Abbott

i-STAT TBI CARTRIDGE

OBJECTIVELY ASSESS MILD TBI AT THE POINT OF CARE

WITH DUAL BRAIN-SPECIFIC BIOMARKERS

TBIs CAN HAVE A SIGNIFICANT IMPACT ON THE LIVES OF PATIENTS AND THOSE AROUND THEM

4.8 MILLION

TBI evaluations occur annually in the US[1]

17% OF PATIENTS

report being out of work 12 months after a TBI injury[2]

82% OF TBI PATIENTS UNDERGO CT, **YET 90% SHOW NO EVIDENCE OF TRAUMATIC ABNORMALITY[1].**

WHEN ASSESSING A SUSPECTED TBI, DETERMINING PRESENCE OF AN INTRACRANIAL LESION IS A TOP PRIORITY

Physical exams do not always reduce uncertainty of brain bleeds, especially for challenging-to-assess patients.

CT SCANS CAN PROVIDE OBJECTIVE DATA, BUT HAVE LIMITATIONS:

- Require additional time and resources
- Extend the assessment beyond the point of care
- Exposes patient to high dose of radiation
- May not always be ideal or possible for every patient

HOW CAN YOU GET OBJECTIVE DATA WITHOUT A CT SCAN?

MEASURING BIOMARKERS ENABLES **OBJECTIVE ASSESSMENT** OF PATIENTS WITH SUSPECTED MILD TBI

GFAP

(glial fibrillary acidic protein)

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

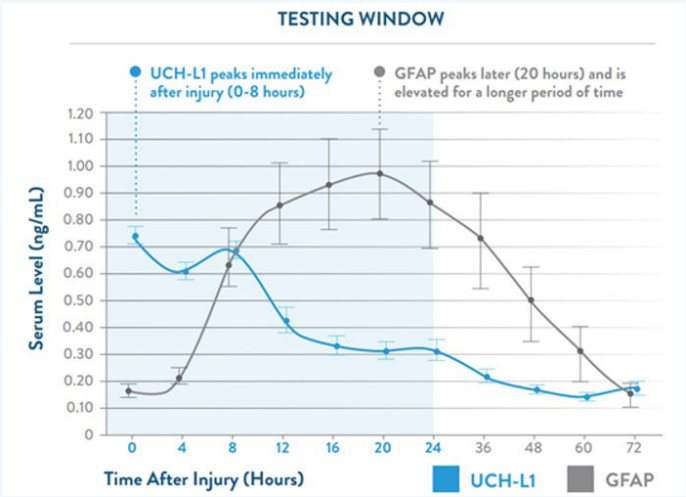
UCH-LI

(ubiquitin carboxyl-terminal hydrolase L1)

Degradation enzyme highly and exclusively expressed in neurons.

Following a TBI, there is increased permeability and leakage of molecules across the blood-brain barrier[3,4]

RELIABLE 24-HOUR TESTING WINDOW FROM THE COMPLEMENTARY KINETICS OF UCH-L1 AND GFAP



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.

THE i-STAT TBI CARTRIDGE

MEASURE TWO BRAIN-SPECIFIC BIOMARKERS AT THE POINT OF CARE

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[5]

BIOMARKER LEVEL	INDICATE	CONSIDERATIONS
Elevated *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 *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 either is elevated, further clinical evaluations and CT should still be considered. 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.

OBJECTIVELY ASSESS MILD TBI

AT THE POINT OF CARE WITH THE i-STAT TBI CARTRIDGE

96.5%
NEGATIVE PREDICTIVE VALUE AND CLINICAL SENSITIVITY[5]

RESULTS IN 15 MINUTES

REDUCE UNNECESSARY CT SCANS BY UP TO 40%[5]

CONFIDENTLY AND EFFICIENTLY
deploy care to those who need it and provide peace of mind to those who don't

WHAT IMPACT WILL THE I-STAT TBI CARTRIDGE HAVE ON YOUR PATIENTS AND CARE TEAM?

TO LEARN MORE, SCAN THE QR CODE OR CONTACT YOUR ABBOTT REPRESENTATIVE.

*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%.

REFERENCES:

1. 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. **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.** Zetterberg H et al. Nat Rev Neurol. 2016;12(10):563-574. **4.** Chodobski A et al. Transl Stroke Res. 2011;2(4):492-516. **5.** i-STAT TBI cartridge. Instructions for use. Abbott Point of Care Inc. Abbott Park, IL; 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. This material is intended for U.S. healthcare professionals only.
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