

The Biomarker Company

Diagnostic solutions for acute and critical care settings

Our Mission

To improve patient outcomes with innovative diagnostic solutions for acute and critical care settings:

Actionable insights in real-time.



“Biomarkers are not molecules, biomarkers are information. This information must provide a substantial added value for an unmet medical need.”

Dr. Andreas Bergmann, CSO and Founder of SpingoTec

SpingoTec was founded by Dr. Andreas Bergmann, serial entrepreneur and co-founder of B.R.A.H.M.S. AG who developed Procalcitonin (PCT), today’s gold standard for diagnosis and monitoring of antibacterial treatment in sepsis.

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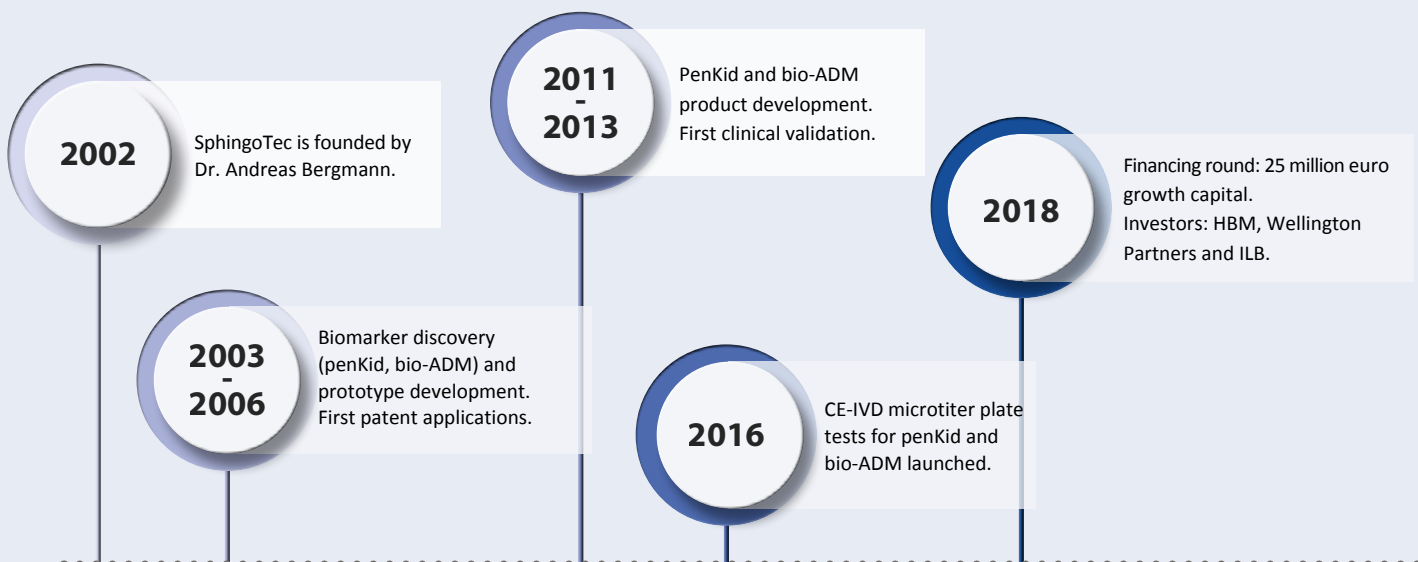
SpingoTec develops and markets innovative in vitro diagnostic (IVD) solutions for novel and proprietary blood-based protein biomarkers. Our aspiration is to effectively translate scientific advancements to routine clinical practice and support clinicians in improving patient outcomes. We bring innovations to frontline healthcare by discovering biomarkers, developing IVD assays and making them available on different diagnostic platforms. We commercialize our biomarkers through several channels: Direct sales to early adopters, license agreements with global IVD companies and cooperation with pharma companies.

The innovations are addressing diagnostically underserved acute and critical care conditions such as acute kidney injury (AKI), sepsis, and acute heart failure. Our biomarker portfolio includes Proenkephalin A 119-159 (penKid)*, a biomarker for assessment of kidney function and bioactive Adrenomedullin 1-52 (bio-ADM)*, a biomarker for assessment of endothelial function. First and foremost, our solutions support better management of critically ill patients, where fast and reliable information is of essence in taking treatment decisions.

*Disclaimer:

Spingotest® penKid® and spingotest® bio-ADM® are offered for in vitro diagnostics. “penKid” and “bio-ADM” represent the analytes Proenkephalin A 119-159 and bioactive Adrenomedullin 1-52, respectively.

History



Located in Hennigsdorf, Germany

SphingoTec is a privately held company with a long history of biomarker discovery, development and validation. We are the legal manufacturer of the CE-IVD microtiter plate assays. Committed to providing solutions that meet and exceed customer and regulatory requirements, we manufacture our products in accordance with EN ISO 13485:2016.



