

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB: 8/27/1990
Gender: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

Phospho-Tau/Total-Tau/A Beta42, CSF

ARUP test code 3016444

Phospho-Tau/Total-Tau/A Beta42, Interp

SEE NOTE

This test detected a reduced A-beta 42 to T-tau Index (ATI) and elevated levels of P-tau protein in the cerebrospinal fluid (CSF).

Performed by: Athena Diagnostics, Inc.
200 Forest Street, 2nd Floor
Marlborough, MA 01752

V Datta MD, PhD,

Phospho-Tau/Total-Tau/A Beta42, Results

SEE NOTE

Interpretive Result Table

-----INTERPRETATION: Alzheimer Disease TEST: A-beta 42
TECHNICAL RESULT: 457.8 pg/mL REFERENCE RANGE: Not
consistent with AD: P-Tau <54 pg/mL and ATI >1.2,
Borderline: P-Tau 54-68 pg/mL and/or ATI 0.8-1.2, AD: P-Tau
>68 pg/mL and ATI <0.8

-----INTERPRETATION: TEST: T-Tau TECHNICAL RESULT: 672.2
pg/mL REFERENCE RANGE:

-----INTERPRETATION: TEST: P-Tau TECHNICAL RESULT:
112.35 pg/mL REFERENCE RANGE:

-----INTERPRETATION: TEST: ATI TECHNICAL RESULT: 0.44
REFERENCE RANGE:

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V Datta MD, PhD,

Phospho-Tau/Total-Tau/A Beta42, Comments

SEE NOTE

H=High, L=Low, *=Abnormal, C=Critical

Comments: This analysis detected levels of CSF A-beta 42 peptide (A-beta 42) and total tau (T-tau) proteins, reflected in a reduced A-beta 42 to T-tau Index (ATI). The level of phospho-tau (P-tau) was also elevated. These results are consistent with a diagnosis of Alzheimer's disease (AD).

Recommendations: Health care providers, please contact the Athena Diagnostics Client Services Department at 1-800-394-4493 if you wish to speak with a clinical consultant regarding this test result.

Background information: Alzheimers disease (AD) is the most common form of dementia, accounting for 60-70% of cases (1). AD manifests initially with subtle progressive memory loss that eventually becomes severe and incapacitating. Behavioral deficits, including social withdrawal, aggression, depression and hallucinations, are also present (3). Pathologically, AD is characterized by the formation of beta-amyloid plaques and neurofibrillary tangles within the brain, and cerebral cortical atrophy (4). The CSF based biomarkers A-beta 42 peptide (A-beta 42), phospho-tau (P-tau) and total tau (T-tau) can aid in the diagnosis of AD. The combination of A-beta 42 and T-tau results are express as the A-beta 42 to T-tau Index (ATI). ATI is calculated as $A\text{-beta }42 / (240 + 1.18 \times T\text{-tau})$ and represents a ratio normalized by the discrimination line $A\text{-beta }42 = 240 + 1.18 \times T\text{-tau}$ (4, 5). Studies performed with over 70 participants, showed that the cutoff value of $ATI = 1$, yields a sensitivity of 85-94% and specificity of 54-95% in distinguishing AD from non-AD populations (4, 5). An ATI of <1.0 is typical of AD, while a value >1.0 is typical of control populations. Additionally, the CSF levels of P-tau have been found to discriminate AD from other dementias with sensitivities of 72-88% and specificities of 78-83% (1). Athena considers ATI values of 0.8 to 1.2 and P-tau levels of 54-68 pg/ml as borderline results. The combination of all three biomarkers has been reported to have an average sensitivity and specificity of 85% and 90%, respectively (6).

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Phospho-Tau/Total-Tau/A Beta42, Method

SEE NOTE

Detection of proteins was performed by Enzyme Linked Immunosorbent Assay (ELISA) methodology.

Limitations of analysis: Although rare, false positive or false negative results may occur. All results should be interpreted in the context of clinical findings, relevant history, and other laboratory data.

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Phospho-Tau/Total-Tau/A Beta42, Ref

SEE NOTE

H=High, L=Low, *=Abnormal, C=Critical

1. Ferreira, D, et al. (2014) Front Aging Neurosci 6: 47. (PMID: 24715863) 2. Bird, T. (2008) Genet Med 10:231-9 (PMID:18414205) 3. Braak, H, et al. (1991) Acta Neuropathol 82: 239-59. (PMID: 1759558) 4. Hulstaert, F, et al. (1999) Neurology 52: 1555-62. (PMID: 10331678) 5. Blennow, K. (2004) NeuroRx 1: 213-25. (PMID: 15717022) 6. Blennow, K, et al. (2015) Alzheimers Dement 11: 58-69. (PMID: 24795085)

This test was developed and its analytical performance characteristics have been determined by Athena Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes. Laboratory oversight provided by Vivekananda Datta, M.D., Ph.D., CLIA license holder, Athena Diagnostics (CLIA# 22D0069726) Testing performed at: Athena Diagnostics 200 Forest Street Marlborough, MA 01752

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Marlborough, MA 01752

V Datta MD, PhD,

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Phospho-Tau/Total-Tau/A Beta42, Interp	23-123-105364	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Phospho-Tau/Total-Tau/A Beta42, Results	23-123-105364	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Phospho-Tau/Total-Tau/A Beta42, Comments	23-123-105364	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Phospho-Tau/Total-Tau/A Beta42, Method	23-123-105364	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Phospho-Tau/Total-Tau/A Beta42, Ref	23-123-105364	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at: