

Beckman Coulter and SphingoTec Partner to Improve Kidney Health Assessment in Critical Care

- Alliance marks first penKid licensing agreement for high throughput immunoassay.
- Partnership leverages SphingoTec's proficiency in acute kidney injury testing, and Beckman Coulter's extensive, globally installed Access Family of immunoassay analyzers.

HENNIGSDORF/BERLIN, GERMANY — **October 9, 2024**: Diagnostic company SphingoTec GmbH ("SphingoTec") today announced a new partnership with <u>Beckman Coulter Diagnostics Inc</u>. ("Beckman Coulter"). Through this collaboration, the companies will bring an assay for SphingoTec's innovative kidney function biomarker, Proenkephalin 119-159 (penKid), to Beckman Coulter's extensive test menu for use on the Access Family of Immunoassay Analyzers. This alliance marks the first central laboratory license for a penKid assay and aims to significantly enhance the diagnostic capabilities for acute kidney injury (AKI) globally, by leveraging Beckman Coulter's global installed base of instruments.

PenKid is a real-time biomarker in plasma designed to address critical gaps in the standard diagnostic practices for AKI, particularly in critical care environments. Specifically, scientific evidence shows that, unlike current methods, a penKid assay offers early detection of kidney function decline, unaffected by inflammation, potentially enabling earlier intervention and improved patient outcomes (1,2,3). The incidence of AKI is increasing in both hospital and community settings; it is estimated that more than 13 million people are affected by AKI annually worldwide (4, 5).

Under the terms of the agreement, Beckman Coulter will develop and validate a fully automated diagnostic test for penKid, leveraging SphingoTec's IVD certified assay. This assay has already been implemented as a routine test in the first university hospitals. This collaborative effort will facilitate high-throughput availability of penKid assays in central laboratories, supporting critical care physicians with the ability for timely and precise kidney health assessment.

"Acute kidney injury exerts a profound impact on patients globally, complicates acute and chronic illnesses frequently resulting in poor outcomes, and rivals many other critical diseases in its severity and consequences," said Kevin O'Reilly, President, at Beckman Coulter Diagnostics. "The published evidence for penKid testing combined with SphingoTec's scientific expertise provides an exciting opportunity to improve kidney health management. Working with SphingoTec, our goal is to expand access to and improve workflow from this important kidney health innovation underscoring our commitment to enhancing patient care worldwide."

Deborah Bergmann, Managing Director and CEO of SphingoTec, emphasized, "The development of a penKid-based assay for use on Beckman Coulter's globally installed immunoassay platforms represents a significant step toward realizing our vision of transforming diagnostic innovation into tangible patient benefits. This partnership accelerates our mission to deliver precise, actionable insights to clinicians worldwide, ultimately improving outcomes for patients suffering from acute kidney injury."



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References:

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- (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>
- (4) Mehta RL et al. International Society of Nephrology's 0by25 initiative for acute kidney injury (zero preventable deaths by 2025): a human rights case for nephrology. Lancet. 2015 Jun 27;385(9987):2616–43. <u>http://dx.doi.org/10.1016/S0140-6736(15)60126-X</u>
- (5) Susantitaphong P et al. World incidence of AKI: a meta-analysis. Clin J Am Soc Nephrol. 2013 Sep;8(9):1482–93. <u>http://dx.doi.org/10.2215/CJN.00710113</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. Discover more on www.sphingotec.com

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