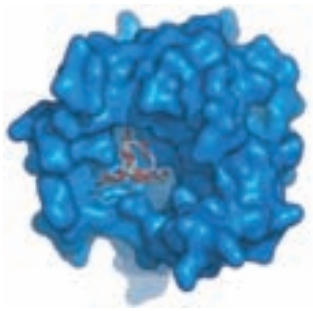
ARCHITECT Urine NGAL*

Neutrophil gelatinase-associated lipocalin



Physiology/Pathophysiology

Neutrophil gelatinase-associated lipocalin (NGAL) is a protein belonging to the lipocalin superfamily initially found in activated neutrophils. NGAL, a small molecule of 25 kDa, is also found in certain epithelia, such as renal tubulus, where its expression is dramatically increased in ischemic or nephrotoxic injury.

The increase in NGAL production may have self-defensive properties, since NGAL has been suggested to act as growth and differential factor in multiple cell types including developing and mature renal epithelia.

Clinical Application

Current clinical practice relies on an increase in serum creatinine to diagnose acute kidney injury (AKI); however, creatinine is not useful for early diagnosis. There is increasing evidence of the suitability of urinary NGAL as a marker for the early identification of AKI.

NGAL may be used to detect AKI early in the following cases:

- Pediatric and adult cardiopulmonary bypass operations
- Percutaneous coronary interventions (PCI)
- Critically ill patients presenting at the emergency department or in the intensive care unit (heart failure, sepsis, multi-organ failure)
- Renal transplantation
- Patients with chronic kidney disease

ARCHITECT Urine NGAL

The ARCHITECT Urine NGAL assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative detection of neutrophil gelatinase-associated lipocalin (NGAL) in human urine.

The asset has a dynamic range that extends to 1500 ng/mL. Controls are available with the following concentrations: 20 ng/mL (low), 200 ng/mL (medium) and 1200 ng/mL (high). Urine is utilized as sample type.

* in development

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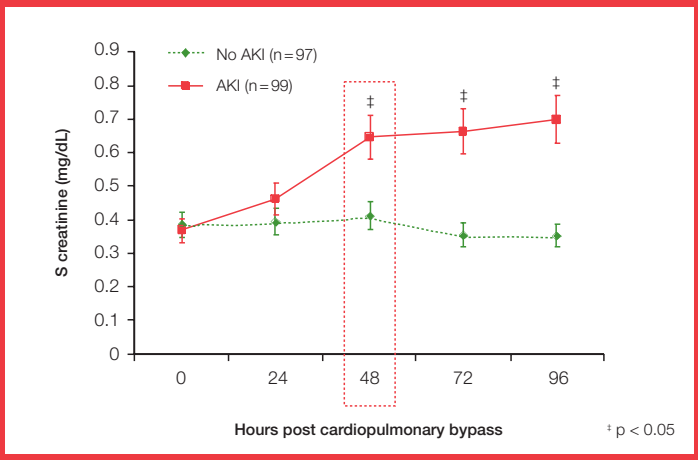
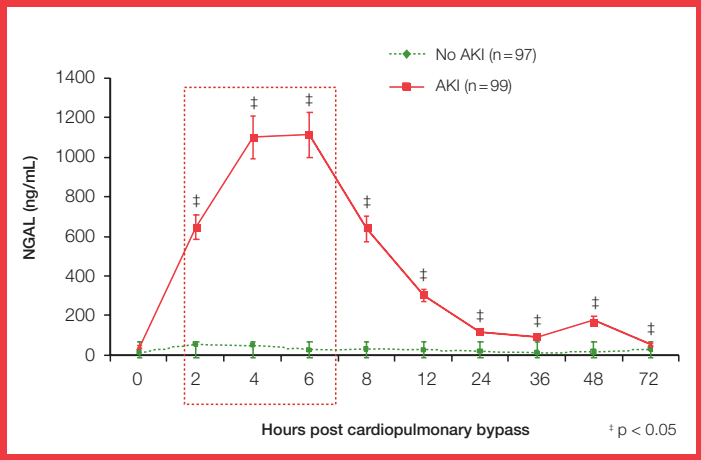
Early Detection of Acute Kidney Injury (AKI) after Cardiac Surgery

With Urine NGAL an earlier detection of acute kidney disease after cardiopulmonary bypass (CPB) operation in children was possible compared to creatinine.

Serum creatinine post-CPB



Urine NGAL measurements obtained by ARCHITECT assay* post-CPB



Adapted from: Bennett et al., Clin J Am Soc Nephrol 2008

Conclusions from Publications

"By multivariate analysis, the amount of NGAL in urine at 2 h after cardiopulmonary bypass was the most powerful independent predictor of acute renal injury."
J. Mishra et al., Lancet 2005, 365: 1231 – 1238

"A single measurement of urinary NGAL helps to distinguish acute injury from normal function."
T. Nickolas et al., Ann Intern Med 2008, 148: 810 – 819

"NGAL levels clearly correlate with severity of renal impairment, probably expressing the degree of active damage underlying the chronic condition."
D. Bolignano, Am J Kidney Dis 2008, in press

"Accurate measurements of urine NGAL are obtained using the ARCHITECT platform. Urine NGAL is an early predictive biomarker of AKI severity after cardiopulmonary bypass."
M. Bennett et al., Clin J. Am Soc Nephrol 2008, 3: 665 – 673

"In summary, NGAL is emerging as an important biomarker in AKI, with tremendous potential for early diagnosis"
Chriac et al., Crit Care Med 2008, Vol. 36, No. 4 (Suppl.)

"NGAL in urine but not plasma represents a novel biomarker for renal disease activity in pSLE (pediatric systemic lupus erythematosus)."
M. Suzuki et al., Pediatr Nephrol 2008, 23: 403 – 412

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