Abbott

POINT-OF-CARE TESTING

i-STAT TBI CARTRIDGE

# A MORE COMPREHENSIVE MILD TBI ASSESSMENT

## AT THE POINT OF CARE WITH DUAL BRAIN-SPECIFIC BIOMARKERS

Results in

15 MINUTES

FOR *IN VITRO* DIAGNOSTIC USE ONLY.

WHEN ASSESSING SUSPECTED TBI,

# QUICKLY DETERMINING ABSENCE OF AN INTRACRANIAL LESION IS A TOP PRIORITY

**69 MILLION**

TBI evaluations occur annually worldwide[1]

## TBIs, EVEN WHEN MILD, CAN HAVE A LASTING IMPACT, HIGHLIGHTING THE NEED FOR A COMPREHENSIVE ASSESSMENT

**17% OF PATIENTS** report being out of work 12 months after a mild TBI[2]

Physical exams may not always complete your assessment or reduce uncertainty of intracranial lesions, especially for challenging-to-assess patients.

For example:

*Is the intoxicated patient's slurred speech due to alcohol, or did they experience a TBI?*

*Is the elderly patient who fell disoriented because of a TBI or due to their history of dementia?*

*Is the victim of intimate partner violence sharing the full extent of their trauma due to abuse?*

A CT scan can help reduce uncertainty about the absence of an intracranial lesion, yet CT scans have limitations:

- Require additional time and resources
- Exposes patient to high dose of radiation
- May not always be ideal or possible for every patient

While many patients presenting with suspected TBI undergo CT, **more than 90% show NO EVIDENCE of traumatic abnormality**[3]

How can you get a **more comprehensive mild TBI assessment at the point of care?**

# COMPLEMENT CLINICAL EXAMS AT THE POINT OF CARE BY MEASURING BLOOD BIOMARKERS

Following a TBI, there is increased leakage of brain-specific biomarkers across the blood-brain barrier[4,5]

## GFAP

*(glial fibrillary acidic protein)*

Specific marker of glial injury in white or gray matter, not affected by extracranial trauma or exercise.

## UCH-L1

*(ubiquitin carboxyl-terminal hydrolase L1)*

Degradation enzyme highly and exclusively expressed in neurons.

# USE OF BLOOD BIOMARKERS ARE NOW INCLUDED IN CLINICAL GUIDELINES AND CONSENSUS STATEMENTS

FOR THE MANAGEMENT OF TBI*

Clinical guidelines and consensus statements that include the use of blood biomarkers:

### AMERICAN COLLEGE OF SURGEONS BEST PRACTICE GUIDELINES

*THE MANAGEMENT OF TRAUMATIC BRAIN INJURY*[6]

### FRENCH GUIDELINES

*FOR THE MANAGEMENT OF PATIENTS WITH MILD TRAUMATIC BRAIN INJURY*[7]

### THE AMERICAN CONGRESS OF REHABILITATION MEDICINE

*DIAGNOSTIC CRITERIA OF MILD TRAUMATIC BRAIN INJURY*[8]

### EUROPEAN JOURNAL OF EMERGENCY MEDICINE CONSENSUS PAPER

*ASSESSMENT OF ADULT PATIENTS WITH TBI WITH GCS 13-15 AT THE EMERGENCY DEPARTMENT*[9]

* Product is not available in all regions. Clinical guidelines and consensus statements may include information not in line with product intended use. For intended use and complete product information, visit www.globalpointofcare.abbott.

# ONLY THE i-STAT TBI CARTRIDGE MEASURES BRAIN-SPECIFIC BIOMARKERS, GFAP AND UCH-L1, AT THE POINT OF CARE

## HELPING YOU TO QUICKLY AND CONFIDENTLY DETERMINE THE APPROPRIATE CARE FOR YOUR PATIENTS, SUCH AS IMAGING OR DISCHARGE

| BIOMARKER LEVEL | INDICATE | CONSIDERATIONS |
|---|---|---|
| **Elevated**<br>*GFAP and/or UCH-L1 are elevated* | Traumatic intracranial lesion cannot be ruled out | Suggests patient warrants further clinical evaluations and CT should still be considered |
| **Not elevated**<br>*Both GFAP and UCH-L1 are not elevated* | Associated with absence of traumatic intracranial lesion | May forgo head CT if no other clinical indication is present |

**When both GFAP and UCH-L1 are 'Not elevated,' this is associated with the absence of acute traumatic intracranial lesions that would be visualized on a head CT scan[11]**

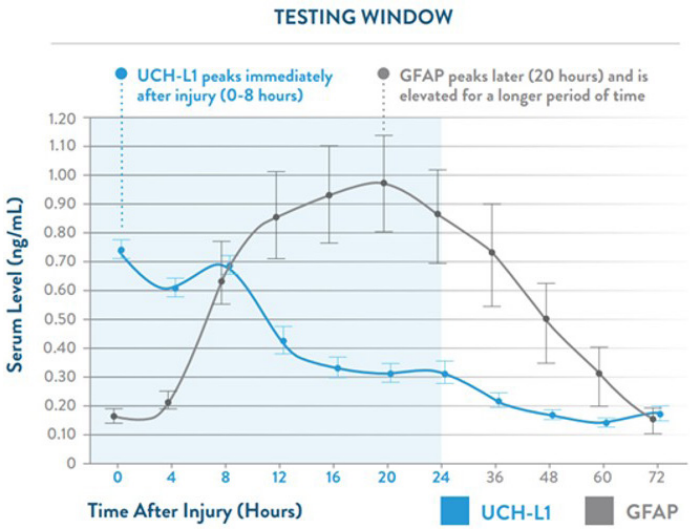
The *i-STAT TBI* cartridge is not intended to be used as a stand-alone device but as an adjunct to other clinical information to aid in the evaluation of patients who are being considered for standard of care neuroimaging.

