

### **Siemens launches first automated standardised direct biomarker panel for liver fibrosis – a leading indicator of Chronic Liver Disease**

**Availability of the Enhanced Liver Fibrosis test on Siemens ADVIA Centaur Systems gives clinical laboratories an innovative new assay that delivers results in less than 60 minutes**

Siemens Healthcare Diagnostics has announced that its Enhanced Liver Fibrosis (ELF)<sup>TM</sup> test\* has been CE-marked for use on the ADVIA Centaur<sup>®</sup> Immunoassay Systems. This first fully automated standardised direct biomarker panel offers clinicians a quick, reliable, minimally invasive blood test option to assess liver fibrosis – a leading indicator of Chronic Liver Disease (CLD) – with results in less than one hour. With the addition of the ELF test, Siemens is currently the only company to offer an integrated portfolio of diagnostic solutions for managing liver health, which includes routine chemistry tests, hepatitis serology tests, viral load testing, and ultrasound systems.

Liver fibrosis is an important indicator of CLD, such as cirrhosis and liver cancer, which are now among the top ten causes of death worldwide.<sup>i ii</sup> The ELF test is a simple, standardised blood test that assesses the severity of liver fibrosis by combining three direct serum biomarkers - hyaluronic acid (HA), procollagen III amino terminal peptide (PIIINP), and tissue inhibitor of metalloproteinase 1 (TIMP-1) - in an algorithm. The result is an ELF score, which correlates to the level of liver fibrosis assessed by liver biopsy,<sup>iii</sup> the current standard of care for liver fibrosis diagnosis.

“The discovery of the ELF markers represents a significant advance in the diagnosis of patients with liver disease,” said William Rosenberg, MBBS, D. Phil, Peter Scheuer Chair in Liver Diseases Joint Director of the Centre for Hepatology University College London. “Of particular benefit, the ELF test can help to identify patients with mild-to-moderate liver fibrosis, which is usually asymptomatic, so that clinicians are able to intervene before significant damage to the liver occurs.”

“While liver biopsy is the standard for assessing liver fibrosis, unfortunately, there are challenges with this procedure, including patient discomfort and difficulties in interpreting the results,” explains Dave Hickey, CEO, Chemistry, Immunoassay, Automation, and Diagnostics IT Business Unit at Siemens Healthcare Diagnostics. “By offering an automated, routine, minimally invasive blood test, Siemens provides an additional tool to physicians to aid them to easily assess the severity of liver fibrosis in their patients with chronic liver disease.”

The ELF test has been clinically validated on an Immuno-1 auto analyzer in an international multi-centre study with a mix of patient groups, including viral hepatitis, non-alcoholic fatty liver disease (NAFLD), and alcoholic patient groups. Additionally, a 7-year follow-up study involving over 450 patients has shown that the ELF markers are at least comparable to liver histology at predicting clinical outcomes of CLD.<sup>iv</sup>

For more information about the Siemens ELF Test, visit [www.siemens.com/ELF](http://www.siemens.com/ELF).

- ends -

**Notes to editor:**

<sup>i</sup> Griffiths et al., (2005) “Leading Causes of Death in England and Wales - How Should We Group Causes?” *Health Statistics Quarterly* 28:6–17.

<sup>ii</sup> Bosetti et al., (2007) “Worldwide Mortality from Cirrhosis: An Update to 2002,” *Journal of Hepatology* 46(5):827–39.

<sup>iii</sup> Rosenberg et al, (2004), “Serum Markers Detect the Presence of Liver Fibrosis: A Cohort Study” *Gastroenterology*; 127:1704-1703

<sup>iv</sup> Parkes et al., (2010) “Enhanced Liver Fibrosis Test Can Predict Clinical Outcome in Patients with Chronic Liver Disease,” *Gut* (online Aug 2010)

**About Liver Fibrosis**

Liver fibrosis is the scarring process that represents the liver’s response to injury or disease. In response to chronic liver injury, stellate cells in the sinusoidal space are activated and deposit a collagen matrix (fibrosis). Over time, the fibrosis may become severe, leading to cirrhosis that may require a liver transplant or result in death. The three biomarkers that are combined to obtain the ELF score reflect integral extracellular matrix (ECM) components of fibrogenesis and fibrolysis processes which correlate to the progression of disease.

\*The Siemens ELF test is available in the U.S. for Research Use Only. Not for use in diagnostic procedures.

**About Siemens Healthcare**

The **Siemens Healthcare Sector** is one of the world’s largest suppliers to the healthcare industry and a trendsetter in medical imaging, laboratory diagnostics, medical information technology and hearing aids. Siemens offers its customers products and solutions for the entire range of patient care from a single source – from prevention and early detection to diagnosis, and on to treatment and aftercare. By optimizing clinical workflows for the most common diseases, Siemens also makes healthcare faster, better and more cost-effective. Siemens Healthcare employs some 48,000 employees worldwide and operates around the world. In fiscal year 2010 (to September 30), the Sector posted revenue of 12.4 billion euros and profit of around 750 million euros. For further information please visit: [www.siemens.com/healthcare](http://www.siemens.com/healthcare)

Approximately 265 words

15 June 2011

**For more information or images please contact:**

Georgina Wright / Thomas O'Neill

Media Safari

T: 01225 471202

E: [georginaw@mediasafari.co.uk](mailto:georginaw@mediasafari.co.uk) / [thomaso@mediasafari.co.uk](mailto:thomaso@mediasafari.co.uk)

Siemens Healthcare Diagnostics

Alison Edgington

T: 01276 696000

E: [alison.edgington@siemens.com](mailto:alison.edgington@siemens.com)

W: <http://www.siemens.co.uk/diagnostics>

**Picture caption:** Siemens Healthcare Diagnostics has announced that its Enhanced Liver Fibrosis (ELF)<sup>™</sup> test\* has been CE-marked for use on the ADVIA Centaur<sup>®</sup> Immunoassay Systems. This first fully automated standardised direct biomarker panel offers clinicians a quick, reliable, minimally invasive blood test option to assess liver fibrosis with results in less than one hour.

