CertuitAD™

Test Details

Clinical Significance (Use)[1]

CertuitAD is an *in vitro* plasma test that measures tau protein fragments phosphorylated at threonine 217 (P-tau217) using a chemiluminescent immunoassay.

CertuitAD is intended to be used in adult patients, aged 60 years and older, presenting with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive decline.

Interpretive Information

A test result reported as **negative** is consistent with absence of amyloid deposition in brain as detected by amyloid PET scan. A negative CertuitAD result reduces the likelihood that a patient's cognitive impairment is due to AD.

A test result reported as **positive** is consistent with the presence of amyloid deposition in brain as measured by amyloid PET scan. Note that a positive CertuitAD 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.

CertuitAD results must be interpreted in conjunction with other patient clinical information, which may include other laboratory and radiographic findings, as well as genetic testing. CertuitAD is not intended to be used as a screening or stand-alone diagnostic test and is not intended for therapeutic monitoring.

TEST SPECIFICATIONS	
INTENDED USE	CertuitAD is intended to be used in adult patients, aged 60 years and older, presenting with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive decline
METHODOLOGY	Immunoassay
EXPECTED TURNAROUND TIME	10 business days after sample receipt (testing schedules may vary)
TEST PERFORMED TIME	Monday – Friday
PATIENT PREPARATION	No specific diet or time restrictions have been designated

Assay Category[1]
This laboratory developed test (LDT) was developed and its performance characteristics determined by Eli Lilly Clinical Diagnostics Laboratory, LLC (ELCDL). The US 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 is an LDT for use in the United States only and cannot currently be used for patients in New York, California, Maryland, Pennsylvania, Rhode Island, or Washington DC until state-specific approval is granted.

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SPECIMEN DETAILS	
SPECIMEN TYPE	Plasma, minimum 1 mL
SPECIMEN CONTAINER	• Lavender top K2 EDTA (collection tube) • Polypropylene cryovial with screw top (transport tube)
SPECIMEN LABELING	Each patient specimen must be labeled with • Patient's full name and date of birth (DOB) • Date and time of collection
SPECIAL HANDLING INSTRUCTIONS	• Specimen should be centrifuged within 2 hours of collection • Place plasma in transport tube and freeze immediately at a temperature of appoximately -80° C
REJECTION CRITERIA	• Hemolysis 3+ or greater • Missing identifiers • Insufficient volume • Patient is less than 60 years of age
SPECIMEN STABILITY	**Frozen:** at -80°C: 18 weeks

Specimen Collection Instructions

1. Fill collection tube.
2. Mix immediately by gently inverting the tube at least 8 to 10 times.
3. Promptly centrifuge at 1500 to 2000 x g for at least 15 minutes at room temperature until cells and plasma are separated.
4. Use a polyethylene disposable pipette to transfer a minimum of 1mL of plasma (carefully avoid the buffy coat) into polypropylene transport tube.
5. Process and store as indicated in the special handling instructions.
6. Contact the courier to schedule specimen pickup.

For questions or more information, please call the ELCDL at 833-INFO-CDL (833-463-6235) or email Diagnostic_Testing_Support@lilly.com.

Guidance on Best Practices in Phlebotomy[2]

For more detailed guidance on phlebotomy practices, please refer to section 3.3 Practical Guidance on Best Practices in Phlebotomy of the following website link: https://www.ncbi.nlm.nih.gov/books/NBK138496/

Guidance on Order of Draw[2]

For more detailed information on the laboratory tube collection, please refer to the following website link: https://www.ncbi.nlm.nih.gov/books/NBK555991/

References

1. Data on File, Eli Lilly Clinical Diagnostics Laboratory, LLC, DOF-CT-US-0011.
2. Data on File, Eli Lilly Clinical Diagnostics Laboratory, LLC, DOF-CT-US-0001.

Eli Lilly Clinical Diagnostics Laboratory