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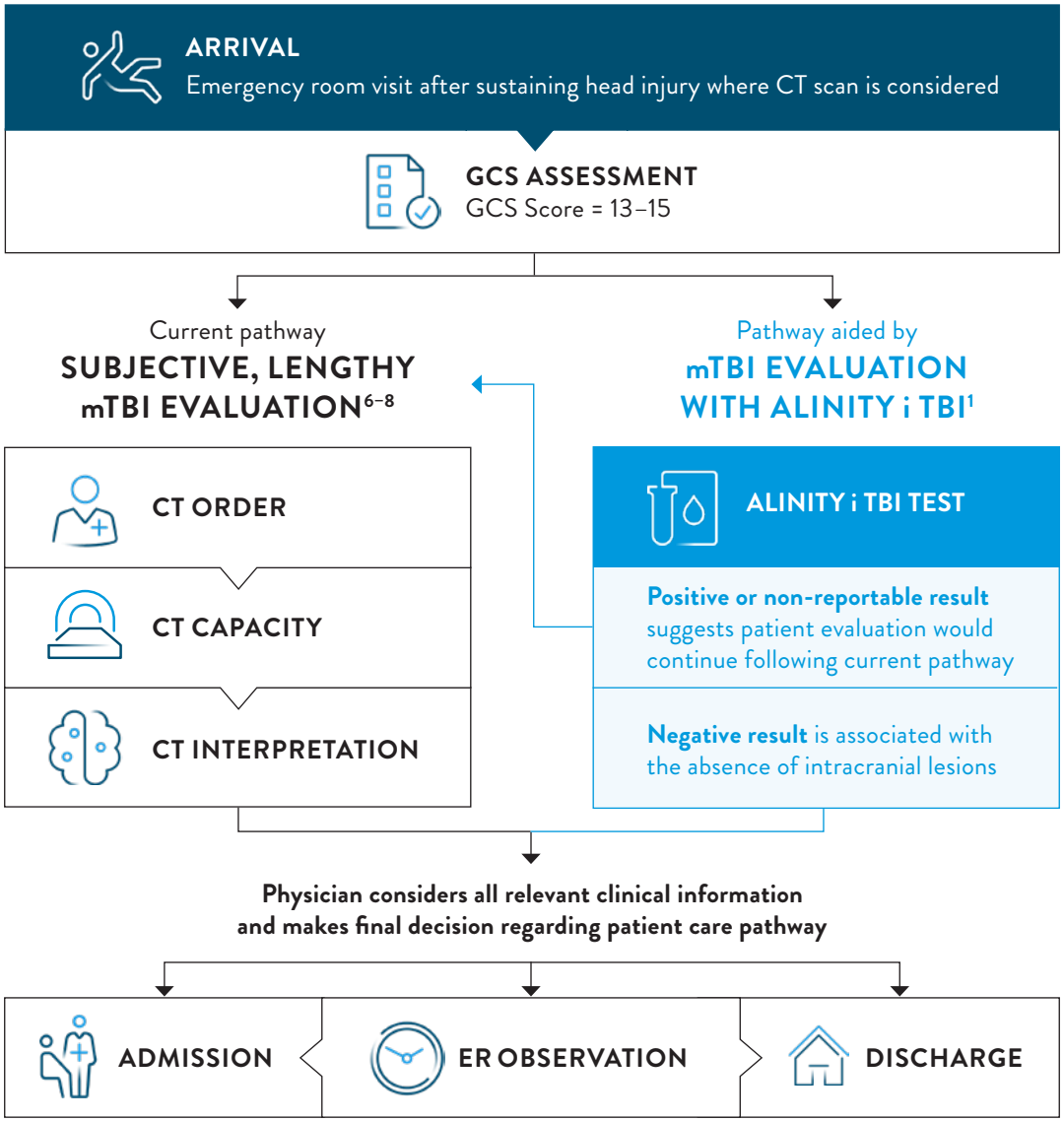
IT'S MORE THAN A TEST.

