Cognivue Clarity®

Intended as an adjunctive tool for objectively evaluating multidomain cognitive function in adults (18 years and older), providing immediate age-adjusted results to support clinical assessment.

Supplier Commentary: Cognivue Clarity is supported by a robust and continuously evolving body of clinical evidence spanning foundational regulatory validation, psychometric validation, longitudinal reliability, biomarker-characterized cohorts, and real-world implementation across diverse care settings and adult populations.

The FDA De Novo pivotal clinical validation program represents the foundational evidence supporting Cognivue Clarity and established the regulatory and scientific basis for the first FDA-authorized Class II Computerized Cognitive Assessment Aid.[1,2] These complementary studies established Cognivue Clarity's classification thresholds, prospectively validated clinical performance against the St. Louis University Mental Status (SLUMS) examination, and demonstrated psychometric validity, construct validity, and high test-retest reliability. Together, these studies established the intended use of Cognivue Clarity as an objective assessment aid for evaluating cognitive function and supporting clinical decision making.

Since the FDA De Novo authorization, both the science and the field of digital cognitive assessments have evolved substantially. The Cognivue evidence base has expanded through complementary studies designed to address different scientific objectives, including refinement of psychometric performance and demographic-adjusted normative interpretation through the independently conducted FOCUS Diverse Population Validation study[3], evaluation of Cognivue Clarity performance within the independent Bio-Hermes biomarker-characterized cohort demonstrating clinical detection performance in a contemporary Alzheimer's disease population[4], and development and validation of the Cognivue Amyloid Risk Measure (CARM) for estimating the likelihood of amyloid positivity.[5] Together, these complementary studies demonstrate the evolution of the Cognivue evidence base from foundational regulatory validation to contemporary clinical application across diverse adult populations.

Across the Cognivue clinical program, reference standards have included established neuropsychological assessments, expert clinical diagnosis, standardized diagnostic criteria, validated cognitive reference standards, and molecular biomarkers, including amyloid PET imaging and blood-based biomarkers, as appropriate for each study objective. Clinical performance should always be interpreted within the context of the study design, intended use, patient population, prevalence of cognitive impairment, reference standard, and analytical threshold. Because each study was intentionally designed to answer a different scientific question, direct comparison of performance metrics across studies should be made within the appropriate clinical context.

A key strength of the Cognivue evidence base is that it is cumulative rather than duplicative. Each major study was intentionally designed to build upon the previous evidence, demonstrating reproducibility, high test-retest reliability, low practice effects, broader clinical applicability, and performance across increasingly rigorous and clinically relevant populations. Results should be interpreted by a licensed healthcare professional as one component of a comprehensive clinical evaluation and are intended to support, not replace, clinical judgment.

Test Overview[a]	What is the test measuring? ***CEOi Detection DCA Use Case[6]: Single or multidomain cognitive function to discriminate CI from CU[b]***	Cognivue Clarity objectively measures multidomain cognitive function to support the detection of cognitive impairment in adults. Domains assessed include memory, executive function, attention, visuospatial processing, reaction time, visual salience, and adaptive motor control.
	Administration time ***CEOi Recommendation[6]: Short (~3-5 minutes)***	~10 minutes
	Regulatory status	First FDA-cleared adaptive DCA (FDA De Novo Class II medical device); Health Canada Class I licensed medical device; UKCA marked medical device.
	Setting and mode of use	In-clinic, self-guided DCA requiring minimal staff involvement. Following brief setup, the assessment is completed independently by the patient with automated scoring and immediate reporting.
	Platform	Dedicated FDA-cleared Cognivue Clarity® medical device with proprietary integrated software, providing a standardized platform for objective cognitive assessment.
	Supported devices	Dedicated Cognivue Clarity® medical device.
	Accessibility	Available in English and Spanish. Intuitive, self-guided patient interface with standardized visual prompts. Does not rely on auditory stimuli, supporting assessment in individuals with hearing impairment.
	Internet connectivity	Internet or Wi-Fi connectivity is not required for testing. Results may be synchronized to a HIPAA-secure cloud dashboard when connectivity is available.
	EHR integration	FHIR-enabled API supporting standardized EHR integration and data exchange.
	Supplier support	Implementation and staff training are included, with ongoing technical, clinical, scientific, and retraining support available throughout routine use.
	Results and outputs	Immediate, auto-scored PDF report with an overall cognitive score, age-adjusted interpretation, performance across four cognitive domains, clinician guidance, and optional Cognivue Amyloid Risk Measure (CARM) results to support diagnostic evaluation and patient communication.

