

# The Biomarker Company

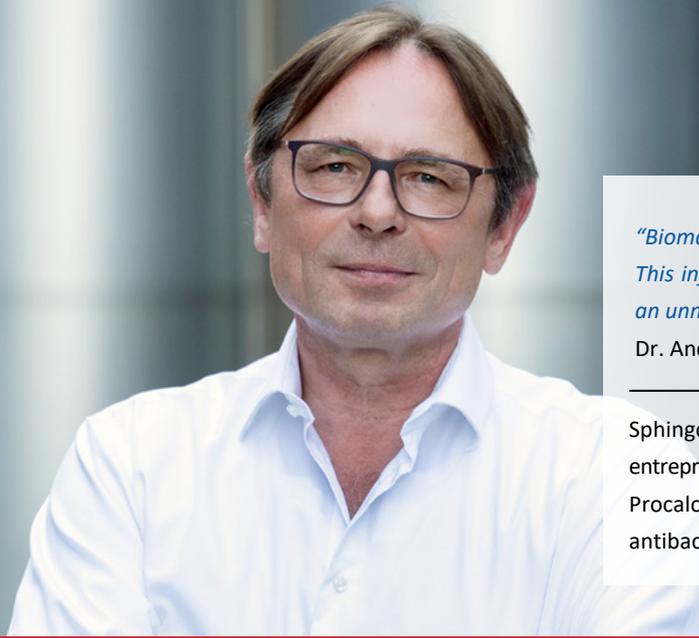
Integrated diagnostic solutions for critical care settings

# Our Mission

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To improve patient outcomes with innovative diagnostic solutions for acute care 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, Founder and CEO

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 antibacterial treatment monitoring in sepsis.

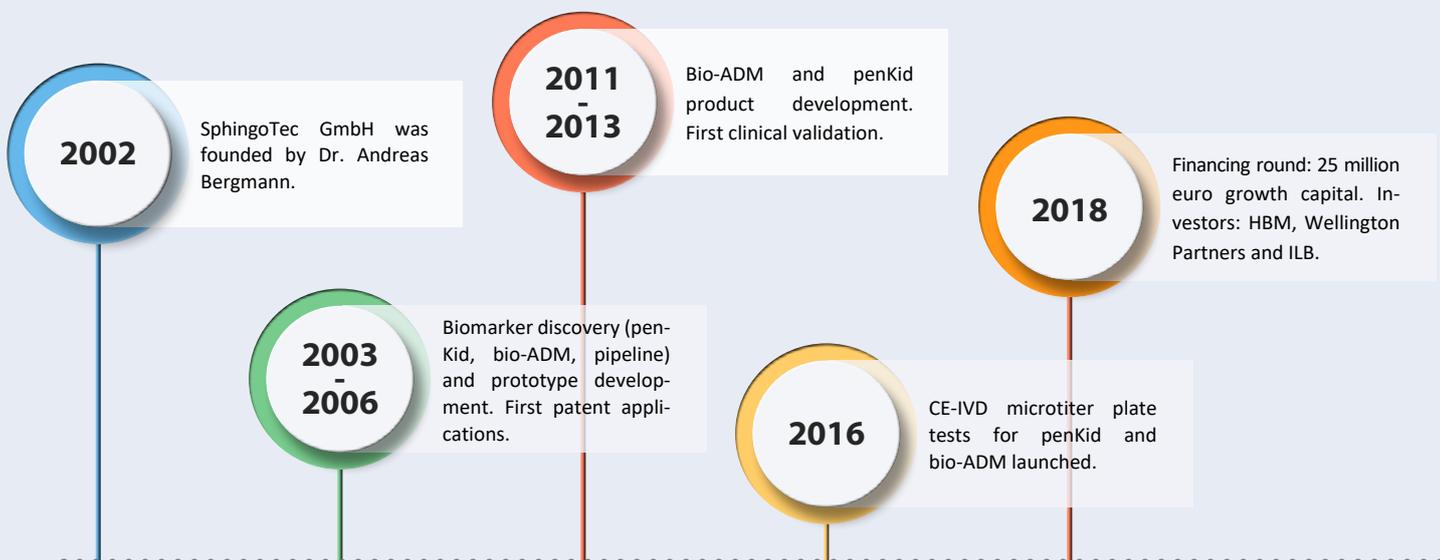
## The Biomarker Company

SpingoTec develops and markets innovative in vitro diagnostics solutions for novel and proprietary blood-based protein biomarkers. Our aspiration is to effectively translate scientific advancements to routine clinical practice. We develop biomarkers addressing diagnostically underserved critical care conditions such sepsis, acute heart failure, acute kidney injury, and cardiogenic shock. First and foremost, our portfolio of tests supports a better management of critically ill patients, where fast and reliable information is of an essence in taking treatment decisions.

