

## FibroMAX™

### SERVICE SPECIFICATION SHEET

If you have any queries regarding the test specifications outlined below please contact Lab21 Customer Service to discuss prior to sending samples for analysis.

**Intended Use:** To provide a service to measure liver fibrosis, necroinflammatory activity, hepatic steatosis, non-alcoholic steatohepatitis (NASH) and alcoholic steatohepatitis (ASH). FibroMax™ is ordered as a single testing service which comprises of five component tests; FibroTest™, ActiTest™, AshTest™, NashTest™ and SteatoTest™. FibroTest™ measures the level of liver fibrosis. ActiTest™ measures active liver disease. SteatoTest™ measures hepatic steatosis or 'fatty liver'. NashTest™ measures the level of NASH. AshTest™ is used to monitor liver damage in cases of severe ASH.

**Technical Information:** FibroMAX™ performs the following analyses; FibroTest, ActiTest, NashTest, SteatoTest and AshTest. It combines the measurement of 10 indirect parameters adjusted to age, sex, weight & height which include: Alpha 2-macroglobulin, Haptoglobin, Apolipoprotein A1, Total bilirubin, Gamma Glutamyl Transpeptidase (GGT), Alanine Amino Transferase (ALT), Aspartate aminotransferase (ASAT), Fasting glucose, Triglycerides & Total Cholesterol.

Please refer to Form166 "FibroMAX Result Interpretation" for full information on this service. Further information can also be found on our website at [www.lab21.com](http://www.lab21.com)

Serum testing is performed on Dade Behring Dimension® Xpand® and BN ProSpec® systems.

This test has been CE marked under the European IVD Directive 98/79/EC.

**Testing Time:** Turnaround: 48 hours after receipt of sample.

**Specimen Requirements:** Contact your GP or Clinic to arrange for a blood sample to be drawn. Lab21 will provide suitable blood tubes and packaging in the Lab21 Ltd Patient Sample Pack which will be returned for analysis to Lab21 Ltd.

**Specimen Handling:** See Form 145 'Patient Advice Form – FibroMAX™'.

**Reporting of Results:** Test results will be sent to the ordering physician to be discussed with the patient.

- References:**
1. Ratziu V, *et al.* Diagnostic value of biochemical markers(FibroTest FibroSURE) for the prediction of liver fibrosis in patients with non-alcoholic fatty liver disease. *BMC Gastroenterol.* 2006; 6: 6.
  2. Halfon P, *et al.* Independent prospective multicenter validation of *biochemical markers* (Fibrotest-Actitest) for the prediction of liver fibrosis and activity in patients with chronic hepatitis C. *Am J Gastroenterol.* 2006; 101: 547-555.
  3. Poynard T, *et al.* FibroTest-FibroSURE: towards a universal biomarker of liver fibrosis? *Expert Rev Mol Diagn.* 2005; 5: 15-21.
  4. Thabut D, *et al.* The diagnostic value of biomarkers (AshTest) for the prediction of alcoholic steato-hepatitis in patients with chronic alcoholic liver disease. *J Hepatol.* 2006; 44: 1175-1185.
  5. Poynard T, *et al.* The diagnostic value of biomarkers (SteatoTest) for the prediction of liver steatosis. *Com Hepatol.* 2005; 4:10.
  6. Kleiner DE, *et al.* Design and validation of a histological scoring system for non-alcoholic fatty liver disease. *Hepatol.* 2005; 41:1313-1321.
  7. Clark JM, *et al.* The epidemiology of non-alcoholic fatty liver disease in adults. *Clin Gastroenterol.* 2006; (Suppl 1):S5-s10.
  8. Naveau S, *et al.* The diagnostic value of biomarkers for the prediction of liver fibrosis in patients with chronic alcoholic liver disease. *Clin. Gastroenterol.* 2005; 3:167-174.