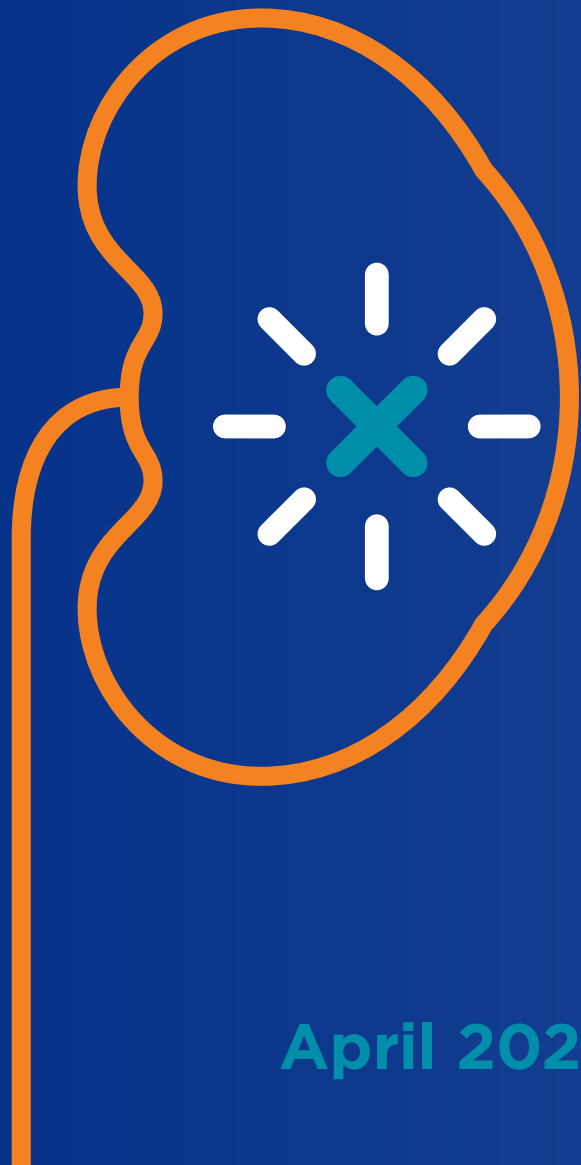


Biomarkers Reported to be Useful in Acute Kidney Injury



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Disclaimer

The views and opinions expressed in this publication are those of the authors and do not necessarily reflect the official policies of any KHI member organization, FDA, the U.S. Department of Veterans Affairs, or the U.S. Department of Health and Human Services, nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.



Biomarkers Reported to be Useful in AKI

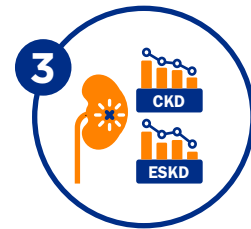
The below table provides an overview of potential biomarkers, including what they can be used to measure and a summary of relevant studies. Each biomarker may have value for one or more of the following use cases:



1
Diagnose and monitor kidney injury at an early stage
(Diagnostic, Safety, Monitoring)



2
Predict which patients are more susceptible to developing acute kidney injury (AKI) in response to a therapeutic or procedure
(Predictive, Susceptibility/Risk)



3
Identify AKI patients who are likely to progress to chronic kidney disease (CKD) and/or end-stage kidney disease (ESKD)
(Susceptibility/Risk, Prognostic)



4
Measure response to a therapeutic intervention for AKI
(Pharmacodynamic/Response)



5
Predict which patients will have a positive response to an intervention to prevent or treat AKI
(Predictive)

The U.S. Food and Drug Administration (FDA) also offers a [full list of qualified biomarkers](#).

For historical examples of how early biomarkers have evolved into validated endpoints that can serve as the basis for approval or licensure, see the [FDA Table of Surrogate Endpoints](#).

Note: The **Relevant References** are not intended to be comprehensive. Please check PubMed for additional references.

α 1-microglobulin (A1M)



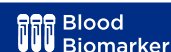
Used for

- Detecting proximal renal tubule dysfunction and injury
- Determining kidney's ability to withstand injury; elevated levels suggest decreased proximal tubular re-absorptive capacity

