Abbott Receives FDA Clearance For First Commercially Available Lab-Based Blood Test To Help Evaluate Concussion

- New test will run on Abbott's Alinity® i laboratory instrument, complementing Abbott's rapid i-STAT TBI Plasma test, cleared by the FDA in 2021
- Given the significant number of Alinity i instruments in use in labs across the U.S., Abbott's lab test will make concussion testing available to more people across the country
- Test helps doctors evaluate patients with mild traumatic brain injury (mTBI), commonly known as concussion, by ruling out the need for a CT scan

ABBOTT PARK, Ill., March 7, 2023 /PRNewswire/ -- Abbott (NYSE: ABT) has received U.S. Food and Drug Administration clearance for what will be the first commercially available laboratory traumatic brain injury (TBI) blood test, making it widely available to hospitals in the United States. The test, which runs on Abbott's Alinity® i laboratory instrument, will provide clinicians with an objective way to quickly assess individuals with mild TBIs, also known as concussions.

Abbott's Alinity i TBI lab test offers a new reliable result in 18 minutes to help clinicians quickly assess concussion and triage patients. For those with negative results, it rules out the need for a CT scan and can eliminate wait time at the hospital. The test measures two biomarkers in the blood that, in elevated concentrations, are tightly correlated to brain injury.

For decades, standard concussion assessment has remained the same, with doctors leveraging the Glasgow Coma Scale, a subjective doctor assessment, and CT scans to detect brain tissue damage or lesions. Having a blood test available could help reduce the number of unnecessary CT scans by up to 40%, potentially reducing costs to the healthcare system and the patient as well as the amount of time they spend in the emergency department.

Millions of people in the U.S. suffer a concussion each year, but more than half of people who suspect they have a concussion never get it checked.

"People sometimes minimize a hit to the head, thinking it's no big deal. Others wonder if a visit to the doctor or emergency room for a possible concussion will provide them with meaningful answers or care," said Beth McQuiston, M.D., medical director in Abbott's diagnostics business. "Now that this test will be widely available in labs across the country, medical centers will be able to offer an objective blood test than can aid in concussion assessment. That's great news for both doctors and people who are trying to find out if they have suffered a traumatic brain injury."

TBIs are caused by a bump, blow or whiplash to the head and can pose risk of both short- and long-term effects. People who experience a TBI may experience impairment of memory, movement, sensation (e.g., vision and hearing), and emotional functioning (e.g., personality changes, psychological symptoms). Effects of TBI can last anywhere from a few days post-injury or may be permanent. People who sustain a TBI are more likely to have another one – similarly to how a sprained ankle or torn ligament is more susceptible to future injury.

These effects are worsened by misdiagnosis or lack of diagnosis, so providing tools that can objectively aid in the evaluation of a TBI or concussion is essential to giving people the answers and treatment they need.

Abbott has been pioneering breakthroughs in TBI testing technology for over a decade. This FDA clearance complements Abbott's i-STAT TBI Plasma test, the first rapid blood test for concussion, which is already cleared by the FDA. With the Alinity i clearance, a TBI blood test can now be run on Abbott's high throughput Alinity i laboratory instrument. The advancement will make TBI testing more available because the Alinity i instrument is widely used in hospitals and laboratories across the U.S.

The Alinity i test can be used when a patient shows up to the hospital with a suspected mTBI within 12 hours of injury. A blood sample is drawn from the arm and sent to the lab for preparation and the test is run on the Alinity i instrument. Results are available in as little as 18 minutes and shared with the treating healthcare provider for evaluation.

Broadening the availability of the TBI blood test for use on lab-based instruments is an important step in Abbott's strategy to ensure its tests are available in all settings where people seek care for head injuries.

About Alinity i laboratory test for TBI

The Alinity i TBI test measures complementary biomarkers in blood plasma and serum - Ubiquitin C-terminal Hydrolase L1 (UCH-L1) and Glial Fibrillary Acidic Protein (GFAP), that, in elevated concentrations, are tightly correlated to brain injury. It provides test results with 96.7% sensitivity and 99.4% negative predictive value.

Testing for these two biomarkers in the immediate aftermath of an injury can help health care providers decide appropriate next steps and develop a plan to care for patients. The test is for use 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.

The test previously received European Union clearance and has been available in markets outside the U.S. since 2021.

About Abbott

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices,

nutritionals and branded generic medicines. Our 115,000 colleagues serve people in more than 160 countries.

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The i-STAT TBI blood test was developed in collaboration with the U.S. Department of Defense (DoD) – which has been dedicated to developing a solution for the objective detection and evaluation of TBI for more than a decade. The DoD, through U.S. Army Medical Research and Development Command's (USAMRDC) U.S. Army Medical Materiel Development Activity (USAMMDA), played a critical role in developing the test run on Abbott's i-STAT Alinity platform.

The Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) research team were the first to demonstrate how this TBI blood test can be used for the benefit of TBI patients in clinical care.

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