Put It on the Board

Lumipulse G β-Amyloid Ratio test has breakthrough device designation

March 2019—Fujirebio Diagnostics received on Feb. 1 breakthrough device designation from the FDA Center for Devices and Radiological Health for its Lumipulse G β-Amyloid Ratio (1-42/1-40) quantitative in vitro diagnostic test.

The test uses measurable β-amyloid 1-42 and β-amyloid 1-40 concentrations found in human cerebral spinal fluid and combines those concentrations into a numerical ratio of β-amyloid 1-42/β-amyloid 1-40 to estimate the presence of β-amyloid neuritic plaque pathology in the brain.

The Lumipulse G β-Amyloid Ratio (1-42/1-40) combines the results of Lumipulse G β-amyloid 1-42 and β-amyloid 1-40 using the Lumipulse G System. The ratio results are intended to aid in assessing adult patients, ages 50 and over, who present with cognitive impairment and are being evaluated for Alzheimer's disease and other causes of cognitive decline. The results must be interpreted in conjunction with other diagnostic tools such as neurological examination.

A negative Lumipulse G β-Amyloid Ratio (1-42/1-40) result is consistent with a negative amyloid PET scan result. A positive Lumipulse G β-Amyloid Ratio (1-42/1-40) result is consistent with a positive amyloid PET scan result. A positive result does not establish a diagnosis of AD or other cognitive disorder. This test is not intended as a screening or standalone diagnostic assay.

FDA grants de novo designation for AML/MDS FISH probes

Oxford Gene Technology has been granted de novo classification by the FDA for eight Cytocell Aquarius Hematology FISH probes for acute myeloid leukemia and myelodysplastic syndromes.

The probes form the largest FDA-cleared in vitro diagnostic FISH probe range for AML and MDS on the market, according to OGT, and will address a substantial proportion of hematological FISH testing. The cleared probes will reduce the level of validation required in laboratories, OGT says, and provide accurate, easy-to-interpret detection of chromosomal rearrangements reported in AML and MDS.

The FDA-cleared Cytocell Aquarius FISH probes are as follows:

- AML1/ETO (RUNX1/RUNX1T1) Translocation, Dual Fusion
- CBFβ (CBFB)/MYH11 Translocation, Dual Fusion
- Del(5q) Deletion
- Del(7q) Deletion
- Del(20q) Deletion
- EVI1 (MECOM) Breakapart
- MLL (KMT2A) Breakapart
- P53 (TP53) Deletion

FDA clears digital PCR system and test for monitoring CML treatment

Bio-Rad Laboratories' QXDx AutoDG ddPCR System, which uses Bio-Rad's Droplet Digital PCR technology, and the QXDx BCR-ABL %IS Kit are the first digital PCR products to be cleared by the Food and Drug Administration. Bio-Rad says its system and kit, when used together, can precisely and reproducibly monitor molecular response to

treatment in patients with chronic myeloid leukemia.

The QXDx AutoDG ddPCR System is designed to be flexible, allowing users to run on the platform either FDA-cleared in vitro diagnostic tests or lab-developed tests.

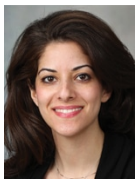
Thermo Fisher signs agreement to sell AP business

Thermo Fisher Scientific has signed a definitive agreement to sell its anatomic pathology business to PHC Holdings for about $1.14 billion in cash.

The anatomic pathology business generates about $350 million in annual revenue and is part of Thermo Fisher's Specialty Diagnostics Segment. Thermo Fisher expects to close the transaction in the second quarter of this year.

In vivo, ex vivo microscopy section in *Archives*

The first of two special sections on in vivo and ex vivo microscopy is published in this month's issue of *Archives of Pathology & Laboratory Medicine*.



Dr. Hariri

Six articles provide information on the optical imaging modalities, potential clinical applications, ongoing research areas in applications and technology development, and how IVM and EVM can be incorporated into the clinical workflow of pathologists.

"We hope the special section will excite and inspire the community with the opportunities IVM and EVM provide for pathologists to expand their skills beyond traditional microscopy," Lida P. Hariri, MD, PhD, organizer of the special section, tells CAP TODAY. Dr. Hariri is an assistant professor of pathology at Massachusetts General Hospital and Harvard Medical School and vice chair of the CAP IVM Committee.

Dr. Hariri says IVM and EVM are primed for use in many "high-impact clinical applications," but before the technologies can become part of standard clinical care, the field will need an expert in interpretation. "The field requires a designated expert who has expertise in microscopic disease features, experience with pattern recognition, and broad knowledge of disease entities that can occur in each organ setting. This," she says, "makes pathologists the perfect choice to step into this emerging role."

IVM provides the opportunity to visualize disease at a microscopic level in real time within patients. Among its applications are disease detection for guided biopsy (Barrett's esophagus, lung nodules, breast lesions), in vivo margin assessment for tumor resection, "and possibly even primary diagnosis, particularly in settings where biopsy is risky for patients," Dr. Hariri says. The technologies can also be used to assess excised tissue in a benchtop setting for tissue block selection for specimen grossing and/or biobanking, identification of disease that is not grossly visible, rapid core biopsy adequacy assessment, and as a complement to frozen section.

"Because of the synergies between IVM/EVM and traditional pathology," Dr. Hariri says, "pathologists are an obvious choice to fill this need."

The CAP worked with the AMA's CPT editorial panel and Relative Value Scale Update Committee to establish in 2013 the new pathology CPT code 88375: *Optical endomicroscopic image(s), interpretation and report, real time or referred, each endoscopic session.* In 2016, additional CPT codes were added for reflectance confocal microscopy of skin. Category III CPT codes are in place for optical coherence tomography of breast. The CAP continues to be

active in CPT and RVS Update Committee processes.

“EVM does not currently have a reimbursement code,” Dr. Hariri says. “However, we anticipate that as a larger number of studies are published demonstrating the impact of EVM on clinical care, a reimbursement code may be successfully obtained for EVM just as it was for IVM.”

The second special section will be published in an upcoming issue of *Archives*. —Sherrie Rice

New celiac test ordering module for CAP program

A module on celiac disease testing is the latest to be added to the CAP Test Ordering Program, which provides CAP members with information about commonly misapplied lab tests so optimal ordering can be addressed with clinicians and others.

The celiac disease module is the program’s sixth module. The others are on HCV infection, colorectal cancer biomarkers, BNP and NT-proBNP, RBC folate testing, and cardiac markers. The program became available in 2017 and is free to all members. For the modules, go to www.cap.org/member-resources/test-ordering-program.