## FibroMeter



Non-invasive blood testing for the evaluation and management of liver fibrosis







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



healthcare costs in the United States



## 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**

Calculated Scores	<ul> <li>Score ranges from 0 to 1, 1 being the most severe stage:</li> <li>Fibrosis score (FibroMeter)</li> <li>Cirrhosis score (CirrhoMeter)</li> <li>Activity score (InflaMeter)</li> </ul>
Metavir Classifications	<ul> <li>Corresponding classifications are reported together with the scores</li> <li>F0-F4 for fibrosis/cirrhosis</li> <li>A0-A3 for activity grade</li> </ul>

### **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.

	≥F2	F4
AUROC	0.85-0.89	0.91
Sensitivity %	80.5-89.0	94.1
Specificity %	84.1-89.9	87.6
PPV %	82.0-86.3	68.0
NPV %	77.6-82.5	94.7

Leroy V, et al. Clin Biochem 2008 and Cales P, et al. Hepatol 2005.

### FibroMeter =

	FibroMeter	Liver Biopsy
Nature of Test	Non-invasive	Invasive
Advantages	Measures global fibrosis, suitable for serial observations	Direct, evaluates co-exisiting pathologies
Limitations	Indirectly measures functional liver changes	Sampling error, inter-observer variability, possible hospitalization
Risks	Very little risk	Pain, bleeding, pneumothorax, hemothorax, infection
Cost	Less expensive than biopsy	Expensive
Contradictions	None known	Uncooperative patient, severe coagulopathy, extrahepatic biliary obstruction, ascites, morbid obesity

### Easy Interpretation of Results

Duce:       r.g       Gentor:       Projection:       Collection Date: 10/17/2018         Patient letimitient:       Physician:       Collection Date: 10/17/2018       Received in lab: 10/19/2018         FibroMeter       0.27       F1[F1-F2]       Prodominance of F1, but F2 is possible       Contention Date: 10/22/2018         CirrhoMeter       0.02       F1[F1-F2]       Prodominance of F1, but F2 is possible       Contention Date: 10/22/2018         CirrhoMeter       0.02       F1[F1-F2]       Prodominance of F1, but F2 is possible       Contention Date: 10/22/2018         Patient Elood Marker Results       Interpretive Information	Patient:	Aco:	Gondori	Client:	ARUP Test	Code: 2005661	
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A REAL PROPERTY AND A REAL	Marker           Alpha-2-Macroglobulin           AST           ALT           GGT           BUN           Platelets*           Prothrombin Index*           *           Metavir is a histologic           F0 = no fibrosis           F1 = portal fibrosis w           *	Result           220           27           22           45           13           150           104           xal scoring syst           STAGE           without septla           d by client.	Reference           Interval           131-293           9-40           5-40           7-33           7-20           90-120           em for determin           OF FIBROSIS           FF = 1           FF = 1           F = 4	Units mg/dL U/L U/L mg/dL K/UL %	Interpretive intr Interpretive intr - Calculations for the final report are based on a platelet count. If any of this information needs to Client Services to request a recalculation. Client 242-2787. - The Echoesne FibroMeter profile serves as a s driftosis, and neero-inflammatory activity. A pro- source (from 0 to 1) and a correlated throosis stage (Metavir AO-A3). The fibrosis/cirrhosis score is fi- system to detect anomalous profile results which score as needed. - Results should be interpreted in conjunction wi particularly when the rules-based system has m int of liver fibrosis and inflammatio pta without cirrhosis GRAI Patien	vination courate data for ag be corrected, plea Services may be c urrogate marker of orietary algorithm c the age and gender urther evaluated by a may modify the fil th the patient's clin dified the scores.	e, gender, and see contact ARUP contacted at (800) f liver fibrosis, halculates and to provide a patie and activity grade prosis/cirrhosis nical history; Liver Fi

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ARUP LABORATORIES | 500 Chapter Way, Sat Lose Crip, Unit M106-1221 (Internet (001) 583-2787 | Nit Tele (002) 525-2787 | www.orugateb.idee JULIC C. DIUGADO, MD, ME | Director of Laboratories

#### Patient Score (Range 0-1) Metavir Classification' FibroMeter F1 0.37 (fibrosis score) 0.2 Patient Blood Marker Results Result Reference Units Marker Alpha-2-Macroglobulin 300 131-293 mg/dL AST 33 9-50 U/L GGT 30 7-51 U/L Platelets<sup>2</sup> 225 k/uL Prothrombin Index<sup>3</sup> 100 90-120 %

Physician:

#### Patient FibroScan Results

ARU

Marker	Result	Units
Liver Stiffness <sup>2</sup>	6.0	kPa

Interpretive Information

- FibroMeter VCTE is intended to assess liver fibrosis in patients with chronic hepatitis B or C (with or without HIV co-infection) or with non-alcoholic fatty liver disease (NAFLD). A proprietary algorithm was used to integrate the liver stifmess result measured by FibroScan) with the results of five blood markers plus information on age and gender to provide a liver fibrosis score of 0 - 1 and a correlated fibrosis stage (Metaivr F0 - F4).

0.3

ARUP Test Code: 3001379

Collection Date: 05/29/2019 Received in lab: 05/29/2019 Completion Date: 05/29/2019

n/n

84 85 86 87

0.8

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 protrombin index inclue anticoagulater the directaions, vitamin K deliciency, and bleeding disorders. Conditions that may affect platelet count include thromborybopenia, aremai, and letkemia.

Note: This test is not indicated for patients with conditions affecting BOTH the prothrombin index and platelet counts. If you have questions please contact ARUP Client Services at (800) 242-2787.

 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. It has severe chronic inflammatory disease such as arthritis, has organ failure other than the liver (i.e. kidney), and/or an iron deficiency arthritis. condition.

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

STAGE OF FIBROSIS (F scale)

F0 = no fibrosis F1 = portal fibrosis without septa F2 = portal fibrosis with few septa

F3 = numerous septa without cirrhosis F4 = cirrhosis

<sup>2</sup> Values provided by the client.

<sup>3</sup>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



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Patient: ARUP Accession: 19-149-101804

END OF CHART ARUP Enhanced Reporting | May 31, 2019 | page 1 of 1

#### osis - FibroMeter Vibration Controlled Transient Elastography (FibroMeter plus FibroScan VCTE)

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