2018

SphingoTec enters market by deploying the novel biomarkers via a point-of-care solution and distribution network.

2020

The innovative biomarkers are introduced in routine measurements in European university hospitals.

2022

First licensing agreement for penKid closed with Boditech Med, Inc.

2020

Over 80,000 patients have been measured with our biomarker tests.

2022

SphingoTec is ISO 13485:2016 certified.



Innovative biomarkers: Scientific evidence

Driven by understanding the disease biology, we have been working together with the scientific community to identify hidden pathophysiological pathways in critical care settings. We have identified biomarkers that address unmet clinical needs and will aid clinicians in diagnosing and monitoring for the first time some of the biggest mortality drivers in critically ill patients. Measured in over 80,000 patients, our biomarker tests have been shown to support the diagnosis, outcome prediction, and monitoring of conditions such as sepsis, acute heart failure, and acute kidney injury. The burden of these conditions is affecting patient lives and healthcare systems worldwide.

1 in 3 patients

AKI is affecting 1 in 3 patients in intensive care units (1).

penKid - kidney function biomarker

The limitations of the current standard of care diagnostics are well known, thus the need to implement new biomarkers to assist better management of AKI. Timely information on kidney function is crucial to early initiate and adapt renal replacement therapy and nephroprotective strategies.

PenKid is a dynamic blood biomarker for the real-time assessment of kidney function. PenKid is a blood-based solution that is suitable for clinical routine testing. PenKid correlates to the true glomerular filtration rate (true GFR) and is independent from inflammation and common comorbidities. Validated in over 40,000 patients, penKid is a promising biomarker to not only predict AKI 48 hours earlier than today's standard of care, but also to detect the presence and severity of the disease, to identify patients at high risk of unfavorable outcomes and to indicate the renal recovery, even under dialysis (2,3).

11 million deaths

The global burden of sepsis worldwide counts for 49 million cases a year (4).

bio-ADM - endothelial function biomarker

Endothelial dysfunction is a hallmark of many acute and critical care conditions such as sepsis and acute heart failure and is causing the formation of edema, shock and subsequent organ failure. The endothelium is the interior wall of the blood vessels that acts as a barrier separating the blood from its surroundings.

Bio-ADM is a dynamic blood biomarker for the real-time assessment of endothelial function, even before the symptoms become visible (5). High bio-ADM levels indicate severe hypotension, edema formation, need for inotropic/vasopressor use and for organ support. Being a dynamic biomarker, low or decreasing bio-ADM blood levels indicate improved outcomes (6).

References

- (1) Edelstein C. Biomarkers of kidney disease. Boston (MA): Elsevier; 2016.
- (2) 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 ;3(6):1424-1433.
- (3) 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).
- (4) Rudd K et al. Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study. *The Lancet* 2020; 395:10219.
- (5) Geven C et al. Adrenomedullin and Adrenomedullin-Targeted Therapy As Treatment Strategies Relevant for Sepsis. *Frontiers in immunology.* 2018;9:292.
- (6) Mebazaa A et al. Circulating adrenomedullin estimates survival and reversibility of organ failure in sepsis: the prospective observational multinational Adrenomedullin and Outcome in Sepsis and Septic Shock-1 (AdrenOSS-1) study. *Crit Care.* 2018;22(1):354.

Commercialization of our biomarkers

Solutions for laboratories

To convey the clinical value of our biomarkers, we work together with hospitals that implement our manual assay technology in their central laboratory to allow for daily measurements. The innovative biomarkers are available as CE-IVD microtiter plate assays, a standard tool in analytical laboratories. It is a high-throughput solution, allowing the measurement of approximately 41 patient samples at once. SphingoTec's MTP assays are a non-automated immunoluminometric assay (ILMA).

Assay Portfolio
sphingotest® penKid® Proenkephalin A 119-159 (penKid) (up to 41 double determinations per package)
sphingotest® bio-ADM® Bioactive Adrenomedullin 1-52 (bio-ADM) (up to 41 double determinations per package)



Out-licensing of biomarkers

For a broad market adoption of our first-in-class biomarkers, we partner with global IVD companies. Our portfolio is available for licensing to companies wishing to enrich their immunoassay portfolios and to develop biomarker-based diagnostics for clinical use on their high-throughput and near-patient testing platforms.



Collaboration with pharma companies

Our diagnostic solutions address critical disease pathways, for which other companies develop treatments. The use of biomarkers to identify treatment responders and non-responders becomes increasingly important. Our biomarkers can provide a solution for the enrichment and increased efficacy strategies in critical care drug discovery to de-risk drug developments.





Collaborations

SphingoTec takes a collaborative approach in the discovery and validation of novel biomarkers. Contact us with your ideas and interest at:
collaborations@sphingotec.com

Business Development

For broad market adoption of our first-in-class biomarkers, we partner with global IVD companies. If you are interested in obtaining licenses to our proprietary biomarkers, please contact us at:
business@sphingotec.com