### RELIABLE 24-HOUR TESTING WINDOW

from the complementary kinetics of GFAP and UCH-L1[10]

### MEANINGFUL RESULTS FOR CONFIDENT DECISIONS

with results up to 24 hours after injury[11]




Adapted from Papa et. al., 2016 – Profiles of Glial Fibrillary Acidic Protein (GFAP) and Ubiquitin C-Terminal Hydrolase L1 (UCH-L1) from adult trauma patients GCS 9-15.

# COMPLEMENT YOUR CLINICAL EXAMS FOR MORE COMPREHENSIVE MILD TBI ASSESSMENTS AT THE POINT OF CARE WITH THE i-STAT TBI CARTRIDGE

## LAB-QUALITY RESULTS IN 15 MINUTES

for informed decisions to help quickly determine appropriate care or confidently discharge[11]

## REDUCE HEAD CT SCANS BY UP TO 40%[11]

while providing a more complete point-of-care assessment to:

### AVOID PATIENT TRANSPORT

for patients who do not require further evaluation

### OPTIMIZE TEAM RESOURCES

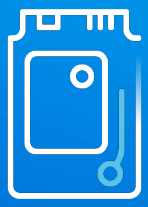
by prioritizing patient care

**96.5%**
NEGATIVE PREDICTIVE VALUE*[11]

**96.5%**
CLINICAL SENSITIVITY[11]

*In a pivotal clinical study, the prevalence of CT scan-positive subjects for acute intracranial lesions was 29.2% (283/970). The adjusted NPV is 99.4% for a prevalence of 6%.

## POSITIVELY IMPACT YOUR PATIENTS AND CARE TEAM WITH A MORE COMPREHENSIVE MILD TBI ASSESSMENT AT THE POINT OF CARE



## TO LEARN MORE, VISIT WWW.GLOBAL POINTOCARE.ABBOTT OR CONTACT YOUR ABBOTT i-STAT REPRESENTATIVE.


**REFERENCES:**

1. Dewan MC, Rattani A, Gupta S, Baticulon RE, Hung YC, Punchak M, Agrawal A, Adeleye AO, Shrime MG, Rubiano AM, Rosenfeld JV, Park KB. Estimating the global incidence of traumatic brain injury. J Neurosurg. 2018 Apr 27;130(4):1080-1097. 2. Gaudette É, Seabury SA, Temkin N, Barber J, DiGiorgio AM, Markowitz AJ, Manley GT; TRACK-TBI Investigators. Employment and Economic Outcomes of Participants With Mild Traumatic Brain Injury in the TRACK-TBI Study. JAMA Netw Open. 2022 Jun 1;5(6):e2219444. doi: 10.1001/ jamanetworkopen.2022.19444. PMID: 35767257; PMCID: PMC9244609. 3. Korley FK, Kelen GD, Jones CM, Diaz-Arrastia R. Emergency department evaluation of traumatic brain injury in the United States, 2009-2010. J Head Trauma Rehabil. 2016;31(6):379-387. 4. Zetterberg H et al. Nat Rev Neurol. 2016;12(10):563-574. 5. Chodobski A et al. Transl Stroke Res. 2011;2(4):492-516. 6. American College of Surgeons. 2024 Oct. Best Practices Guidelines: The Management of Traumatic Brain Injury 7. Maas, A. I. R., Bragge, P., Silverberg, N. D., Undén, J., & Lecky, F. E. (2023). French guidelines for the management of patients with mild traumatic brain injury. Anaesthesia, critical care & pain medicine, 42(4), 101261. https://doi.org/10.1016/j.accpm.2023.101261 8. Silverberg, Noah D. et al. Archives of Physical Medicine and Rehabilitation, Volume 104, Issue 8, 1343 - 1355 9. Backus BE, Moustafa F, Skogen K, Sapin V, Rane N, Moya-Torrecilla F, Biberthaler P, Tenovuo O. Consensus paper on the assessment of adult patients with traumatic brain injury with Glasgow Coma Scale 13-15 at the emergency department: A multidisciplinary overview. Eur J Emerg Med. 2024 Aug 1;31(4):240-249 10. Papa L et al. JAMA Neurol. 2016;73(5):551-560. 11. i-STAT TBI cartridge. Instructions for use. Abbott Point of Care Inc. Princeton, NJ; 2024.


**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

FOR *IN VITRO* DIAGNOSTIC USE ONLY. THIS MATERIAL IS INTENDED FOR USE IN CANADA.
For complete product information, visit www.globalpointofcare.abbott. Any photos displayed are for illustrative purposes only.
©2025 Abbott. All rights reserved. *i-STAT* and *Alinity* are trademarks of Abbott.
Abbott | Point of Care Diagnostics | 400 College Road East, Princeton, NJ 08540 | 609.454.9000
*i-STAT TBI* Core Visual Aid Brochure-CA APOC-25002516.1

Abbott