



ASTUTE
MEDICAL



NEPHROCHECK Biomarkers TIMP-2 and IGFBP7 Included in Groundbreaking Consensus Statement of Best Practices to Enhance Recovery after Heart Surgery

Marcy l'Étoile (France) and San Diego (California) - May 2nd, 2018 – The biomarkers in the NEPHROCHECK test, an FDA-cleared and CE-marked urine test that indicates kidney stress in advance of acute kidney injury (AKI), have been included in consensus guidelines from ERAS[®] Cardiac Surgery, a non-profit, multi-professional and multi-disciplinary medical society whose mission is to optimize perioperative care of cardiac surgical patients through collaborative discovery, analysis, expert consensus, and dissemination of best practices that will improve both short- and long-term outcomes and decrease complications and readmissions.

This follows the recent publication of two randomized controlled trials^{1,2} that demonstrated significant improvement in patient outcomes, length of stay, and decreased costs due to AKI following cardiac and non-cardiac surgery by using NEPHROCHECK to initiate kidney-protecting interventions.

The new guidelines were presented as part of evidenced-based expert consensus statements at the American Association for Thoracic Surgery (AATS) meeting on April 28th, 2018. These were developed in a formal process over 15 months to provide cardiac surgery programs best practices to enhance recovery after surgery. It is anticipated that the final work product will be submitted for peer review publication, facilitating its dissemination to surgeons and heart programs around the world.

“We hope that these recommendations will encourage cardiac surgical programs around the world to join us to standardize best practice,” said ERAS[®] Cardiac Surgery President Daniel T. Engelman, M.D.. *“Since our inaugural meeting a year ago, we’ve solicited input, considered protocols, and assessed the class and strength of evidence for each that may help enhance recovery after heart surgery. This is the first time such a comprehensive evidence-based approach has been presented at a major cardiovascular surgery meeting.”*

“Evidence-based patient care guidelines are crucial for standardizing medical care and enhancing patient outcomes,” said Mark Miller, Executive Vice President and Chief Medical Officer for bioMérieux. *“NEPHROCHECK is a simple, urine-based test that provides vital information to healthcare providers so that they can act promptly to prevent harmful consequences for the patient’s kidneys. The evidence continues to grow that routine use of NEPHROCHECK will be an important tool for improving the management of adult cardiac surgery patients in order to protect their kidneys from both acute and long-term damage. Additional studies of NEPHROCHECK in other patient populations are also underway.”*

AKI is a frequent complication in patients undergoing major surgery, and is known to increase morbidity, mortality and costs³. Additional AKI-associated expenses during U.S. hospitalizations have been reported at \$38,000 per patient⁴, resulting in U.S. healthcare expenditures between \$5.4 to \$24 billion annually⁵. Currently available indicators of AKI, such as elevated blood levels of creatinine, may not be present until kidney damage has already occurred⁶. Recent studies have called for the pursuit of innovative strategies to combat this major public health concern^{7,8}.

PRESS RELEASE



ABOUT NEPHROCHECK

The NEPHROCHECK test detects two biomarkers, urinary tissue inhibitor of metalloproteinases-2 (TIMP-2) and insulin-like growth factor binding protein 7 (IGFBP7), that increase in a patient's urine in response to early kidney cell stress which can lead to AKI. This allows the biomarkers to function as an early alarm of kidney stress before progression to AKI so that maneuvers to protect the kidneys can be undertaken⁹.

The NEPHROCHECK test is intended to be used in conjunction with clinical evaluation in patients who currently have or have had within the past 24 hours acute cardiovascular and/or respiratory compromise and are intensive care unit (ICU) patients as an aid in the risk assessment for moderate or severe AKI within 12 hours of patient assessment. The NEPHROCHECK test is intended to be used in patients 21 years of age or older. For more information on the NEPHROCHECK test visit www.NephroCheck.com.

ABOUT ASTUTE MEDICAL

Astute Medical Inc., a company dedicated to improving the diagnosis of high-risk medical conditions and diseases through the identification and validation of protein biomarkers. In particular, Astute developed the NEPHROCHECK test, an FDA-cleared and CE marked test for the early risk assessment of acute kidney injuries (AKI) based on the level of two biomarkers, IGFBP-7 (Insulin-like Growth Factor-Binding Protein-7) and TIMP-2 (Tissue Inhibitor Metalloproteinases-2).

bioMérieux has announced the acquisition of Astute Medical Inc, on April 4th, 2018.

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ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for more than 50 years, bioMérieux is present in more than 150 countries through 43 subsidiaries and a large network of distributors. In 2017, revenues reached €2.3 billion, with over 90% of international sales.

bioMérieux provides diagnostic solutions (systems, reagents, software) 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.



bioMérieux is listed on the Euronext Paris stock market

Symbol: BIM - ISIN Code: FR0013280286

Reuters: BIOX.PA/Bloomberg: BIM.FP

Corporate website: www.biomerieux.com Investor website: www.biomerieux-finance.com.

More about ERAS: www.erassociety.org

More about ERAS[®] Cardiac Surgery: www.erascardiac.org

CONTACTS

Investor Relations

bioMérieux

Sylvain Morgeau

Tel.: + 33 4 78 87 22 37

investor.relations@biomerieux.com

Media Relations

bioMérieux

Aurore Sergeant

Tel.: + 33 4 78 87 20 53

media@biomerieux.com

bioMérieux Inc.

Tim Baker

Tel.: +1 (216) 407 5354

timothy.baker@biomerieux.com

Image Sept

Laurence Heilbronn

Tel.: + 33 1 53 70 74 64

lheilbronn@image7.fr

¹ Göcze I, Jauch D, Götz M, et al. Biomarker-guided intervention to prevent acute kidney injury after major surgery: the prospective randomized BigpAK Study. *Ann Surg*. Published online August 2017.

² Meersch M, Schmidt C, Hoffmeier A, et al. Prevention of cardiac surgery-associated AKI by implementing the KDIGO guidelines in high risk patients identified by biomarkers: the PrevAKI randomized controlled trial. *Intensive Care Med*. 2017 Jan 21.

³ Hobson C, Ozrazgat-Baslanti T, Kuxhausen A, et al. Cost and mortality associated with postoperative acute kidney injury. *Ann Surg*. 2014;00:1-8.

⁴ Alshaikh H, Katz N, Gani F, et al. Financial Impact of Acute Kidney Injury After Cardiac Operations in the United States. *Ann Thorac Surg*. 2018 Feb;105(2):469-475.

⁵ Silver SA, Chertow GM. The Economic consequences of AKI. *Nephron*. 2017;137:297-301.

⁶ McCullough PA, Shaw AD, Haase M, et al. Diagnosis of acute kidney injury using functional and injury biomarkers: workgroup statements from the tenth Acute Dialysis Quality Initiative Consensus Conference. *Contrib Nephrol*. 2013;182:13-29.

⁷ Thakar CV. Acute Kidney Injury: A Paradigm In Quality and Patient Safety. *Adv Chronic Kid Dis*. 2017;24(4):192-193.

⁸ Silver SA, Chertow GM. The Economic consequences of AKI. *Nephron*. <https://doi.org/10.1159/000475607>. Published online June 9, 2017.

⁹ Kellum JA, Chawla LS. Cell-cycle arrest and acute kidney injury: the light and dark sides. *Nephrol Dial Transplant*. (2015) 0: 1–7doi: 10.1093/ndt/gfv130.