



PUBLICATION:

Whole-blood point-of-care glial fibrillary acidic protein and ubiquitin C-terminal hydrolase L1 biomarkers after traumatic brain injury in the United States: a prospective diagnostic prediction of intracranial injury on head CT

AUTHORS: Puccio AM, McCrea MA, Okonkwo DO, et al.

SOURCE: The Lancet Regional Health – Americas. 2026; 101539.
DOI: 10.1016/j.lana.2026.101539

PIVOTAL CLINICAL EVIDENCE

STUDY HIGHLIGHTS

STUDY HIGHLIGHTS	RESULT
ADULTS WITH SUSPECTED MTBI (GCS 13–15)	970
SENSITIVITY* FOR CT-POSITIVE INTRACRANIAL INJURY	96.5%
NEGATIVE PREDICTIVE VALUE**	96.5%
POTENTIALLY NEUROSURGICAL LESIONS IDENTIFIED	14/14
WHOLE-BLOOD TIME TO RESULT	~15 minutes

*10 participants with CT-positive findings had a Not Elevated result; none required neurosurgical intervention.

**Negative Predictive Value is influenced by prevalence and may vary across clinical settings.

CLINICAL TAKEAWAY

In a prospective multicenter study of 970 adults with suspected mTBI (GCS 13–15), the *i-STAT TBI* cartridge on the *i-STAT Alinity System* demonstrated high sensitivity and high negative predictive value for CT-positive intracranial injury. All potentially neurosurgical lesions were correctly identified, and no false-negative participant required neurosurgical intervention. Results were available in approximately 15 minutes from whole blood. Findings support use of GFAP/UCH-L1 testing as an objective aid in determining the need for head CT when used alongside clinical assessment and standard patient management.

WHY THIS STUDY MATTERS

Traumatic brain injury is a common reason for emergency department evaluation, and determining which patients may require CT imaging can be challenging. Blood-based biomarkers such as GFAP and UCH-L1 provide objective information to support clinical assessment and CT decision-making in patients with suspected mTBI.

This study provides evidence supporting the clinical performance of the *i-STAT TBI* cartridge on the *i-STAT Alinity System* for predicting the absence of CT-positive intracranial injury and supporting decisions regarding the need for head CT in adults with suspected mTBI (GCS 13–15).

The *i-STAT TBI* test measures GFAP and UCH-L1 directly from whole blood and delivers results in approximately 15 minutes without centrifugation.

STUDY OVERVIEW

OBJECTIVE

To evaluate the diagnostic performance of the *i-STAT TBI* cartridge on the *i-STAT Alinity System* as an aid in determining the need for head CT in adults presenting to the emergency department with suspected mTBI (GCS 13–15). The study generated clinical evidence supporting regulatory clearance of the platform.

STUDY DESIGN

CHARACTERISTIC	DESCRIPTION
STUDY TYPE	Prospective multicenter cohort study
NETWORK	TRACK-TBI
SITES	20 U.S. trauma centers
SITE TYPE	Level 1 and Level 2 trauma centers
ENROLLMENT PERIOD	July 2020–June 2023
EVALUABLE PARTICIPANTS	970
CLINICALTRIALS.GOV	NCT04171960

STUDY POPULATION

CHARACTERISTIC	VALUE
EVALUABLE PARTICIPANTS	970
MEAN AGE	46.8 years
AGE RANGE	18-97 years
FEMALE	36%
MALE	64%
WHITE	68.6%
BLACK	17.7%
HISPANIC/LATINO	19.4%
GCS INCLUSION RANGE	13-15
GCS 15	78.6%
GCS 13-14	21.4%



TECHNOLOGY EVALUATED

i-STAT TBI CARTRIDGE ON THE i-STAT ALINITY SYSTEM

- Whole-blood multiplex immunoassay that simultaneously measures GFAP and UCH-L1
- Provides a semi-quantitative interpretation of Elevated or Not Elevated
- Pre-specified biomarker cutoffs:
 - GFAP: 65 pg/mL
 - UCH-L1: 360 pg/mL
- Results available in approximately 15 minutes
- No centrifugation required



PRIMARY ENDPOINT

Clinical performance of the *i-STAT TBI* test (sensitivity, specificity, negative predictive value, and positive predictive value) for detection of CT-positive intracranial injury following trauma.



REGULATORY CONTEXT

This pivotal study generated the clinical evidence supporting regulatory clearance of the *i-STAT TBI* cartridge on *i-STAT Alinity System* as an aid in determining the need for head CT in adults with suspected mTBI (GCS 13–15) within 24 hours of injury.

