Lifting the Fog

New biomarkers. New perspectives.

We build on thirty years of experience with Alzheimer's disease as we continue to invest in the development of new biomarker tests for routine and research, including for the broader spectrum of neurodegenerative diseases.

In 1995, we were the first to market with a biomarker for the early detection of Alzheimer's disease in cerebrospinal fluid (CSF). Since then, we have worked closely with the scientific community to develop several first-in-class biomarkers for neurodegeneration testing.

Today, we are the only company with a comprehensive product line for Alzheimer's disease that can be used on fully automated systems. Recognizing the scope of what remains to be achieved, we continue to invest in the development of new markers and easy-to-perform blood tests, not only for the diagnosis of Alzheimer's disease, but having the full spectrum of neurodegenerative diseases in our focus.

These terrible diseases can affect both the central as well as the peripheral nervous system with severe outcomes for the individual patient. A common problem is that the diagnosis is made at late stages, despite the fact that the disease can sometimes start years before clinical symptoms appear. What is needed is a wide range of simple tests in both CSF and blood to assist clinicians in identifying the patients early and accurately, select the right therapies and monitor them, and thus better help and support patients suffering from neurodegenerative diseases. This is what we are working on at Fujirebio.

A comprehensive Neuro panel

	CSF	Blood
Lumipulse® G		
β-Amyloid 1-42	+	+
β-Amyloid 1-40	+	+
pTau 181	+	+
Total Tau	+	
NfL	+	+
ApoE4		+
Pan-ApoE		+
pTau 217*		+
GFAP*	+	+
INNOTEST®		
β-AMYLOID$_{(1-42)}$	+	
β-AMYLOID$_{(1-40)}$	+	
PHOSPHO-TAU$_{(181P)}$	+	
hTAU Ag	+	
sTREM2	+	
NPTX2	+	

Lumipulse G assays should be run on fully automated CLEIA analyzers LUMIPULSE G600 II and LUMIPULSE G1200; INNOTEST assays are in the ELISA format. CLEIA = chemiluminescent enzyme immunoassay; CSF = cerebrospinal fluid; ELISA = enzyme-linked immunosorbent assay.
* In development

FUJIREBIO

Effective solutions for neurodegenerative disease testing

INNOTEST® CSF AD biomarkers (CE-IVDD / RUO)

Using the basic ELISA principle, the INNOTEST hTAU Ag was the first fluid biomarker assay for the early detection of Alzheimer's disease (AD) in 1995. In the following years, the INNOTEST biomarker panel was extended to include the four core biomarkers (β-amyloid$_{1-42}$, β-amyloid$_{1-40}$, total Tau and pTau$_{181}$) in cerebrospinal fluid (CSF) and was the most widely used platform to generate scientific evidence required for wide-spread implementation of CSF biomarkers to support the diagnosis of AD. These assays are available worldwide through our extensive sales network.

Lumipulse® G CSF AD biomarkers (CE-IVDR / JP-IVD / US-FDA / RUO)

The Lumipulse G assays, intended to measure β-amyloid$_{1-42}$, β-amyloid$_{1-40}$, total Tau and pTau$_{181}$ in CSF to aid in the diagnosis of patients with AD and other causes of cognitive decline, are part of Fujirebio's fully automated Neuro product line and are specifically designed to be run on the LUMIPULSE G instruments. Due to the mono-test cartridge principle where one test equals one cartridge, waste of reagents and the need for batch-testing can be avoided, while a quality result is guaranteed during the entire shelf life. The Lumipulse CSF panel for AD has very fast become the industry standard since its availability in 2018. In addition, the Lumipulse G β-Amyloid (1-42/1-40) Ratio became the first FDA-authorized fluid biomarker for AD in 2022.

Lumipulse® G Plasma AD biomarkers (RUO)

There is hope that blood-based testing for AD can become an even simpler, more accessible, and more scalable approach to help support the diagnosis and/or early risk assessment of AD. With the launch of the Lumipulse G pTau 181, β-Amyloid 1-42 and β-Amyloid 1-40 Plasma assays, automated blood-based biomarker testing for AD allows researchers and clinical research professionals to further study the clinical utility of this marker on the LUMIPULSE G platform that meets the necessary throughput, quality and regulatory requirements to support possible future routine use.

