KIDNEY INJURY BIOMARKERS

“ Nexelis is setting the gold standard for kidney injury biomarker analysis”

nexelis
disciplined agility
assay development ◦ specialty testing

PSTC
CRITICAL PATH INSTITUTE

The PSTC selected Nexelis (formerly Pacific Biomarkers) to support the FDA qualification of the Composite Measure, which is composed of six renal biomarkers that can be used to detect drug-induced kidney tubular injury during Phase I clinical trials.

- **More than 50% of drug development projects fail due to unacceptable safety.**
- **A time-course evaluation in early phase clinical trials can rapidly and accurately diagnose drug-induced kidney injury (DIKI), more effectively than creatinine and BUN.**

Assess drug safety with biomarkers of kidney injury

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Better understand your drug

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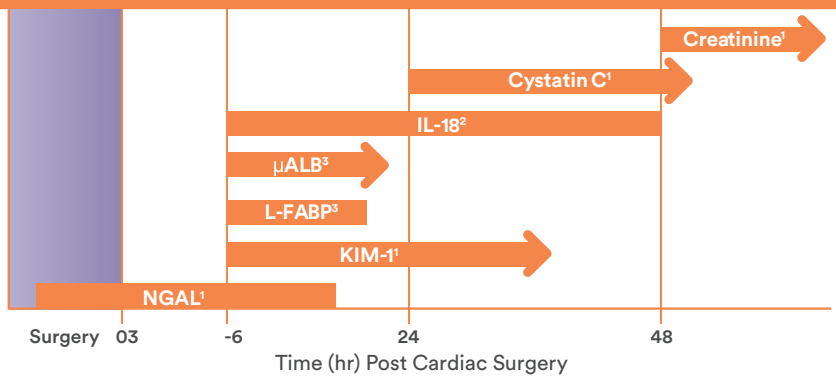
Avoid late-stage failures in drug development

Kidney Injury Markers Available at Pacific Biomarkers

Biomarker	Type of Injury / Location
Cystatin C	Glomerular in serum; tubular in urine
NGAL	Proximal tubule
KIM-1	Proximal tubule
Osteopontin	Distal tubule
Clusterin	Tubular epithelium
a-GST	Proximal tubular epithelium
RBP4	Proximal tubular epithelial
IL-18	Apoptotic processes in the tubule epithelium
NAG	Proximal tubule
Total Protein	Glomerular and tubular function
Albumin	Glomerular and tubular function

Clinical Example

Acute Kidney Injury (AKI) due to drug treatment or major surgery can be identified using more sensitive biomarkers long before serum creatinine



Orange bars indicate periods when levels are associated with injuries leading to AKI

References:
1. McIlroy DR, Wagener G, Lee HT. Anesthesiology (2010) 112: 998-1004.
2. Parikh CR, Mishra J, Thiessen-Philbrook H, Dursun B, Ma Q, Kelly C, Dent C, P Devarajan and C L Edelstein. Kidney International (2006) 70: 199–203.
3. Portilla D, Dent C, Sugaya T, Nagothu KK, Kundi I, Moore P, E Noiri and P Devarajan Kidney International (2008) 73: 465–472.

OUR LEGACY

Over almost 30 years, Nexelis has maintained a “fit-for-purpose” assay development and validation philosophy.
This covers a range of ratification options, from feasibility to full validations using CAP, CLSI, or FDA bioanalytical guidelines that match the intended use.

Our validation procedures apply to novel biomarkers, proprietary technology transfers, and comprehensive bioanalytical services for biologics, where PK, ADA and immunogenicity assays are required.

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