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 aruplab.com/fibrometer
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
- Score ranges from 0 to 1, 1 being the most severe stage:
  - Fibrosis score (FibroMeter)
  - Cirrhosis score (CirrhoMeter)
  - Activity score (InflaMeter)
- 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>


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### FibroMeter vs. Liver Biopsy

<table>
<thead>
<tr>
<th>Nature of Test</th>
<th>Non-invasive</th>
<th>Invasive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advantage</td>
<td>Measures global fibrosis, suitable for serial observations</td>
<td>Direct, evaluates co-existing pathologies</td>
</tr>
<tr>
<td>Limitation</td>
<td>Indirectly measures functional liver changes</td>
<td>Sampling error, inter-observer variability, possible hospitalization</td>
</tr>
<tr>
<td>Risk</td>
<td>Very little risk</td>
<td>Pain, bleeding, pneumothorax, hemothorax, infection</td>
</tr>
<tr>
<td>Cost</td>
<td>Less expensive than biopsy</td>
<td>Expensive</td>
</tr>
<tr>
<td>Contradiction</td>
<td>None known</td>
<td>Uncooperative patient, severe coagulopathy, extrahepatic biliary obstruction, ascites, morbid obesity</td>
</tr>
</tbody>
</table>
Liver Fibrosis, Chronic Viral Hepatitis (Echosens FibroMeter)

Patient Score (Range 0-1) 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

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) 242-2707.

- 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.

- Conditions that may affect prothrombin index include anticoagulant medications, vitamin K deficiency, and bleeding disorders. Conditions that may affect platelet count include thrombocytopenia, anemia, and leukemias.

- Results should be interpreted in conjunction with the patient's clinical history; particularly when the rule-based system has modified the scores.

Liver Fibrosis - FibroMeter Vibration Controlled Transient Elastography (FibroMeter plus FibroScan VCTE)

Patient Score (Range 0-1) 0.37  F1

Interpreter Information

- FibroMeter VCTE is intended to assess liver fibrosis in patients with chronic hepatitis B or C (with or without HIV coinfection) or with non-alcoholic fatty liver disease (NAFLD). A proprietary algorithm was used to integrate the liver stiffness result (measured by FibroScan) with the results of five blood markers plus information on age and gender to provide a liver fibrosis score of F0-4 and a correlated fibrosis stage (Metavir F0-F4).

- If no evidence was provided to indicate the patient’s prothrombin index or platelet count has been affected by other conditions, the standard algorithm was used. Conditions that may affect prothrombin index include anticoagulant medications, vitamin K deficiency, and bleeding disorders. Conditions that may affect platelet count include thrombocytopenia, anemia, and leukemias.

- Results should be interpreted in conjunction with the patient’s clinical history. Interpret results with caution if the patient is pregnant, has acute hepatitis or another cause of chronic liver disease, has severe chronic inflammatory disease such as arthritis, has organ failure other than the liver (i.e., kidney), and/or an iron deficiency condition.

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References

This test was developed and its performance characteristics determined by ARUP Laboratories. The U.S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.