

Boditech Med and SphingoTec Announce Launch of AFIAS penKid® Assay for Kidney Function Diagnostics

- *Boditech Med and SphingoTec announce the launch of the AFIAS sphingotest® penKid® assay, a diagnostic tool designed to aid in kidney function assessment for critically ill patients.*
- *The IVDR-marked assay provides quantitative measurements of Proenkephalin A 119-159 (penKid), supporting clinical decision-making in acute and critical care.*
- *This launch follows a licensing agreement granting Boditech the rights to develop and commercialize penKid-based assays, as well as a market development agreement between the two companies.*

Gangwon-do, Republic of Korea, and Hennigsdorf/Berlin, Germany, May 6, 2025 - Boditech Med Inc. ("Boditech") and SphingoTec GmbH ("SphingoTec") today announced the commercial launch of the AFIAS sphingotest® penKid® assay. The assay is designed to provide clinicians with a tool for assessing kidney function in critically ill patients by measuring Proenkephalin A 119-159 (penKid), a biomarker that reflects real-time kidney function independently of inflammation or comorbidities.

The AFIAS sphingotest® penKid® assay is IVDR-marked for its intended use as an automated fluorescence immunoassay for the in vitro diagnostic quantitative determination of Proenkephalin A 119-159 in human whole blood/plasma, serving as an aid in the diagnosis of acute kidney injury (AKI) in adult patients with sepsis or septic shock. It provides additional information to support clinical decision-making in managing critically ill patients at risk of acute kidney injury (AKI). This launch is the result of a strategic collaboration between Boditech and SphingoTec, including a licensing agreement granting Boditech the rights to develop and commercialize penKid-based assays on its diagnostic platforms, as well as a market development agreement aimed at accelerating global commercialization efforts.

Eui-Yul Choi, CEO of Boditech Med, commented: *"We are proud to introduce the AFIAS sphingotest® penKid® assay to clinicians worldwide. This launch reflects our commitment to delivering innovative diagnostic solutions that address critical needs in healthcare. Our collaboration with SphingoTec has been instrumental in bringing this important tool to market."*

Deborah Bergmann, CEO of SphingoTec, added: *"The launch of AFIAS sphingotest® penKid® demonstrates how partnerships can drive innovation and improve access to advanced diagnostics. By combining our biomarker expertise with Boditech's diagnostic capabilities, we are reaching a new chapter in our collaboration. We are streamlining our processes to support the business of our license partners and further expand our global reach. This enables us to provide clinicians with essential tools to enhance patient care."*

Scientific insights on penKid

PenKid is a biomarker that enables real-time assessment of kidney function (1). Unlike traditional markers such as serum creatinine, penKid levels are not influenced by inflammation or other confounding factors like age or sex (1,2,3). Studies have shown that penKid allows earlier detection of acute kidney injury (AKI), predicting changes in serum creatinine up to 48 hours before conventional diagnostic criteria are met (1,3). This early detection capability is particularly valuable in critically ill patients, including those with sepsis or septic shock (1,3,4). Additionally, penKid has shown potential for monitoring renal recovery under dialysis and could help predict successful weaning from renal replacement therapy (5,6).

##

References

1. Hollinger A, et.al. *Proenkephalin A 119-159 (Penkid) Is an Early Biomarker of Septic Acute Kidney Injury: The Kidney in Sepsis and Septic Shock (Kid-SSS) Study*. *Kidney Int Rep*. 2018 Aug 22;3(6):1424-1433. doi: 10.1016/j.ekir.2018.08.006.
2. Beunders et al. *Assessing GFR With Proenkephalin*, *Kidney International Reports*, 2023, DOI: <https://doi.org/10.1016/j.ekir.2023.08.006>
3. 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
4. Moledina DG. *Penkid: A Novel Biomarker of Reduced GFR in Sepsis*. *Kidney Int Rep*. 2018 Nov 15;4(1):17-19. doi: 10.1016/j.ekir.2018.11.002.
5. von Groote T et al. *Proenkephalin A 119–159 predicts early and successful liberation from renal replacement therapy in critically ill patients with acute kidney injury: a post hoc analysis of the ELAIN trial*. *Crit Care* 26, 333 (2022). doi.org/10.1186/s13054-022-04217-4
6. von Groote T, et al. *Evaluation of Proenkephalin A 119-159 for liberation from renal replacement therapy: an external, multicenter pilot study in critically ill patients with acute kidney injury*. *Crit Care*. 2023 Jul 10;27(1):276. doi: 10.1186/s13054-023-04556-w.

About Boditech

Boditech Med (based in Chuncheon, Gangwon-do, Republic of Korea) is a leading company in the field of point-of-care diagnostics, which has accumulated 25 years of business expertise in the field. The company has more than 80 types of in vitro diagnostic products that detect biomarkers related to infectious diseases, diabetes, cardiovascular diseases, cancer, and hormone-related diseases with its immunofluorescence lateral flow technology, quantitative immunofluorescence technology and spectrophotometric technology. And the list continues to grow with new high-value-added products. With its instrument platform installed in more than 120 countries, the company also has a stable revenue model. The company is currently strengthening its value as a global company by expanding its manufacturing bases in the US, China, India, and Indonesia.

About SphingoTec

SphingoTec GmbH ("SphingoTec"; Hennigsdorf near Berlin, Germany) is a diagnostic company focusing on the out-licensing of innovative critical care biomarkers for diagnosing, predicting, and monitoring acute medical conditions. SphingoTec develops its biomarkers to the commercial stage and partners with IVD companies to make them 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, commercially available on diagnostic platforms AFIAS and Nexus IB10 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

Contact:

Ruxandra Lenz
Head of Marketing and Communication
SphingoTec GmbH
Phone +49-3302-20565-0
Email: press@sphingotec.com