i-STAT TBI

Neurology

First point-of-care, whole blood test to aid in the evaluation of patients with suspected mild traumatic brain injury

ROLE OF PRODUCT

The *i-STAT TBI* cartridge is a point-of-care, whole blood biomarker-based assay that measures the level of biomarkers associated with brain injury in the bloodstream 24 hours after injury.[1] The objective data this test provides helps assess patients with suspected mTBI.

- Lab-quality results in just 15 minutes
- Assists in making confident decisions to safely discharge patients without performing CT when clinical suspicion is low[2]
- Potential to optimize care and resources, as well as improve ED efficiency and patient satisfaction[1]

KEY BENEFIT OF PRODUCT

The *i-STAT TBI* cartridge with the *i-STAT Alinity* instrument provides lab-quality results at the point-of-care for assessing patients with suspected mTBI. The test combines two brain-specific and complementary biomarkers in a single, multiplex test - Glial fibrillary acidic protein (GFAP) and Ubiquitin C-terminal hydrolase L1 (UCH-L1)

PERFORMANCE

i-STAT TBI cartridge offers proven sensitivity and clinical utility to aid in determining the need for a CT scan of the head.[1]

- May reduce unnecessary CT for suspected mTBI by up to 40%[1,3]
  - Potential reduction of unnecessary CT may have positive implications for patient satisfaction, ED workflow, and resource utilization
- 96.5% NPV* and clinical sensitivity
  - *i-STAT TBI* cartridge can provide confidence by aiding decisions for the safe discharge of patients without performing CT[1]

INTENDED USE

The *i-STAT TBI* cartridge 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" TBI 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.

PRODUCT CODE/LIST NUMBER

- 03S09-25 *i-STAT TBI* cartridge
- 06P17-25 *i-STAT TBI Control Level 1*
- 06P17-26 *i-STAT TBI Control Level 2*
- 06P17-24 *i-STAT TBI* Calibration Verification 1-3

CARTRIDGE SPECIFICATIONS

Cartridge Box	9.625" (W) x 2" (H) x 3.75" (D)
Quantity per box	25 portion packs
Cartridge Portion Pack	3.7" (L) x 1.95" (W) x 0.37" (H)
Shipment Time-temperature Indicator	Included in shipment; time-temperature indicator that provides a visual non-reversible record of temperature exposure at, or above, 10°C and 34°C for exposure period of 5 days at 30°C and 3 hours at 34°C
Refrigerated Storage	35-46° F / 2-8° C until date indicated on box and portion pack. Shelf-life is 6 months (179 days) from manufacture.

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CARTRIDGE SPECIFICATIONS

Room Temp. Equilibration	• 5 minutes for a single cartridge • 1 hour for an entire box
Sample Type	Venous whole blood collected with EDTA anticoagulant
Sample Size	Approximately 20uL
Panel Name	TBI
Test/Analyte(s)	GFAP, UCH-L1
Analysis Time	Approximately 15 minutes
Reportable Range	GFAP: 47-10000 pg/mL, UCH-L1: 87-3200 pg/mL
Reference Range	Each facility should establish it's own reference range to assure proper representation of specific populations
Traceability	No internationally recognized standard reference is available. i-STAT controls and calibration verification materials are traceable to Abbott's working calibrators prepared using recombinant GFAP and UCH-L1.
Latex Rubber	The "diaphragm pump" contains natural rubber latex
CLIA Categorization	Moderate complexity

CONTROL SPECIFICATIONS

Control Box	4.25" (W) x 2.406" (H) x 0.718" (D)
Quantity per box	• each box contains 6 vials • each vial contains 1ml of frozen serum
Frozen Storage	Store frozen at ≤ -20 °C (-4°F) until the expiration date printed on the box and vial labels. Shelf-life is 12 months from manufacture.
Room Temp. Equilibration	Minimum of 45 minutes to a maximum of 4 hours prior to reconstitution. Test the fluids immediately after reconstitution.
After thawing	Material may be stored capped at room temperature 18-30°C (64-86°F) or refrigerated 2-8°C (35-46°F) for up to 4 hours prior to testing. DO NOT refreeze.
Control Levels	Levels 1 and 2

CAL/VER SPECIFICATIONS

CAL/VER Box	4.25" (W) x 2.406" (H) x .718" (D)
Quantity per box	• Each box contains 6 vials (two vials of each level) • Each vial contains 1mL of frozen serum
Frozen Storage	Store frozen at ≤ -20 °C (-4°F) until the expiration date printed on the box and vial labels. Shelf-life is 12 months from manufacture.
Room Temp. Equilibration	Minimum of 45 minutes to a maximum of 4 hours prior to reconstitution. Test the fluids immediately after reconstitution.
After thawing	Material may be stored capped at room temperature 18-30°C (64-86°F) or refrigerated 2-8°C (35-46°F) for up to 4 hours prior to testing. DO NOT refreeze.
CalVer Levels	• Levels 1, 2, and 3 • Low, mid and high result values across the reportable range

SYSTEM COMPATIBILITY

The *i-STAT TBI* cartridge is compatible with the *i-STAT Alinity* instrument; the latest addition to the *i-STAT* family of harmonized solutions.
The award winning[4] *i-STAT Alinity* instrument is designed to improve operator competency and enable greater quality control and compliance.

TRAINING AND COMPLIANCE

Resources designed to ensure competency of *i-STAT* users and assist in meeting regulatory compliance requirements are available for download from the website, **www.globalpointofcare.abbott.**

INTERACTIVE REMOTE TRAINING

- Calender available for sessions related to the *i-STAT* system and performing software updates.

ADDITIONAL INFORMATION

To obtain additional product information and support, visit **www.globalpointofcare.abbott**.

REFERENCES

1. 510(k) Pre Market Notification *i-STAT TBI* (K234143). Available at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. [Accessed April 01, 2024].
2. Easter J.S., Haukoos J.S., Meehan W.P., Novack V., Edlow J.A. Will neuroimaging reveal a severe intracranial injury in this adult with minor head trauma?: The rational clinical examination systematic review. JAMA. 2015 Dec 22-29;314(24):2672–2681.
3. Data on file. Abbott Point of Care Inc.
4. A' Design Award & Competition. 2017 Award Winning Design, Silver A'Design Award. https://competition.adesignaward.com/design.php?ID=51018 [Accessed October 12, 2023].

*The NPV obtained from the study was 96.5% at a CT positive prevalence of 29.2%. Adjusted NPV of 99.4% when adjusted to a CT positive prevalence of 6% for comparison purpose against the clinical performance observed in the ALERT-TBI study.

For *in vitro* diagnostic use only.
This material is intended for a U.S. audience only.

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i-STAT TBI Cartridge Sell Sheet | 5306.REV1 04/24

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