Lumipulse® G NfL CSF and Blood (RUO)

The Neurofilament light (NfL) solutions are one of the latest developments in the growing Lumipulse Neuro menu and represent two individual immunoassays for the sensitive quantification of NfL in CSF and plasma/serum, respectively. The new biomarker tests will allow researchers and clinical research professionals across the world to further study the clinical utility of NfL in diverse chronic conditions such as multiple sclerosis, amyotrophic lateral sclerosis, frontotemporal dementia, Parkinson's disease, or AD as well as in acute situations such as traumatic brain injury. NfL is considered a promising biomarker for disease activity, progression, prognosis, and monitoring effectiveness of therapies.

Lumipulse® G ApoE4 & Pan-ApoE (RUO)

These fully automated assays allow for the quantitative measurement of the E4 isoform of the apolipoprotein E (ApoE4), specifically, and for all isoforms of the same protein (Pan-ApoE) in plasma, respectively. When both assays are combined, the ApoE4/Pan-ApoE ratio can be calculated to determine the ApoE proteotype status for the sample tested meaning absence of ApoE4, presence of ApoE4 only (homozygous) or in combination with ApoE2 or E3 (heterozygous). Molecular testing remains the golden standard for APOE genotyping, however quantification of the ApoE proteins using immunoassays could provide information related to the expression of the proteins.

DiaPlexQ™ ApoE Genotyping Kit (CE-IVDD)

Fujirebio also provides the DiaPlexQ™ ApoE Genotyping Kit, developed by SolGent, which is designed to screen for single nucleotide polymorphisms in positions 112 and 158 of the APOE gene using a real-time multiplex allele-specific PCR. The APOE β4 allele is the most common genetic risk factor of AD.

INNOTEST® sTREM2 and NPTX2 (RUO)

The INNOTEST® NPTX2 and sTREM2 assays are ELISAs for the quantitative determination of neuronal pentraxin-2 (NPTX2) and soluble Triggering Receptor Expressed on Myeloid cells 2 (sTREM2) in CSF. These two proteins are linked to synaptic dysfunction and neuroinflammation, respectively. Drug targets related to other (non-amyloid, non-Tau) mechanisms are gaining more interest. Well-characterized assays for these novel markers offer researchers the required tools to further elucidate the pathogenesis of neurodegenerative diseases further and support the AD drug development pipeline.

Order Information

INNOTEST®	Packaging	Reference	Regulatory label	Sample volume
EIA kit				
INNOTEST® β-AMYLOID$_{(1-42)}$ (CSF)	96 tests	81576	CE-IVDD	2 x 25 µL
		81583	RUO	
INNOTEST® β-AMYLOID$_{(1-40)}$ (CSF)	96 tests	80462	CE-IVDD	2 x 25 µL (1:100 dilution)
		81585	RUO	
INNOTEST® hTAU Ag (CSF)	96 tests	81572	CE-IVDD	2 x 25 µL
		81579	RUO	
INNOTEST® PHOSPHO-TAU$_{(181P)}$ (CSF)	96 tests	81574	CE-IVDD	2 x 75 µL
		81581	RUO	
INNOTEST® sTREM2 (CSF)	96 tests	81056	RUO	2 x 15 µL (1:4 dilution)
INNOTEST® NPTX2 (CSF)	96 tests	80908	RUO	2 x 25 µL (1:2 dilution)
CAL-RVC packs				
Aβ$^{(1-42)}$ CAL-RVC pack	2 x 6 CAL (0.2 mL)	81577	CE-IVDD	
	2 x 2 RVC (0.2 mL)	81584	RUO	
Aβ$^{(1-40)}$ CAL-RVC pack	2 x 8 CAL (0.4 mL)	80461	CE-IVDD	
	2 x 2 RVC (0.4 mL)	81586	RUO	
Tau Ag CAL-RVC pack	2 x 6 CAL (0.2 mL)	81573	CE-IVDD	
	2 x 2 RVC (0.2 mL)	81580	RUO	
PHOSPHO-TAU CAL-RVC pack	2 x 6 CAL (0.4 mL)	81575	CE-IVDD	
	2 x 2 RVC (0.4 mL)	81582	RUO	
sTREM2 CAL-RVC pack	1 x 8 CAL (0.4 mL) 2 x 2 RVC (0.4 mL)	81057	RUO	
NPTX2 CAL-RVC pack	1 x 8 CAL (0.4 mL) 2 x 2 RVC (0.4 mL)	80909	RUO	

