

## Non-Alcoholic Fatty Liver Disease Advanced Fibrosis Rule-Out Cascade

### Introduction

Non-alcoholic fatty liver disease (NAFLD) is one of the leading causes of end-stage liver disease, hepatocellular carcinoma, and liver transplantation. Non-alcoholic steatohepatitis (NASH) and fibrosis severity have been identified as important contributing factors to the long-term prognosis of NAFLD patients. Thus, identification of patients at higher risk of NASH and advanced fibrosis is very important to optimize their management. Non-invasive blood biomarkers can help in identifying those patients using a rule-out approach. Liver biopsy is still required to definitively diagnose patients with NASH and NASH fibrosis.<sup>1</sup> However, most patients do not get a confirmatory liver biopsy until very late in the disease, in some cases, until they have liver cirrhosis.

### Use

The Non-Alcoholic Fatty Liver Disease Advanced Fibrosis Rule-Out Cascade's test number is 402205. The intended use of this cascade is to rule out patients with low risk of liver fibrosis. The cascade is intended for use in patients with suspected NASH with advanced fibrosis, including subjects with no alcohol-related disorders and any of the following features:

- Imaging evidence of fat accumulation
- Elevated liver function tests
- Obesity
- Type 2 diabetes
- Metabolic syndrome
- Dyslipidemia
- Polycystic ovary syndrome

These patients may be at high risk for progression to advanced liver fibrosis that can cause a fast progression to end-stage liver disease, hepatocellular carcinoma, and liver transplantation.<sup>1,2</sup>

The NAFLD rule-out cascade starts with AST and Platelets with APRI. APRI (AST to Platelets Ratio Index) is reported to be a simple, noninvasive, and readily available laboratory test index that can stratify patients with NAFLD who are at high or low risk for significant fibrosis and cirrhosis with high degree of accuracy.<sup>2,3</sup> If the APRI result stratifies the patient to be at low risk, the testing will stop and the result will be reported with the following comment:

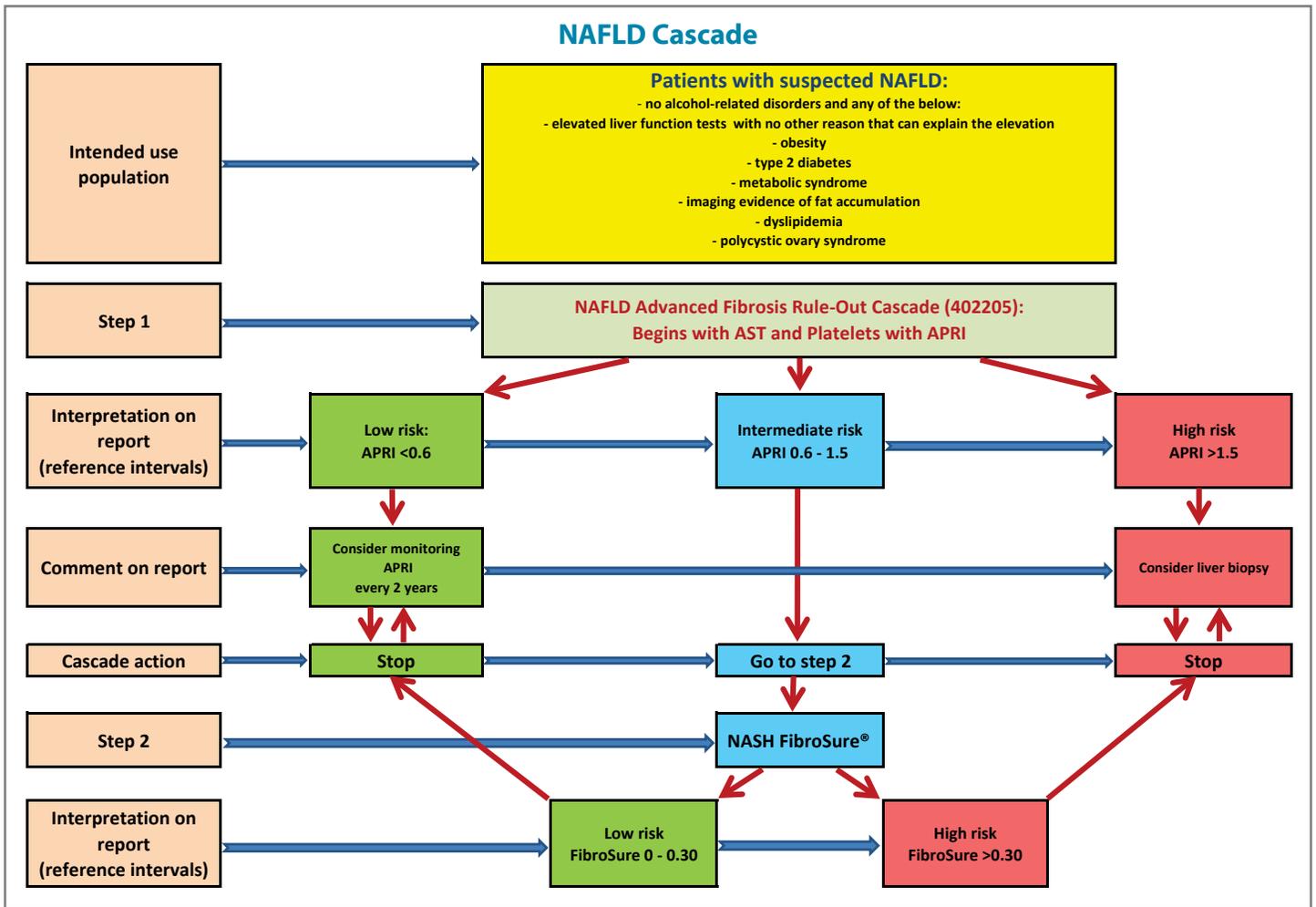
**“Low risk for liver fibrosis, consider monitoring APRI every 2 years.”**

