Put It on the Board

FDA approves CRCdx RAS Mutation Detection Kit as companion diagnostic

December 2023—The Food and Drug Administration granted approval for EntroGen's CRCdx RAS Mutation Detection Kit as a companion diagnostic for Vectibix (panitumumab), used in the treatment of colorectal cancer.

The mutation detection kit, which EntroGen said is available immediately, is a qualitative real-time PCR in vitro diagnostic test intended for the detection of 35 variants of *KRAS* and *NRAS* exon 2, 3, 4 somatic mutations in genomic DNA extracted from formalin-fixed, paraffin-embedded colorectal cancer tissue samples. It is intended as a companion diagnostic to aid in identifying colorectal cancer patients who may benefit from treatment with Vectibix based on a no-mutation-detected test result in accordance with the approved therapeutic product labeling.

Paige Lymph Node granted breakthrough designation

The Food and Drug Administration granted breakthrough device designation for Paige Lymph Node, an AI application used to detect breast cancer metastases in lymph node tissue. It is the first AI application of its kind to receive FDA breakthrough device designation.

Paige Lymph Node is derived from a deep learning model that has been trained with more than 32,000 digitized H&E lymph node slides. If the lymph node tissue is suspicious for cancer, it will highlight each area of concern for further review by the pathologist.

Paige's Prostate Detect is the only FDA-authorized digital pathology application to date.

Roche HPV test approved for use on Cobas 5800

The Food and Drug Administration approved the Cobas HPV test for use on Roche's next-generation Cobas 5800 molecular instrument, which will broaden access to HPV testing in midsize and smaller labs in the U.S.

The Cobas HPV test is indicated for use in routine cervical cancer screening as per medical guidelines, including triage of ASC-US cytology, cotesting with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. The Cobas 5800 supports loading primary collection vials directly onto the compact system.

Elecsys NfL test granted breakthrough designation

The Roche Elecsys Neurofilament Light Chain test for multiple sclerosis received Food and Drug Administration breakthrough device designation. The NfL test is intended to be used as an aid in detecting disease activity in adults (ages 18 to 55) with relapsing-remitting multiple sclerosis or secondary progressive multiple sclerosis.

Increases in NfL concentrations have been reported in individuals with other neurodegenerative diseases, such as Alzheimer's and Huntington's diseases, and in indications beyond neurology.

Elecsys NfL has the potential to help scale multiple sclerosis testing on automated and standardized Roche Cobas instruments.

The FDA last year also granted breakthrough device designation to Roche's Elecsys Amyloid Plasma Panel.

Abbott HPV test approved for use as primary screen

Abbott received Food and Drug Administration approval for its Alinity m high-risk HPV assay.

The assay is approved as a test for HPV detection and for use in routine cervical cancer screening as per medical

guidelines. It is also approved for use in cotesting. It provides information on five risk groups covering the 14 potentially cancer-causing genotypes of the virus.

“The Alinity m HR HPV assay was carefully designed to support patient care and streamline HPV testing,” Keith Cienkus, Abbott vice president of molecular business, said in a Nov. 2 news release.