# Press Release Humedics

## Independent trial shows accurate staging of liver fibrosis with the LiMAx® test

### *Clinical study from the University of Essen reveals superiority of the LiMAx® test for noninvasively detecting different stages of fibrosis and cirrhosis in patients with chronic liver disease*

**Berlin, Germany, October 24, 2018 – Humedics GmbH, a specialist in real-time measurement of liver function capacity, announced results of a retrospective study that assessed the diagnostic accuracy of the LiMAx® test in patients with chronic liver disease. Results showed that the test can be a useful method to noninvasively determine hepatic disease severity.**

Chronic liver disease is a worldwide health issue and a major cause of morbidity and mortality. Inflammatory processes during disease progression lead to increasing stages of liver fibrosis with liver cirrhosis as the terminal disease stage. Since liver tissue can regenerate, early forms of fibrosis are reversible. Therefore, accurate assessment of the fibrosis stages is important for treatment decisions. Reliable detection of cirrhosis is clinically important as this condition increases the risk of developing further complications and liver cancer. Usually a liver biopsy is needed to accurately determine hepatic disease severity and to differentiate fibrosis from cirrhosis. However, this invasive procedure implies risks, is painful for the patient and thus not suited for repeated therapy monitoring.

With the need for a noninvasive method to assess fibrosis and cirrhosis in mind, the Department of Gastroenterology and Hepatology at the University Clinic of Essen conducted a study to evaluate the diagnostic accuracy of the LiMAx® test for this purpose, as well as other methods, such as serum biomarkers and transient elastography in comparison with biopsy-based histological results (classification according to Desmet score). 102 patients with chronic liver disease of different etiologies were included into the retrospective study.

Decreasing liver function as measured by the LiMAx® test showed a strong correlation to the increasing histologically proven degree of fibrosis and the classification of different fibrosis stages. The LiMAx® test was demonstrated to be superior in comparison to other noninvasive methods. In their conclusion, the authors of the study emphasized the added benefits of the LiMAx® test for the noninvasively staging of fibrosis and as a viable alternative to the current standard of care.

Karsten Damgaard-Iversen, CEO of Humedics, commented: “We see a strong and growing interest in our LiMAx® liver function test as liver specialists continue to document its unique value in the diagnosis and clinical management of patients with impaired liver function. The present study impressively demonstrates the accuracy of the LiMAx® test for the noninvasive staging of chronic liver disease and the differentiation of fibrosis from cirrhosis.”

Erwin de Buijzer, COO of Humedics, continued: “This independent research shows the need for innovative and non-invasive diagnostic liver tests that can complement the current diagnostic tools and fill the void for functional analysis that currently exists in daily clinical practice.”

Reference:
https://www.ncbi.nlm.nih.gov/pubmed/30278435

**Visit us at**
AASLD Liver Meeting, San Francisco, USA, November 9-13, 2018

**About Humedics**

Humedics has developed a breath test based *in vivo* diagnostic system (the LiMAx® test), which comprises a CE-marked medical device, breathing masks and a diagnostic drug. The LiMAx® test enables the clinician to quantitatively determine the individual liver function capacity of a patient within minutes. This allows for selection of treatment strategies and disease monitoring optimally adapted to the individual patients’ liver status. Current clinical applications, studies of which have already been published in highly respected peer-reviewed scientific journals, include diagnosis of the liver function before and after liver transplantation, liver surgery planning (e.g. assessment of the amount of liver to be resected without potentially increasing the risk of acute liver failure) and assessment of diseases such as liver fibrosis and cirrhosis. Over 20 trials in new indications such as the diagnosis of chronic liver diseases like non-alcoholic steatohepatitis (NASH) and the improvement of treatment decisions in liver oncology are ongoing. These investigator initiated trials impressively demonstrate the further potential of the LiMAx® test. The LiMAx® test is already being used in over 30 top-tier university clinics across Europe and more than 20,000 tests have already been performed. The LiMAx® test is commercially available in Germany, Austria and the UK.

**LiMAx® Test**

Based on the specific metabolic action of the liver enzyme CYP1A2, which is expressed in all functioning hepatocytes, performing the LiMAx® test is a simple procedure. The diagnostic drug solution is administered intravenously, and the liver immediately starts to metabolize the drug into low dose paracetamol and $^{13}CO_2$ (non-radioactive). The latter is exhaled in the breath, collected via a respiratory mask and guided to the LiMAx® system where, within 1-2 minutes following the injection, the LiMAx® IR laser spectroscopy system allows real-time and very precise quantification of the increase in $^{13}CO_2$ content. The resulting LiMAx® value, measured in micrograms per kilo body weight per hour, is a reliable and repeatable measure of the maximum functional capacity of the liver.

**Humedics Contact:**
Humedics GmbH
Erwin de Buijzer MD MBA
Marie-Elisabeth-Lüders Str. 1
10625 Berlin
Phone: +49 30 590083240
E-Mail: info@limaxtest.com
Homepage: www.limaxtest.com

**PR Contact:**
Almut Gebhard
Strategische Kommunikation
Hasenheide 56
10967 Berlin
Phone: +49 (0)30 - 6120 1081
Mobile +49 (0)174 3017754
E-Mail: ag@almutgebhard.de