bioMérieux receives FDA Clearance for NEPHROCHECK® test on VIDAS®

Marcy l'Etoile, France – July 28 , 2022 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced the FDA Clearance of the innovative VIDAS® NEPHROCHECK® assay to detect kidney stress in patients at risk of acute kidney injury (AKI).

AKI is a common complication, affecting between 7 and 18% of all hospitalized patients and up to 50% of critically ill patients[1-3]. The condition is associated with a 10-fold increase in hospital mortality and a higher rate of chronic kidney disease among post-op patients[4].

While a number of acute risk factors and patient characteristics have been identified which predispose patients to AKI, current diagnostic tools are inadequate for a clinician to establish a clear risk profile for any given patient[5]. Delays in recognizing AKI can potentially lead to irreversible consequences. In many cases, adverse patient outcomes are avoidable if the condition is identified and managed in a timely fashion.

NEPHROCHECK® is an innovative test that detects kidney stress prior to actual damage, when a timely intervention can still make a difference. It is intended to be used in conjunction with clinical evaluation as an aid to support the risk assessment of moderate or severe AKI in acutely ill patients. With this early information, clinicians can intervene sooner to either rule out kidney stress with confidence, or implement a series of protective measures for the kidneys.

"*As a predictive tool for AKI, NEPHROCHECK® provides clinicians with high medical-value information and can lead to benefits in patient care and improved outcomes. The development of this test is consistent with our focus on improving care for individuals with acute medical and critical conditions. It complements our existing pioneering assays for these patients, such as procalcitonin (PCT)*," said Mark Miller, Executive Vice President, Chief Medical Officer, bioMérieux.

VIDAS® is an automated system that provides laboratory personnel with increased throughput and full traceability of test results. The addition of the innovative NEPHROCHECK® assay onto the VIDAS® platform is complementary to other tests that can be run concurrently to aid in the diagnosis of sepsis, which is a significant risk factor for AKI.

NEPHROCHECK® test kits are FDA cleared on both ASTUTE140® meter and VIDAS® instrument. VIDAS® NEPHROCHECK® will be available in the US in 2023.

"*Considering the proportion of individuals affected each year, AKI represents a significant burden to patients, the functioning of intensive care units and has a huge economic impact on healthcare systems. Innovative assays like NEPHROCHECK® not only contribute to improved patient outcomes but could potentially help optimize hospital costs,*" said Pierre Boulud, Chief Operating Officer, Clinical Operations of bioMérieux.

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Since early 2021, VIDAS® NEPHROCHECK® is available in key European markets and in selected countries that recognize CE marking. The FDA clearance provides the opportunity to serve a key market of bioMérieux– US hospitals and reference laboratories will be able to run this innovative test on bioMérieux's VIDAS® 3 system, which allows for higher throughput, automation and traceability.

ABOUT NEPHROCHECK®

The NEPHROCHECK® test relies on the detection of 2 innovative urinary biomarkers: TIMP-2 (tissue inhibitor of metalloproteinases-2) and IGFBP-7 (insulin-like growth factor-binding protein 7). Both proteins are produced by stressed kidney cells as an early warning signal, before the onset of AKI. Specific to kidney stress, they are not affected by any of the usual co-morbidities (such as sepsis, trauma, chronic kidney disease or cancer).

ABOUT VIDAS®

Launched 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, covering a wide range of pathologies, including infectious diseases and chronic diseases, as well as a range of tests dedicated to emergency and critical care. A number of these parameters are part of the bioMérieux full solution to address the global challenges of antimicrobial resistance (AMR) and sepsis. As it enters into its fourth decade, VIDAS® remains a major focus of the bioMérieux immunoassay strategy with ongoing research into new parameters and frequent launches that create value for labs and clinicians, ultimately bringing benefits for patients.

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 2021, revenues reached €3.4 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.

BIM LISTED EURONEXT

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

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