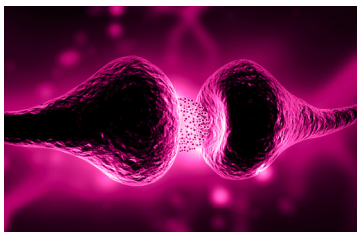
LUMIPULSE® G β-AMYLOID RATIO (1-42/1-40) TEST

Chemiluminescent Enzyme Immunoassay

The first FDA-authorized in-vitro diagnostic test for Alzheimer's disease

Lumipulse G β-Amyloid Ratio (1-42/1-40) = **Lumipulse G β-Amyloid 1-42 (results in pg/mL) / Lumipulse G β-Amyloid 1-40 (results in pg/mL)** = **A numerical value from 0.001-1.000**



- The Lumipulse G β-Amyloid Ratio (1-42/1-40) is an in-vitro cerebral spinal fluid (CSF) test that combines the results of Lumipulse G β-Amyloid 1-42 and Lumipulse G β-Amyloid 1-40 assays into a ratio of β-Amyloid 1-42 to β-Amyloid 1-40 concentrations.
- It is intended to be used in adult patients, aged 55 years and over, presenting with cognitive impairment, who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline.
- The Lumipulse G β-Amyloid Ratio (1-42/1-40) results must be interpreted in conjunction with other patient clinical information. This test is not intended as a screening or stand-alone diagnostic assay.

PERFORMANCE MEASUREMENTS

		PET				
		POSITIVE	NEGATIVE	TOTAL	PREDICTIVE VALUE (%) 95% CI	FREQUENCY OF RESULTS (%) 95% CI
Lumipulse G β-Amyloid Ratio (1-42/1-40)	**Positive (Ratio ≤ 0.058)**	171	6	177	96.6% (171/177) (92.8%-98.4%)	60.6 % (177/292) (54.9%-66.1%)
	Likely positive (0.059 ≤ Ratio ≤ 0.072)	13	9	22	59.1% (13/22) (38.7%-66.7%)	7.5% (22/292) (5.0%-11.1%)
	Negative (Ratio ≥ 0.073)	15	78	93	16.1% (15/93) (10.0%-24.9%)	31.8% (93/292) (26.8%-37.4%)
	Total	199	93	292	Prevalence of PET positive = 68.2% (199/292) (62.6%-73.2%)	

In this clinical study 97% of individuals with Lumipulse G β-Amyloid Ratio (1-42/1-40) positive results had the presence of amyloid plaques by PET scan and 84% of individuals with negative results had a negative amyloid PET scan.

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KIT COMPONENTS

PRODUCT	CONFIGURATION	PART NUMBER
β-Amyloid 1-42 Immunoreaction Cartridges	3 x 14 cartridges	231432
β-Amyloid 1-42 Calibrators	2 x 1 mL (3 concentrations)	230343
β-Amyloid 1-40 Immunoreaction Cartridges	3 x 14 cartridges	231753
β-Amyloid 1-40 Calibrators	2 x 1 mL (3 concentrations)	231531
β-Amyloid Control	2 x 1 mL (3 concentrations)	231548

PRECAUTION: The Lumipulse G β-Amyloid Ratio (1-42/1-40) must be calculated using the results obtained from Lumipulse G β-Amyloid 1-42 and Lumipulse G β-Amyloid 1-40 on the same patient sample and same LUMIPULSE G 1200 analyzer. Use of another manufacturers' assays may result in significantly different ratios. β-amyloid 1-42 and β-amyloid 1-40 values determined on patient samples using other manufacturers' assays cannot be interchangeably used to calculate the Lumipulse G β-Amyloid Ratio (1-42/1-40) which could lead to wrong diagnostic conclusions.

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.

For more information on our Lumipulse® G β-Amyloid Ratio (1-42/1-40) Test and the LUMIPULSE® G1200, contact your Fujirebio representative at CustomerSupport.US@Fujirebio-US.com

Visit our website: www.fujirebio.com

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