Non-invasive blood testing for the evaluation and management of liver fibrosis
FibroMeter may help reduce costly and invasive liver biopsies.

A laboratory test combining biomarkers and a liver stiffness measurement by FibroScan to provide enhanced classification accuracy for patients with chronic hepatitis B or C (with or without co-infection with HIV), or patients with non-alcoholic fatty liver disease (NAFLD).

Features and Benefits
- Enhanced classification accuracy
- Integrated patient report combining the FibroScan liver stiffness measurement and FibroMeter results.

Biomarkers Measured
- Platelets, alpha-2-macroglobulin, AST, GGT, prothrombin index

Specimen and Information Required
- FibroScan result (transient elastography)
- 3 mL serum and 1 mL citrated plasma
- Platelet count performed on EDTA whole blood
- Age and gender


For more information, visit www.aruplab.com/fibrometer

>150,000 biopsies performed in the United States
~$300,000,000 healthcare costs in the United States
$2,000 average cost per liver biopsy

* Yearly estimates are based on Medicare and private payer claims data (Definitive Healthcare).
FibroMeter may help reduce costly and invasive liver biopsies.

Specifically designed for patients with chronic viral hepatitis (B, C) with or without HIV co-infection.

Features and Benefits

- High diagnostic accuracy confirmed by a rules-based expert system to detect discordant results
- No interference from patients with Gilbert disease or hemolysis (e.g., induced by ribavirin)
- Enhanced graphical reporting available

Biomarkers Measured

- Platelets, alpha-2-macroglobulin, ALT, AST, GGT, prothrombin index, and urea

Results Provided

Calculated Scores

Score ranges from 0 to 1, 1 being the most severe stage:

- Fibrosis score (FibroMeter)
- Cirrhosis score (CirrhoMeter)
- Activity score (InflaMeter)

Metavir Classifications

Corresponding classifications are reported together with the scores:

- F0—F4 for fibrosis/cirrhosis
- A0—A3 for activity grade

Specimen and Information Required

- 3 mL serum and 1 mL citrated plasma
- Platelet count performed on EDTA whole blood

FibroMeter NAFLD (non-alcoholic fatty liver disease) assesses the stage of liver fibrosis in patients with metabolic steatosis.

Biomarkers Measured

- Platelets, ALT, AST, glucose, and ferritin

Specimen and Info Required

- 3 mL serum and 1 mL citrated plasma
- Platelet count performed on EDTA whole blood

For more information, visit www.aruplab.com/fibrometer
Accurate, Reproducible Results

**FibroMeter** outperforms other non-invasive assessments of liver fibrosis by utilizing an **expert system** to detect anomalous profiles and maximize diagnostic reliability. While liver biopsy remains the reference method for managing patients with chronic liver disease, non-invasive assessment with FibroMeter can triage patients and reduce the number of biopsies.

<table>
<thead>
<tr>
<th></th>
<th>≥F2</th>
<th>F4</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUROC</td>
<td>0.85–0.89</td>
<td>0.91</td>
</tr>
<tr>
<td>Sensitivity %</td>
<td>80.5–89.0</td>
<td>94.1</td>
</tr>
<tr>
<td>Specificity %</td>
<td>84.1–89.9</td>
<td>87.6</td>
</tr>
<tr>
<td>PPV %</td>
<td>82.0–86.3</td>
<td>68.0</td>
</tr>
<tr>
<td>NPV %</td>
<td>77.6–82.5</td>
<td>94.7</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>FibroMeter</th>
<th>Liver Biopsy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nature of Test</strong></td>
<td>Non-invasive</td>
</tr>
<tr>
<td><strong>Advantages</strong></td>
<td>Measures global fibrosis, suitable for serial observations</td>
</tr>
<tr>
<td><strong>Limitations</strong></td>
<td>Indirectly measures functional liver changes</td>
</tr>
<tr>
<td><strong>Risks</strong></td>
<td>Very little risk</td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>Less expensive than biopsy</td>
</tr>
<tr>
<td><strong>Contraindications</strong></td>
<td>None known</td>
</tr>
</tbody>
</table>
Liver Fibrosis, Chronic Viral Hepatitis (Echosens FibroMeter)

Patient Score (Range 0 -1)  
Metavir Classification¹  
FibroMeter (fibrosis score) 0.27 F1[F1-F2]  
Predominance of F1, but F2 is possible  
CirrhoMeter (cirrhosis score) 0.02 F1[F1-F2]  
Predominance of F1, but F2 is possible  
InflaMeter (activity score) 0.31 A1/A2  
Equal probability between A1 and A2

Patient Blood Marker Results

<table>
<thead>
<tr>
<th>Marker</th>
<th>Result</th>
<th>Reference Interval</th>
<th>Units</th>
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</thead>
<tbody>
<tr>
<td>Alpha-2-Macroglobulin</td>
<td>220</td>
<td>131-293</td>
<td>mg/dL</td>
</tr>
<tr>
<td>AST</td>
<td>27</td>
<td>9-40</td>
<td>U/L</td>
</tr>
<tr>
<td>ALT</td>
<td>22</td>
<td>5-40</td>
<td>U/L</td>
</tr>
<tr>
<td>GGT</td>
<td>45</td>
<td>7-33</td>
<td>U/L</td>
</tr>
<tr>
<td>BUN</td>
<td>13</td>
<td>7-20</td>
<td>mg/dL</td>
</tr>
<tr>
<td>Platelets²</td>
<td>150</td>
<td>90-120</td>
<td>k/uL</td>
</tr>
<tr>
<td>Prothrombin Index³</td>
<td>104</td>
<td>90-120</td>
<td>%</td>
</tr>
</tbody>
</table>

Interpretive Information

- Calculations for the final report are based on accurate data for age, gender, and platelet count. If any of this information needs to be corrected, please contact ARUP Client Services to request a recalculation. Client Services may be contacted at (800) 242-2787.
- The Echosens FibroMeter profile serves as a surrogate marker of liver fibrosis, cirrhosis, and necro-inflammatory activity. A proprietary algorithm calculates and compares results from 7 blood markers along with age and gender to provide a patient score (from 0 to 1) and a correlated fibrosis stage (Metavir F0-F4) and activity grade (Metavir A0-A3). The fibrosis/cirrhosis score is further evaluated by a rules-based system to detect anomalous profile results which may modify the fibrosis/cirrhosis score as needed.
- Results should be interpreted in conjunction with the patient’s clinical history; particularly when the rules-based system has modified the scores.

¹ Metavir is a histological scoring system for determining the extent of liver fibrosis and inflammation.

² Patient result provided by client.

³ The Prothrombin Index test expresses the Prothrombin Time (PT) as a percentage of normal, and is used to standardize PT results across different instrument/reagent combinations. Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS