MAYO CLINIC
Mayo Medical Laboratories

TEST OBSOLETE
NOTIFICATION DATE: August 13, 2014
EFFECTIVE DATE: Immediately

Liver Fibrosis Panel (HepaScore)
Test ID: FLFP

EXPLANATION: Effective immediately, Test ID FLFP, referred to Quest Diagnostics Nichols Institute, will become obsolete due to reagent issues. Quest has listed the recommended alternative as LabCorp code 550123.

ALTERNATIVE TEST: FHFIB – Hepatitis C Virus (HCV) FibroSURE

METHODOLOGY: Immunologic, Colorimetric, Kinetic – colorimetric, Nephelometry

REFERENCE VALUES:

Fibrosis Score		0.00 - 0.21
Necroinflammat Activity Score		0.00 - 0.17
Alpha-2-Macroglobulins, Qn		110 - 276 mg/dL
Haptoglobin		34 - 200 mg/dL
Apolipoprotein A-1	Females:	110 - 205 mg/dL
	Males:	110 - 180 mg/dL

Bilirubin, Total

Newborns, term and near term:
24 hours old: 0.0 - 8.0 mg/dL
48 hours old: 0.0 - 12.2 mg/dL
72 hours old: 0.0 - 15.6 mg/dL
96 hours to 1 month old: 0.0 - 1.2 mg/dL
Children 1 month and older and
Adults: 0.0 - 1.2 mg/dL

GGT	Females:	0 - 60 IU/L
	Males:	0 - 65 IU/L
ALT (SGPT)	Females:	0 - 40 IU/L
	Males:	0 - 55 IU/L

Interpretations:
Quantitative results of 6 biochemical tests are analyzed using a computational algorithm to provide a quantitative surrogate marker (0.0-1.0) for liver fibrosis (METAVIR F0-F4) and for necroinflammatory activity (METAVIR A0-A3).
Fibrosis Scoring:

<0.21 = Stage F0 - No fibrosis
0.21 - 0.27 = Stage F0 - F1
0.27 - 0.31 = Stage F1 - Portal fibrosis
0.31 - 0.48 = Stage F1 - F2
0.48 - 0.58 = Stage F2 - Bridging fibrosis with few septa
0.58 - 0.72 = Stage F3 - Bridging fibrosis with many septa
0.72 - 0.74 = Stage F3 - F4
>0.74 = Stage F4 - Cirrhosis

Macroinflamm Activity Scoring:

<0.17 = Grade A0 - No Activity
0.17 - 0.29 = Grade A0 - A1
0.29 - 0.36 = Grade A1 - Minimal activity
0.36 - 0.52 = Grade A1 - A2
0.52 - 0.60 = Grade A2 - Moderate activity
0.60 - 0.62 = Grade A2 - A3
>0.62 = Grade A3 - Severe activity

Limitations:

The negative predictive value of a Fibrotest score <0.31 (absence of clinically significant fibrosis) was 85% when compared to liver biopsy in 1,270 HCV infected patients with a 38% prevalence of significant liver fibrosis (F2, 3 or 4). The positive predictive value of a Fibrotest score >0.48 (F2, 3, 4) was 61% in that same patient cohort. HCV FibroSURE is not recommended in patients with Gilbert Disease, acute hemolysis (e.g. HCV ribavirin therapy mediated hemolysis), acute hepatitis of the liver, extra-hepatic cholestasis, transplant patients, and/or renal insufficiency patients. Any of these clinical situations may lead to inaccurate quantitative predictions of fibrosis and necroinflammatory activity in the liver.

The performance characteristics of this test have been determined by LabCorp. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not currently required. LabCorp is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and is certified to perform high complexity testing.

SPECIMEN REQUIREMENTS:

Draw blood in a plain red-top tube(s) or serum gel tube(s). Separate serum from cells within 1 hour and send 2 tubes of serum, 2.5 mL in first tube and 0.5 mL in second tube frozen in plastic screw-capped tubes. Ship frozen.

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time
Serum	Frozen (preferred)	
	Refrigerated	72 hours

CPT CODE:
82172, 82247, 82977,
83010, 83883, 84460

FEE:
$253.30

DAY(S) SET UP:
Varies: Monday through Friday

ANALYTIC TIME:
10-14 days

QUESTIONS: Contact Mary Erath, MML Referrals Supervisor
Telephone: 800-533-1710