For Earlier Diagnosis of Acute Kidney Injury (AKI)

Detected 2-3 days before creatinine rises[1]
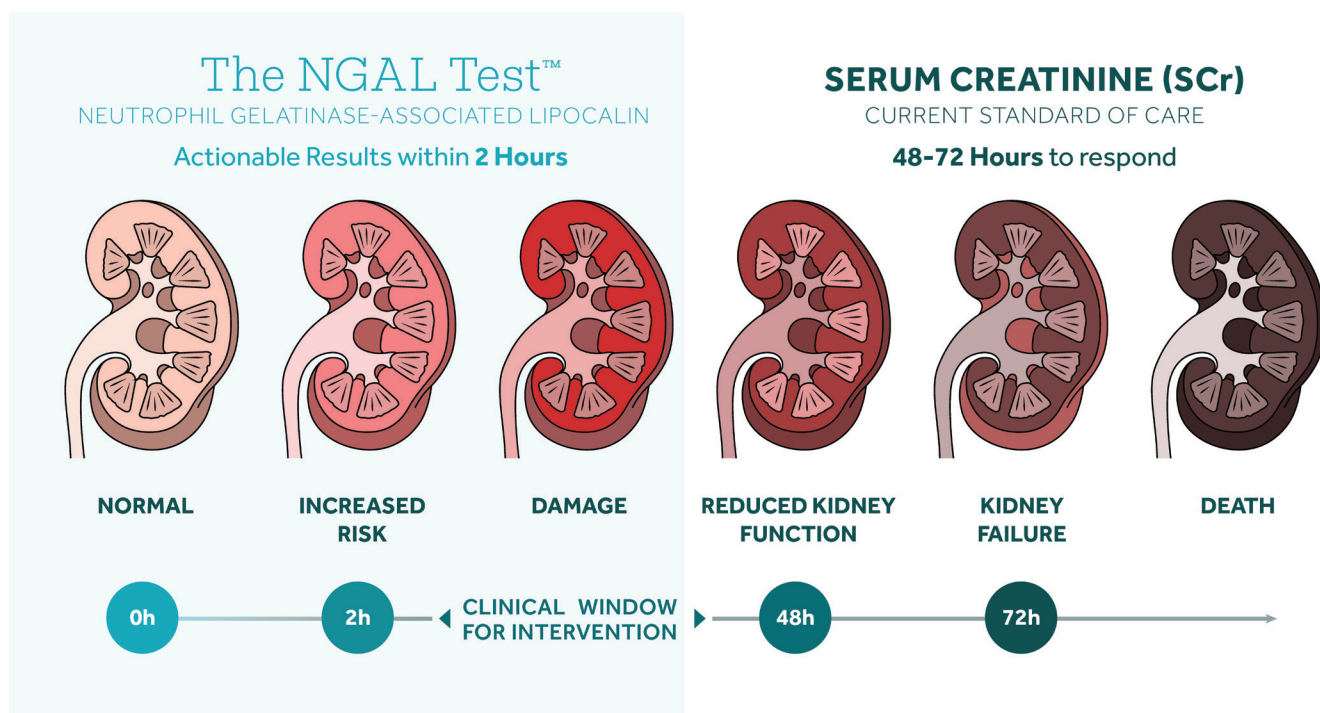
The NGAL Test™
NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN

Actionable Results within 2 Hours

NORMAL   INCREASED RISK   DAMAGE

0h   2h   ◄ CLINICAL WINDOW FOR INTERVENTION ►

SERUM CREATININE (SCr)
CURRENT STANDARD OF CARE

48-72 Hours to respond

REDUCED KIDNEY FUNCTION   KIDNEY FAILURE   DEATH

48h   72h

The NGAL Test is CE-Marked for IVD use and is currently available for Research Use Only in the United States.

Benefits

FAST
Responds 2 hours after injury;[1]
2-3 days earlier than serum creatinine.[2]

PROGNOSTIC
Identifies patients at risk of subclinical
through moderate to severe AKI.[4]

CLINICALLY RELEVANT [5]
Informs clinical decisions[5] around fluid management
(diuretics, RRT) and nephrotoxic medications.

