Creyos Dementia Screener

Indicated for use as a screening tool for age-related cognitive impairment in adults age 50+

Supplier Commentary: The Creyos Dementia Screener is a 2-task, fully automated screen (Number Ladder, visuospatial working memory; Feature Match, attention) returning a single result that flags individuals for further evaluation. It is self-administrable, requires no clinical supervision or specialized training, and runs in a browser on a computer or tablet; at 5 to 6 minutes, it sits just above the 3-to-5-minute recommendation for the CEOi-defined Detection DCA use case. The machine-learning model was trained on Creyos data from healthy adults (n=2,859) and neurology-clinic patients seen for dementia or age-related cognitive decline (n=1,856), then applied without modification to the validation samples below.

MCI detection: 49 community-dwelling older adults (mean age 81), with screener results cross-classified against MoCA (version 7.1) impairment at its optimal cutoff for MCI (<23). Because the MoCA carries known error (73.5% sensitivity, 91.3% specificity at this cutoff), the reported figures estimate accuracy against MCI status using simulation-based latent class estimation, an established approach for imperfect reference standards[1] previously applied to MoCA accuracy for MCI,[2] implemented here with a simulation-based procedure suited to the sample size. For details on this approach, see this online resource. A manuscript describing this approach and the underlying data is in preparation for peer-reviewed publication.

Dementia detection: case-matched cohort of 14 patients with neurologist-diagnosed Alzheimer's dementia and 14 controls matched on age, sex, and education.[3] Every patient was flagged, including one whose MMSE score fell in the unimpaired range.

Test Overview[a]	What is the test measuring? ***CEOi Detection DCA Use Case[4]: Single or multidomain cognitive function to discriminate CI from CU[b]***	Multidomain cognitive function to discriminate cognitive impairment from cognitively unimpaired.
	Administration time ***CEOi Recommendation[4]: Short (~3-5 minutes)***	5 to 6 minutes
	Regulatory status	FDA-registered Class II medical device
	Setting and mode of use	Clinician or technician-initiated, no clinical supervision required; suitable for in-clinic or remote assessment
	Platform	Web-based, HIPAA and SOC 2 Type II compliant platform with a physician portal
	Supported devices	Computer or tablet
	Accessibility	• Available in 14 languages, including English, French, and Spanish (written instructions and audio voiceover) • Vision: WCAG-aligned interface with dark mode, color-blind–safe contrast, enlarged text, and larger buttons • Auditory: optional voiceover narration of all task and questionnaire text • Literacy/motor: simplified low-literacy instructions with guided onboarding and practice rounds
	Internet connectivity	Internet required (online delivery)
	EHR integration	Integrates with Epic, AdvancedMD, athenahealth, eClinicalWorks and others through custom integrations and interoperability partner Redox.
	Supplier support	Every client receives a dedicated account manager who provides hands-on support — from strategic guidance and implementation planning to email and phone access, billing assistance, and direct lines to Creyos staff scientists.
	Results and outputs	Automatically generated PDF report indicates if further testing is suggested (suspected cognitive impairment) or further testing is not suggested. Includes patient and assessment details, result interpretation, recommended next steps, supporting information on how the result was determined, references, and disclaimers.

		Validation for MCI detection Older adults from retirement homes, simulation-adjusted for MoCA reference-standard error[c] *Link to resource*	**Validation for Dementia Detection** AD dementia patients with matched CU controls[d] *Link to peer-reviewed data*
Performance Data	Cutoffs	**Machine-learning probability-based classification (impaired vs. unimpaired)**	**Machine-learning probability-based classification (impaired vs. unimpaired)**
	Sensitivity (%) ***CEO Recommendation[4]: ≥80% to detect CI***	**95.0%**	**100.0%**
	Specificity (%) ***CEO Recommendation[4]: ≥85%***	**83.5%**	**86.0%**
	Prevalence of MCI/AD dementia in study population (%)	**40.4% (MCI)**	**50.0% (AD dementia)**
	Positive predictive value (PPV)[e] (%)	**79.6%**	**87.5%**
	Negative predictive value (NPV)[e] (%)	**96.1%**	**100.0%**
	Reference standard	**Modelled latent MCI status adjusted for MoCA misclassification[f]**	**Clinical diagnosis**
	For details on the simulation-based latent class approach used to estimate performance for MCI detection, see this online resource.		
Study Population	Sample size (N)	49	28
	Age (mean)	81	Not reported
	Diagnosis of study population (n)	MoCA-classified impaired (11), MoCA-classified unimpaired (38)	AD dementia (14), cognitively normal (14)
	Sex (% female)	82%	Not reported
	Race (% nonwhite)	Not reported	Not reported
	Ethnicity (% hispanic/latino)	Not reported	Not reported
	Years of education (mean)	Not reported	Not reported

Limitations: The screener is a first-line tool that flags individuals for further testing. It supports, rather than replaces, comprehensive neuropsychological evaluation, and does not stage severity or function as a standalone diagnostic tool.

Reported accuracy is preliminary. Both validation samples were small (n=49 and n=28), and the MCI sample comprised community-dwelling older adults (mean age 81) with high educational attainment, classified by MoCA score rather than consensus clinical diagnosis. Race and ethnicity data were unavailable. Misclassification-adjusted estimates are conditional on the assumed inputs reported above. Further validation in diverse, real-world clinical populations is needed.

Access: Available through a browser-based Creyos Health subscription, running on existing computers or tablets with no specialized hardware. Subscriptions are tiered, with per-patient rates decreasing at higher volumes, and include unlimited testing per patient and unlimited practitioner accounts.

[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]Observed data from 49 older adults recruited from retirement homes. Accuracy was estimated against MCI status using simulation, accounting for known MoCA error (73.5% sensitivity, 91.3% specificity) and assuming 40.4% MCI prevalence; [d]14 patients with neurologist-diagnosed AD dementia and 14 age-, sex-, and education-matched controls from a normative database; [e]PPV/NPV at prevalence of MCI or AD dementia in study population; [f]MoCA sensitivity 73.5%, specificity 91.3% at its optimal cutoff for MCI (<23). DCA, digital cognitive assessment; FDA, US Food and Drug Administration; HIPAA, Health Insurance Portability and Accountability Act; MCI, mild cognitive impairment; MoCA, Montreal Cognitive Assessment; SOC 2, Service Organization Control 2; WCAG, Web Content Accessibility Guidelines. 1. Staquet et al., Journal of Chronic Diseases. 1981; 2. Wang et al., European Journal of Medical Research. 2023; 3. Urian et al., Journal of Alzheimer's Disease. 2026; 4. Thompson et al., Alzheimers & Dementia. 2025.