Eli Lilly Clinical Diagnostics Laboratory

Lab Report

Patient: Patient0001, Test
DOB: 05/05/1943 **Age:** 80y **Sex:** M
Ordered Date: 02/09/2024 9:26AM

Ordering Location: Test Location PRD01
Physician: TestPRD01, Doctor
Order ID: 01000-01-24040

CertuitAD

Sample ID: 240400000001
Final - Approved 02/09/2024 9:47AM
Collected: 02/09/2024 9:25AM

TEST	RESULT
CertuitAD	Negative

CertuitAD Results Interpretation:

CertuitAD results must be interpreted in conjunction with other patient clinical information. CertuitAD is not intended to be used as a screening or stand-alone diagnostic test and is not intended for therapeutic monitoring.

A test result reported as negative is consistent with a negative amyloid PET scan result. A negative result reduces the likelihood that a patient's cognitive impairment is due to Alzheimer's disease (AD).

A test result reported as positive is consistent with a positive amyloid PET scan result. A positive result by itself does not establish a diagnosis of AD or other cognitive disorder.

A test result reported as indeterminate indicates that amyloid plaques may or may not be present. Additional diagnostic testing, such as other laboratory testing or amyloid PET scan, should be considered based on clinical presentation. If symptomatology persists or evolves, repeat testing may be helpful.

"Negative" or "positive" amyloid PET scan was defined by a cut-off of 24 Centiloids, with <24 being negative and >=24 being positive.

In a predominantly White clinical trial population, the negative predictive value (NPV) of a NEGATIVE result decreased to 65% in participants carrying the APOE e4 gene (hetero- or homozygous). Correlation of a NEGATIVE result with genetic testing may be warranted if there is strong clinical suspicion for AD, bearing in mind that clinical risk conferred by APOE status varies with race and ethnicity.

This laboratory developed test (LDT) was developed and its performance characteristics determined by Eli Lilly Clinical Diagnostics Laboratory, LLC (ELCDL). The U.S. Food and Drug Administration (FDA) has not approved or cleared this test. ELCDL is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. This test is for use in the United States only and may be unavailable to patients residing in certain states.

For additional information about CertuitAD, please visit: www.certuitAD.com