Strategy for Early Detection and Diagnosis for

Brain Neurological Disorders

Using Ezdiatech's Multiplexed Biomarker Kits

ezDiaTECH

GIVE CONCERNS, TAKE HEALTH

RUO-3202-R0

Ezdiatech's cutting edge Solution

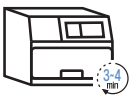
MFDS Medical Device approved

CE IVDR approved

VEUDx Analyzer

- Principle : Fluorescence coding / analysis
- Size : 530 mm(W) X 485 mm(D) X 465 mm(H)
- Weight : 33.8 kg
- Cartridge slots: up to 6 cartridges Desorption Tray type
- Power Supply : AC 100-120V, 50/60Hz or AC 200-240V, 50/60Hz
- Display : 7 inch Touch LCD, 1024 x 600

Features

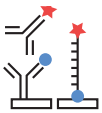


Fast warming time

With no warming time required, the system enables immediate testing as it can reach 37℃ within 3-4 min , reducing test preparation time.

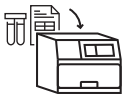
Efficient mixing / washing

The up&down / well to well movement technology of magnetic particles makes reaction and washing easy and reduces both waste generation and automatic device size, enabling economical and eco-friendly use.



Multiplex assay

Based on the magnetic particle size-based coding system, the VEUS system allows multiplexed diagnostics.



ALL-IN-ONE system

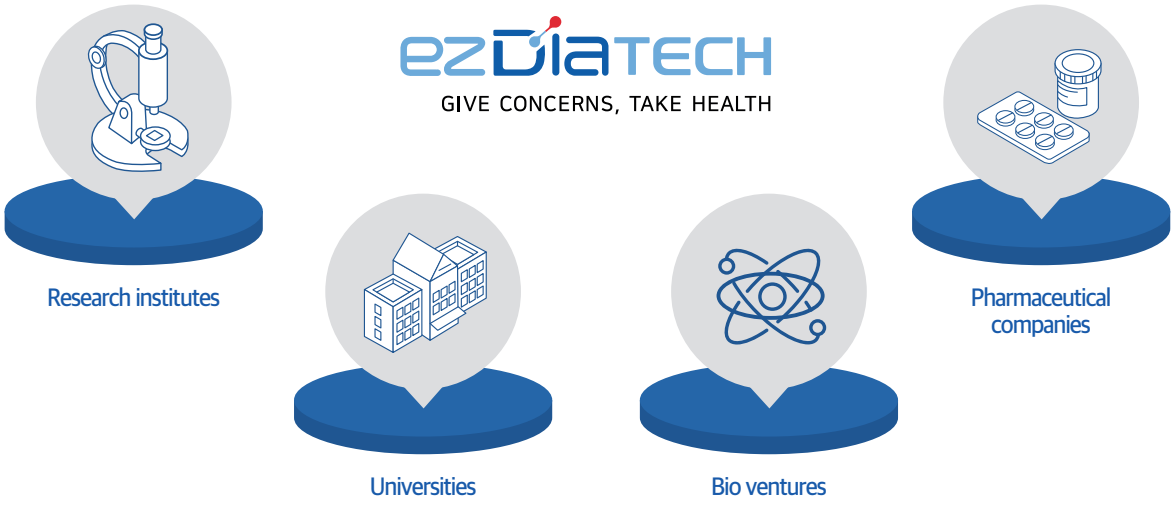
With the reaction and optical modules integrated as a unit, the VEUS system allows easy operation.

Multiplexed diagnostics of brain diseases (Neurology)

The rapid increase of patients with brain diseases, due to rapidly ageing population worldwide, is expected to incur two trillion USD medical care costs from 75 million patients by 2030. As population ageing in Korea is progressing 4.5times faster than that of other OECD countries, it is evident that brain diseases such as dementia, Alzheimer's, and cerebral infarction will become a more serious social issue. Traditionally, for diagnosis of dementia, Alzheimer's and other brain diseases, combined tests including tests on brain blood vessel disease / brain atrophy through MRI and Alzheimer's Disease Assessment Scale (ADAS) are conducted. However, these diseases can be detected only when brain atrophy or other diseases have early progressed. Therefore, active R&D is underway for using biomarkers to determine the exact cause of diseases and perform early treatment through early diagnosis before symptoms appear.