IT'S AN OBJECTIVE APPROACH TO AID IN RULING OUT THE PRESENCE OF ACUTE INTRACRANIAL LESIONS.[1]

Integrating the Alinity i TBI test into evaluation pathways for suspected mild traumatic brain injury (mTBI) offers **the potential to reduce unnecessary CT scans by up to 40%** and may help optimize care and resources in your emergency room (ER).[1–6]

96.7% CLINICAL SENSITIVITY

99.4% NEGATIVE PREDICTIVE VALUE



INTENDED USE

The TBI test is a panel of *in vitro* diagnostic chemiluminescent microparticle immunoassays (CMIA) used for the quantitative measurements of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in human plasma and serum and provides a semi-quantitative interpretation of test results derived from these measurements using the Alinity i system.

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) within 12 hours of injury, to assist in determining the need for a CT (computed tomography) scan of the head. A negative test result is associated with the absence of acute intracranial lesions visualized on a head CT scan. The TBI test is intended for use in clinical laboratory settings by healthcare professionals.

See reverse page for Important Safety Information

IMPACT OF INTEGRATING ALINITY i TBI

IT'S MORE THAN A TEST.

It's confidence—an objective result, with high sensitivity to detect blood-based biomarkers of mild brain injury within 12 hours of head trauma—giving clinicians the power to predict the absence of intracranial lesions in adult patients with suspected mTBI.[1]

It's optimizing care and resources—with the potential to reduce unnecessary CT scans by up to 40%.[1,2] Protect patients from a costly procedure that exposes them unnecessarily to radiation.[1,3–5]

It's a more efficient ER and a better experience for patients and their families. When physicians are empowered to accurately assess the absence of intracranial lesions without a CT scan, it may help them discharge patients faster from the emergency room—increasing patient throughput and reducing length of stay.[1,6] So patients can get back to what matters most to them.

IMPORTANT SAFETY INFORMATION
Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

Rx ONLY (For use by or on the order of a physician only).

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. This product contains sodium azide. Contact with acids liberates very toxic gas. Dispose of contents / container in accordance with local regulations.

REFERENCES:
1. Alinity i TBI [package insert] 802673R01. Instructions for use. Abbott Diagnostics. May 2023. **2.** Data on file at Abbott. **3.** Bazarian JJ, Biberthaler P, Welch RD, et al. Serum GFAP and UCH-L1 for prediction of absence of intracranial injuries on head CT (ALERT-TBI): a multicentre observational study. *Lancet Neurol*. 2018;17(9):782–789. doi:10.1016/S1474-4422(18)30231-X **4.** Wang KKW, Kobeissy FH, Shakkour Z, Tyndall JA. Thorough overview of ubiquitin C-terminal hydrolase-L1 and glial fibrillary acidic protein as tandem biomarkers recently cleared by US Food and Drug Administration for the evaluation of intracranial injuries among patients with traumatic brain injury. *Acute Med Surg*. 2021;8(1):e622. doi:10.1002/ams2.622 **5.** Bazarian JJ, Welch RD, Caudle K, et al. Accuracy of a rapid GFAP/UCH-L1 test for the prediction of intracranial injuries on head CT after mild traumatic brain injury [published online ahead of print, 2021 Aug 6]. *Acad Emerg Med*. 2021;10.1111/acem.14366. doi:10.1111/acem.14366 **6.** Michelson EA, Huff JS, Loparo M, et al. Emergency department time course for mild traumatic brain injury workup. *West J Emerg Med*. 2018;19(4):635-640. doi:10.5811/westjem.2018.5.37293 **7.** Stiell IG, Clement CM, Rowe BH, et al. Comparison of the Canadian CT Head Rule and the New Orleans Criteria in patients with minor head injury. *JAMA*. 2005;294(12):1511–1518. doi:10.1001/jama.294.12.1511 **8.** 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;31:379–387. doi:10.1097/HTR.0000000000000187

For *In Vitro* Diagnostic Use.

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