SolGent	Packaging	Reference	Regulatory label
DiaPlexQ ApoE Genotyping Kit (oral epithelial cells, hair roots, and whole blood)	100 tests	81311	CE-IVDD

* Can be used in combination with Lumipulse® G β-Amyloid 1-42 and Lumipulse® G β-Amyloid 1-40 Immunoreaction Cartridges and Calibrators.

** Can be used in combination with Lumipulse® G β-Amyloid 1-42 Plasma and Lumipulse® G β-Amyloid 1-40 Plasma Immunoreaction Cartridges and Calibrators.

Can be used in combination with Lumipulse® G ApoE4 and Lumipulse® G Pan-ApoE Immunoreaction Cartridges and Calibrators.

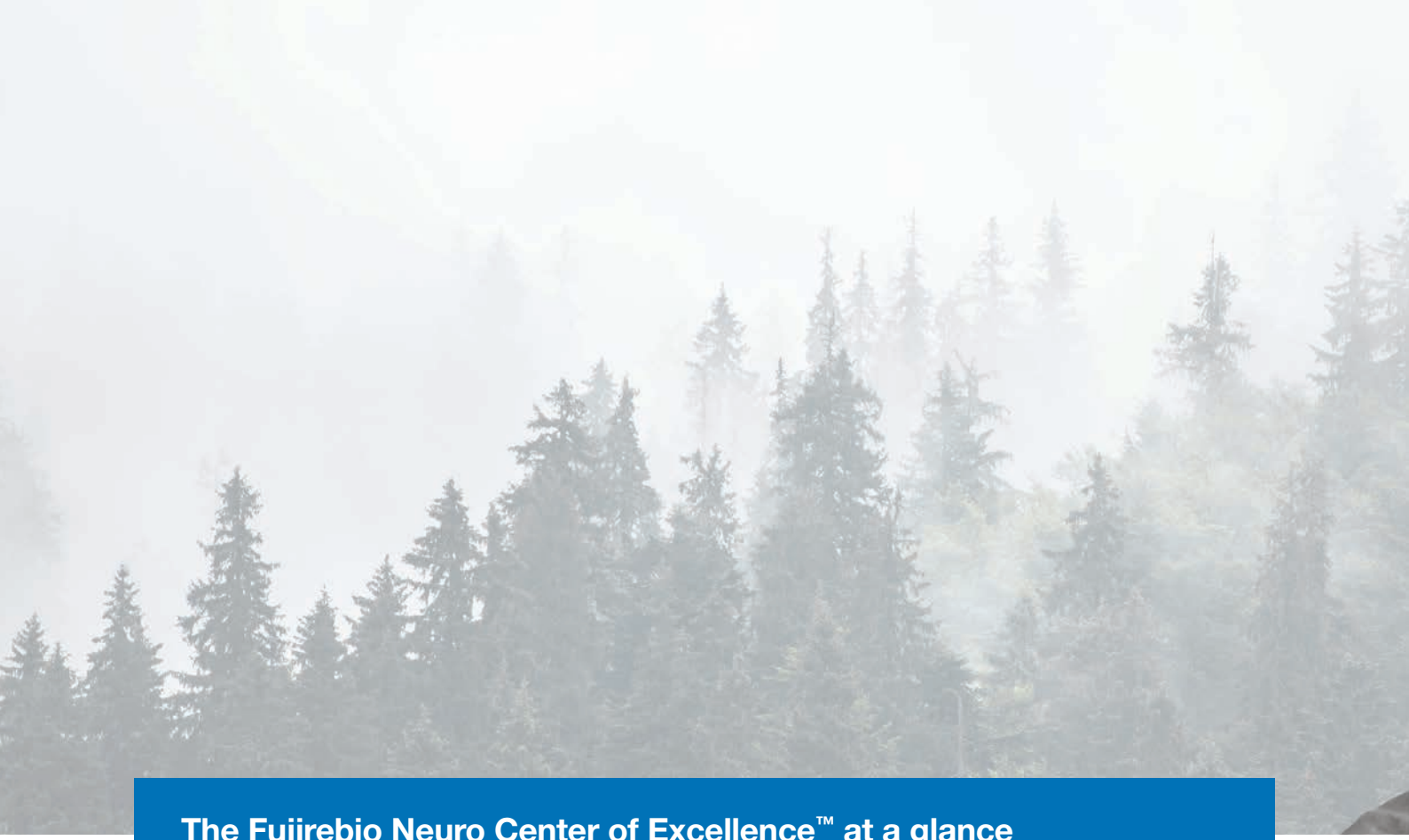
Contact your local distributor for assessing compatibility of sample containers with the LUMIPULSE® G System.

