FDA clears Abbott TBI lab-based blood test

March 9, 2023—Abbott has received FDA clearance for its Alinity i laboratory traumatic brain injury blood test.

The test measures complementary biomarkers ubiquitin C-terminal hydrolase L1 and glial fibrillary acidic protein in blood plasma and serum and is for use to aid in the evaluation of patients 18 years of age or older presenting with suspected mild traumatic brain injury (Glasgow Coma Scale score of 13–15) within 12 hours of injury. Results are provided in 18 minutes on the company's Alinity i instrument with 96.7 percent sensitivity and 99.4 percent negative predictive value.

This FDA clearance complements Abbott's i-STAT TBI Plasma test, which is already cleared by the FDA. The Alinity i test has received European Union clearance and has been available in markets outside the United States since 2021.