Put It on the Board

Elecsys Amyloid Plasma Panel granted breakthrough device designation

August 2022—The FDA has granted breakthrough device designation to Roche's Elecsys Amyloid Plasma Panel for detection of early Alzheimer's disease. It detects and measures AD biomarkers in blood plasma to indicate the need for further confirmatory testing.

The panel measures phosphorylated Tau (pTau) 181 protein assay and apolipoprotein (APOE) E4 assay in human blood plasma. Elevations in pTau occur in early stages of the disease. The presence of APOE E4 constitutes the most common genetic risk factor for AD. Patients testing negative with the panel are unlikely to be amyloid positive, Roche says, and should be investigated for other causes of cognitive decline.

Study: chronic HBV, latent TB coinfections and testing

Concurrent testing for chronic hepatitis B and tuberculosis is performed in a minority of patients who test positive for either condition, despite similar risk profiles and, for some, risk of TB therapy-induced liver damage, according to a new Quest Diagnostics Health Trends study (Wong RJ, et al. *J Public Health Manag Pract.* 2022;28[5]:452–462).

The study was conducted by researchers from Quest, Stanford University School of Medicine, and the Veterans Affairs Palo Alto Health Care System. It is based on an analysis of results of 17,635,261 deidentified laboratory tests for hepatitis and 5,205,393 tests for TB performed by Quest between 2016 and 2020.

Among patients tested for both infections, nearly one in five (19.6 percent) with chronic hepatitis B also have latent TB, more than twice the TB positivity of patients without chronic hepatitis B (7.3 percent). Among patients tested for both, the positivity rate for chronic hepatitis B among those latent TB-positive was three times higher than for patients found not to have latent TB (1.5 percent versus 0.5 percent).

Only one in three (32.3 percent) patients who tested positive for latent TB was also tested for HBV infection. Commonly used TB treatments can cause liver injury if administered to patients who are also co-infected with HBV. The study also found that only 10.7 percent of chronic HBV patients were also tested for latent TB.

Chronic HBV infection was defined as any combination of two positive HBV surface antigen, HBV e antigen, or detectable HBV DNA tests at least six months apart. LTBI was defined as a positive QuantiFeron-TB or T-Spot.TB test without evidence of active tuberculosis infection.

A joint venture to fight antimicrobial resistance

Boehringer Ingelheim, Evotec, and BioMérieux announced they have formed a joint venture to create the next generation of antimicrobials and actionable diagnostics to fight antimicrobial resistance.

The resulting company, Aurobac Therapeutics SAS, will combine the capabilities of the three founding companies to develop a new precision medicine approach, the companies said in announcing the news in July.

Alexandre Mérieux, BioMérieux chairman and CEO, said in a statement: "Our role within the joint venture is to develop and commercialize diagnostic tests, including companion diagnostics, which deliver rapid, reliable, and actionable results."

Aurobac will work to shift the strategy related to antibiotic treatment regimens to new effective and targeted modalities combined with rapid and actionable diagnostics.

The joint venture's headquarters will be in Lyon, France, and the company will combine the expertise of life science company Evotec with BioMérieux's expertise in infectious disease diagnostics and with Boehringer Ingelheim's drug discovery and clinical development capabilities.

CellaVision launches workflow solution for low-volume hematology labs

CellaVision launched at the AACC meeting in July its Diff-Line by Cella-Vision, a workflow solution for low-volume hematology laboratories.

Diff-Line by CellaVision consists of three instruments for smearing, staining, and analyzing peripheral blood smears: CellaVision DC-1 (launched in 2019, FDA cleared in 2020), RAL SmearBox, and RAL StainBox.

The DC-1 is a single-slide analyzer that automates and digitizes the analysis of peripheral blood smears. It has an automated microscope, a digital camera, and a computer system that uses artificial intelligence to locate, digitally capture, and preclassify cells from stained blood smears. The preclassified cells are presented on a computer screen for review and verification.

The RAL SmearBox produces peripheral blood smears. The automated instrument uses a patented consumable to produce smears directly from a closed whole sample tube. CellaVision introduced the RAL SmearBox at the AACC meeting.

The RAL StainBox is a semiautomated instrument that uses the bath method and guides the laboratory through a step-by-step staining process. It uses MCDh methanol-free stains to ensure high stain quality and reproducibility while reducing exposure to toxic chemicals.

Diff-Line was available on the European market beginning in July, and CellaVision says it will be rolled out in additional markets this year.

New add-on digital pathology codes

The AMA CPT editorial panel in July released 13 new digital pathology add-on codes for 2023. CPT codes 0751T–0763T will be used to report additional clinical staff work and service requirements associated with digitizing glass slides for primary diagnosis. The new category III codes are the result of work the CAP did with the AMA panel.