Siemens ELF test gets FDA breakthrough device designation

August 2023—The FDA has granted a breakthrough device designation for Siemens Healthineers Enhanced Liver Fibrosis test, the only blood test granted FDA marketing authorization for prognostication of disease progression in patients with advanced fibrosis due to nonalcoholic fatty liver disease.

“Advanced liver damage due to NASH often goes unrecognized until after liver decompensation, at which point few interventions are available other than transplant. Earlier identification creates an opportunity for intervention. In some cases, this may halt or even reverse disease progression,” Chuck Cooper, chief medical officer of Siemens Healthineers Diagnostics, said in a press statement. “The limited tools available to aid in diagnosis remain the roadblock to earlier patient care. A simple blood test that can help identify high-risk individuals before disease is clinically evident has the potential for detecting the disease earlier, and subsequent treatment cost savings.”

The test directly measures liver fibrosis and is composed of three direct biomarkers: hyaluronic acid, procollagen III amino-terminal peptide, and tissue inhibitor of metalloproteinase 1 in a proprietary algorithm. Prognostic risk assessments using the test help identify patients who could benefit from additional examinations.

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