Roche amyloid plasma panel designated a breakthrough device

July 20, 2022—Roche announced yesterday that the FDA has granted breakthrough device designation to the Elecsys Amyloid Plasma Panel. The test detects and measures Alzheimer disease biomarkers in blood plasma to indicate the need for further confirmatory testing for Alzheimer disease.

The qualitative test combines the result of the phosphorylated tau 181 protein assay and apolipoprotein E4 assay in human plasma. Elevations in pTau occur in early stages of Alzheimer disease, while the presence of APOE E4 constitutes the most common genetic risk factor for Alzheimer disease. Patients who test negative with the Roche panel are unlikely to be amyloid positive and should be investigated for other causes of cognitive decline.

Roche received a breakthrough device designation in 2018 for the Elecsys ß-Amyloid (1-42) CSF and Elecsys Phospho-Tau (181P) CSF in vitro diagnostic immunoassays measuring beta-amyloid (1-42) and phospho-tau concentrations in cerebrospinal fluid in adult patients with cognitive impairment who are being evaluated for Alzheimer disease or other causes of dementia