Price **1/5 Less**	Time Spent less than half	Our multiplexed diagnostics of brain diseases (Neurology) using VEUS, a multiplex immunoassay system, does not only enable diagnosis before patients are symptomatic by accurately and rapidly investigate various brain disease-specialized biomarkers, but also provide accurate solutions for proper treatments.
Expert Not needed	Accuracy more than 90%	**Our brain disease (Neurology) multiplexed assay kit can investigate 3~4 biomarkers simultaneously, providing more than 90% accurate results.**

Business application fields



RUO Product Order Information

Category	Model No.	Product Name	Unit
Equipment	V1-01A-2	VEUDx analyzer	Set
	CF01010	Spin down Centrifuge with Rotor	Set
IVD kit	EZ-TBIV	VEUPLEX™ TBI assay - CE	60 test / Kit
RUO kit	EZ-VI-NFL01	VEUPLEX™ Neuro 1p-A (NfL)	60 test / Kit
	EZ-VI-GFA01	VEUPLEX™ Neuro 1p-B (GFAP)	60 test / Kit
	EZ-VI-UCH01	VEUPLEX™ Neuro 1p-C (UCH-L1)	60 test / Kit
	EZ-VI-TBIV01	VEUPLEX™ Neuro 2p-A (GFAP, UCH-L1)	60 test / Kit
	EZ-VI-TAU01	VEUPLEX™ Neuro 3p-A (pTau 181, pTau 231, Total Tau)	60 test / Kit
	EZ-VI-TAU02	VEUPLEX™ Neuro 1p-D (pTau 181)	60 test / Kit
	EZ-VI-TAU03	VEUPLEX™ Neuro 1p-E (pTau 231)	60 test / Kit
	EZ-VI-TAU04	VEUPLEX™ Neuro 1p-F (Total Tau)	60 test / Kit
	EZ-VI-NEU02	VEUPLEX™ Neuro 2p-B (Amyloid β 40, 42)	60 test / Kit
	EZ-VI-NEU03	VEUPLEX™ Neuro 1p-G (Amyloid β 40)	60 test / Kit
	EZ-VI-NEU04	VEUPLEX™ Neuro 1p-H (Amyloid β 42)	60 test / Kit
	EZ-VI-NEU05	VEUPLEX™ Neuro 1p-I (α-synuclein)	60 test / Kit
Quality Control	EZ-VI-TBIV02	VEUPLEX™ Neuro 2p-A (GFAP, UCH-L1) QC	10 test / Kit
Calibrator	EZ-VI-TBIV03	VEUPLEX™ Neuro 2p-A (GFAP, UCH-L1) Calibrator	2 test / Kit
Consumables	EZ-VI-TIP04	T-tip	60 ea / Pack

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Alzheimer's disease, it's more than an individual now, and became a societal problem.

■ The rise of an ageing society

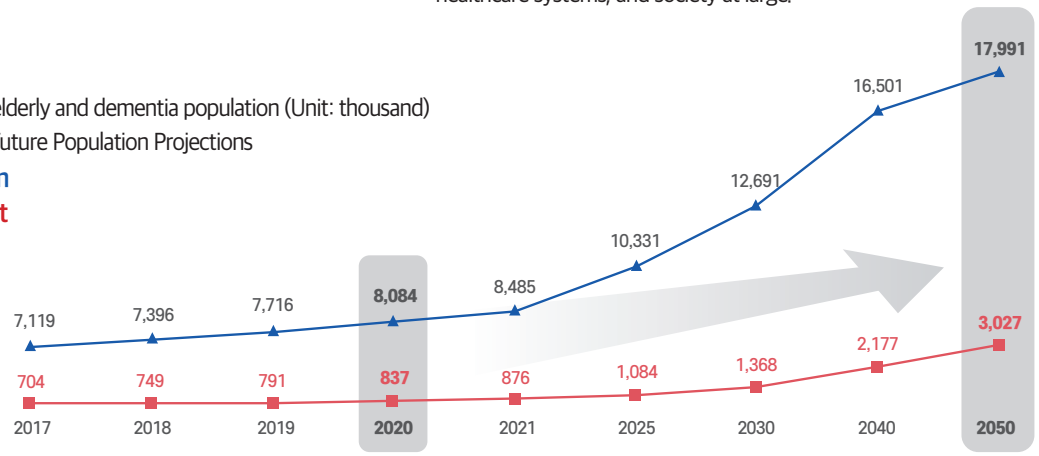
The average life expectancy is increasing to over 78 years old, with women living an average of 5.5 years longer than men. The number of people with Alzheimer's disease is also increasing rapidly.

