cost, slow turnaround, and poor patient tolerability. Advances in high-sensitivity immunoassays have enabled a shift to blood-based biomarker detection, offering a minimally invasive, scalable solution for the early AD screening and diagnosis.

The clinical value of blood-based biomarkers is increasingly recognized in leading clinical guidelines and consensus statements

(NIA-AA) Revised Criteria for the Diagnosis and Staging of Alzheimer's Disease (2024)

Changes in blood-based AD biomarkers, such as Aβ and p-tau, align with neuropathological alterations, supporting their feasibility for clinical diagnosis of AD

Chinese Expert Consensus on the Diagnosis and Treatment of Mild Cognitive Impairment Due to Alzheimer's Disease (2024)

Plasma Aβ42/40, p-tau217, p-tau181, NfL, and GFAP, along with integrated models, are recommended for early screening, diagnosis, and disease progression evaluation in ADrelated MCI, may serve as DMT follow-up biomarkers (Π b)

Chinese Guideline for Clinical Application of Fluid Biomarkers for Alzheimer's Disease (2024 Edition)

Individual plasma Aβ42, Aβ42/40, p-tau181, or p-tau21 can be used for AD diagnosis and assessing the risk of disease progression (1B)

Plasma Aβ42/40 ratio, p-tau181, and p-tau217 can be used for screening AD patients, whereas plasma GFAP and NfL can be used for dementia screening (1B)

Clinical Practice Guideline for Blood-Based Biomarker Tests for Alzheimer's Disease (2024)

Screening: Blood p-tau217 and p-tau181 are highly correlated with AD pathology in AD-derived MCI or AD (IA)

Diagnosis: Blood p-tau217 and p-tau181 are highly correlated with AD pathology in AD-derived MCI or AD (IA)

Peripheral blood biomarkers for early clinical research of AD

1. Blood based multi-biomarker panels, compared to single biomarkers, provide more accurate predictions
2. Blood based multi-biomarker panels, compared to CSF analysis and PET, offer a simpler and minimally invasive alternative
3. Suitable for large-scale screening, long-term monitoring, and beyond

Our Capabilities

AD fluid biomarkers support a range of applications —from screening, diagnosis, to disease staging, prognosis, and clinical trial enrollment. We provide high-quality standardized central labratory support for AD therapeutic development using multiple ultra-sensitive platforms, including Lumipulse and Simoa, to deliver reliable, regulatory-ready biomarker data.

	A Amyloid- β	T Tau (T)	N Neurodeg-eneration	I Inflammation	Genetic risk-related genes
Cerebrospinal fluid/blood	Aß 1-42 Aß 1-40	P-tau 181 P-tau 217 P-tau 231	NfL	GFAP	APOE, PSEN1, PSEN2, APP, SORL1, TREM2, ABCA7, etc.

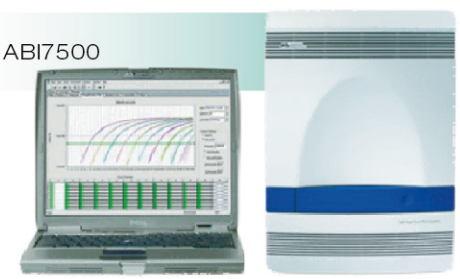
High-sensitivity platforms such as Lumipulse and MSD cover core AD fluid biomarkers, while molecular platforms such as qPCR and NGS comprehensively cover AD-related genetic risk genes

Lumipulse (Fujirebio)

MSD

NovaSeq600

ABI7500



KingMylab Lumipulse Platform:
Empowering Efficient Solutions for Alzheimer's Disease Clinical Trials

| International high-quality standards central lab

Built upon internationally recognized quality systems including CAP, CLIA, and ISO 15189;
Full compliant with GCP/GCLP requirements for clinical trials under NMPA, FDA, and EMA.

CSF and plasma biomarkers completed developed and analytical validated on Lumipulse: Aβ42, Aβ40, P-tau181, P-tau217, NfL, GFAP
Enabling early AD detection, disease progression monitoring, and therapeutic development.

Test list	Index
amyloid-β	Aβ1-42
	Aβ1-40
Tau (T)	P-tau 181
	P-tau 217
AD-related index	NfL
	GFAP

| Product features

Minimally Invasive
Peripheral blood sampling

Rapid
Multiplex biomarker results in just 30 minutes

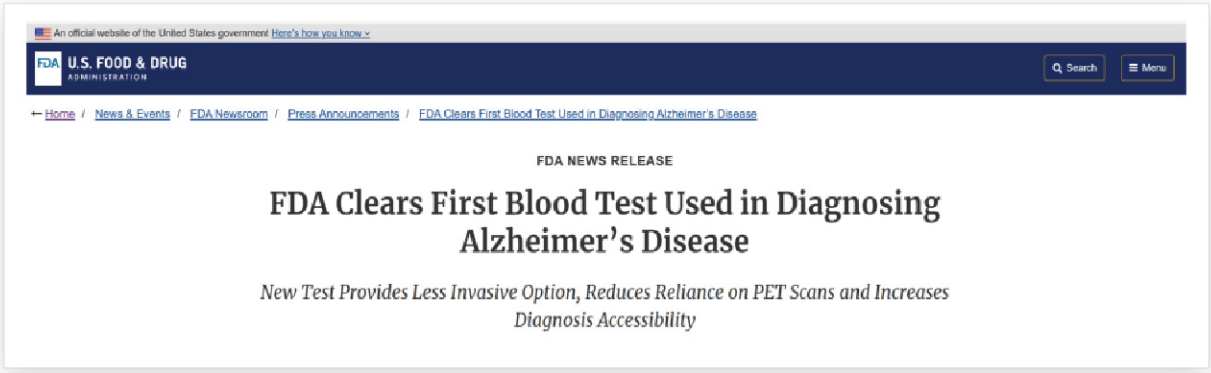
Ultra-Sensitive
Picogram-level analytical sensitivity

Accurate
High specificity
High accuracy
Excellent reproducibility

Authoritative
NMPA/ FDA/CE Registered
Full 3Q validation

User-Friendly
Highly automated workflow
Minimizes manual intervention & variability

| First FDA-Cleared AD Blood Test on Lumipulse: P-tau217/Aβ42


An official website of the United States government Here's how you know
U.S. FOOD & DRUG ADMINISTRATION
Search Menu
Home / News & Events / FDA Newsroom / Press Announcements / FDA Clears First Blood Test Used in Diagnosing Alzheimer's Disease
FDA NEWS RELEASE
FDA Clears First Blood Test Used in Diagnosing Alzheimer's Disease
New Test Provides Less Invasive Option, Reduces Reliance on PET Scans and Increases Diagnosis Accessibility

KingMYlab

Scientific, Compliant & Comprehensive
Central Laboratory and Data Services for Clinical Trials

Accelerating drug development, advancing human health

www.kingmylab.com

Address: [Hong Kong] Unit 1, 1F, Remington Centre, 23 Hung To Road, Kwun Tong, Hong Kong, P.R. China.
[GuangZhou] 6F, Building 2, Unit 2 Luoxuan 4th Road, GuangZhou International Bio Island, Guangdong, P.R.China;
[Shanghai] 5F, Building 3, 115 Xinjun Ring Road, Minhang District, Shanghai, P.R. China;
E-mail: kingmylab@kingmylab.com
Tel: 020-28330088