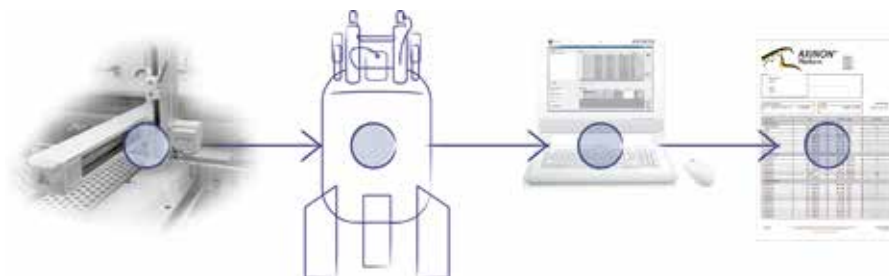


Metabolic diagnostics – as individual as the patient

New opportunities for personalised medicine using metabolomics

Having waited months, if not years, for a donor organ, kidney recipients face a further period of uncertainty in the post-operative phase. Will the body accept the new kidney? Or will it reject it, threatening the health of the patient and the loss of the donor organ? Post-operative examinations can be a time-consuming process and, if biopsies are involved, a rather unpleasant experience for patients. If it were possible to obtain comparable data on a patient's condition using something as simple as a regular urine test, we could have an earlier indication of incipient issues and prevent their development by adapting the medication or other treatment.

Figure 1: The AXINON® system



The AXINON® system from numares is a high-throughput product delivering automated results within minutes. These results can be used by clinicians for diagnosis and treatment selection. (1) Using the AXINON® Kit, it is possible to prepare samples in just a few minutes. (2) The samples are then measured using the AXINON® software and a qualified NMR device. (3) The software analyses the metabolic data and (4) generates a report with the test results.

While that scenario might seem rather futuristic, it is happening right now. Over the past year, more than 100 kidney recipients at the University Hospital Regensburg have benefited from this type of diagnostic care. Thanks to a totally new test system developed by med-tech company numares, it is now possible to identify whether a transplanted kidney has been accepted by the patient and is functioning well or if there are signs of rejection and loss of function. Having successfully completed the clinical

trial in Regensburg, numares is now expanding the technique to include other renal conditions, such as acute kidney injury (AKI), which occurs in up to 65 percent of ICU patients.

More than 800,000 tests already completed

Fast and reliable testing for renal conditions is only one of the possible applications for this new diagnostic system, which numares has been developing for the past 12 years. Indeed, it is



AUTHORS:

Dr. Titus Kaletta is responsible for the marketing of numares test systems in Europe and Asia. He has over 17 years of international management experience in the fields of R&D and strategic business development. A graduate in biochemistry, Kaletta received his PhD from the Max Planck Institute in Munich and has an MBA from the Vlerick Business School in Belgium.

Dipl.-Biol. Christiane Proll is in charge of corporate communications and marketing for numares. Having spent more than 12 years in the biotechnology and medical technology sectors, she has a wealth of experience in the marketing of biotechnology products. Proll studied biology in Marburg and general management at OTH Regensburg.

already part of the clinical routine for blood lipid analysis.

In the United States, for example, a number of numares systems have been in operation since 2014, analysing up to 60,000 blood samples every month to offer early warning of cardiovascular conditions that might ultimately lead to a heart attack or stroke. The test results show the distribution of lipids and cholesterol as well as of lipoprotein particles. These particles serve as packing and are believed to have various atherogenic effects. The potential market here is huge, considering that pathological lipid metabolism is a precursor to many common conditions such as atherosclerosis, diabetes mellitus and coronary heart disease. Another example of the growing uptake can be found in Germany, where the local market leader in medical laboratories, the Limbach Group, this year introduced the lipoComplete test from numares for use in high-throughput routine analysis.

Genomic information is only part of the story

As genome analysis promises to revolutionise our understanding of medical conditions, investors are taking a growing interest in the many start-up companies in this sector. So far, however, there is little sign of a definitive solution – which is hardly surprising given that genomics alone provides only a limited picture of the human organism, omitting the important context of external influences, e.g., environment and lifestyle.

For a more holistic view, we have to turn to metabolomics – the study of metabolism. Through analysis of metabolites and metabolite networks, we can acquire a much better insight into the human phenotype, i.e., the organism's current characteristics and traits. Here, among the body's metabolic products, we can find potential markers for a range of diseases. Having measured the metabolites in a body fluid such as blood, urine or cerebrospinal fluid, we can form a clearer picture of a patient's condition and thus arrive at a more accurate diagnosis and more appropriate treatment. As cardiovascular, oncological and central nervous

system diseases become increasingly common as causes of death worldwide, there is a corresponding rise in market demand for fast and inexpensive lab and diagnostic services.

Metabolomics is now an integral part of diagnostics

The AXINON® diagnostic system from numares is based on nuclear magnetic resonance (NMR) spectroscopy, a technique that was developed in the field of structural chemistry and has been used widely in research for many years. numares has now evolved this technology to create a proprietary diagnostic system that uses detailed spectroscopic analysis of metabolites as a basis for accurate diagnosis of specific conditions as well as continuous monitoring of treatment.

For the purposes of in-vitro diagnostics, NMR requires extensive standardisation to ensure accurate and comparable results. numares has achieved this by adapting the technology to create a technology called Magnetic Group Signaling (MGS®). MGS® provides software-aided and fully automated analysis of metabolites based on a single NMR spectrum. Calibration and standardisation of the NMR spectrum is essential here for the reliability required in routine laboratories. Using specially developed statistical procedures, the system identifies the relationships between individual metabolic products and derives markers or marker combinations for specific diseases or risk factors. These metabolic profiles are then clinically validated.

Just like next-generation sequencing (NGS) allows the processing of an individual human genome in only a few days, MGS® makes it possible to use a human metabolome, i.e., the metabolic characteristics of an individual organism, in the context of in-vitro diagnostics. Through the standardisation and qualification of NMR spectroscopy, MGS® offers totally new diagnostic insights based on metabolic data. Consequently, this new procedure provides the ideal platform for the continued development of personalised medicine, allowing metabolomics to take its place in modern precision medicine. ■

INVESTIEREN SIE MIT UNS IN DEN WACHSTUMSMARKT GESUNDHEIT.

Die SANEMUS AG schafft Mehrwert für Investoren und Unternehmen.

UNSER PROFIL

Wir investieren fokussiert in Unternehmens- und Vermögensbeteiligungen im deutschen Gesundheitsmarkt.

Unternehmen mit neuen, innovativen Geschäftsmodellen helfen wir bei der Realisierung ihrer Geschäftsideen (Seed-/Start-Up-Phase) und Wachstumspläne (Growth Phase)

Ein wesentlicher Schwerpunkt unserer Beratungstätigkeit ist das Thema Personalisierte Medizin.

UNSERE ZIELBRANCHEN

Life Science Bereich mit den Teilmärkten Pharma, Biotech, Medtech und Diagnostika

UNSERE LEISTUNGEN

- Strategic-Advisory, z.B. Life-Cycle- und Portfoliomanagement
- Financial-Advisory, z.B. Beratung von Anlegern bei Life Science Investments
- Merger & Acquisition-Advisory, z.B. Commercial Due Diligence

Sprechen Sie uns an:
SANEMUS AG
Frauenstraße 12 | 80469 München
info@sanemus.com
www.sanemus.com
+49 (0)89 189 44 89 0




SANEMUS
INVESTING IN HEALTH