FDA authorizes Fujirebio test for Alzheimer disease

May 11, 2022—Fujirebio Diagnostics announced that the FDA has granted de novo marketing authorization for its Lumipulse G β-Amyloid Ratio (1-42/1-40) in vitro diagnostic test for assessing β-amyloid pathology in patients who are being evaluated for Alzheimer disease and other causes of cognitive decline.

The test measures the concentrations of β-amyloid 1-42 and β-amyloid 1-40 in cerebrospinal fluid to calculate a numerical ratio as a proxy for the presence of β-amyloid plaque in the brain. It is intended for use in adult patients aged 55 years and older, the company says, and is not intended as a screening or standalone assay to diagnose AD. Results must be interpreted in conjunction with other patient clinical information.

The assay is analyzed on Fujirebio's fully automated Lumipulse G1200 system, which is available to clinical laboratories nationwide.