Health Technology Review	
Technology Ref.:	HTA-23071
Technology Name/Version/Model:	Blood Biomarker for mild Traumatic Brain Injury- Version 1.
Approvals by International Bodies:	FDA Approval and CE Mark
Company name:	Abbott Point of Care
Agent in UAE:	Abbott Laboratories GMBH
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Short Description of the Technology:	The i-STAT TBI Plasma 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 plasma 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) within 12 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.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The i-STAT TBI Plasma test measures the level of biomarkers associated with brain injury in the blood stream to assist in determining the need for a CT scan of the head which lead to reducing the Time waiting in ED, and Radiology Department.

Advantages	Disadvantages
The Scientist magazine cited the i-STAT Alinity system (which test Blood Biomarker for mild Traumatic Brain Injury) as one of the Top 10 Innovations of 2017	The i-STAT TBI Plasma test is not intended to be used in point-of-care settings.
Reducing the Time of ER/Hospital stay as the results are released in 15 minutes.	The i-STAT TBI Plasma test cannot be used in pediatric age.
Reduced radiation exposure.	
Potential to optimize care and resources, as well as improve ED efficiency and patient satisfaction.	

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. The technology should be performed by authorized healthcare laboratory.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology "Blood Biomarker for mild Traumatic Brain Injury"

- **Population/ Intended User**;
  - patient suspected mild traumatic brain injury (Glasgow Coma Scale 13-15) within 12 hours of injury.
- **To be performed by**:
  - Medical Lab Technology
- **Clinical Setting:**
  - Hospitals, Emergency Department
- **Condition of use:**
  - 18 years of age or older
  - Glasgow coma scale 13-15 as the Negative Predictive Value (NPV) is 99.3% .