■ Family and social burdens

Alzheimer's disease requires long-term treatment and ongoing care. It has a profound impact not only on patients, but also on families, healthcare systems, and society at large.

Projected growth of the elderly and dementia population (Unit: thousand)
Source: Statistics Korea, Future Population Projections

▲ : Elderly population
■ : Dementia patient



What are the limitations of traditional diagnostics, and why are they difficult?

■ Complex disease mechanisms

Alzheimer's disease is a brain disorder with many different causes.

■ The burden of invasive diagnostics

Tissue testing can cause damage to brain cells, and cerebrospinal fluid (CSF) testing places a heavy burden on the patient.

■ Clear limitations of imaging (PET)

PET scans are only available after symptoms have developed, so early diagnosis is not possible. In addition, not all patients can be accurately diagnosed, as some patients with advanced symptoms may not show abnormalities on PET scans.

■ Single biomarker tests are not enough

A comprehensive analysis of multiple biomarkers is essential for an accurate diagnosis of Alzheimer's disease.

A diagnostic framework for precise classification of Alzheimer's disease : AT-NIVS

A : Amyloid beta(Aβ) T : Tau N : NfL(for Neurodegeneration) I : GFAP(for Inflammation) V : Vascular Brain Injury
S : α-Synuclein(for Synucleinopathy)

| AT-NIVS Profile Analysis

A	T	N (NfL)	I (GFAP)	V (MRI/CT)	S (α-syn)	Interpretation (e.g.)
O	-	-	-	-	-	Early A+ status (Preclinical AD)
O	O	-	-	-	-	Typical AD early stages
O	O	O	-	-	-	AD in progress, with neurodegeneration
-	-	O	-	-	-	Non-AD neurodegenerative diseases (LATE, ALS, CTE, etc.)
-	-	-	O	-	-	Brain inflammation-based disease or abnormal immune activity
-	-	-	-	O	-	Vascular Cognitive Impairment, Small Vessel Disease
-	-	-	-	-	O	Lewy body pathology (DLB, Parkinson's disease dementia, etc.)

"Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup"(2024)

- Need for a comprehensive diagnostic classification system that considers both core AD biomarkers (Aβ, Tau) and non-core AD biomarkers (N, I, V, S)
- Blood-based multiplex assay technology is needed to make this possible.

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KURULUŞ 1993

K-Q TSE-ISO-EN 9000

TÜRKAK

" Evaluating the diagnostic efficiency of multiple biomarkers for Alzheimer's disease diagnosis"

■ Purpose

- To assess the validity of an early diagnostic test for Alzheimer's disease / review its clinical applicability

■ Sample size / type

- 100 samples (Istanbul, Turkey) / Serum & Plasma (50 µL)

■ Methods

- Ezdiatech VEUDx analyzer & RUO kit
- Biomarkers: pTau 231, pTau 181, Total Tau, Aβ42, Aβ42/Aβ40 ratio

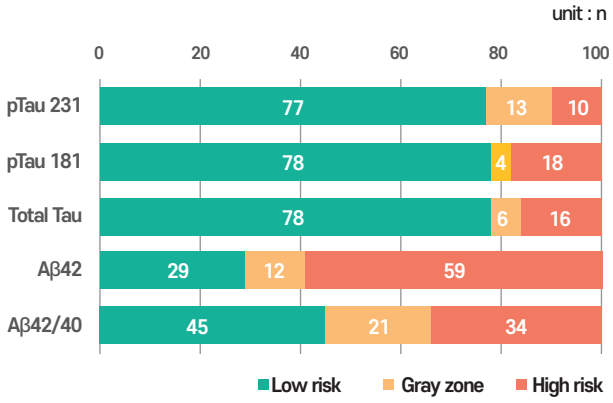
Finding 1. A key to the accurate AD diagnosis.

