

Patient: **SAMPLE PATIENT**

DOB:

Sex:

MRN:

## 5400 Alzheimer's Risk Assessment - Whole Blood

Methodology: single molecule assay (Simoa ©)

Test	Result	Interpretation	Reference Range
Plasma p-Tau217 (tau protein phospho-Thr217)	0.59	Elevated	$\leq 0.34$ ng/L

Testing performed by Neurocode, USA Inc. 3548 Meridian, Suite 101, Bellingham, WA 98225 | Kelly A. Lloyd, MD - Medical Director | CLIA# 50D2158817

### Commentary

#### INTERPRETATION

**A test result  $\leq 0.34$  ng/L** is a negative result and is consistent with a negative amyloid positron tomography (PET) scan. A negative result indicates a low likelihood that a patient's cognitive impairment is due to Alzheimer's disease (AD).

**A test result between 0.34 and 0.47 ng/L** is considered intermediate. An intermediate result does not establish a diagnosis of AD or other cognitive disorder and has increased uncertainty in regard to amyloid PET positivity.

**A test result  $\geq 0.47$  ng/L** is elevated and is consistent with a positive amyloid PET scan. High p-Tau217 plasma levels alone do not establish a diagnosis of AD. Results should be interpreted in the context of other clinical signs and symptoms of AD.

This test is a single molecule assay (Simoa ©) using the ALZpath Dx antibody to p-Tau217 developed by ALZpath Inc. This is a laboratory developed test (LDT) whose performance characteristics were determined by Neurocode, USA Inc. at Northwest Pathology, P.S., dba Avero Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration. The laboratory is regulated under CLIA to perform high-complexity testing. p-Tau results obtained with different methods cannot be used interchangeably.

#### LIMITATIONS

Test is intended to be used in adult patients, aged 45 years and older, presenting with cognitive impairment who are being evaluated for AD and other causes of cognitive decline. There are comorbid conditions that may affect phosphorylated tau levels in the blood. These can include conditions affecting hepatic and renal function, such as chronic kidney disease (CKD), as well as a history of stroke or myocardial infarction. Certain medications to support kidney function may also play a role in heightened levels of p-Tau217. Additionally, differences in results based on racial and ethnic background, sex, and age have not yet been established.

## Commentary

### References

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4. Telser J, Risch L, Saely CH, Grossmann K, Werner P. P-tau217 in Alzheimer's disease. *Clinica chimica acta; international journal of clinical chemistry*. 2022;531:100-111.
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