° FDA-authorized product Lumipulse® G β-Amyloid (1-42/1-40) Ratio: The Lumipulse® G β-Amyloid 1-42 assay should only be used with the Lumipulse® G β-Amyloid 1-40 to calculate the ratio of β-amyloid 1-42 / β-amyloid 1-40. The Lumipulse® G β-Amyloid 1-42 and Lumipulse® G β-Amyloid 1-40 assays are not intended to be used individually.

LUMIPULSE® G				
Immunoreaction Cartridges	**Packaging**	**Reference**	**Regulatory label**	**Sample volume**
Lumipulse® G β-Amyloid 1-42 Immunoreaction Cartridges (CSF)	3 x 14 tests	230336	CE-IVDR / JP-IVD	50 µL
		231432	US-FDA°	
		231685	RUO (US)	
Lumipulse® G β-Amyloid 1-40 Immunoreaction Cartridges (CSF)	3 x 14 tests	231524	CE-IVDR / JP-IVD	40 µL
		231753	US-FDA°	
		231463	RUO (US)	
Lumipulse® G Total Tau Immunoreaction Cartridges (CSF)	3 x 14 tests	230312	CE-IVDR / JP-IVD	75 µL
		231302	RUO (US)	
Lumipulse® G pTau 181 Immunoreaction Cartridges (CSF)	3 x 14 tests	230350	CE-IVDR / JP-IVD	40 µL
		231654	RUO (US)	
Lumipulse® G NfL CSF Immunoreaction Cartridges	3 x 14 tests	81426	RUO (EU / US)	60 µL
		261170	RUO (Japan)	
Lumipulse® G β-Amyloid 1-42 Plasma Immunoreaction Cartridges	3 x 14 tests	81301	RUO (EU / US)	110 µL
		260845	RUO (Japan)	
Lumipulse® G β-Amyloid 1-40 Plasma Immunoreaction Cartridges	3 x 14 tests	81298	RUO (EU / US)	70 µL
		260869	RUO (Japan)	
Lumipulse® G pTau 181 Plasma Immunoreaction Cartridges	3 x 14 tests	81288	RUO (EU / US)	130 µL
		260890	RUO (Japan)	
Lumipulse® G NfL Blood Immunoreaction Cartridges (plasma, serum)	3 x 14 tests	81215	RUO (EU / US)	100 µL
		261330	RUO (Japan)	
Lumipulse® G ApoE4 Immunoreaction Cartridges (plasma)	3 x 14 tests	81453	RUO (EU / US)	20 µL
		261316	RUO (Japan)	
Lumipulse® G Pan-ApoE Immunoreaction Cartridges (plasma)	3 x 14 tests	81449	RUO (EU / US)	20 µL
		261286	RUO (Japan)	
Calibrators	**Packaging**	**Reference**	**Regulatory label**	
Lumipulse® G β-Amyloid 1-42 Calibrators set	2 x 3 conc x 1.0 mL	230343	CE-IVDR	
		234884	US-FDA°	
		231487	RUO (US)	
		260258	JP-IVD	
Lumipulse® G β-Amyloid 1-40 Calibrators set	2 x 3 conc x 1.0 mL	231531	CE-IVDR	
		234891	US-FDA°	
		231692	RUO (US)	
		260241	JP-IVD	
Lumipulse® G Total Tau Calibrators set	2 x 3 conc x 1.0 mL	230329	CE-IVDR	
		231326	RUO (US)	
		260203	JP-IVD	
Lumipulse® G pTau 181 Calibrators	1 x 3 conc x 1.5 mL	230367	CE-IVDR	
		231661	RUO (US)	
		260227	JP-IVD	
Lumipulse® G NfL CSF Calibrators	1 x 5 conc x 1.5 mL	81413	RUO (EU / US)	
		261187	RUO (Japan)	
Lumipulse® G β-Amyloid 1-42 Plasma Calibrators	1 x 5 conc x 1.5 mL	81303	RUO (EU / US)	
		260852	RUO (Japan)	
Lumipulse® G β-Amyloid 1-40 Plasma Calibrators	1 x 5 conc x 1.5 mL	81299	RUO (EU / US)	
		260876	RUO (Japan)	
