

## Interdepartmental testing of the kidney function biomarker penKid in routine care at Heidelberg University Hospital and the Heidelberg Kidney Center

- Acute kidney injury (AKI) is a complex syndrome, which results in a rapid loss of kidney function, affecting 1 in 5 patients (1) during hospitalization.
- Four units at the University Hospital Heidelberg and Heidelberg Kidney Center implement Proenkephalin (penKid) in a pilot biomarker-based treatment approach to diagnose AKI faster and monitor it more accurately across departments.
- PenKid is a proposed biomarker for real-time kidney function that potentially closes on the gaps of the standard diagnostic procedures.

**Hennigsdorf, Germany, August 26, 2022** - The diagnostic company SphingoTec GmbH (SphingoTec) announces the introduction of novel biomarker penKid in the clinical routine management of patients on a test basis in a total of four units at the University Hospital Heidelberg (UKHD) and Heidelberg Kidney Center (NZH). This includes the normal, the intermediate care (IMC), the nephrology, and the intensive care units (ICU) of both clinics in Heidelberg. According to recent data, the new diagnostic tool provides a faster and more accurate assessment of kidney function than current practice and aims to improve the management of patients with AKI. The condition is associated with high morbidity and mortality, and is a frequent complication of severe diseases, such as sepsis.

The pilot implementation of penKid was started in cooperation with the Clinic for Anesthesiology at UKHD and the NZH with the long-term goal of improving the monitoring of patient's kidney function. This routine use of penKid on a centralized level in the hospital drives innovation on multiple wards such as nephrology, ICU and IMC. The biomarker will be used on top of standard of care, in order to compare penKid with the existing standard diagnostics. Better and faster information assessment of kidney function helps detect AKI earlier, so that prompt action can be taken to protect renal function and improve patient prognosis.

Prof. Dr. med. Martin Zeier, Medical Director at NZH added, "After the first experience of penKid on the point of care analyzer from SphingoTec, we have decided to implement it in the central laboratory to apply the test in more patients at the same time. The goal is to investigate the added value compared to established renal function parameters in routine diagnostics. To date, our data suggest better and more direct information about kidney function, which may allow for more rapid action. Acute kidney injury is a serious condition that needs to be detected early and counteracted promptly. When the critically ill patients are undergoing renal replacement therapy, the decision to terminate the treatment is of high importance for the success of the therapy. With penKid we may achieve better insights that complement our current practices, and we have strong hopes that this will help us improve patient outcomes on short and long term."

PenKid is a promising biomarker to determine kidney function. It has been studied in over 55,000 patients showing the potential to reflect kidney function in real-time (2,3). Data from the PredARRT-Sep-Trial

enrolling patients hospitalized in the surgical ICU of UKHD showed that penKid is a kidney function biomarker with rapid kinetics. According to these findings shared with the scientific community during the AKI&CRRT 2021 conference in San Diego US (4), penKid especially indicates changes in kidney function more dynamically than established functional markers. For those patients in critical conditions who require dialysis, penKid seems to be an early indicator of the kidney function and a potential tool to monitor kidney function and recovery during dialysis.

Prof. Dr. med. Markus Weigand, Medical Director of the Clinic for Anesthesiology at UKHD commented “On the ICU we experience the extreme of human disease, and AKI remains a serious complication in critically ill patients. A biomarker alerting changes in the kidney function faster than the currently known standards and uninfluenced by inflammation, has a significant potential for improving patient management. The sooner we identify a patient with kidney dysfunction, the faster we can intervene with life-saving procedures.”

Dr. Andreas Bergmann, founder and CSO of SphingoTec added “Testing penKid in routine practice at University Hospital Heidelberg brings the scientific advancements directly to those needing them the most: the patients. AKI is usually diagnosed after symptoms manifest, with diagnostic tests that have limited ability to identify early the onset of the disease. The blind spots in diagnosing kidney dysfunction are well known to the medical community, therefore penKid is a functional biomarker that addresses a clear unmet need and provides actionable information on all stages of the disease evolution.”

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#### References:

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#### About SphingoTec

SphingoTec GmbH ("SphingoTec"; Hennigsdorf near Berlin, Germany) develops and markets innovative in vitro diagnostic (IVD) tests for novel and proprietary biomarkers for the diagnosis, prediction and monitoring of acute medical conditions. SphingoTec's proprietary biomarker portfolio includes bioactive Adrenomedullin (bio-ADM), a unique biomarker for real-time assessment of endothelial function in conditions like sepsis or congestive heart failure, Proenkephalin (penKid), a unique biomarker for real-time assessment of kidney function, and Dipeptidyl Peptidase 3 (DPP3), a unique biomarker for cardiac depression. IVD tests for SphingoTec's proprietary biomarkers are made available as sphingotest® microtiter plate tests as well as point-of-care tests on the Nexus IB10 immunoassay platform by SphingoTec's subsidiary Nexus Dx Inc. (San Diego, CA, USA) alongside a broad menu of established and commonly used tests for acute and critical care.



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