		Clinical validation study In at-risk adults[c] *Link to FDA decision summary*	Clinical validation study Bio-Hermes-001[d] *Link to peer-reviewed study*
Performance Data	Cutoffs[e]	**Score ≤50 = Impaired Score 51-74 = Intermediate Score ≥75 = Unimpaired**	**Cognitive Impairment: Overall Score ≥ 66**
	Sensitivity (%) ***CEO Recommendation[6]: ≥80% to detect CI***	**82%**	**73.90%**
	Specificity (%) ***CEO Recommendation[6]: ≥85%***	**98%**	**58.60%**
	Prevalence of CI in study population (%)	**27%**	**56.30%**
	Positive predictive value (PPV)[f] (%)	**93.8%**	**71.70%**
	Negative predictive value (NPV)[f] (%)	**93.6%**	**62.70%**
	Reference standard	**SLUMS**	**Clinical diagnosis**
	For evidence supporting psychometric performance, demographic-adjusted normative scoring, and expanded use in adults aged ≥18 years, please see Galvin et al., 2024 DOI: 10.3233/JAD-240331 (Link).		
Study Population	Sample size (N)	401	887
	Age (mean)	Not reported, Age range 55-95 years	71.8
	Diagnosis of study population (n)	impaired (107), intermediate (174), unimpaired (120)	cognitively normal (388), MCI (282), probable AD (217)
	Sex (% female)	Not reported	56.40%
	Race (% nonwhite)	Not reported	21.20%
	Ethnicity (% hispanic/latino)	Not reported	9.80%
	Years of education (mean)	Not reported[g]	15.5

		Cognivue Amyloid Risk Measure (CARM) Bio-Hermes-001[c] *Link*
Performance Data	Cutoffs	**Four-level amyloid likelihood classification (CARM 1 = lowest; CARM 4 = highest); CARM ≥3 indicates elevated likelihood of amyloid positivity**
	Sensitivity (%)	**73%**
	Specificity (%)	**55%**
	Prevalence of amyloid in study population (%)	**37.4%**
	Positive predictive value (PPV)[h] (%)	**49%**
	Negative predictive value (NPV)[h] (%)	**77%**
	Reference standard	**Amyloid PET**
Study Population	Sample size (N)	887
	Age (mean)	71.8
	Diagnosis of study population (n)	True Controls (297), Preclinical AD (91), MCI due to AD (111), AD (130), MCI (non-AD) (171), non-AD dementia (87)
	Sex (% female)	56.40%
	Race (% nonwhite)	21.20%
	Ethnicity (% Hispanic/Latino)	9.80%
	Years of education (mean)	15.5

Limitations: Results should be interpreted by a licensed healthcare professional as part of a comprehensive clinical evaluation. Cognivue Clarity provides objective cognitive information to support diagnostic evaluation and should not be used as a standalone diagnostic tool. When available, the Cognivue Amyloid Risk Measure (CARM) complements the overall cognitive assessment by providing an estimate of the likelihood of amyloid positivity. CARM is intended for interpretation only in conjunction with the overall Cognivue Clarity assessment and is applicable only for individuals whose overall Cognivue Clarity score falls below the normal range. CARM should not be interpreted as a standalone result or used independently of the overall cognitive assessment, clinical findings, and other diagnostic information.

Access: Available directly from Cognivue. Product information and ordering: www.cognivue.com.

[a]Information in this section was provided by the supplier and has not been independently verified by CEOi; [b]Use cases are DCA Workgroup-defined and do not reflect FDA designations; [c]Community-dwelling adults aged 55–95 years at risk for age-related cognitive decline or dementia; [d]Community-based cohort; [e]Cutoff values vary across studies because they were optimized for different intended uses, reference standards, study populations, and statistical objectives. These study-specific thresholds reflect the clinical context and do not represent changes to the Cognivue Clarity scoring algorithm; [f]PPV/NPV at prevalence of CI in study population; [g]FDA labeling notes safety and effectiveness were not established for individuals with less than 12 years of education; [h]PPV/NPV at prevalence of amyloid in study population. AD, Alzheimer's disease; API, Application Programming Interface; DCA, digital cognitive assessment; EHR, electronic health record; FDA, US Food and Drug Administration; FHIR, Fast Healthcare Interoperability Resources; MCI, mild cognitive impairment; SLUMS, The Saint Louis University Mental Status; PET, positron emission tomography; UKCA, United Kingdom Conformity Assessed. 1. Cahn-Hidalgo et al., World J Psychiatry. 2020; 2. FDA decision summary available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN130033.pdf; 3. Galvin et al., Journal of Alzheimer's Disease. 2024; 4. Galvin et al., Scientific Reports. 2024; 2. Galvin et al., Neurology & Therapy. 2025; 6. Thompson et al., Alzheimers & Dementia. 2025.