

## New assay may enable blood test of concussions/TBIs

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Amanda Pedersen  
Senior Staff Writer

**Quanterix** (Lexington, Massachusetts), a developer of high definition diagnostics, reported that *JAMA Neurology* has published a ground-breaking study in which it's Simoa (single molecule array) technology was used to directly measure the brain protein Tau in the blood of athletes who had sustained mild traumatic brain injuries or concussions. These measurements have never before been possible in blood, the company noted.

In this paper, levels of plasma Tau, implicated in neurodegeneration, were studied in connection with sports-related head injuries. Post-concussion Tau levels were followed over about six days and were compared with Tau levels measured in a group of hockey players prior to the start of the hockey season. The results indicate that Tau is significantly elevated following mild to severe concussion and remains elevated compared to pre-season levels for up to six days post-concussion.

Julien Bradley, senior director at Quanterix, told *Medical Device Daily* that the study could be the first step towards a Tau blood test that could be used to determine if athletes should return to play or not after a concussion.

"What really makes this exciting is currently the way these brain biomarkers are measured is through a spinal tap," Bradley said. He explained that the brain is very good at protecting itself with what's known as a blood-brain barrier, which makes it hard to measure biomarkers in the brain.

A blood-based test for these brain injuries would be an ideal way to measure what is happening in the brain, he added, but existing technology has not been able to detect brain biomarkers accurately.

"Our Simoa technology is about a thousand times more sensitive," Bradley said. The use of this single molecule array to directly measure Tau in the blood enables research into this area, which could lead to the development of a new diagnostic tool for TBIs in athletes and in military personnel.

"The main value here is it is empowering new research that couldn't be done before," Bradley said. "Our end goal is we would like to see new discoveries made which could be translated into new diagnostics." He added that "we dream of the day we can take a version of our technology and have it" put into a small device that could be used in a sports arena or on the battlefield and be able to tell athletes right away whether they've had a concussion. Right now, he said, it's just a guessing game.

The Simoa platform uses single molecule measurements to access previously undetectable proteins. With this unprecedented sensitivity and full automation, Simoa offers significant benefits to both research and clinical testing applications, the company noted.

"This study demonstrates a great ability to further the understanding of the long term effects of TBI," said Paul Chapman, CEO of Quanterix. "One of the most promising applications for our Simoa platform is to provide a simple blood test that could speed the diagnosis of a concussion in a clinical setting and on the sidelines in a sports arena, therefore, improving overall treatment."

Traumatic brain injury, particularly mild traumatic brain injury, is a common occurrence in athletes performing contact sports and in military personnel deployed in combat. Currently, neuronal proteins like Tau require cerebrospinal fluid (CSF) collection as their concentrations in peripheral circulation are below the detection limit of conventional tests. CSF collection is an invasive, expensive and time-consuming procedure requiring that a spinal tap be performed on the patient. With Simoa, the need for such testing is eliminated as Simoa delivers a 3000-fold improvement in sensitivity compared to standard tests available today, according to Quanterix. The Simoa platform offers the ability to measure low-abundance biomarkers of brain function such as Tau in a simple blood test, providing new insights for diagnosis, monitoring and treatment of several neurological and neurodegenerative conditions.

In January, Quanterix reported that it has been selected as a winner of the GE and NFL Head Health Challenge from more than 400 entries across 27 countries by a panel of healthcare experts in brain research, imaging technologies and advocates for the advancement of brain research. The grant provides funding to help further advance development of tests to quickly diagnose TBIs through the Simoa technology.

With this grant, GE and the NFL have singled out Quanterix for its effort to advance the detection and management of mild to moderate TBIs. This team will look to help physicians make more accurate diagnoses of brain injuries and better predict long-term prognosis of individuals having undergone acute and repetitive injuries. The Simoa technology will be used to develop and validate biomarkers that quantify disease severity and predict long-term outcomes from repetitive injuries.

"This challenge was a call to action to advance head health research and innovation. The breakthrough ideas submitted will help us better understand brain injuries and the brain overall. We are excited to work with Quanterix to advance research for a blood test that would speed the diagnosis of a concussion and therefore help doctors improve treatment," said Alan Gilbert, director of global government and NGO strategy, GE healthymagination.

Launched in March 2013, the Head Health Challenge is part of a four-year, \$60 million collaboration between GE and the NFL to speed diagnosis, and improve treatment for mild to traumatic brain injury. The initiative also includes a four-year, \$40 million research and development program from the NFL and GE intended to evaluate and develop next generation technologies to improve diagnosis and enable targeted treatment therapy for patients with mild to traumatic brain injury.

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