ABSTRACT SUMMARY

Evaluating the Need for Head CT in Mild TBI Patients Using a Whole Blood Point-of-Care Test Within 24 hours of Suspected Head Injury[1]

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BACKGROUND AND OBJECTIVES:

- Approximately 69 million people worldwide experience a traumatic brain injury (TBI) annually.[2]
- In the emergency department (ED), over 80% of patients evaluated for TBI undergo head CT scans, but fewer than 10% reveal acute traumatic abnormalities.[3]
- This highlights the need for objective, rapid, and accurate tools to help clinicians assess patients with suspected mild TBI.
- The *i-STAT TBI* cartridge measures two brain-injury biomarkers, glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1), with results in 15 minutes to help determine the need for head CT scan in patients presenting with suspected mild TBI.
- This pivotal clinical study evaluated the performance of the *i-STAT TBI* cartridge.

STUDY DESIGNS:

- Prospective, multi-center study across 20 U.S. clinical sites included adults (18+) presenting to the ED with suspected mild TBI, Glasgow Coma Scale (GCS) scores of 13–15, and a CT scan ordered as part of standard care.
- Testing was conducted by point-of-care (POC) staff with venous whole blood samples drawn within 24 hours of injury.
- CT scans were independently reviewed by two blinded neuroradiologists, with a third consulted if needed.
- CT results were classified as positive or negative based on the presence or absence of acute traumatic intracranial lesions.
- A total of 970 subjects were included in the analysis.

RESULTS AND CONCLUSION:

- Median time from head injury to blood draw was 8.1h (1.5-24h).
- CT positive prevalence within enrolled patients was 29.2%.
- GCS 13-15 prevalence was 4%, 17.4%, and 78.6% respectively.
- 10 patients (3.5%; 10/283) had an *i-STAT TBI* test interpretation of 'Not Elevated' and a CT-positive result. None of the 10 patients were identified with a lesion requiring surgical intervention.
- 14 patients with CT-positive results were associated with lesions requiring surgical intervention, all of whom had an 'Elevated' *i-STAT TBI* test interpretation.
- The *i-STAT TBI* cartridge demonstrated clinical performance in ruling out intracranial lesions visible on CT imagining in adult mild TBI patients seen within 24 hours of injury.

i- STAT TBI Clinical Performance Parameters (N=970)	
CT Positive Prevalence	29.2% (283/970)
Clinical Sensitivity	96.5% (273/283)
Clinical Specificity	40.3% (277/687)
Negative Predictive Value (NPV)	96.5% (277/287)
NPV, adjusted at 6% prevalence	99.4%
Positive Predictive Value (PPV)	40.0% (273/683)

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References:

1. "Evaluating the Need for Head CT in Mild TBI Patients Using a Whole Blood Point-of-Care Test Within 24 hours of Suspected Head Injury" Association for Diagnostics & Laboratory Medicine (ADLM) Abstract (2025)
2. Dewan MC et al., "Estimating the global incidence of traumatic brain injury." J Neurosurg. 2018 Apr 27; 130(4):1080-1097
3. F. Korley et. al., "Emergency Department Evaluation of Traumatic Brain Injury in the United States, 2009-2010." J Head Trauma Rehabilitation, 2016; 31:379-387

Intended Use:

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.

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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