We are a fully integrated diagnostics company: our innovative biomarkers are commercially available on the point of care platform Nexus IB10. The assay portfolio for near patient testing goes beyond innovation: on the Nexus IB10 platform, clinicians can deploy a wide range of commonly used parameters in acute and critical care settings, making the analyzer a useful addition to intensive care units (ICU), emergency departments (ED), and other near patient settings.

*“We bring innovations to frontline healthcare by developing biomarkers and make them available on a point of care technology. Our goal is to support clinicians in improving patient outcomes and reduce mortality in critical care settings, “ says Dr. Andreas Bergmann.*

## History



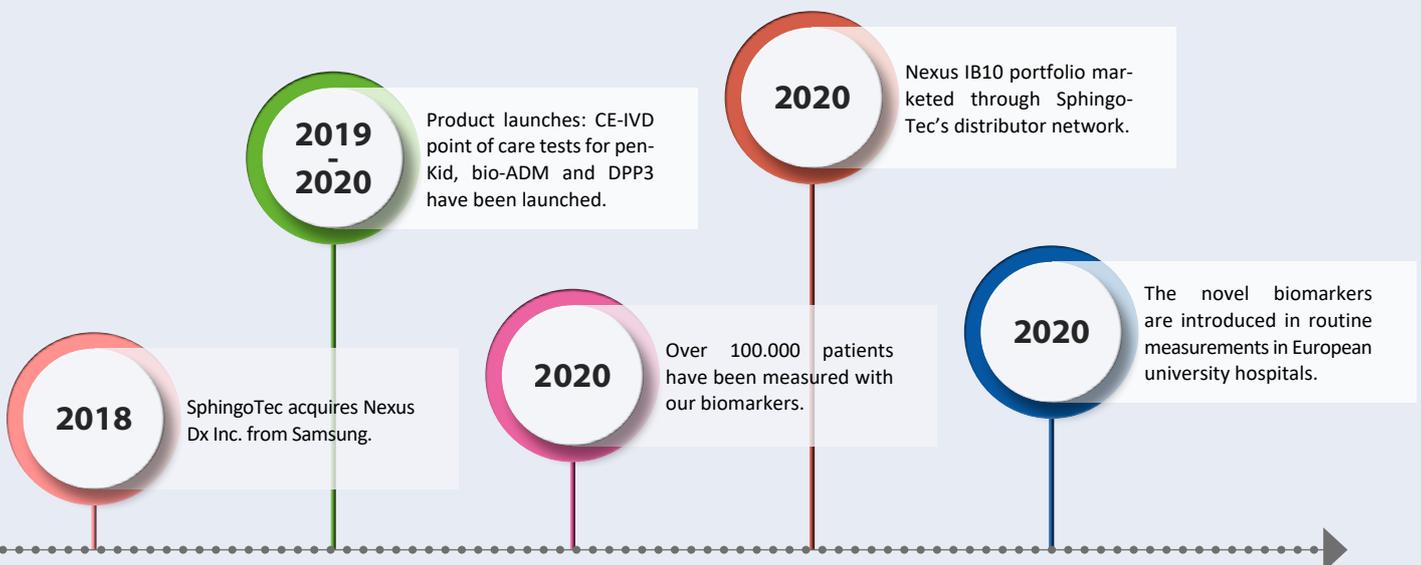
## Headquarter in Hennigsdorf, Germany

SphingoTec is a privately held company with the headquarter in Hennigsdorf near Berlin and with a wholly owned subsidiary in San Diego, USA. The headquarter has a long history of biomarker discovery, development and validation and is the legal manufacturer of the microtiter plate assays. The German company is leading the global commercialization of the diagnostic solutions with a clear goal: improving patient management and reducing healthcare costs.



## Manufacturing facility in San Diego, US

Nexus Dx Inc., a wholly-owned subsidiary of SphingoTec, located in San Diego, CA, USA, is a global provider of a near patient testing system and diagnostic solution. Fully compliant to ISO13485:2016 regulations, Nexus Dx is improving patient care by providing the medical community with rapid and reliable information at the point of care, delivering patient information when and where it is needed most.





## Innovative proprietary biomarkers

Fueled 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 aid clinicians in diagnosing and monitoring for the first time some of the biggest mortality drivers in critically ill patients. Measured in over 100,000 patients, our biomarkers have been shown to support the diagnosis, outcome prediction, and monitoring of conditions, such as sepsis, acute heart failure, cardiogenic shock and acute kidney injury. The burden of these conditions is affecting patient lives and healthcare systems worldwide.

