Put It on the Board

FDA clears blood test for concussion assessment

April 2023—Abbott has received FDA clearance for its Alinity i TBI laboratory test for traumatic brain injury. The test provides a result in 18 minutes to help clinicians assess concussion and triage patients.

The Alinity i TBI test measures complementary biomarkers in blood plasma and serum—ubiquitin C-terminal hydrolase L1 (UCH-L1) and glial fibrillary acidic protein (GFAP)—that, in elevated concentrations, are tightly correlated to brain injury. Abbott reports that it provides test results with 96.7 percent sensitivity and 99.4 percent negative predictive value.

The test is for use as an aid in evaluating patients, age 18 or older, who present with suspected mild traumatic brain injury (Glasgow Coma Scale score 13–15) within 12 hours of injury, to assist in determining the need for a CT scan of the head.

The test previously received European Union clearance and has been available in markets outside the United States since 2021. Abbott's i-Stat TBI Plasma test was cleared in 2021.

Roche, Lilly to collaborate for early Alzheimer's disease diagnosis

Roche has entered into a collaboration with Eli Lilly and Company to support the development of Roche's Elecsys Amyloid Plasma Panel. The FDA granted the panel breakthrough device designation in July 2022.

If approved, Roche says, the panel test would be an additional tool to identify low likelihood of amyloid pathology in patients with symptoms of Alzheimer's disease and to determine whether they should proceed to further evaluation and testing that may confirm a diagnosis.

The panel measures phosphorylated tau (pTau) 181 protein assay and apolipoprotein (APOE) E4 assay in human blood plasma.

FDA clears high-throughput test for infectious vaginitis

BD received 510(k) clearance from the FDA for its BD Vaginal Panel on the BD Cor system.

The BD Vaginal Panel is a microbiome-based PCR assay that uses a single swab and test to simultaneously detect organisms associated with bacterial vaginosis, vulvovaginal candidiasis, and *Trichomonas vaginalis,* and it reports a clear positive or negative result for each condition separately. The 510(k)-cleared BD Vaginal Panel on the BD Cor system is the first high-throughput version of the test. The panel was launched in 2016 for use on the BD Max system.

Urging legislative solutions to pathologist shortage

In a March 20 letter, CAP president Emily Volk, MD, listed the steps Congress should take to reduce the shortage of pathologists.

A February hearing of the Senate Committee on Health, Education, Labor and Pensions on health care workforce shortages prompted committee chair Sen. Bernie Sanders (I-Vt.) and ranking member Sen. Bill Cassidy, MD (R-La)., to request information on the drivers of the workforce shortage and the remedies.

The primary drivers of the pathologist workforce shortage seem to be, Dr. Volk said, a lack of Medicare-supported GME positions, a demand for pathologists that is far exceeding the supply of new pathologists, the J-1 visa home country requirement, the lack of incentives to practice in rural and underserved areas, and state and local governments not providing the funding needed for resources for forensic pathologists.

One of the CAP's recommendations to remedy the shortage is for Congress to pass the soon-to-be-reintroduced Resident Physician Shortage Reduction Act, which would provide 14,000 new Medicare-supported graduate medical education positions over seven years. While not enough to remedy the shortage, Dr. Volk said, the 14,000 positions "are a critical step in the right direction."

Another recommendation is to craft and pass legislation that would reserve a certain number of Medicare-supported GME positions only for pathology.

Dr. Volk said the CAP also supports the Conrad State 30 and Physician Access Reauthorization Act (S. 665), which will increase the number of waivers for a state from 30 to 35 and provide incentive for qualified international medical graduates who are citizens of other nations to work in underserved communities. "For agreeing to these terms," Dr. Volk said, "physicians will not have to leave the U.S. for two years before they are eligible to apply for an immigrant visa or permanent residence," thus making it possible for them to begin to provide patient care once they complete their residency.

The CAP's other recommendations are to pass the Specialty Physicians Advancing Rural Care Act (S. 705), craft and pass legislation establishing student loan repayment options and greater physician visa waiver flexibility for forensic pathologists, pass the Resident Education Deferred Interest Act (S. 704/H.R. 1202), oppose legislation that would expand the scope of practice for nonphysician practitioners, and establish a National Health Care Workforce Commission.

The full letter is at https://capatholo.gy/40EnzRJ.