Analyzer TBI Test | Information Sheet

Traumatic Brain Injury Center of Excellence | July 2025

What is the ATBI Test?

- The ATBI test was developed by U.S. Army Medical Materiel Development Activity in conjunction with Abbott Laboratories.
- It is a panel of in vitro diagnostic immunoassays that measure two brain-derived proteins in whole blood using the i-STAT Alinity instrument.
- It has FDA clearance to rule out the need for a head CT scan to evaluate for intracranial lesions in those with suspected mild TBI (Glasgow Coma Scale 13–15).
- The test **is not intended as a standalone device or assessment of injury severity** and should be used along with other clinical data.

What is its intended use?

- The test is intended to help evaluate patients 18 years or older with suspected **mild TBI** within 24 hours of injury.[1]
- Clinicians should consider biomarker testing for service members with moderate risk for intracranial lesions, and in accordance with Joint Trauma System Clinical Practice Guideline *Use of TBI Whole Blood Biomarkers after Potentially Concussive Event* (ID: 90).

What does the ATBI Test measure?

- The test measures glial fibrillary acidic protein and ubiquitin carboxyl-terminal hydrolase L1, which are proteins detected in blood following structural damage to cells within the brain.
- GFAP is primarily expressed in astrocytes, while UCH-L1 is primarily expressed in neurons.
- Studies show that analyzing both proteins in blood is more accurate in predicting the need for a CT scan than analyzing them individually.

How should the results be interpreted?

- While the test provides both quantitative and qualitative results, currently **only the qualitative results ("Not elevated" or "Elevated") are FDA cleared** to inform patient assessment and care.
  - An "Elevated" result indicates traumatic intracranial lesion cannot be ruled out.
  - A "Not elevated" result is associated with the absence of traumatic intracranial lesion that would be visualized on a CT.

How accurate is the test?

- Sensitivity: 96.5%
- Specificity: 40.3%
- Pos Predictive Value: 99.4%
- Neg Predictive Value: 96.5%
- False Positive Rate: 59.6%
- False Negative Rate: 3.5%

Cartridge Specifications

Refrigerated Storage	Refrigerated Shelf Life	Room Temp. Storage	Sample Type	Specimen Stability	Sample Volume	Analysis Time	Assay Cutoff	Cost Considerations*
35-46º F until the dated indicated on the box or portion pack	Shelf life is 6 months (179 days) from manufacture	64-86º F for up to 14 days	Venous whole blood collected with EDTA anticoagulant tube (K2 or K3 EDTA tube with lavender or pink top)	1 hour from collection	20 µL	15 minutes	GFAP: 65 pg/mL UCH-L1: 360 pg/mL	Total cost for initial operation: $16,246 Whole blood cartridges: $1,180 for set of 25

**As of June 2025.*

1. Joint Trauma System Clinical Practice Guideline. Use of Traumatic Brain Injury Biomarkers after a Potentially Concussive Event. Updated 2025. Available from: https://jts.health.mil/assets/docs/cpgs/Use_of_TBI_WB_Biomarkers_after_Potentially_Concussive_Event_14_Apr_2025_ID90.pdf