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Siemens launches a new 60 minute blood test for earlier detection of liver damage.

According to official figures from the Department of Health, alcoholic liver disease in the under 30s has risen by 50 per cent in the last ten years.

Liver disease is now the country's fifth biggest killer. The coalition government wants a "drink strategy" with input from both the health lobby and the drinks industry.

Siemens Healthcare Diagnostics is helping patients suffering from liver disease, with the launch of the first automated liver fibrosis test – an important indicator of Chronic Liver Disease.

Doctors in primary care are flooded with patients with obesity and hazardous drinking, all of whom could be at risk of chronic liver disease. The use of a simple blood test to accurately identify those with significant liver disease will greatly aid triage and the appropriate targeting of interventions including weight loss, exercise, and therapeutic interventions.

Liver fibrosis refers to the accumulation of tough, fibrous scar tissue in the liver. The formation of this tissue (through the deposition of new collagen) is a normal bodily response to injury, but in fibrosis this healing process goes awry.

The traditional reference standard for detecting and assessing liver fibrosis has been trans-abdominal needle biopsy of the liver. Small sample size and the patchy distribution of some liver pathology can result in a significant degree of sampling error. Also, the procedure can be painful and hazardous; bleeding is caused in approximately one in 1000 cases and death in one in 10,000 cases. This also results in a high cost to the NHS with patients requiring an overnight stay in hospital at a cost of approximately £1,000.

This first fully automated standardised direct biomarker panel offers doctors a quick, reliable, minimally invasive blood test option to assess liver fibrosis – an important 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.

Chronic liver disease, resulting from alcoholic liver disease, fatty liver, or viral hepatitis, is increasingly recognised as a major cause of morbidity and mortality. Standard liver function tests do not accurately reflect the true extent of fibrotic damage or, in many cases, may detect it too late.

Fibrosis is a common outcome in chronic liver disease, with progression to cirrhosis accounting for thousands of deaths each year. Liver biopsies are routinely performed to assess liver damage (fibrosis) and to try to monitor the effectiveness of pharmaceutical drugs in tackling the disease. Performing a liver biopsy is a hazardous, expensive and painful experience for the patient and does not always provide accurate results because of difficulties in sampling and interpretation. Fibrosis is not evenly distributed throughout the liver and because such a small amount of biological material is sampled, 55 percent of 15mm

biopsies may be misclassified. Larger biopsies can be performed but even with 25mm sections, 45 percent will be erroneous.

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 and Joint Director of the Centre for Hepatology at 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 analyser 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.ⁱ

For more information about the Siemens ELF Test, visit www.siemens.com/ELF.

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Notes to editor:

ⁱ 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.

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

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