Siemens ELF test designated as a breakthrough device

Nov. 14, 2018—The FDA has granted a breakthrough device designation for the Advia Centaur Enhanced Liver Fibrosis Test from Siemens Healthineers. The ELF Test would support clinicians, in conjunction with additional clinical evidence, in assessing the fibrosis stage of chronic liver disease through a blood test. The test is designed to analyze data regarding three serum biomarkers—hyaluronic acid, procollagen III amino-terminal peptide, and tissue inhibitor of metalloproteinase 1—in an algorithm that provides a single ELF score.

“As cases of liver disease increase, so does the demand for efficient, accurate, and noninvasive diagnostic tools,” Deepak Nath, PhD, Siemens’ president of laboratory diagnostics, said in a statement. “Siemens Healthineers is committed to improving the patient experience for those with chronic liver disease, of which nonalcoholic fatty liver disease [NAFLD] accounts for the majority of cases, by seeking a noninvasive prognostic tool to assess the risk of progression to cirrhosis and liver-related clinical events.”

The ELF testing service, for research use only, is exclusively available in the United States for clinical trials testing from Siemens Healthcare Laboratory; the test is not FDA cleared or approved. Siemens is collaborating with Gilead Sciences to seek FDA clearance of the test.