Elecsys CSF assays get breakthrough approval

July 25, 2018—The Food and Drug Administration granted breakthrough device designation to Roche's Elecsys ß-Amyloid (1-42) CSF and Elecsys Phospho-Tau (181P) CSF. These in vitro diagnostic immunoassays are for the measurement of the ß-amyloid (1-42) and phospho-tau concentrations in cerebrospinal fluid in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease or other causes of dementia.

Measuring biomarkers with CSF immunoassays, associated with AD pathology, increases certainty of a diagnosis of AD and can help to evaluate the progression of the disease, according to a press release from Roche. The breakthrough device designations are for indication of use with Elecsys β-Amyloid (1-42) CSF and Elecsys Phospho-Tau (181P) CSF in concordance with amyloid PET visual read result and risk of cognitive or functional decline.

"We are excited about FDA's recognition of the potential clinical benefit the Elecsys CSF assays can bring to clinicians, laboratories, and their patients in diagnosing AD at an early stage," Roland Diggelmann, CEO of Roche Diagnostics, said in the release.

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