# Put It on the Board

## Roche receives FDA clearance for additional Alzheimer's CSF assays

July 2023—Roche's Elecsys beta-Amyloid (1-42) CSF II (Abeta42) and Elecsys Total-Tau CSF assays (tTau) have received Food and Drug Administration 510(k) clearance. They are used as a tTau/Abeta42 ratio, which will become available in the fourth quarter of this year.

Roche's Elecsys beta-Amyloid (1-42) CSF II (Abeta42) and Elecsys Phospho-Tau (181P) CSF (pTau181) assays (used as a pTau181/Abeta42 ratio) received FDA 510(k) clearance in 2022. The pTau181/Abeta42 ratio is available now.

The only FDA-cleared methods to confirm amyloid pathology are CSF tests and PET scan imaging. Roche says the tTau/Abeta42 ratio is consistent with a negative amyloid PET scan if the result is less than or equal to the cutoff (negative). It is consistent with a positive amyloid PET scan if the result is above the ratio cutoff (positive).

## FDA clears Max Generation 3 hemostasis systems

The Food and Drug Administration issued 510(k) clearance for the Diagnostica Stago Max Generation 3 family of analyzers including STA R Max 3 and STA Compact Max 3.

The company says its Max Generation 3 analyzers offer a combination of Stago's viscosity-based detection system mechanical clot methodology and a comprehensive preanalytical module that ensures quality results with fewer interventions and flags and efficient, automated sample management.

Max Generation 3 analyzers are set to be introduced to the U.S. market at the AACC meeting this month.

Stago says its new expert preanalytical check ensures preanalytical sample integrity with checks for proper fill volumes, hemolysis, icterus, and lipemia in advance of testing with no additional cuvettes, reagents, or plasma consumed.

## Lunaphore to join Bio-Techne

Bio-Techne reached an agreement to acquire Lunaphore, a spacial biology company. The plan is to bring Advanced Cell Diagnostics-branded RNAscope technology together with the Lunaphore Comet platform to develop the first fully automated spatial multiomics workflow with same-slide hyperplex detection of protein and RNA biomarkers.

Comet is an end-to-end spatial biology platform, with staining, imaging, and image preprocessing steps integrated into a fully automated, high-throughput instrument.

## Laboratory data reveal HCV care gap

Only one in three adults with evidence of hepatitis C viral infection achieved viral clearance, despite the availability of curative therapies, according to a June 30 *MMWR* report.

The report is based on an analysis by researchers from the CDC and Quest Diagnostics of deidentified data from laboratory tests performed by Quest on more than 1.7 million individuals between 2013 and 2022.

"This study demonstrates the power of laboratory data to illuminate gaps in care for large populations," coauthor William Meyer, PhD, medical and technical laboratory consultant, Quest Diagnostics, said in a statement.