Elecsys NfL test granted FDA breakthrough device designation

Nov. 10, 2023—Roche announced that its Elecsys neurofilament light chain test for multiple sclerosis received breakthrough device designation from the FDA. The test is intended to be used as an aid in detecting disease activity in adults 18 to 55 years old with relapsing-remitting multiple sclerosis or secondary progressive multiple sclerosis.

“Around 2.8 million people are estimated to live with multiple sclerosis. After diagnosis, many face challenges with managing their disease due to significant gaps in access to testing,” Matt Sause, CEO of Roche Diagnostics, said in a press statement. “We are excited about the potential Elecsys NfL has to improve outcomes for MS patients by offering a minimally invasive blood draw that can deliver rapid results.”

The test will run on the company’s Cobas instruments.