

SphingoTec launches point-of-care test for bio-ADM, a biomarker for life threatening endothelial dysfunction

- *Endothelial dysfunction is driving pathophysiological processes such as congestion in heart failure, shock in sepsis, and lung dysfunction in COVID-19*
- *Bioactive Adrenomedullin (bio-ADM®) is a proprietary biomarker for real-time assessment of endothelial function in acute and critical care settings.*
- *High blood levels of bio-ADM® have been shown to predict septic shock, to diagnose residual congestion in heart failure, and the need for organ support in critically ill patients, including COVID-19*
- *IB10 sphingotest® bio-ADM® runs on SphingoTec's automated Nexus IB10 point-of-care platform and quantitatively measures levels of bio-ADM® directly in blood samples*

Hennigsdorf/Berlin, Germany, July 22, 2020 – Diagnostics company SphingoTec GmbH (“SphingoTec”) today announced the launch of its IB10 sphingotest® bio-ADM®, a CE-IVD-marked point-of-care test to quantitatively determine blood levels of Bioactive Adrenomedullin (bio-ADM®). Blood levels of bio-ADM® reflect in real-time the functional status of the endothelium, the inner cell sheet of blood vessels. The test is made available on the company’s rapid point-of-care platform Nexus IB10 that uses whole blood samples without any pre-processing, requires less than three minutes hands-on-time, and delivers results after 20 minutes. Nexus IB10 can be flexibly deployed in laboratories or near-patient settings such as intensive care units (ICUs) and Emergency Departments (EDs).

In numerous studies on more than 22,000 patients admitted to ICUs and EDs, bio-ADM® has been shown to predict distortions of the inner cell sheet of blood vessels, the endothelium (1). Failure of the endothelial function has been demonstrated to precede edema and the life-threatening blood pressure drop that causes shock and multiorgan failure e.g. in patients with sepsis at ICUs and EDs (2-3). In heart failure patients, bio-ADM® blood-levels reliably and objectively reflect tissue congestion and residual congestion (4). Recent data show that elevated blood levels of this functional biomarker also identifies patients in the general ICU patient population who require immediate life-saving therapeutic interventions (5). In ICU patients with severe COVID-19, endothelial dysfunction has been identified to play a crucial role in the disease progression, thus providing a rationale to monitor bio-ADM® to guide the therapy stabilizing the endothelium (6).

Dr. Andreas Bergmann, CEO and founder of SphingoTec commented: “The endothelial function plays a key role in a large number of critical care conditions, such as sepsis, septic shock, acute heart failure, and COVID-19. A distortion in the endothelial function predicts the patient’s

progression to a critical stage. Therefore, bio-ADM® screening can identify high-risk patients who require early life-saving therapeutic intervention. With the launch of this rapid test for bio-ADM® on our widely established Nexus IB10 immunoassay platform, we aim to support earlier treatment decisions and improve outcomes of acute care patients.”

The IB10 sphingotest® bio-ADM® assay is commercialized in Europe and other regions that accept CE-IVD certification through SphingoTec’s network of distribution partners for the Nexus IB10 platform, together with a broad menu of standard tests for acute and critical care.

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References:

(1) Geven (2018): *Vascular Effects of Adrenomedullin and the anti-Adrenomedullin Antibody Adrecizumab in Sepsis. Shock.* doi: 1097/SHK.0000000000001103

(2) Mebazaa (2018): *Circulating adrenomedullin estimates survival and reversibility of organ failure in sepsis: the prospective observational multinational Adrenomedullin and Outcome in Sepsis and Septic Shock (AdrenOSS-1) study.* doi:10.1186/s13054-018-2243-2

(3) Caironi (2017): *Circulating biologically active adrenomedullin (bio-ADM) predicts hemodynamic support requirement and mortality During Sepsis. Chest.* doi: 10.1016/j.chest.2017.03.035.

(4) ter Maaten (2019): *Bio-adrenomedullin as a marker of congestion in patients with new-onset and worsening heart failure, Eur J Heart Fail.* doi:10.1002/ejhf.1437(5)

Lemasle (2020): Bioactive Adrenomedullin, Organ Support Therapies, and Survival in the Critically Ill: Results from the French and European Outcome Registry in ICU Study, Crit. Care. Med, doi: 10.1097/CCM.0000000000004044

(6) Varga (2020): *Endothelial cell infection and endotheliitis in COVID-19, Lancet,* [https://doi.org/10.1016/S0140-6736\(20\)30937-5](https://doi.org/10.1016/S0140-6736(20)30937-5)

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, such as sepsis, acute heart failure, circulatory shock, and acute kidney injury in order to support patient management and provide guidance for treatment strategies. 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. In addition, SphingoTec develops a portfolio of novel biomarkers, which predict the risks of developing obesity, breast cancer and cardiovascular diseases. IVD tests for SphingoTec's proprietary biomarkers are made available as sphingotest® microtiterplate 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.

About Nexus Dx Inc. and the IB10 Platform

Nexus Dx Inc., a wholly-owned subsidiary of SphingoTec, headquartered in San Diego, CA, USA, is a global provider of a near patient testing system and advanced diagnostic solution. The company is improving patient care by providing the medical community with rapid and reliable information at the point of care (POC), delivering patient information when and where it is needed most. The company has invested over \$160m to develop and market the IB10 analyzer system which, without the need for sample preparation, automatically separates plasma from whole blood with subsequent reliable and quantitative detection of biomarkers in the plasma by means of antibodies. With a hands-on-time of less than 3 minutes the easy-to-use system provides in only 20 minutes test results for biomarkers that are crucial in the management of critical care patients. The portfolio of IB10 assays includes tests for established critical care parameters such as Procalcitonin, Troponin I, CK-MB, Myoglobin, NT-proBNP, and D-Dimer as well as tests for SphingoTec's proprietary biomarkers such as DPP3, an assay for Dipeptidyl Peptidase 3, a unique and proprietary biomarker for cardiac depression, Proenkephalin (penKid®), a unique and proprietary biomarker for real-time assessment of kidney function and the IB10 assay for bioactive Adrenomedullin (bio-ADM®), a unique and proprietary biomarker for endothelial function.

About bio-ADM®

sphingotest® bio-ADM® measures blood levels of bioactive adrenomedullin (bio-ADM®), a hormone maintaining endothelial function. The endothelium contributes to blood pressure and separates blood from the surrounding tissue. Elevated blood levels of bio-ADM® predict blood pressure break down and leaky vessels resulting in oedema. Imbalanced endothelial function is the major cause of shock ultimately resulting in organ dysfunction and death. Early identification of an imbalance in endothelial function allows guidance of vasopressor and diuretic therapy in critically ill patients to improve outcomes.

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