If the APRI result stratifies the patient to be at high risk, the testing will stop and the result will be reported with the following comment:

**“High risk for liver fibrosis, consider liver biopsy.”**

If the APRI result stratifies the patient to be at intermediate risk, the testing cascade will reflex to NASH FibroSure®.

This test is a noninvasive assessment of liver status in patients with NAFLD. Quantitative results of 10 biochemicals in combination with age, gender, height, and weight are analyzed using a computational algorithm to provide a quantitative surrogate marker (0.0 – 1.0) of liver fibrosis, hepatic steatosis, and nonalcoholic steatohepatitis (NASH). The absence of steatosis precludes the diagnosis of NASH.



If the NASH FibroSure® result stratifies the patient to be at low risk, the testing will stop and the result will be reported with the following comment:

**“Low risk for liver fibrosis, consider monitoring APRI every 2 years.”**

If the NASH FibroSure® result stratifies the patient to be at high risk, the testing will stop and the result will be reported with the following comment:

**“High risk for liver fibrosis, consider liver biopsy.”**

LabCorp is pleased to offer NAFLD Advanced Fibrosis Rule-out Cascade that will help physicians in management of patients who may be at risk of fibrosis using the rule-out approach.

**References**

1. Vilar-Gomez E, Chalasani N. Non-invasive assessment of non-alcoholic fatty liver disease: Clinical prediction rules and blood-based biomarkers. *J Hepatol.* 2018 Feb;68(2):305-315.
2. Rinella ME, Sanyal AJ. Management of NAFLD: a stage-based approach. *Nat Rev Gastroenterol Hepatol.* doi: 10.1038/nrgastro.2016.3.
3. Shaheen AA, Myers RP. Diagnostic accuracy of the aspartate aminotransferase-to-platelet ratio index for the prediction of hepatitis C-related fibrosis: a systematic review. *Hepatology.* 2007 Sep;46(3):912-921.

Test Name	Test Number
<b>Non-Alcoholic Fatty Liver Disease Advanced Fibrosis Rule-Out Cascade</b>	<b>402205</b>

For the most current information regarding test options, including specimen requirements and CPT codes, please consult the online Test Menu at [www.LabCorp.com](http://www.LabCorp.com).



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