

Study shows Abbott's TBI test could predict outcomes from brain injury

September 2022—Abbott announced that a study published in *Lancet Neurology* demonstrates the ability of two blood-based biomarkers to predict how a person will recover from traumatic brain injury (TBI) (Korley FK, et al. *Lancet Neurol.* 2022;21[9]:803–813).

Researchers measured levels of glial fibrillary acidic protein (GFAP) and ubiquitin carboxy-terminal hydrolase L1 (UCH-L1) present in blood plasma within 24 hours of injury. Abbott's FDA-cleared i-Stat TBI Plasma test and the company's Architect instrument measured the markers using research prototype assays. Results are available about 15 minutes after inserting a plasma sample in the test i-Stat cartridge.

In the study, researchers examined the day-of-injury blood tests of 1,696 patients with TBI and compared those with patients' six-month assessment, using the Glasgow Outcome Scale-Extended. The researchers found that high values of GFAP and UCH-L1 correlate with death and severe injury. The day-of-injury blood tests had a high probability of predicting death at six months—87 percent for GFAP and 89 percent for UCH-L1—and a high probability of predicting severe disability at the same time point, 86 percent for both GFAP and UCH-L1.

Abbott says it is pursuing FDA clearance under the breakthrough devices program for the TBI test on its Alinity i and Architect instruments. The TBI test on the Alinity i is CE marked and available outside the United States.

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