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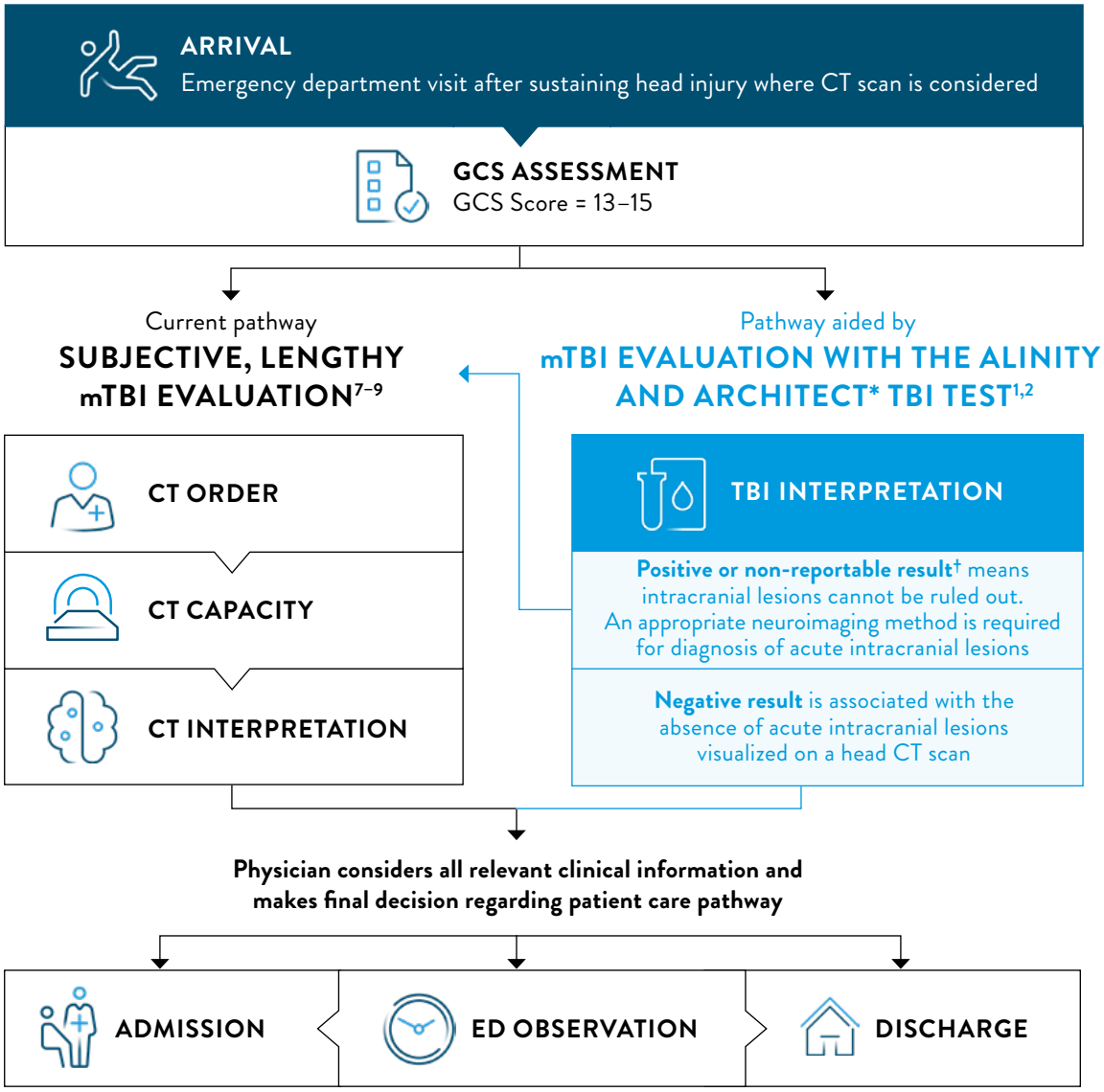
IT'S MORE THAN A TEST.

IT'S AN OBJECTIVE APPROACH TO AID IN RULING OUT THE PRESENCE OF ACUTE INTRACRANIAL LESIONS.[1,2]

Integrating the Alinity i and ARCHITECT* 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 department (ED).[1–7]

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 or ARCHITECT 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.[1,2]

*This test is available on ARCHITECT i1000SR only.

†An automated TBI interpretation will not be reported for specimens without a result for GFAP and/or UCH-L1.

IMPACT OF INTEGRATING THE ALINITY i AND ARCHITECT* TBI TEST

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.[1,2]

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.[1,2,4–6]

It's a more efficient ED and a better experience for patients and their families—when physicians can accurately assess the absence of intracranial lesions without a CT scan, it may help them discharge patients faster from the ED—increasing patient throughput and reducing length of stay.[1,2,7]

REFERENCES:

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For *In Vitro* Diagnostic Use.

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All ARCHITECT analyzers are Class I laser products.

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