Lifting the fog

New biomarkers. New perspectives.

With more than thirty years of experience in the field of neurological diseases, we are commited to working on the development of new biomarker tests for both routine diagnostics and research.

In 1995, we were the first to market biomarkers for the early detection of Alzheimer's disease (AD) 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 AD 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 AD, but also with the full spectrum of neurological diseases in 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 often made at late stages, despite the fact that the first pathophysiological events can start years before. What is needed is a wide range of simple and reliable tests in both CSF and blood to assist clinicians in identifying the patients early and accurately, select the right therapies and monitor the progress. At Fujirebio, we are dedicated to developing these essential tests to better support patients suffering from neurological diseases.

A comprehensive neuro panel

	CSF	Blood
Lumipulse® G		
β-Amyloid 1-42	+	+
β-Amyloid 1-40	+	+
pTau 181	+	+
pTau 217	+*	+
Total Tau	+	
NfL	+	+
ApoE4		+
Pan-ApoE		+
GFAP		+
sTREM2	+	+
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 neurological disease testing

Lumipulse® G CSF AD biomarkers (CE-IVDR)

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. The mono-test cartridge principle where one test equals one cartridge, minimizes reagent waste and eliminates the need for batch-testing, while a quality result is guaranteed during the entire shelf life. The Lumipulse CSF panel for AD rapidly 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.

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 and pTau 217, 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 standards to support potential future routine use.

Lumipulse® G NfL CSF and Blood (RUO)

The neurofilament light chain (NfL) solutions represent two immunoassays for the sensitive quantification of NfL in CSF and plasma/serum, respectively. These tests allow researchers and clinical research professionals across the world to further study the clinical utility of NfL in various conditions such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), frontotemporal dementia (FTD), Parkinson's disease (PD), or AD as well as in acute situations such as traumatic brain injury (TBI). NfL is considered a promising biomarker for disease activity, progression, prognosis, and monitoring effectiveness of therapies.

Lumipulse® G GFAP (RUO)

This fully automated assay allows detection of glial fibrillary acidic protein (GFAP) in serum and plasma. GFAP is increased in reactive astrocytes e.g. as a response to neuronal injury and inflammation, which is often observed in neurological dieases including MS, AD or PD, but also brain-related acute traumatic injuries. Evidence is emerging that GFAP may be a promising biomarker for diagnosis, progression and monitoring in various neurological conditions.

Lumipulse® G sTREM2 (RUO)

The Soluble Triggering Receptor Expressed on Myeloid Cells 2 (sTREM2) solution is an immunoassay for the quantitative measurement of sTREM2 in human CSF, serum and plasma. Studies demonstrated that sTREM2 is linked to neurological diseases through its association with microglial activation and neuroinflammation. Therefore, sTREM2 could serve as a promising biomarker offering insights into disease mechanisms, progression and severity of neurological diseases.

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. When both assays are combined, the ApoE4/Pan-ApoE ratio can be calculated to determine the ApoE proteotype status of the sample tested indicating 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 valuable information about the protein expression.

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* ε4 allele is the most common genetic risk factor of AD.

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

Using the basic ELISA principle, the INNOTEST hTAU Ag was the first fluid biomarker assay for the early detection of 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 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.

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 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-IVDR	2 x 25 µL
		81583	RUO	
INNOTEST® β-AMYLOID$_{(1-40)}$ (CSF)	96 tests	80462	CE-IVDR	2 x 25 µL (1:100 dilution)
		81585	RUO	
INNOTEST® hTAU Ag (CSF)	96 tests	81572	CE-IVDR	2 x 25 µL
		81579	RUO	
INNOTEST® PHOSPHO-TAU$_{(181P)}$ (CSF)	96 tests	81574	CE-IVDR	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-IVDR	
	2 x 2 RVC (0.2 mL)	81584	RUO	
Aβ$_{(1-40)}$ CAL-RVC pack	2 x 8 CAL (0.4 mL)	80461	CE-IVDR	
	2 x 2 RVC (0.4 mL)	81586	RUO	
Tau Ag CAL-RVC pack	2 x 6 CAL (0.2 mL)	81573	CE-IVDR	
	2 x 2 RVC (0.2 mL)	81580	RUO	
PHOSPHO-TAU CAL-RVC pack	2 x 6 CAL (0.4 mL)	81575	CE-IVDR	
	2 x 2 RVC (0.4 mL)	81582	RUO	
sTREM2 CAL-RVC pack	1 x 8 CAL (0.4 mL)	81057	RUO	
	2 x 2 RVC (0.4 mL)			
NPTX2 CAL-RVC pack	1 x 8 CAL (0.4 mL)	80909	RUO	
	2 x 2 RVC (0.4 mL)			

