

## **mTBI Biomarker FAQs**

### **1 – What are the proteins in this test?**

The biomarker test is actually 2 proteins. GFAP (found in astrocytes) and UCH-L1 primarily found in CNS neurons. UCH-L1 has a more rapid rise and fall in serum levels after trauma (detectable within 1 hour) whereas GFAP has a slower rise and fall. The test is considered positive if either one of these proteins is elevated above their threshold value.

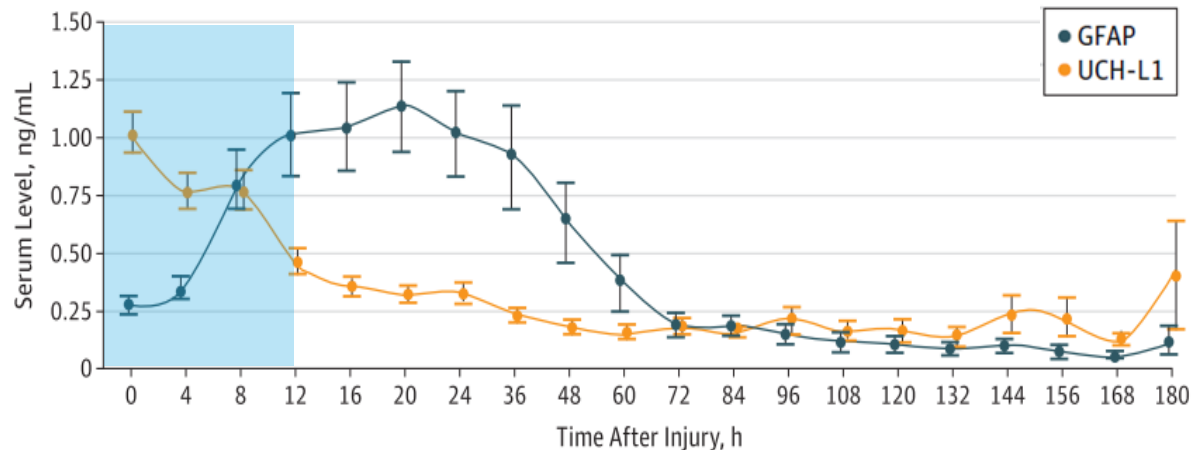


Figure 1 from Papa et al 2016

### **2- What is the time range for this test?**

The whole blood test (no need to centrifuge) that is used in the iSTAT machines is approved for 1-24 hours after injury. It was approved by Health Canada for use earlier this year.

### **3 – What is the sensitivity of the test?**

Sensitivity is 96%, negative predictive value is over 99%. For comparison, the sensitivity of D-dimer for PE is 97% and sensitivity of CTPE for PE is 94%. The few cases that were biomarker negative but had findings on CT scan were all managed conservatively. No neurosurgical intervention on any of these cases. The test is sensitive enough that it can detect injuries or bleeds so small that they don't appear on CT scan, only subsequent MRI scans (biomarker +ve, CT -ve, MRI +ve).

### **4 – What is the specificity of the test?**

Specificity is 37%. This is similar to the specificity of D-dimer for PE (41%).

### **5 – Who can the test be used on?**

It is approved for any patient with a minor traumatic head injury over the age of 18. There is no upper age limit. Current guidelines indicate that it is still accurate in intoxicated patients

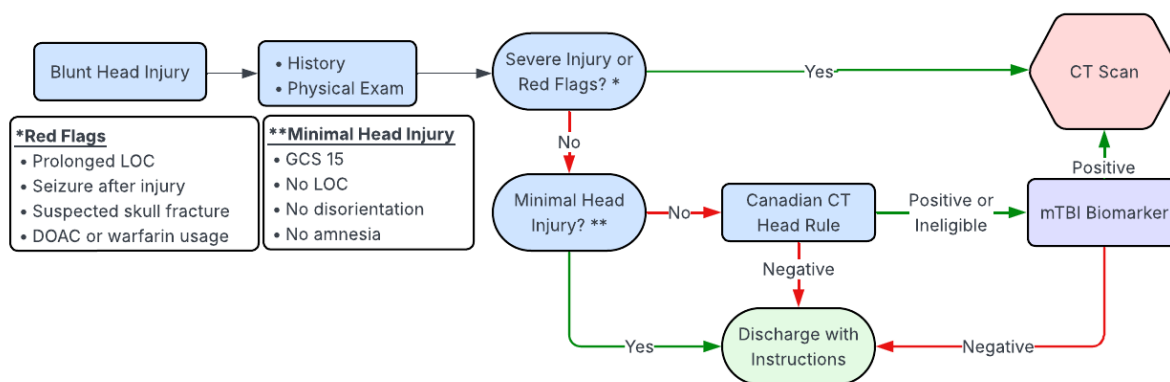
and those patients taking ASA. Studies are currently underway to verify its accuracy in patients on warfarin or DOAC although this will likely end up being safe as well as it is rule-out test instead of a confirmation test.

## 6 – How is the test run?

Whole blood taken from the patient is loaded into an iSTAT cartridge which is then used in a handheld iSTAT machine. The results are available in about 15 minutes. The machine has a built-in threshold calculator so it will give you a simple TEST: Positive or TEST: Negative result.

## 7 – How can I incorporate this into my ED practice?

If you have a patient over the age of 18 that is not on warfarin or a DOAC and you are considering a CT of their head after a head injury, you can use this test instead. The following algorithm can be used:



So if the patient had more than a slight bump on their head and the Canadian CT head rule says to scan (or the patient is ineligible for the Head Rule because of ASA, age, or intoxication) you should run the biomarker. If it is negative, you can safely discharge the patient with safe return to ED instructions.

## 8 – Is this test being used anywhere else?

Yes, it is already incorporated into standard ED workflows in EU and some centers in US.

## 9 – Are there any other uses for this test?

There appears to be a correlation between how high the GFAP/UCH-L1 levels are and how severe the post-concussion symptoms will be. Some centers in EU/US are starting neurology concussion clinics to follow up those patients to avoid prolonged post-concussion syndromes. Work on this is ongoing currently.