

Ortho Clinical Diagnostics

Ortho Clinical Diagnostics Supports ERAS® Cardiac Surgery Consensus Statement of Best Practices to Enhance Recovery After Heart Surgery

May 1, 2018

Recommends use of NEPHROCHECK biomarkers TIMP-2 x IGFBP-7 to assess risk of acute kidney injury

Ortho Clinical Diagnostics, a global leader in in vitro diagnostics, welcomes and supports today's inclusion of 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), in consensus guidelines released by [ERAS® Cardiac Surgery](#).

The new guidelines were presented as part of evidence-based expert consensus statements at the American Association for Thoracic Surgery (AATS) meeting on April 28, 2017. 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.

AKI is a frequent complication in patients undergoing major surgery, and is known to increase morbidity, mortality and costs.¹ Additional AKI-associated expenses during U.S. hospitalizations have been reported at \$38,000 per patient,² resulting in U.S. health care expenditures between \$5.4 to \$24 billion annually.³ Some other available indicators of AKI, such as elevated blood levels of creatinine, may not be present until kidney damage has already occurred.⁴ Recent studies have called for the pursuit of innovative strategies to combat this major public health concern.^{5,6}

"Preventing AKI is one of the biggest unmet clinical and economic needs in health care globally," said Robert Yates, chief operating officer of Ortho Clinical Diagnostics. "The availability of the important NephroCheck Test for use on Ortho's VITROS® Systems helps labs incorporate this critical test into their daily operations in an effective, efficient way to improve and save lives."⁷

Ortho developed its VITROS® NEPHROCHECK®, the first fully automated AKI risk assessment tool, which is CE-marked but not currently available for use on Ortho's VITROS® Systems in the U.S.

The NephroCheck Test detects two biomarkers, urinary tissue inhibitor of metalloproteinases-2 (TIMP-2) and insulin-like growth factor binding protein 7 (IGFBP-7), 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 undertaken.⁸

ERAS is 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. It released the consensus statement today.

The NephroCheck Test Intended Use (United States)

The NephroCheck Test System 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 System is intended to be used in patients 21 years of age or older. For more information on the NephroCheck Test visit [NephroCheck.com](#).

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About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics is a global leader in in vitro diagnostics serving the clinical laboratory and immunohematology communities. Across hospitals, hospital networks, blood banks and labs in more than 125 countries and territories, Ortho's high-quality products and services enable health care professionals to make better-informed treatment decisions. For the immunohematology community, Ortho's blood typing products help ensure every patient receives blood that is safe, the right type and the right unit. Ortho brings sophisticated testing technologies, automation, information management and interpretation tools to clinical laboratories around the world to help them run more efficiently and effectively and improve patient care. Ortho's purpose is to improve and save lives with diagnostics, and it does that by reimagining what's possible. This is what has defined Ortho for more than 75 years, and it's what drives Ortho forward.

More about ERAS: www.erassociety.org

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

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2. 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.
3. Silver SA, Chertow GM. The Economic consequences of AKI. *Nephron.* 2017;137:297-301.
4. 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.

5. Thakar CV. Acute Kidney Injury: A Paradigm In Quality and Patient Safety. *Adv Chronic Kid Dis.* 2017;24(4):192-193.
6. Silver SA, Chertow GM. The Economic consequences of AKI. *Nephron.* <https://doi.org/10.1159/000475607>. Published online June 9, 2017.
7. VITROS NEPHROCHECK is available for use in CE Mark countries. It is not available for use in the U.S.
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