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

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	50 µL
Lumipulse® G β-Amyloid 1-40 Immunoreaction Cartridges (CSF)	3 x 14 tests	231524	CE-IVDR	40 µL
Lumipulse® G Total Tau Immunoreaction Cartridges (CSF)	3 x 14 tests	230312	CE-IVDR	75 µL
Lumipulse® G pTau 181 Immunoreaction Cartridges (CSF)	3 x 14 tests	230350	CE-IVDR	40 µL
Lumipulse® G NfL CSF Immunoreaction Cartridges	3 x 14 tests	81426	RUO	60 µL
Lumipulse® G β-Amyloid 1-42 Plasma Immunoreaction Cartridges	3 x 14 tests	81301	RUO	110 µL
Lumipulse® G β-Amyloid 1-40 Plasma Immunoreaction Cartridges	3 x 14 tests	81298	RUO	70 µL
Lumipulse® G pTau 181 Plasma Immunoreaction Cartridges	3 x 14 tests	81288	RUO	130 µL
Lumipulse® G pTau 217 Plasma Immunoreaction Cartridges	3 x 14 tests	81472	RUO	100 µL
Lumipulse® G NfL Blood Immunoreaction Cartridges (plasma, serum)	3 x 14 tests	81215	RUO	100 µL
Lumipulse® G ApoE4 Immunoreaction Cartridges (plasma)	3 x 14 tests	81453	RUO	20 µL
Lumipulse® G Pan-ApoE Immunoreaction Cartridges (plasma, serum)	3 x 14 tests	81449	RUO	20 µL
Lumipulse® G GFAP Immunoreaction Cartridges (plasma, serum)	3 x 14 tests	261255	RUO	100 µL
Lumipulse® G sTREM2 Immunoreaction Cartridges (CSF, plasma, serum)	3 x 14 tests	81656	RUO	20 µL (CSF: pretreated)
Calibrators	**Packaging**	**Reference**	**Regulatory label**	
Lumipulse® G β-Amyloid 1-42 Calibrators set	2 x 3 conc x 1.0 mL	230343	CE-IVDR	
Lumipulse® G β-Amyloid 1-40 Calibrators set	2 x 3 conc x 1.0 mL	231531	CE-IVDR	
Lumipulse® G Total Tau Calibrators set	2 x 3 conc x 1.0 mL	230329	CE-IVDR	
Lumipulse® G pTau 181 Calibrators	1 x 3 conc x 1.5 mL	230367	CE-IVDR	
Lumipulse® G NfL CSF Calibrators	1 x 5 conc x 1.5 mL	81413	RUO	
Lumipulse® G β-Amyloid 1-42 Plasma Calibrators	1 x 5 conc x 1.5 mL	81303	RUO	
Lumipulse® G β-Amyloid 1-40 Plasma Calibrators	1 x 5 conc x 1.5 mL	81299	RUO	
Lumipulse® G pTau 181 Plasma Calibrators	1 x 5 conc x 1.5 mL	81289	RUO	
Lumipulse® G pTau 217 Plasma Calibrators	1 x 5 conc x 1.5 mL	81471	RUO	
Lumipulse® G NfL Blood Calibrators	1 x 5 conc x 1.5 mL	81422	RUO	
Lumipulse® G ApoE4 Calibrators	1 x 5 conc x 0.3 mL	81454	RUO	
Lumipulse® G Pan-ApoE Calibrators	1 x 5 conc x 0.3 mL	81450	RUO	
Lumipulse® G GFAP Calibrators set	1 x 2 conc x 1.0 mL	235539	RUO	
Lumipulse® G sTREM2 Calibrators	1 x 5 conc x 1.5 mL	81657	RUO	
Controls	**Packaging**	**Reference**	**Regulatory label**	
Lumipulse® β-Amyloid Controls*	2 x 3 conc x 1.0 mL	231548	CE-IVDR	
Lumipulse® Total Tau Controls	2 x 3 conc x 1.0 mL	230237	CE-IVDR	
Lumipulse® pTau 181 Controls	2 x 3 conc x 1.0 mL	230220	CE-IVDR	
Lumipulse® NfL CSF Controls	2 x 3 conc x 1.5 mL	81414	RUO	
Lumipulse® β-Amyloid Plasma Controls**	2 x 2 conc x 1.5 mL	81300	RUO	
Lumipulse® pTau 181 Plasma Controls	2 x 2 conc x 1.5 mL	81297	RUO	
Lumipulse® pTau 217 Plasma Controls	2 x 2 conc x 1.5 mL	81473	RUO	
Lumipulse® NfL Blood Controls	2 x 2 conc x 1.5 mL	81421	RUO	
Lumipulse® ApoE Controls#	2 x 2 conc x 0.5 mL	81452	RUO	
Lumipulse® GFAP Controls	2 x 2 conc x 1.0 mL	235522	RUO	
Lumipulse® sTREM2 Controls	2 x 3 conc x 1.5 mL	81658	RUO	

