Quest Diagnostics™

NAFLD Fibrosis Score

Test Code: 91979

Specimen Requirements: Preferred: 1 mL room-temperature serum (SST, red-top tube) **and** 1 mL room-temperature whole blood (EDTA, lavender-top tube)

Minimum: 0.5 mL serum **and** 0.5 mL whole blood

Patient should fast 9-12 hours prior to specimen collection.

Provide patient information for risk calculation: age, gender, height (feet and inches), weight (pounds), and diabetes status (yes or no).

CPT Codes*: 82947, 84450, 84460, 85049, 82040

CLINICAL USE

- Determine risk of fibrosis in patients with nonalcoholic fatty liver disease (NAFLD)

CLINICAL BACKGROUND

Nonalcoholic fatty liver disease is characterized by steatosis, the accumulation of fat within hepatocytes. Diagnostic criteria include no history of alcohol abuse or other identifiable cause of the steatosis.[1] NAFLD is the most common liver disease worldwide,[2] and is estimated to affect 20% to 46% of people in the United States.[3,4] Risk factors include metabolic syndrome, insulin resistance, diabetes mellitus, obesity, sedentary lifestyle, and a high-fat diet.[5]

The disease ranges from simple, asymptomatic steatosis to nonalcoholic steatohepatitis (NASH), which includes liver inflammation.[1] Approximately 10% to 25% of patients with simple steatosis develop NASH, and 5% to 8% of these develop fibrosis and cirrhosis within 5 years.[1] The degree of liver fibrosis predicts progression and outcome: those with more advanced fibrosis are at higher risk of progression to decompensated cirrhosis, portal hypertension, and death.[6]

In the absence of overt cirrhosis, the nature and stage of NAFLD are assessed based on fibrosis severity seen on liver biopsy.[1] However, liver biopsy is an invasive procedure associated with significant complications and potential for sampling error.[7]

The NAFLD fibrosis score is a noninvasive tool for identifying patients with significant liver fibrosis.[8] The score is based on analytes that are individually useful for evaluating patients with liver disease: alanine aminotransferase (ALT), albumin, aspartate aminotransferase (AST), glucose, and platelet count. The patient age and body mass index (BMI) are also used to calculate the score. A metaanalysis of 13 studies showed that the NAFLD fibrosis score has high accuracy for predicting advanced fibrosis (bridging fibrosis and cirrhosis), with an area under the receiver operating characteristic curve (ROC) of 0.85. A "perfect" test would have an area of 1.0. An NAFLD fibrosis score less than -1.455 excludes significant fibrosis with 90% sensitivity and 60% specificity. A score >0.676 predicts the presence of significant fibrosis with 67% sensitivity and 97% specificity.[9]

Tapper et al reported that use of the NAFLD fibrosis score to stratify patients according to risk of advanced fibrosis is cost-effective. In the study, patients with high risk received care from a specialist, while patients with low risk received care from their primary physician. Only patients with indeterminate risk were offered liver biopsy. Use of the fibrosis score resulted in the lowest number of biopsies, the lowest cost of care, and the highest quality-adjusted life-years when compared to either vibration-controlled transient elastography (VCTE) or standard liver biopsy.[10]

Multiple professional societies recommend use of the NAFLD fibrosis score for the evaluation of NAFLD. These include the American Association for the Study of Liver Diseases (AASLD), the American College of Gastroenterology (ACG), and the American Gastroenterological Association (AGA).[11] European guidelines recommend its use to rule out advanced cirrhosis.[12]

INDIVIDUALS SUITABLE FOR TESTING

- Individuals suspected of having NAFLD

METHOD

Panel components and methods are shown in the Table. Calculation of the NAFLD fibrosis score is based on ALT, albumin, AST, glucose levels, platelet count, age, and BMI.[8]

REFERENCE RANGE

Significant fibrosis:	>0.676
No significant fibrosis:	less than -1.455

Reference ranges for the individual analytes are shown in the laboratory report.

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Table. NAFLD Fibrosis Score Panel Components and Methods

Test Code	Test Name	Method
823	Alanine aminotransferase (ALT)	Spectrophotometry
223	Albumin	Spectrophotometry
822	Aspartate aminotransferase (AST)	Spectrophotometry
483	Glucose	Spectrophotometry
723	Platelet count, EDTA	Electronic cell sizing/counting/ cytometry/microscopy

INTERPRETIVE INFORMATION

An NAFLD fibrosis score less than -1.455 is consistent with the absence of significant fibrosis. A score of >0.676 indicates the presence of significant fibrosis with 90% certainty.[8] Patients with such a score may benefit from liver biopsy or elastography. A score of -1.455 to 0.676 indicates an indeterminate probability of significant fibrosis.

A score cannot be calculated if all patient data have not been supplied (age, weight, height, diabetes status). If the patient was not fasting, caution should be used when interpreting the glucose and fibrosis score results.

References

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12. European Association for the Study of the Liver (EASL); European Association for the Study of Diabetes (EASD); European Association for the Study of Obesity (EASO). EASL-EASD-EASO clinical practice guidelines for the management of non-alcoholic fatty liver disease. *J Hepatol*. 2016;64:1388-1402.

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