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i-STAT TBI CARTRIDGE

RULE OUT A BRAIN BLEED AT THE POINT OF CARE

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 A BRAIN BLEED IS A TOP PRIORITY

Physical exams do not always reduce uncertainty of brain bleeds, especially for certain 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
- May not detect microscopic bleeds
- May not always be ideal or possible for every patient

HOW CAN YOU GET OBJECTIVE DATA WITHOUT A CT SCAN?

MEASURING BRAIN-SPECIFIC BIOMARKERS ENABLES OBJECTIVE ASSESSMENT TO HELP RULE OUT A BRAIN BLEED

GFAP

(glial fibrillary acidic protein)

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

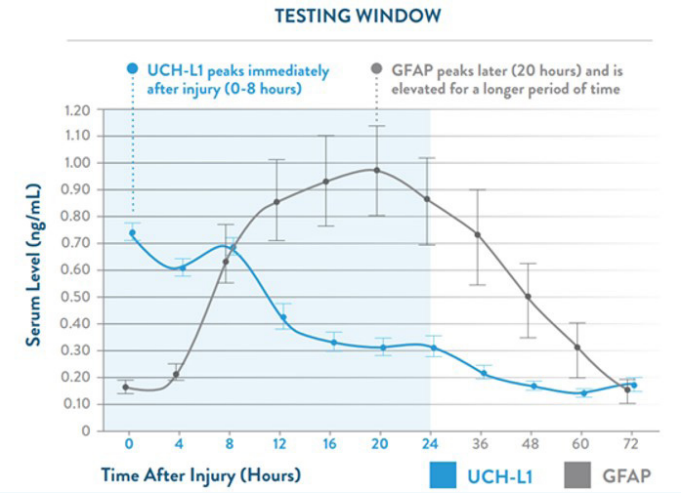
UCH-LI

(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]
- Presence of brain-specific biomarkers in the blood may indicate a brain bleed and have a reliable **24 hour** testing window[3-5]

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

MEASURING GFAP AND UCH-L1 BIOMARKERS CAN HELP RULE OUT A BRAIN BLEED WITHOUT THE NEED FOR CT[6]

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, a brain bleed may be present. When neither is elevated, a brain bleed can be ruled out. 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.

RULE OUT A BRAIN BLEED

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

96.5%
NEGATIVE PREDICTIVE VALUE AND CLINICAL SENSITIVITY*[6,7]

RESULTS IN APPROXIMATELY 15 MINUTES

REDUCE UNNECESSARY CT SCANS BY UP TO 40%[7]

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

WHAT WILL THE IMPACT OF EASIER, FASTER MILD TBI MANAGEMENT BE ON YOUR PATIENTS AND YOUR CARE TEAM?

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

*Clinical Performance Parameters (N=970) In the clinical study, the prevalence of adjudicated CT scan-positive subjects was 29.2% (283/970). Adjusted NPV at 6% prevalence is 99.4%.

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.** Papa L et al. *JAMA Neurol.* 2016;73(5):551-560. **6.** 510(k) Pre Market Notification *i-STAT TBI* (K234143). **7.** Data on file. Abbott Point of Care Inc.

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 13-1 5), 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. audience only.
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i-STAT TBI Leave Behind Brochure | 5452.REV1.APOC.EN-US

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