Noninvasive blood testing for the evaluation and management of liver fibrosis
Biopsies performed in the United States*  
>150,000

Healthcare costs in the United States*  
~$300,000,000

Average cost per liver biopsy  
$2,000

* Yearly estimates are based on Medicare and private payer claims data (Definitive Healthcare).

FibroMeter may help reduce costly and invasive liver biopsies.

FibroMeter Virus is specifically designed for patients with chronic viral hepatitis (B, C) with or without HIV coinfection.

Features and Benefits
- High diagnostic accuracy confirmed by a rules-based expert system to detect discordant results
- No interference in specimens collected 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 (nonalcoholic fatty liver disease) assesses the stage of liver fibrosis in patients with metabolic steatosis.

Biomarkers Measured
- Platelets, ALT, AST, glucose, and ferritin

Specimen and Information Required
- 3 mL serum and 1 mL citrated plasma
- Platelet count performed on EDTA whole blood
Accurate, Reproducible Results

FibroMeter outperforms other noninvasive 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, noninvasive assessment with FibroMeter can help triage patients and reduce the number of biopsies.

<table>
<thead>
<tr>
<th></th>
<th>≥F2</th>
<th>F4</th>
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<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>
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<tr>
<td>Specificity %</td>
<td>84.1–89.9</td>
<td>87.6</td>
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<tr>
<td>PPV %</td>
<td>82.0–86.3</td>
<td>68.0</td>
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<tr>
<td>NPV %</td>
<td>77.6–82.5</td>
<td>94.7</td>
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### Nature of Test

<table>
<thead>
<tr>
<th>FibroMeter</th>
<th>Liver Biopsy</th>
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<tbody>
<tr>
<td>Nature of Test</td>
<td>Noninvasive</td>
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<tr>
<td>Advantages</td>
<td>Measures global fibrosis, suitable for serial observations</td>
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<tr>
<td>Limitations</td>
<td>Indirectly measures functional liver changes</td>
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<tr>
<td>Risks</td>
<td>Very little risk</td>
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<tr>
<td>Cost</td>
<td>Less expensive than biopsy</td>
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<tr>
<td>Contraindications</td>
<td>None known</td>
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For more information, visit aruplab.com/fibrometer
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.