

NEW TEST

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Alzheimer's Disease Markers, CSF

3017653, ADMRKS CSF

Specimen Requirements:

Patient Preparation:

Collect: CSF

Specimen Preparation: Tube type: Preferred: 2.5 ml low-bind false bottom CSF tube (Sarstedt, 63.614.625) Acceptable: Sarstedt 72.703.600 (1.5 ml) or Sarstedt 72.694.600 (2 ml) Unacceptable: Polystyrene collection tubes are not acceptable as exposing of CSF to polystyrene tubes may decrease Abeta42 concentrations
Collection instructions: 1. Perform lumbar puncture and discard the first 1 to 2 ml of CSF 2. Collect CSF directly into low-bind false bottom CSF tube using the drip method. Avoid use of syringes or extension tubing. Fill tube at least 50% full. 3. Send specimen in original collection tube (do not aliquot) using transport kit (ARUP Supply #55810) available online through eSupply using ARUP Connect (TM) or contract ARUP Client Services at 800-522-2787.

Transport Temperature: -20- Critical frozen

Unacceptable Conditions: Specimen types other than those listed and hemolyzed CSF. Specimens too viscous to be aspirated by instrument.

Remarks:

Stability: Frozen: 8 weeks

Methodology: Quantitative Electrochemiluminescent Immunoassay (ECLIA)

Performed: Mon

Reported: 1-7 days

Note:

CPT Codes: 83520 x3

New York DOH Approval Status: Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

Interpretive information: The Alzheimer's Disease Markers, CSF panel is intended for use in adult patients aged 55 years and older being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment. The pTau181/Abeta42 and tTau/Abeta42 ratios provide better concordance with amyloid positron emission tomography (PET) imaging when compared to Abeta42, pTau181, and tTau individually.

Limitations: Failure to adhere to the sample collection instructions provided in the Lab Test Catalog may result in falsely reduced Abeta42 concentrations and therefore false elevations in the reported ratios. The ratios reported have not been established for predicting development of dementia or other neurologic conditions or for monitoring responses to therapies. Results of this test must always be interpreted in the context other clinical diagnostic evaluations and should not be used alone to establish a diagnosis of AD or other cognitive disorder.

Methodology: Roche Diagnostics Inc. electrochemiluminescence assay was used. Results obtained with different assay methods or kits may be different and cannot be used interchangeably.

Phospho-Tau (181P) CSF/ β -Amyloid (1-42) CSF ratio	Interpretation
≤ 0.023	A negative result, defined as pTau181/Abeta42 ratio value below cutoff, is consistent with a negative amyloid positron emission tomography (PET) scan result. A negative result reduces the likelihood that a patient's cognitive impairment is due to AD.
> 0.023	A positive result, defined as pTau181/Abeta42 ratio value above cutoff, is consistent with a positive amyloid PET scan result. A positive result does not establish a diagnosis of AD or other cognitive disorder.
Total Tau CSF/ β -Amyloid (1-42) CSF ratio	Interpretation
≤ 0.28	A negative result, defined as

	<p>tTau/Abeta42 ratio value below cutoff, is consistent with a negative amyloid positron emission tomography (PET) scan result. A negative result reduces the likelihood that a patient's cognitive impairment is due to AD.</p>
> 0.28	<p>A positive result, defined as tTau/Abeta42 ratio value above cutoff, is consistent with a positive amyloid PET scan result. A positive result does not establish a diagnosis of AD or other cognitive disorder.</p>

Reference Interval:

Test Number	Components	Reference Interval
	Phospho-Tau(181)/Abeta42 Ratio, CSF	<= 0.023
	Total-Tau/Abeta42 Ratio, CSF	<= 0.28

HOTLINE NOTE: Refer to the Hotline Test Mix for interface build information.