Threshold range

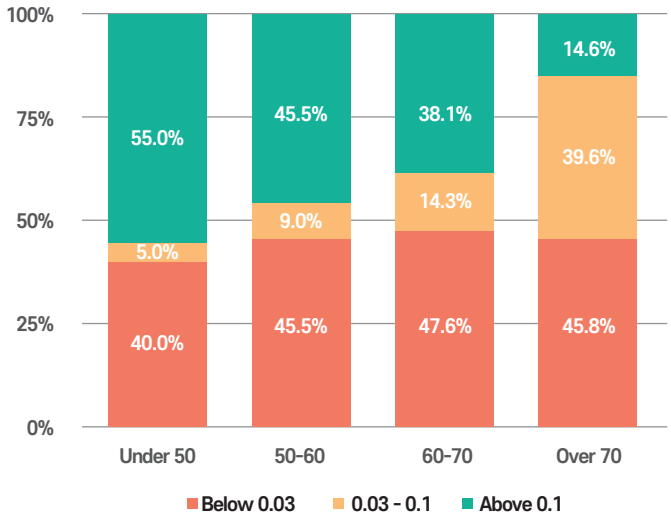
unit : pg/mL

Marker	Low risk	Gray zone	High risk
pTau 231	<0.7	0.7 - 0.8	>0.8
pTau 181	<0.1	1.0 - 1.1	>1.1
Total Tau	<0.7	0.7 - 0.8	>0.8
Aβ42	>20	10 - 20	<10
Aβ42/40 (Ratio)	>0.1	0.03 - 0.1	<0.03

Measurement results



Finding 2. Changes in Aβ42/40 ratio with increasing age are effective in diagnosing AD.



■ Increasing age ▶ decreasing low risk proportion & increasing number of cases of low Aβ42/40 ratio

- High risk rate spikes from mid to late life

Suggesting that the Aβ42/40 ratio is a key biomarker that changes sensitively with ages

Finding 3. The multi-biomarker approach is essential for accurate Alzheimer's diagnosis.

- Alzheimer's disease is a complex condition that is difficult to diagnose accurately using a single biomarker alone.
- Therefore, a "multi-biomarker" approach is required to increase the reliability of the diagnosis.
- Evaluating multiple biomarkers together, such as pTau 231, pTau 181, Total Tau, Aβ42, and Aβ42/40 ratio, allows for a more precise assessment of disease progression and risk, improving overall diagnostic accuracy.

Total Tau	pTau181	pTau231	Aβ42	Aβ42/40	Interpretation (e.g.)
0	0	0	0	0	Complete AD profiles
0	0	-	0	0	AD in progress
-	0	-	0	0	Early AD pathology
-	0	-	0	-	Early Aβ accumulation, onset of tau-centred pathology
0	0	0	-	-	Tau-centred AD pathology
-	0	0	-	-	Tau-based pathologies
0	0	-	-	-	Advanced Tau-driven AD
-	0	-	-	-	Requires monitoring

Conclusions

01

- Practical and Sensitive Methodology

▶**The use of simple plasma and serum instead of cerebrospinal fluid (CSF) and the application of automated, highly sensitive fluorescent immunometry (FIA) proved effective.**

02

- Both Serum and Plasma are Valid

▶**Both plasma and serum were diagnostic, with slightly higher detection sensitivity observed in plasma.**

03

- Established Reference Values

▶**Established clinical reference values for each biomarker.**

04

- Early Onset Signs from Age 30-40

▶**Early abnormalities associated with Alzheimer's disease have been observed in people as young as 30 to 40 years of age, with accelerated disease progression in the 50s and 60s and widespread pathological changes in the 70s and beyond.**

05

- Multiplex Testing Enhances Diagnostic Power

▶**While a single biomarker alone was found to have limited diagnostic accuracy in some patients, when multiple biomarkers were analysed simultaneously, diagnostic accuracy was significantly improved.**

※ This preliminary study utilized the Ezdiatech kit and was conducted with a randomly selected primarily composed of older adults. Accordingly, further investigations encompassing broader age ranges and diverse population groups are warranted to validate and extend these findings.