Lumipulse G pTau 217/β-Amyloid 1-42 Plasma Ratio

In vitro diagnostic (IVD) intended to aid healthcare providers in identifying patients with amyloid pathology associated with Alzheimer's disease.

Context for performance data: The Lumipulse G pTau 217/β-Amyloid 1-42 Plasma Ratio is an in vitro test using human plasma (K2EDTA) that combines the results of Lumipulse G pTau 217 Plasma and Lumipulse G β-Amyloid 1-42-N Plasma assays into a ratio of pTau 217 to β-Amyloid 1-42 concentrations using the LUMIPULSE G1200 System. The Lumipulse G pTau 217/β-Amyloid 1-42 Plasma Ratio is intended to aid healthcare providers in identifying patients with amyloid pathology associated with Alzheimer's disease. A clinical study of 499 patients was conducted to evaluate performance of the Lumipulse G pTau 217/β-Amyloid 1-42 Plasma Ratio. The study patient population was between the ages of 52 and 93 years with amyloid positivity confirmed by historic amyloid PET with an FDA-cleared tracer or FDA-cleared amyloid CSF ratio. Polaris-AD (AriBio) patient samples used for testing were collected from the screening period of the clinical phase III study of AR1001. Skåne University Hospital Memory Clinic, Malmö, Sweden plasma samples used in the study were collected from subjects enrolled in BioFINDER-2. Bio-Hermes-001 samples obtained from Global Alzheimer's Platform Foundation and University of Wisconsin plasma samples from subjects enrolled in Wisconsin Registry for Alzheimer's Prevention (WRAP) were also used in this study.

		CEOi BBM Workgroup Recommendations[1]		Clinical validation study *Link to peer-reviewed study*
		Triage	**Confirmatory**	
Performance	Cutoffs[a]			**Negative: ≤ 0.00370** **Intermediate: 0.00371 to 0.00737** **Positive: ≥ 0.00738**
	Sensitivity (%)	≥90%	≥90%	**97.6%**
	Specificity (%)	≥75% (secondary care) ≥85% (primary care)	≥90%	**90.8%**
	Participants with intermediate results (%)			**19.6%**
	Prevalence of amyloid in study population (%)			**51.1%**
	Positive predictive value (PPV)[b] (%)			**91.8%**
	Negative predictive value (NPV)[b] (%)			**97.3%**
	Reference standard			**Amyloid PET, CSF biomarkers**
Study Population	Sample size (N)			499
	Age (mean)			72
	Diagnosis of study population (n)			MCI (154), AD (290), SCD (49), other cognitive diagnoses (6)
	Sex (% female)			51.9%
	Race (% nonwhite)			15.2%
	Ethnicity (% hispanic/latino)			24.6%
	Years of education (mean)			Not available

Limitations: This device is not intended to be used as a stand-alone test. The test results must be interpreted in conjunction with other diagnostic tools and clinical information. The safety and effectiveness of the device has not been established for predicting development of dementia or other neurologic conditions or for monitoring the effect of any therapeutic product. A positive result is associated with the presence of amyloid plaques or neurofibrillary tangles in the brain but does not establish a diagnosis of Alzheimer's disease as would be established by neuropathological examination. Performance of the test for Asian and other races had high uncertainty due to the limited number of patients studied.

Access: The Lumipulse pTau 217/ β-Amyloid 1-42 Plasma Ratio is available through any CLIA laboratory with a Lumipulse platform. This includes major US reference laboratories, as well as a number of hospital systems

[a]Determined during study; [b]PPV/NPV at prevalence of amyloid in study population. AD, Alzheimer's disease; CLIA, Clinical Laboratory Improvement Amendments; CSF, cerebrospinal fluid; FDA, Food and Drug Administration; MCI, mild cognitive impairment; PET, positron emission tomography; SCD, subjective cognitive decline. 1. Schindler et al., Nature Reviews Neurology. 2024.