KEY FINDINGS

DIAGNOSTIC PERFORMANCE (OVERALL POPULATION)

METRIC	RESULT (95% CI)
STUDY POPULATION	970 adults with suspected mTBI (GCS 13–15)
SENSITIVITY	96.5% (93.6-98.1)
SPECIFICITY	40.3% (36.7-44.0)
NEGATIVE PREDICTIVE VALUE (NPV)	96.5% (93.7-98.1)
POSITIVE PREDICTIVE VALUE (PPV)	40% (38.4-41.5)
POSITIVE LIKELIHOOD RATIO	1.62 (1.52-1.73)
NEGATIVE LIKELIHOOD RATIO	0.09 (0.05-0.16)

CT FINDINGS

OUTCOME	n (%)
CT POSITIVE	283 (29.2%)
CT NEGATIVE	687 (70.8%)
POTENTIALLY NEUROSURGICAL LESIONS	14 (1.4%)

CLINICAL INTERPRETATION

In this prospective multicenter study of 970 adults with suspected mTBI, the *i-STAT TBI* cartridge on the *i-STAT Alinity System* demonstrated 96.5% sensitivity and 96.5% negative predictive value for CT-positive intracranial injury. The high sensitivity and negative predictive value indicate that the test may help identify patients at low risk for CT-positive intracranial injury. Importantly, all potentially neurosurgical lesions were correctly identified, and no false-negative participant required neurosurgical intervention.

Pre-specified biomarker cutoffs were selected to maximize sensitivity and NPV, consistent with the intended use of the test as an aid in determining the need for head CT.

CLINICAL RELEVANCE



This study provides evidence supporting whole-blood GFAP/UCH-L1 testing as an objective aid in determining the need for head CT in adults with suspected mTBI. The study demonstrated that biomarker testing can be performed using whole blood at the point of care, providing results in approximately 15 minutes without laboratory centrifugation.

OPERATIONAL ADVANTAGES

OPERATIONAL ADVANTAGES	BENEFIT
WHOLE-BLOOD	No centrifugation required
POINT-OF-CARE TESTING	Supports near-patient testing
~15 MINUTE RESULTS	Rapid availability of results
BEDSIDE WORKFLOW	Supports acute care assessment

STUDY LIMITATIONS

- The median time from injury to blood testing was approximately 8 hours, and only 7.2% of participants were enrolled within 3 hours of injury
- Conducted primarily in U.S. Level 1 and Level 2 trauma centers which may limit generalizability to other care settings
- Sex- and gender-based analyses were not conducted

STUDY STRENGTHS

STUDY STRENGTHS	DESCRIPTION
MULTICENTER STUDY	20 U.S. trauma centers
PROSPECTIVE DESIGN	Data collected prospectively
INDEPENDENT CT ADJUDICATION	Blinded neuroradiologist review
PRESPECIFIED CUTOFFS	Defined before study initiation
LARGE SAMPLE SIZE	970 evaluable participants

KEY TAKEAWAYS

- Prospective multicenter study of 970 adults across 20 U.S. trauma centers.
- 96.5% sensitivity and 96.5% NPV for CT-positive intracranial injury.
- All potentially neurosurgical lesions (14/14) correctly identified.
- No false-negative participant required neurosurgical intervention.
- Whole-blood point-of-care results available in approximately 15 minutes without centrifugation.
- Clinical evidence supporting regulatory clearance use of the *i-STAT TBI* cartridge on the *i-STAT Alinity System* as an aid in determining the need for head CT in adults with suspected mTBI.

CLINICAL EVIDENCE SUMMARY

INTENDED USE

i-STAT TBI - The *i-STAT TBI* test is a panel of in vitro diagnostic immunoassays for the quantitative measurements of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in whole blood and a semi-quantitative interpretation of test results derived from these measurements, using the *i-STAT Alinity* instrument. The interpretation of test results is used, in conjunction with other clinical information, to aid in the evaluation of patients, 18 years of age or older, presenting with suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15), which may include one of the following four clinical criteria: 1) any period of loss of consciousness, 2) any loss of memory for events immediately before and after the accident, 3) any alteration in mental state at the time of accident, and/or 4) focal neurological deficits, within 24 hours of injury, to assist in determining the need for a CT (computed tomography) scan of the head. A 'Not Elevated' test interpretation is associated with the absence of acute traumatic intracranial lesions visualized on a head CT scan.

The test is to be used with venous whole blood collected with EDTA anticoagulant in point of care or clinical laboratory settings by a healthcare professional.



Learn more about
the science behind
the *i-STAT TBI*.

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i-STAT TBI and the *i-STAT Alinity* System is for in vitro diagnostic use. Not all products are available in all regions. For complete product information, visit www.globalpointofcare.abbott.

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Clinical Evidence Summary - Lancet TBI | APOC-26000487.1 07/2026

