

Advancing Kidney Care With Solidified Evidence – SphingoTec Presents PenKid at AKI & CRRT Course in Vicenza

- SphingoTec and Boditech jointly introduced the kidney function biomarker Proenkephalin A 119-159 (penKid) at the 42nd AKI & CRRT course in Vicenza, highlighting its upcoming integration with the AFIAS platform.
- PenKid is a real-time kidney function biomarker that addresses the standard acute kidney injury (AKI) diagnostic gaps.
- During a scientific session on AKI biomarkers, penKid was presented as a biomarker for risk prediction and early identification of AKI, with performance data that could support clinical routine implementation for effective AKI management.

Hennigsdorf/Berlin, Germany, June 18, 2024 - Diagnostics company SphingoTec GmbH ("SphingoTec") introduced together with Boditech Med Inc. (Boditech) at the 42nd AKI & CRRT Course in Vicenza the innovative kidney function biomarker penKid developed by SphingoTec and licensed to Boditech. They highlighted the benefits of penKid on the AFIAS platform, emphasizing its promise in enhancing kidney function assessment. With the AFIAS penKid[®] test, the companies will focus on market development, engaging with healthcare professionals, and ensuring a successful product rollout starting in Europe.

The current standard of care diagnosis for AKI is to use serum creatinine and urine output, which are both lagging indicators. Many clinical studies point to the delay in AKI identification and its impact on mortality. PenKid is a functional biomarker that overcomes the shortcomings in the standard AKI diagnosis of critically ill patients by assessing kidney function in real time without being influenced by inflammation. A new penKid-based formula for estimating the glomerular filtration rate (eGFR) has been developed, outperforming widely used conventional equations based on creatinine alone (1). In previous studies, penKid has shown the potential to support increased clinical vigilance by risk prediction and identifying sub-clinical AKI, with changes in penKid levels pointing to worsening or recovery of kidney function (2).

Prof. Lui Forni, (Professor and Consultant in intensive care at Royal Surrey County Hospital NHS Foundation Trust and the School of Medicine, University of Surrey) introduced penKid to the international audience during the session "Update on biomarkers". In addition to the well-established scientific evidence on penKid as a kidney function biomarker for critical care settings, the presentation also included the results of a decentralized analysis that consolidates evidence from 11 independent studies and nearly 4,000 patients (3). Beyond unified and compelling evidence of penKid's clinical performance, the systematic meta-analysis explores the role of penKid in identifying patients at high risk for AKI. Incorporating penKid into patient care could enable more intensive surveillance and personalized and early prevention efforts, including optimizing hemodynamic stability and prudent use of nephrotoxic agents.

Prof. Lui Forni emphasizes the potential for penKid to serve as an alternative to serum creatinine in critical care: "While creatinine is the mainstay for monitoring kidney function in chronic kidney disease, its limitations in the acute setting call for better solutions. It's time to embrace novel diagnostics in our day-to-day practice."



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References:

- (1) Beunders et al. Assessing GFR With Proenkephalin, Kidney International Reports, 2023, DOI: <u>https://doi.org/10.1016/j.ekir.2023.08.006</u>
- (2) Caironi et al., Circulating proenkephalin, acute kidney injury, and its improvement in patients with severe sepsis or shock. Clin Chem (2018) DOI:10.1373/clinchem.2018.288068
- (3) Lin, LC., et al. Proenkephalin as a biomarker correlates with acute kidney injury: a systematic review with meta-analysis and trial sequential analysis. Crit Care 27, 481 (2023). <u>https://doi.org/10.1186/s13054-023-04747-5</u>

About SphingoTec

SphingoTec GmbH ("SphingoTec"; Hennigsdorf near Berlin, Germany) is a commercial-stage diagnostic company focusing on innovative critical care biomarkers for diagnosing, predicting, and monitoring acute medical conditions. SphingoTec's innovative markers are made available on different IVD platforms. SphingoTec's proprietary biomarker portfolio includes Proenkephalin A 119-159 (penKid), a biomarker for the assessment of kidney function in critical diseases, and bioactive Adrenomedullin 1-52 (bio-ADM), a biomarker for the assessment of endothelial function in conditions like sepsis.

About penKid

Proenkephalin A 119-159 (penKid) is a blood-based biomarker for assessing kidney function in acute and critical conditions. The biomarker offers a blood-based alternative for the complex and time-consuming in vivo measurement of true glomerular filtration rate (GFR). PenKid is independent of common comorbidities (e.g., hypertension and diabetes) and the frequently occurring inflammation in critically ill patients. Rising penKid blood levels predict acute kidney injury earlier than today's standard of care, and decreasing penKid blood levels indicate the improvement of kidney function, even under dialysis.

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