Relevant References

- Coca, Steven G. "Kidney Injury Biomarkers with Clinical Utility: Has Godot Finally Arrived?" *American Journal of Nephrology* 50, no. 5 (2019): 357–60. <https://doi.org/10.1159/000502899>.
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- Jotwani, Vasantha, Rebecca Scherzer, Alison Abraham, Michelle M. Estrella, Michael Bennett, Mardge H. Cohen, Marek Nowicki, et al. "Association of Urine α 1-Microglobulin with Kidney Function Decline and Mortality in HIV-Infected Women." *Clinical Journal of the American Society of Nephrology* 10, no. 1 (2014): 63–73. <https://doi.org/10.2215/cjn.03220314>.
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- O'Seaghda, Conall M., Shih-Jen Hwang, Martin G. Larson, James B. Meigs, Ramachandran S. Vasani, and Caroline S. Fox. "Analysis of a Urinary Biomarker Panel for Incident Kidney Disease and Clinical Outcomes." *Journal of the American Society of Nephrology* 24, no. 11 (November 2013): 1880–88. <https://doi.org/10.1681/ASN.2013010019>.
- Terzi, I., V. Papaioannou, N. Papanas, C. Dragoumanis, A. Petala, and V. Theodorou. "Alpha1-Microglobulin as an Early Biomarker of Sepsis-Associated Acute Kidney Injury: a Prospective Cohort Study." *Hippokratia* 18, no. 3 (2014). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4309149/>.

β 2-microglobulin (B2M)



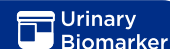
Used for

- Detecting proximal renal tubule dysfunction and injury
- Determining kidney's ability to withstand injury

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α -glutathione S-transferase (GST)



Used for

- Detecting proximal tubule injury

Relevant References

- McMahon, Blaithin A., Jay L. Koyner, and Patrick T. Murray. "Urinary Glutathione S-Transferases in the Pathogenesis and Diagnostic Evaluation of Acute Kidney Injury Following Cardiac Surgery: a Critical Review." *Current Opinion in Critical Care* 16, no. 6 (2010): 550-55. <https://doi.org/10.1097/mcc.0b013e32833fdd9a>.
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π - glutathione S-transferase (GST)



Used for

- Detecting distal tubule injury

Relevant References

- McMahon, Blaithin A., Jay L. Koyner, and Patrick T. Murray. "Urinary Glutathione S-Transferases in the Pathogenesis and Diagnostic Evaluation of Acute Kidney Injury Following Cardiac Surgery: a Critical Review." *Current Opinion in Critical Care* 16, no. 6 (2010): 550-55. <https://doi.org/10.1097/mcc.0b013e32833fdd9a>.
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Angiotensin 1 and 2 (Ang-1 and Ang-2)



Used for

- Identifying the existence or higher risk of AKI, particularly sepsis-induced AKI

Relevant References

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Brain natriuretic peptide (BNP) and N-terminal pro b-type natriuretic peptide (NT-proBNP)



Used for

- Early prediction of AKI

Relevant References

- Fiorentino, Marco, Fadi A. Tohme, Raghavan Murugan, and John A. Kellum. "Plasma Biomarkers in Predicting Renal Recovery from Acute Kidney Injury in Critically Ill Patients." *Blood Purification* 48, no. 3 (2019): 253-61. <https://doi.org/10.1159/000500423>.
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Chemokine ligand 14 (CCL14)



Used for

- Predicting persistent stage-3 AKI

Relevant References

- Hoste, Eric, Azra Bihorac, Ali Al-Khafaji, Luis M. Ortega, Marlies Ostermann, Michael Haase, Kai Zacharowski, et al. "Identification and Validation of Biomarkers of Persistent Acute Kidney Injury: the RUBY Study." *Intensive Care Medicine* 46, no. 5 (2020): 943-53. <https://doi.org/10.1007/s00134-019-05919-0>.

Cysteine-rich protein (Cyr61)



Used for

- Detecting glomerular kidney injury

Relevant References

- Lai, Chun-Fu, Shuei-Liong Lin, Wen-Chih Chiang, Yung-Ming Chen, Vincent Wu, Guang-Huar Young, Wen-Jo Ko, Min-Liang Kuo, Tun-Jun Tsai, and Kwan-Dun Wu. "Blockade of Cysteine-Rich Protein 61 Attenuates Renal Inflammation and Fibrosis after Ischemic Kidney Injury." *American Journal of Physiology-Renal Physiology* 307, no. 5 (2014).
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Dickkopf-3 (DKK3)



Used for

- Detection of the pre-injury phase of kidney injury and renal tubular stress (when measured preoperatively)

Relevant References

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Epidermal growth factor (EGF)



Used for

- Predicting renal injury

Relevant References

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Fetuin A



Used for

- Detecting structural renal injury

Relevant References

- Ragab, Seham M., and Eman A. Badr. "Evaluation of Serum and Urine Fetuin-A Levels in Children with Acute Lymphoblastic Leukemia during and after High-Dose Methotrexate Therapy: Relation to Toxicity." *Hematology* 21, no. 2 (2015): 78–91. <https://doi.org/10.1179/1607845415y.00000000042>.
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Fluorescent GFR tracer agent measured via transdermal monitoring (Medibeacon)



Used for

- Measuring uptake of fluorescent tracer processed by the kidney with the intent of real-time GFR monitoring

