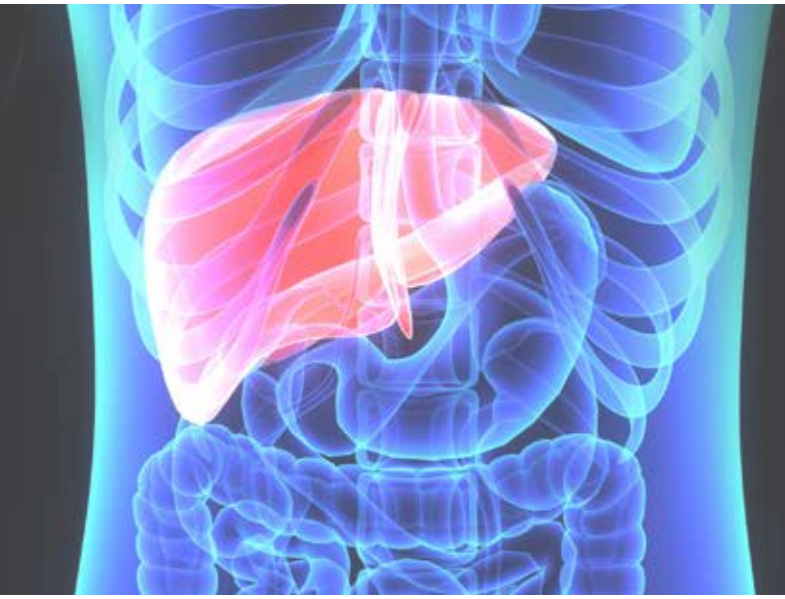
FibroMeter™



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

ARUP® LABORATORIES

>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.

FibroMeter VCTE

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

New! Available Spring 2019.

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

FibroMeter may help reduce costly and invasive liver biopsies.

FibroMeter VIRUS

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

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

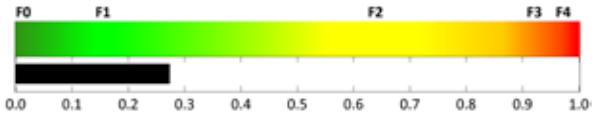
Easy **Interpretation** of Results

ARUP LABORATORIES

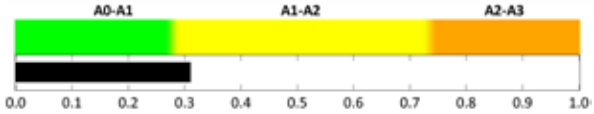
Liver Fibrosis, Chronic Viral Hepatitis (Echosens FibroMeter)

Patient: DOB: Age: Gender: **Patient Identifiers:** **Visit Number (FIN):**	Client: Physician:	ARUP Test Code: 2005661 Collection Date: 10/17/2018 Received in lab: 10/19/2018 Completion Date: 10/22/2018

	Patient Score (Range 0 -1)	Metavir Classification[1]
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	



CirrhoMeter scale is not displayed since FibroMeter is more accurate to determine the fibrosis stage of this patient.



Patient Blood Marker Results

Marker	Result	Reference Interval	Units
Alpha-2-Macroglobulin	220	131-293	mg/dL
AST	27	9-40	U/L
ALT	22	5-40	U/L
GGT	45	7-33	U/L
BUN	13	7-20	mg/dL
Platelets[2]	150		k/uL
Prothrombin Index[3]	104	90-120	%

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.

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

GRADE OF NECRO-INFLAMMATORY ACTIVITY (A scale)
A0 = no activity
A1 = mild activity
A2 = moderate activity
A3 = severe activity

[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

ARUP LABORATORIES | 500 Chipeta Way, Salt Lake City, Utah 84108-1221
phone: (801) 583-2787 | toll free: (800) 522-2787 | www.aruplab.com
JULIO C. DELGADO, MD, MS | Director of Laboratories

Patient:
ARUP Accession: 18-290-120659

END OF CHART

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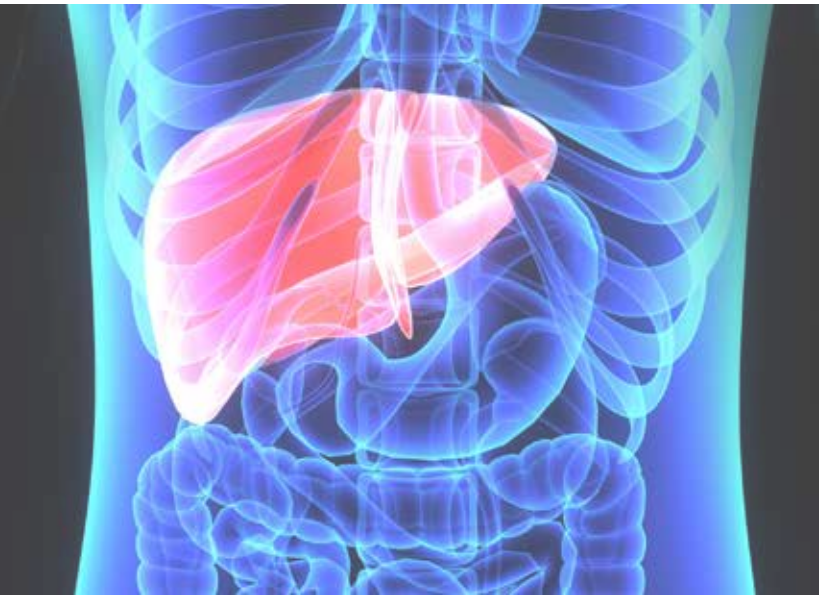
More than 100 Peer-reviewed publications



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ARUP® LABORATORIES

ARUP LABORATORIES
500 Chipeta Way
Salt Lake City, UT 84108-1221
Phone: (800) 522-2787
Fax: (801) 583-2712
www.aruplab.com

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ARUP is a nonprofit enterprise of the University of Utah and its Department of Pathology.

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.