EASY
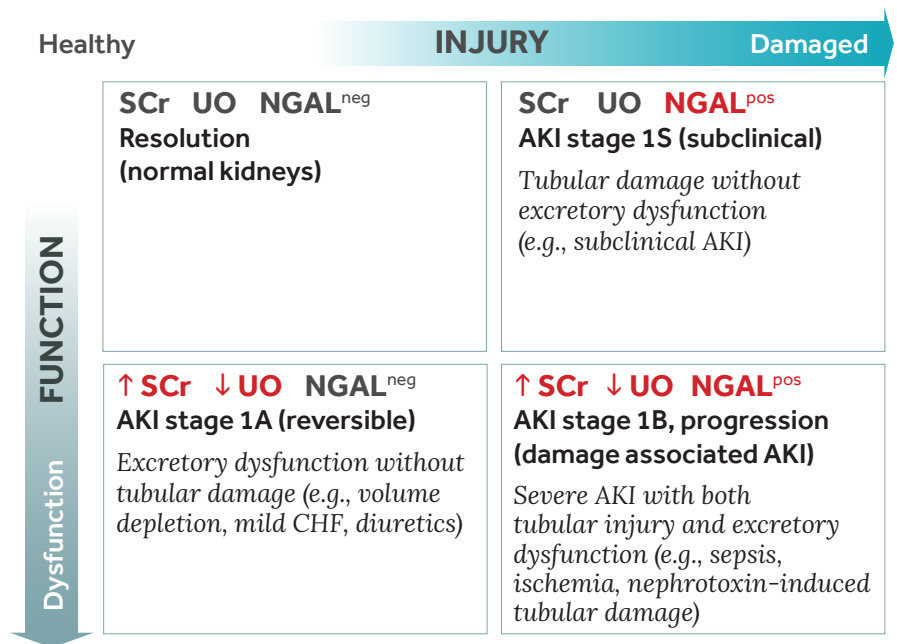Runs on standard chemistry analyzers;
urine or plasma samples.

"NGAL significantly improved the prediction of AKI risk over the clinical model alone." [5]

Acute Disease Quality Initiative (ADQI) 2020 Recommendation

Assessment of Kidney Injury Using Functional and Injury Biomarkers[7]

"Expert consensus identified an **unmet need** for diagnostic tools that identify the location, mechanism, etiology, severity, and prognosis of AKI."[6]

ADQI suggests that "a combination of **damage and functional biomarkers, along with clinical information**, be used to improve the diagnostic accuracy of AKI, to recognize the different pathophysiological processes, to discriminate AKI etiology, and **to assess AKI severity**."[7]

	Healthy	INJURY	Damaged
FUNCTION	**SCr UO NGAL**[neg] **Resolution (normal kidneys)**	**SCr UO NGAL**[pos] **AKI stage 1S (subclinical)** *Tubular damage without excretory dysfunction (e.g., subclinical AKI)*	
Dysfunction	**↑SCr ↓UO NGAL**[neg] **AKI stage 1A (reversible)** *Excretory dysfunction without tubular damage (e.g., volume depletion, mild CHF, diuretics)*	**↑SCr ↓UO NGAL**[pos] **AKI stage 1B, progression (damage associated AKI)** *Severe AKI with both tubular injury and excretory dysfunction (e.g., sepsis, ischemia, nephrotoxin-induced tubular damage)*	

Adapted from: De Oliveira et al. Nat Rev Nephrol 2019 & Ostermann et al. JAMA Netw Open. 2020.
Gray = normal result, **Red** = abnormal result; SCr = serum creatinine, UO = urine output, NGAL = neutrophil gelatinase-associated lipocalin, CHF = congestive heart failure

CE-Marked Intended Use

The NGAL Test™ is a particle-enhanced turbidimetric immunoassay for the quantitative determination of neutrophil gelatinase-associated lipocalin (NGAL) in human urine, EDTA plasma and heparin plasma on automated clinical chemistry analyzers. NGAL measurements are useful in the diagnosis of acute kidney injury which may lead to acute renal failure.

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KDIGO stage-based management of AKI[8]

AKI Stage

	High Risk	1	2	3
Discontinue all nephrotoxic agents when possible				
Ensure volume status and perfusion pressure				
Consider functional hemodynamic monitoring				
Monitor serum creatinine and urine output				
Avoid hyperglycemia				
Consider alternatives to radiocontrast procedures				
Non-invasive diagnostic workup				
Consider invasive diagnostic workup				
Check for changes in drug dosing				
Consider Renal Replacement Therapy				
Consider ICU admission				
Avoid subclavian catheters if possible				

REFERENCES: 1. Krawczeski CD, Goldstein SL, Woo JG, et al. *J Am Coll Cardiol*. 2011. | 2. Devarajan P. *Biomark Med*. 2010;4(2):265-280. | 3. Haase M, Devarajan P, Haase-Fielitz A, et al. *J Am Coll Cardiol*. 2011. | 4. Zappitelli M, Washburn KK, Arikan AA, et al. *Crit Care*. 2007 | 5. Haase-Fielitz A, Haase M, Devarajan P. *Ann Clin Biochem*. 2014. | 6. Mårtensson et. al. Br J Anaesth. 2012;109(6):843-50. | 7. Ostermann M, Zarbock A, Goldstein S, et al. JAMA Netw Open. 2020. | 8. KDIGO Clinical Practice Guidelines for Acute Kidney Injury. Kidney International, Suppl. 2012;2:1-138.