Relevant References

- McMahon, B. A., & Rosner, M. H. (2020). GFR measurement and chemotherapy dosing in patients with kidney disease and cancer. *Kidney360*, 1(2), 141–150. <https://doi.org/10.34067/kid.0000952019>.
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Hepcidin



Used for

- Detecting iron trafficking

Relevant References

- Choi, Nora, Claudio Rigatto, Michael Zappitelli, Ang Gao, Simon Christie, Brett Hiebert, Rakesh C. Arora, and Julie Ho. "Urinary Hepcidin-25 Is Elevated in Patients That Avoid Acute Kidney Injury Following Cardiac Surgery." *Canadian Journal of Kidney Health and Disease* 5 (2018): 205435811774422. <https://doi.org/10.1177/2054358117744224>.
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H-FABP



Used for

- Risk stratification of AKI and mortality after cardiac surgery

Relevant References

- Kavsak, Peter A., Richard Whitlock, Heather Thiessen-Philbrook, and Chirag R. Parikh. "Perioperative Heart-Type Fatty Acid Binding Protein Concentration Cutoffs for the Identification of Severe Acute Kidney Injury in Patients Undergoing Cardiac Surgery." *Clinical Chemistry and Laboratory Medicine (CCLM)* 57, no. 2 (2018). <https://doi.org/10.1515/cclm-2018-0547>.
- Schaub, Jennifer A., Amit X. Garg, Steven G. Coca, Jeffrey M. Testani, Michael G. Shlipak, John Eikelboom, Peter Kavsak, et al. "Perioperative Heart-Type Fatty Acid Binding Protein Is Associated with Acute Kidney Injury after Cardiac Surgery." *Kidney International* 88, no. 3 (2015): 576–83. <https://doi.org/10.1038/ki.2015.104>.

Interleukin-18 (IL-18)



Used for

- Detecting tubular inflammation
- Detecting proximal tubular injury

Relevant References

- Koyner, Jay L., Amit X. Garg, Steven G. Coca, Kyaw Sint, Heather Thiessen-Philbrook, Uptal D. Patel, Michael G. Shlipak, and Chirag R. Parikh. "Biomarkers Predict Progression of Acute Kidney Injury after Cardiac Surgery." *Journal of the American Society of Nephrology* 23, no. 5 (2012): 905–14. <https://doi.org/10.1681/asn.2011090907>.
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- Liu, Xiaoqin, Yi Guan, Sheng Xu, Qingzhao Li, Yuanbo Sun, Ruijie Han, and Chunyang Jiang. "Early Predictors of Acute Kidney Injury: A Narrative Review." *Kidney and Blood Pressure Research* 41, no. 5 (2016): 680–700. <https://doi.org/10.1159/000447937>.
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Kidney Safety Composite Measure Biomarker panel



- Kidney Injury Molecule-1 (KIM-1)
- Clusterin (CLU)
- Cystatin-C (CysC)
- N-Acetyl-beta-D-Glucosaminidase (NAG)
- Neutrophil Gelatinase-Associated Lipocalin (NGAL)
- Osteopontin (OPN)

Used for

- Detecting injury in the proximal tubule (urine KIM-1, CysC, NAG), distal tubule (urine NGAL, OPN), or both (urine CLU)

Relevant References

- "FNIH Biomarkers Consortium and Critical Path Institute Achieve the First Ever Qualification of a Clinical Safety Biomarker by the U.S. Food and Drug Administration." Critical Path Institute, 2018. Accessed July 30, 2020. <https://c-path.org/fnih-biomarkers-consortium-and-critical-path-institute-achieve-the-first-ever-qualification-of-a-clinical-safety-biomarker-by-the-u-s-food-and-drug-administration/>.

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KIM-1:

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- Han, W. K., Bailly, V., Abichandani, R., Thadhani, R., & Bonventre, J. V. (2002). Kidney injury molecule-1 (KIM-1): A novel biomarker for human renal proximal tubule injury. *Kidney International*, 62(1), 237-244. <https://doi.org/10.1046/j.1523-1755.2002.00433.x>.
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CLU:

- Guo, J., Guan, Q., Liu, X., Wang, H., Gleave, M. E., Nguan, C. Y., & Du, C. (2016). Relationship of clusterin with renal inflammation and fibrosis after the recovery phase of ischemia-reperfusion injury. *BMC Nephrology*, 17(1). <https://doi.org/10.1186/s12882-016-0348-x>.
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- Vinken, P., Starckx, S., Barale-Thomas, E., Looszoza, A., Sonee, M., Goeminne, N., Versmissen, L., Buyens, K., & Lampo, A. (2012). Tissue kim-1 and urinary clusterin as early indicators of cisplatin-induced acute kidney injury in rats. *Toxicologic Pathology*, 40(7), 1049-1062. <https://doi.org/10.1177/0192623312444765>.

