

Put It on the Board

Siemens launches Enhanced Liver Fibrosis test in U.S.

February 2022—Siemens Healthineers' Enhanced Liver Fibrosis test is available in the United States, exclusively through collaboration with Labcorp and Quest Diagnostics. This commercial availability in the U.S. follows de novo marketing authorization from the FDA in August 2021.

The ELF test is used to assess prognosis in patients with advanced fibrosis (F3 or F4) due to non-alcoholic steatohepatitis. It uses a routine blood sample and mathematical algorithm to generate a score that assesses the risk of disease progression.

"The availability of the ELF test at major national reference laboratories brings immediate broad access to patients and clinicians nationwide, providing the best possibility to change the landscape for NASH," Jennifer Zinn, Siemens Healthineers' head of diagnostics, North America, said in a Jan. 26 news release.

Illumina partners with Agendia

Illumina announced on Jan. 10 a multiyear partnership with Agendia to co-develop in vitro diagnostic oncology tests. Agendia joins Illumina's portfolio of more than 30 IVD partners developing more than 40 sequencing-based solutions for cancer prognosis, therapy selection, and other applications.

Illumina and Agendia plan to develop new tests to enhance the management of breast cancer patients, using the Illumina MiSeq Dx sequencing platform to expand the range of gene panels for solid tumor analysis. Illumina said it expects Agendia's MammaPrint test, which is FDA cleared and offered via Agendia's central laboratory, to be the first decentralized NGS-based breast cancer recurrence risk test cleared by the FDA.

Illumina also announced a partnership with Boehringer Ingelheim to develop companion diagnostics for several programs in Boehringer Ingelheim's oncology pipeline. The partnership spans current and future companion diagnostics programs, with plans to add CDx claims to an in vitro diagnostic test Illumina is developing that is based on the content of TruSight Oncology 500. The first program will be to co-develop a companion diagnostic for a Boehringer Ingelheim investigational medicine.

TSO 500 is a research-use-only comprehensive pan-cancer assay designed to identify 523 known and emerging tumor biomarkers. Based on the content of TSO 500, Illumina will be adding an in vitro diagnostic test to the TruSight Oncology product family. This comprehensive tumor profiling assay will have similar chemistry and analytics to TSO 500.

CliniSys acquires Horizon Lab Systems

CliniSys has acquired Horizon Lab Systems and will combine with Sunquest Information Systems, under the brand name CliniSys. Roper Technologies, CliniSys' parent company, owns Sunquest.

This acquisition and Sunquest combination create one of the world's largest organizations dedicated to diagnostics and laboratory informatics, CliniSys said in a Jan. 18 news release.

CliniSys describes its vision as going "beyond the walls of the clinical laboratory to embrace a new wave of digital diagnostics and laboratories across the continuum of care and community to improve public health." Horizon is critical to this vision, it says, with its advanced cloud-based laboratory solutions and expertise in environmental, water quality testing, public health, toxicology, and agriculture laboratory solutions.

CliniSys is headquartered in Chertsey, England and Tucson, Ariz.□