Lumipulse® G pTau 181 Plasma Calibrators	1 x 5 conc x 1.5 mL	81289	RUO (EU / US)	
		260906	RUO (Japan)	
Lumipulse® G NfL Blood Calibrators	1 x 5 conc x 1.5 mL	81422	RUO (EU / US)	
		261200	RUO (Japan)	
Lumipulse® G ApoE4 Calibrators	1 x 5 conc x 0.3 mL	81454	RUO (EU / US)	
		261323	RUO (Japan)	
Lumipulse® G Pan-ApoE Calibrators	1 x 5 conc x 0.3 mL	81450	RUO (EU / US)	
		261293	RUO (Japan)	
Controls	**Packaging**	**Reference**	**Regulatory label**	
Lumipulse® β-Amyloid Controls*	2 x 3 conc x 1.0 mL	231548	CE-IVDR	
		234907	US-FDA°	
		260265	JP-IVD	
Lumipulse® Total Tau Controls	2 x 3 conc x 1.0 mL	230237	CE-IVDR	
		231319	RUO (US)	
		260210	JP-IVD	
Lumipulse® pTau 181 Controls	2 x 3 conc x 1.0 mL	230220	CE-IVDR	
		231678	RUO (US)	
		260234	JP-IVD	
Lumipulse® NfL CSF Controls	2 x 3 conc x 1.5 mL	81414	RUO (EU / US)	
		261194	RUO (Japan)	
Lumipulse® β-Amyloid Plasma Controls**	2 x 2 conc x 1.5 mL	81300	RUO (EU / US)	
		260883	RUO (Japan)	
Lumipulse® pTau 181 Plasma Controls	2 x 2 conc x 1.5 mL	81297	RUO (EU / US)	
		260913	RUO (Japan)	
Lumipulse® NfL Blood Controls	2 x 2 conc x 1.5 mL	81421	RUO (EU / US)	
		261217	RUO (Japan)	
Lumipulse® ApoE Controls#	2 x 3 conc x 0.5 mL	81452	RUO (EU / US)	
		261309	RUO (Japan)	
Accessories	**Packaging**	**Reference**	**Regulatory label**	
CSF tube adaptors for LUMIPULSE® G System##	5 pcs	232040	not applicable	

New biomarkers.

New perspectives.



The Fujirebio Neuro Center of Excellence™ at a glance

Our global Fujirebio Neuro Center of Excellence is a hub for our worldwide team of neurodegenerative disease researchers including the team at ADx NeuroSciences, experienced in early R&D. It functions as a research and development lab focused on developing diagnostic solutions, but it's more than that… it is also a meeting place, a forum for experts from all over the world to exchange knowledge. It is a center for partnership and collaboration to find the next generation of diagnostics.

- An R&D lab focused on developing diagnostic solutions.
- An international meeting point for experts and partners to share knowledge.
- A global hub for our worldwide team of researchers into neurodegenerative diseases.
- A starting point for great ideas to find the next generation of diagnostics.

Let's partner in the discovery of tomorrow's neurodegenerative diseases testing solutions. Do you have a project, a question, a request, or an idea that you would like to discuss? Our doors are open and we are happy to talk. Contact us at FNCE@fujirebio.com

For more information about our products and automation solutions, please contact your Fujirebio representative.

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