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### 1 in 3 patients

*Acute kidney injury (AKI) is affecting 1 in 3 patients in intensive care units.*

#### 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 a better management of AKI. Timely information on kidney function is crucial to early initiate nephro-protective strategies.*

Proenkephalin (penKid), is a dynamic biomarker for the real time assessment of kidney function. PenKid is a blood-based solution for detecting true glomerular filtration rate (true GFR) in clinical routine testing and is independent from inflammation and comorbidities. Validated in over 40,000 patients, penKid has been proven 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, identify patients at high risk of unfavorable outcomes and indicate the renal recovery.

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### 11 million deaths

*The global burden of sepsis worldwide counts for 49 million cases a year.*

#### bio-ADM - endothelial function biomarker

*Endothelial dysfunction is a hallmark of many critical care conditions such as sepsis and acute heart failure. Loss of endothelial function is causing the formation of edema, shock and subsequent organ failure.*

Bioactive Adrenomedullin (bio-ADM), is a dynamic blood biomarker for the real time assessment of endothelial function. The endothelium is the interior wall of the blood vessels that acts as a barrier separating the blood from its surroundings. Bio-ADM enables the assessment of endothelial function up to 48 hours before the symptoms become visible. 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.

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### new pathway

*Cardiac depression caused by a newly identified disease mechanism.*

#### DPP3 - a cardiac depressant factor

*Recent studies have shown that the release of the cardiac depressant factor dipeptidyl peptidase 3 (DPP3) into the bloodstream plays a major role in sudden organ failure.*

DPP3 is a dynamic biomarker for cardiac depression. When massive, uncontrolled cell death occurs, for example in major surgeries, cardiogenic shock, sepsis, or burns, DPP3 is released in the bloodstream where it has a toxic-like effect on the human body. Circulating DPP3 causes the inactivation of the heart-stimulating hormone angiotensin II, a process leading to cardiac depression and consequently hemodynamic instability.

# Diagnostic platforms

## Nexus IB10 point of care analyzer

The Nexus IB10 point of care (POC) technology provides test results via whole blood in only 20 minutes and can be flexibly deployed in emergency departments, intensive care units, and any near-patient setting. The Nexus IB10 is an in vitro immunology analyzer that quantitatively measures analytes in whole blood or plasma samples on a consumable disc. The POC platform can perform up to three diagnostic parameters at once. The rapid test portfolio includes commonly used parameters in critical care settings as well as the innovative and proprietary biomarkers penKid, bio-ADM, and DPP3.



### POC Assay Portfolio

**IB10 sphingotest® PCT**

Procalcitonin (package of 10 discs)

**IB10 sphingotest® penKid®**

Proenkephalin (package of 10 discs)

**IB10 sphingotest® bio-ADM®**

bioactive Adrenomedullin (package of 10 discs)

**IB10 sphingotest® DPP3**

Dipeptidyl Peptidase 3 (package of 10 discs)

**IB10 sphingotest® NT-proBNP**

NT-proBNP (package of 10 discs)

**IB10 sphingotest® TSH**

TSH (package of 10 discs)

**IB10 sphingotest® beta-hCG**

beta-hCG (package of 10 discs)

**IB10 sphingotest® Shortness of Breath**

D-Dimer, NT-proBNP, Troponin I (package of 10 discs)

**IB10 sphingotest® D-Dimer**

D-Dimer (package of 10 discs)

**IB10 sphingotest® 3-in-1 Cardiac**

Troponin I, CK-MB, Myoglobin (package of 10 discs)

**IB10 sphingotest® Troponin-99**

Troponin I (package of 10 discs)

## Microtiter plate assay

The microtiter plate is a standard tool in analytical research and laboratories. It is a high-throughput solution, allowing the measurement of 41 patients at once. SphingoTec's microtiter plate assays are based on a chemiluminescence sandwich immunoassay technology. Our proprietary biomarkers for critical care settings are available as CE-IVD microtiter plate assays, including the assay for penKid and bio-ADM.



### MTP Assay Portfolio

**sphingotest® penKid®**

Proenkephalin (41 double determinations per package)

**sphingotest® bio-ADM®**

Bioactive Adrenomedullin (41 double determinations per package)



### **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](mailto:collaborations@sphingotec.com)

### **Partnerships**

For the commercialisation of our microtiter plate assays as well as our Nexus IB10 point-of-care platform and acute care assay portfolio we work with partners worldwide. If you are interested in distributing our products, please contact us at: [commercial@sphingotec.com](mailto:commercial@sphingotec.com)

### **Business Development**

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