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

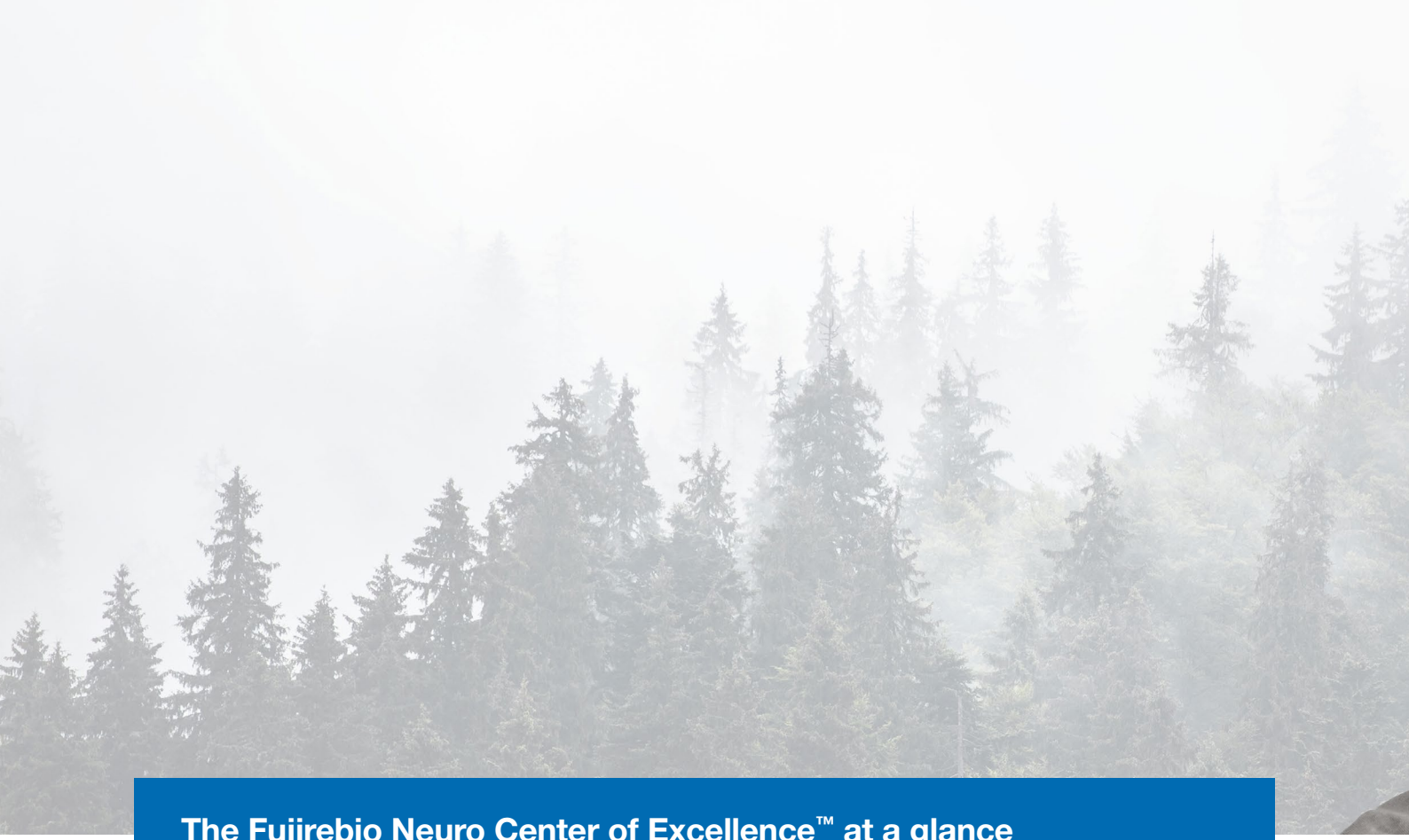
** Can be used in combination with Lumipulse® G β-Amyloid 1-42 Plasma and Lumipulse® G β-Amyloid 1-40 Plasma Immunoreaction Cartridges and Calibrators.

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

General remarks:
All RUO assays mentioned above are for Research Use Only. Not for use in diagnostic procedures.

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 automated solutions, please contact your Fujirebio representative and visit our website www.fujirebio.com/neuro.

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