CysC:

- Kar, S., Paglialunga, S., & Islam, R. (2018). Cystatin C is a more reliable biomarker for determining eGFR to support drug development studies. *The Journal of Clinical Pharmacology*, 58(10), 1239-1247. <https://doi.org/10.1002/jcph.1132>.
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NAG:

- Jiang, C., Qi, C., Sun, K., Xia, L., Xue, W., & Huang, Y. (2012). Diagnostic value of N-acetyl-β-D-glucosaminidase for the early prediction of acute kidney injury after percutaneous nephrolithotripsy. *Experimental and Therapeutic Medicine*, 5(1), 197-200. <https://doi.org/10.3892/etm.2012.737>.
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NGAL:

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Osteopontin (OPN)

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Liver-type fatty acid-binding protein (L-FABP)

Used for

- Detecting proximal tubular injury

Relevant References

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Microalbumin



Used for

- Detecting functional injury
- Detecting glomerular injury

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Monocyte chemoattractant protein 1 (MCP-1)



Used for

- Detecting kidney inflammation
- Detecting proximal tubular injury

Relevant References

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NephroCheck test panel (Astute Medical)



- Tissue inhibitor of metalloproteinases 2 (TIMP 2)
- Insulin-like growth factor-binding protein 7 (IGFBP-7)

Used for

- Detecting tubular cell injury
- Detecting gap 1 cell cycle arrest

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Netrin-1 (Ntn1)



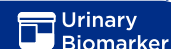
Used for

- Detecting distal tubule injury

Relevant References

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Renal Papillary Antigen-1 (RPA-1)



Used for

- Detecting drug-induced collecting duct injury

Relevant References

- Woodcock, Janet. Biomarker Qualification Decision Letter to Syril D. Pettit, Washington, DC 20005, September 22, 2010. <https://www.fda.gov/media/82521/download>.

Retinol binding protein (RBP)



Used for

- Detecting tubular injury

Relevant References

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Sodium (UNa)



Used for

- Detection of structural kidney injury
- Detection of decreased tubular function

Relevant References

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Sodium/hydrogen exchanger isoform (NHE3)



Used for

- Detection of tubular injury

Relevant References

- Cheyron, Damien Du, Cédric Daubin, Josiane Poggioli, Michel Ramakers, Pascal Houillier, Pierre Charbonneau, and Michel Paillard. "Urinary Measurement of Na⁺/H⁺ Exchanger Isoform 3 (NHE3) Protein as New Marker of Tubule Injury in Critically Ill Patients with ARF." *American Journal of Kidney Diseases* 42, no. 3 (2003): 497-506. [https://doi.org/10.1016/s0272-6386\(03\)00744-3](https://doi.org/10.1016/s0272-6386(03)00744-3).

Soluble Urokinase-type Plasminogen Activator Receptor (suPAR)



Used for

- Identifying the activation of inflammatory and immune systems in response to a renal disease

Relevant References

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Total Protein



Used for

- Detecting glomerular or tubular injury
- Predicting patient outcomes

Relevant References

- Center for Drug Evaluation and Research. "List of Qualified Biomarkers." U.S. Food and Drug Administration. FDA, 2020. <https://www.fda.gov/drugs/cder-biomarker-qualification-program/list-qualified-biomarkers>.
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Trefoil factor 3 (TFF3)



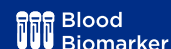
Used for

- Detecting proximal tubular injury
- Detecting ongoing kidney repair

Relevant References

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Tumor Necrosis Factor alpha (TNF-α)



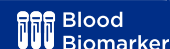
Used for

- Predicting AKI, AKI outcomes, and progression

Relevant References

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Tumor necrosis factor receptor 1 (TNFR1)



Used for

- Predicting AKI and AKI severity

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Tumor necrosis factor receptor 2 (TNFR2)



Used for

- Predicting AKI progression
- Detection of ischemic reperfusion injury

Relevant References

- Holditch, Sara J., Carolyn N. Brown, Andrew M. Lombardi, Khoa N. Nguyen, and Charles L. Edelstein. "Recent Advances in Models, Mechanisms, Biomarkers, and Interventions in Cisplatin-Induced Acute Kidney Injury." *International Journal of Molecular Sciences* 20, no. 12 (2019): 3011. <https://doi.org/10.3390/ijms20123011>.
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Uromodulin (uMOD)



Used for

- Detecting Loop of Henle injury

Relevant References

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Visible fluorescent injectate measured via blood draw (VFI) (FAST Biomedical)



Used for

- Measuring uptake of fluorescent tracer processed by the kidney with the intent of real-time GFR monitoring

Relevant References

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YKL 40



Used for

- Detecting tubular damage
- Detecting kidney repair

Relevant References

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* The relevant references are not intended to be comprehensive. Please check PubMed for additional references.

Biomarkers Reported to be Useful in Acute Kidney Injury



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