bioMérieux receives FDA 510(k) clearance of VIDAS® TBI (GFAP, UCH-L1), an innovative test to improve the assessment of patients with mild traumatic brain injury

Marcy-l'Étoile (France), May 28th, 2024 – bioMérieux, a world leader in the field of *in vitro* diagnostics, announces the U.S. FDA 510(k) clearance of VIDAS® TBI (GFAP, UCH-L1), a serum-based test to support the assessment of patients with mild traumatic brain injury (mTBI), including concussion. The assay uses a unique combination of the biomarkers GFAP and UCH-L1*, proteins that enter circulation following cellular injury[1]. The test can help reduce the number of unnecessary head Computed Tomography (CT) scans performed for mTBI patients by predicting the absence of accute intracranial lesions (ICL).

Traumatic brain injury is defined as the transfer of external mechanical energy to brain tissue resulting in cellular damage, dysfunction, and dysregulation[2]. As a leading cause of death and disability, TBI is a major public health burden. About 69 million people suffer from it worldwide every year[3]. For the clinicians evaluating these patients, it is often imperative to determine the presence or absence of life-threatening hemorrhage and neurologic complications.

Based on clinical presentation and assessment of severity using the Glasgow Coma Scale (GCS), TBI is currently characterized as mild, moderate, or severe. Of these, mild traumatic brain injuries are the most prevalent, accounting for 70-90% of all TBI diagnoses[4]. Fortunately, they are the least likely to result in acute medical emergencies[5]. It is estimated that 90% of mTBI patients who undergo CT scans will be negative for abnormal findings. Despite this statistic, use of imaging remains common with an estimated 82% of all TBI patients receiving scans[6]. A significant number of these scans could be avoided given that they increase patient workup time, expose patients to CT-scan radiation and take up resources of burdened ED departments[5].

A game changing test contributing to an efficient triage for mTBI's

An easy-to-interpret test from the immunoassay range VIDAS®, VIDAS® TBI (GFAP, UCH-L1) measures the concentration of GFAP and UCH-L1, two brain biomarkers that are released into the bloodstream starting from the first hour following a brain injury. When used in conjunction with clinical information, VIDAS® TBI (GFAP, UCH-L1) results can aid clinicians in determining the need for CT imaging of the head in adult patients (18 years or older), presenting within a large testing window of up to 12 hours after injury, and help shorten ED workup time. A negative test result assists in determining the need for a CT-scan by predicting the absence of acute intracranial lesions[7].

"Securing FDA clearance for the VIDAS® TBI (GFAP, UCH-L1), marks another significant milestone in our journey toward innovative solutions for our customers and improving patient outcomes," said Colin Hill, General Manager and Head of Clinical Operations, North America. *"This enables clinicians to confidently perform fast, efficient triage for mTBI's, resulting in faster and more informed decisions for personalized treatment of patients."*

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"In keeping with the legacy of bioMérieux, we remain committed to developing diagnostic solutions that will improve the delivery of healthcare, have a positive societal impact, and help make the world a healthier place," said Dr. Charles K. Cooper, Executive Vice President and Chief Medical Officer. *"In recognizing the enormity of traumatic brain injury, the VIDAS® TBI (GFAP, UCH-L1) assay contributes to the advancement of current practices in disease evaluation."*

VIDAS® TBI (GFAP, UCH-L1) is available on VIDAS® 3 and VIDAS® KUBE™ immunoanalyzers, offering on-demand automated testing 24/7. The assay's commercial launch is planned for the second half of 2024 in the United States. VIDAS® TBI (GFAP, UCH-L1) is also CE-marked** and commercialized in selected European, North African and South American countries.

**GFAP: Glial Fibrillary Acidic Protein ; UCH-L1: ubiquitin C-terminal hydrolase-L1*
*** Notified Body 0459*

[1] *Papa L, Brophy GM, Welch RD, et al. Time Course and Diagnostic Accuracy of Glial and Neuronal Blood Biomarkers GFAP and UCH-L1 in a Large Cohort of Trauma Patients With and Without Mild Traumatic Brain Injury. JAMA Neurol. 2016 May 1;73(5):551-60*
[2] *National Institute of Neurologic Disorders and Stroke. What is a traumatic brain injury? https://www.ninds.nih.gov/health-information/disorders/traumatic-brain-injury. Accessed May 1, 2024.*
[3] *Estimating the global incidence of traumatic brain injury in: Journal of Neurosurgery Volume 130 Issue 4 (2018) Journals (thejns.org) https://doi.org/10.3171/2017.10.JNS17352*
[4] *Peterson B, Zhou H, Thomas KE, Daugherty J. CDC Surveillance Report 2017: Traumatic Brain Injury Related Hospitalizations and Deaths by Age Group, Sex, and Mechanism of Injury. https://www.cdc.gov/traumaticbraininjury/pdf/TBI-surveillance-report-2016-2017-508.pdf Accessed on March 15, 2023.*
[5] *Easter JS, Haukoos JS, Meehan WP, Novack V, Edlow JA. Will neuroimaging reveal a severe intracranial injury in this adult with minor head trauma? the rational clinical examination systematic review. JAMA 2015;314:2672–81.*
[6] *Korley, F.K., et al., Emergency Department Evaluation of Traumatic Brain Injury in the United States, 2009-2010. J Head Trauma Rehabil, 2016. 31(6): p. 379-387.*
[7] *VIDAS® TBI 065299 - 01 - 2023-11 - en. Lyon, France: BioMérieux; 2024.*

ABOUT VIDAS®

Launched over 30 years ago, VIDAS® has transformed the field of immunoassays offering laboratories universal access to a simple, automated, and robust technology providing fast and safe results. Today, VIDAS® is still the most widely used immunoassay system in clinical laboratories worldwide.

The VIDAS® menu comprises around 100 parameters, including infectious and chronic diseases, as well as a range of tests dedicated to emergency and critical care.

bioMérieux maintains ongoing commitment to the VIDAS® range, with continual research and new immunoassay solutions to create value for labs and clinicians, benefiting patient care.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics since 1963, bioMérieux is present in 45 countries and serves more than 160 countries with the support of a large network of distributors. In 2023, revenues reached €3.7 billion, with over 90% of sales outside of France.

bioMérieux provides diagnostic solutions (systems, reagents, software and services) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.
www.biomerieux.com.

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bioMérieux is listed on the Euronext Paris stock market.
Symbol: BIM – ISIN Code: FR0013280286
Reuters: BIOX.PA/Bloomberg: BIM.FP

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