

# **Test Definition: FHFIB**

Hepatitis C Virus (HCV) FibroSURE

Reporting Title: HCV FibroSURE
Performing Location: LabCorp Burlington

### **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 Type	Temperature Time		
Serum	Frozen (preferred)		
	Refrigerated	72 hours	

#### **Result Codes:**

Result ID	Reporting Name	Type Unit		LOINC®
Z0981	HCV FibroSURE Results:	Alphanumeric		N/A
Z0971	Fibrosis Score	Numeric		48795-9
Z0972	Fibrosis Stage	Alphanumeric		48794-2
Z0973	Necroinflammat Activity Score Numeric			48792-6
Z0974	Necroinflammat Activity Grade	Alphanumeric		48793-4
Z0982	Analysis:	Alphanumeric		N/A
Z0975	Alpha 2 Macroglobulins, Qn	Numeric	mg/dL	1835-8
Z0976	Haptoglobin	Numeric	mg/dL	4542-7
Z0977	Apolipoprotein A-1	Numeric	mg/dL	1869-7
Z0978	Bilirubin, Total	Alphanumeric	mg/dL	1975-2
Z0979	GGT	Numeric	IU/L	2324-2
Z0980	ALT (SGPT)	Numeric	IU/L	1743-4



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#### **Components:**

Test ID	Reporting Name	CPT Units	CPT Code	Always Performed	Orderable Separately
Billing only	Bilirubin, total	1	82247		
Billing only	Alanine amino (ALT)(SGOT)	1	84460		
Billing only	Glutamyltransferase,gamma	1	82977		
Billing only	Apolipoprotein, each	1	82172		
Billing only	Haptoglobin, quantitative	1	83010		
Billing only	Nephelometry, each analyt	1	83883		

#### **Reference Values:**

TESTS REFERENCE INTERVAL

HCV FibroSURE Results:

Fibrosis Score 0.00 - 0.21

Fibrosis Stage

Necroinflammat Activity Score 0.00 - 0.17

Necroinflammat Activity Grade

Analysis:

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:



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<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. Comment:

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.

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