Put it On The Board, 3/13

FDA clears ALK automated gene scanner

Applied Spectral Imaging's Gen-ASIs Scan & Analysis automated microscopy platform has received FDA clearance as an aid in ALK gene analysis for lung cancer therapy selection. It offers a way to perform genetic analysis on tissue samples, stained with the Abbott ALK probe kit, and identify the ALK gene rearrangement.

The platform makes possible walkaway automated genetic tissue scanning, using an 81-slide continuous scanning robot.

Abbott's Vysis ALK Break Apart FISH probe test is designed to identify ALK-positive non-small-cell lung cancer patients for Pfizer's Xalkori (crizotinib) oral ALK inhibitor.

Precision medicine center at Weill Cornell, NY-Presbyterian

Weill Cornell Medical College and NewYork-Presbyterian Hospital have formed the Institute for Precision Medicine at Weill Cornell and NewYork-Presbyterian/Weill Cornell Medical Center. Pathologist Mark Rubin, MD, a prostate cancer expert, will lead the translational medicine research hub.

The institute's genomic research discoveries will be of help in the development of novel, personalized therapies to be tested in clinical trials. A comprehensive biobank will be built to improve research and patient care.

Genomics sequencing, biobanking, and bioinformatics are the three main resources that will facilitate the institute's work. Weill Cornell and New-York-Presbyterian will invest in technology to conduct sequencing, a more expansive biobank for all patient specimens and tissue samples, and dedicated bioinformaticians.

Dr. Rubin is vice chair for experimental pathology, director of Translational Research Laboratory Services, Homer T. Hirst III professor of oncology, professor of pathology and laboratory medicine, and professor of pathology in urology at Weill Cornell and a pathologist at NewYork-Presbyterian/Weill Cornell.

"This institute will revolutionize the way we treat disease, linking cutting-edge research and next-generation sequencing in the laboratory to the patient's bedside," Dr. Rubin said in a statement. "We will use advanced technology and the collective wealth of knowledge from our clinicians, basic scientists, pathologists, molecular biologists, and computational biologists to pinpoint the molecular underpinnings of disease—information that will spur the discovery of novel treatments and therapies."

Sequence-based system cleared for HLA typing

Life Technologies on Feb. 5 received FDA 510(k) clearance for its Applied Biosystems' 3500 Dx genetic analyzers and its Invitrogen SeCore human leukocyte antigen typing kits.

The 3500 Dx/3500xL Dx CS2 genetic analyzers, SeCore HLA sequencing kits, and uType Dx HLA sequence analysis software constitute the first 510(k)-cleared sequence-based system for HLA typing in the United States. Clearance is expected to facilitate the development of additional assays using the 3500 Dx and open up new partnerships with assay developers.

"Sanger sequencing remains the gold standard for providing the reliable results clinical labs need, and 510(k) clearance of the 3500 Dx will help to establish sequencing technology as a mainstay of the hospital lab," Ronnie Andrews, Life Tech's president of medical sciences, said in a statement. "The instrument was designed with the

clinical laboratory in mind, featuring a novel design that incorporates the ability to track reagent usage with radio frequency identification tags, as well as redesigned data collection and analysis software."

Abbott to collaborate on companion CLL test

Abbott will partner with Janssen Biotech and Pharmacyclics to explore the benefits of Abbott's FISH technology for use in developing a molecular companion diagnostic test to identify patients with a genetic subtype of chronic lymphocytic leukemia.

Under the deal, Abbott will develop a FISH-based test to identify high-risk CLL patients who have a deletion within chromosome 17p (del17p) and who may respond to ibrutinib, an oral, small-molecule inhibitor of Bruton tyrosine kinase. Janssen and Pharmacyclics are developing ibrutinib for several B-cell malignancies, including chronic leukemia and lymphoma.

Patients harboring a deletion within chromosome 17p are poor responders to chemoimmunotherapy and have limited treatment options.

Cepheid, OHSU to develop oncology assays for Xpert

Cepheid and the Knight Cancer Institute at Oregon Health and Science University will collaborate to develop clinical oncology tests to be performed on Cepheid's GeneXpert system.

The collaboration will establish a system for clinically validating the tests through Knight Diagnostic Laboratories, a division of Knight Cancer Institute. The alliance includes an exclusive license to OHSU intellectual property in prostate cancer and intellectual property co-developed by Lawrence Berkeley National Laboratory and OHSU in breast cancer.

"I think it's a very creative alliance to help enable university-based biomarker signatures to get onto a leading molecular diagnostics platform," Joseph M. Carroll, PhD, told CAP TODAY. Dr. Carroll is associate director of business development, Knight Cancer Institute.

Initial projects include developing the Xpert breast cancer signature test to predict the risk of recurrence in newly diagnosed patients and the Xpert prostate cancer recurrence risk test to predict the likelihood of recurrence in patients after surgery, as well as other prostate cancer applications.

Leading the research will be Joe W. Gray, PhD, associate director of translational research at Knight Cancer Institute, and Michael Bates, MD, Cepheid's vice president of oncology R&D.

The first projects will build on research conducted at Knight Cancer Institute to improve molecular testing to ensure patients receive the right treatment for their tumor's biology.

The collaboration includes an option for Knight Diagnostic Laboratories to develop laboratory-developed tests comprising the multiplexed gene-expression signatures that will eventually appear on the GeneXpert system.

Clarient adopts Qiagen KRAS

Qiagen announced that Clarient has adopted its Therascreen KRAS RGQ PCR kit to be used as a companion diagnostic to guide the use of Erbitux (cetuximab) as a treatment in patients with metastatic colorectal cancer. Clarient selected the Therascreen KRAS test and Qiagen's Rotor-Gene Q MDx instrument after FDA approval of the test in July 2012.

Test could reduce number of repeat biopsies

MDxHealth's ConfirmMDx for Prostate Cancer test correctly identified 68 percent of prostate cancer cases that were false-negative based on histology alone and accurately identified 64 percent of prostate cancer-free men who could safely avoid repeat biopsies. Those are the results of a study that examined prostate biopsy samples from 483 men at high risk for prostate cancer, published this month in the Journal of Urology (2013;189: 1110–1116).

ConfirmMDx assesses the DNA methylation status of the GSTP1, APC, and RASSF1 genes. The effectiveness of the multiplex PCR assay was evaluated in the blinded, multicenter MATLOC (Methylation Analysis To Locate Occult Cancer) study conducted in the UK and Belgium.

Investigators in the study compared the performance of ConfirmMDx to histopathological review of prostate tissue collected via needle biopsy in men at high risk but who had negative biopsy results. Archived tissue samples from previous biopsies of 483 men at high risk were tested with ConfirmMDx, and the results were compared to the cancer detection rate in the repeat biopsies performed on the same patients within 30 months.

In a multivariate model, correcting for age, PSA, digital rectal examination, and histopathological characteristics of the first biopsy, ConfirmMDx proved to be the most significant, independent predictor of patient outcome with an odds ratio of 3.17 (95 percent confidence interval: 1.81–5.53) along with atypical cells in the first biopsy (3.17 odds ratio; 95 percent confidence interval: 1.31–7.70).

The authors conclude: "With the implementation of this epigenetic assay with 68% sensitivity and 64% specificity, the number of unnecessary repeat biopsies can be substantially decreased by up to 64%. Furthermore, the rate of false-negative results can be significantly lowered, resulting in a 90% NPV compared with 70% for histopathology alone."

Ventana, Biocare sign p63 license agreement

Ventana Medical Systems, a member of the Roche Group, and Biocare Medical, LLC have entered into a nonexclusive license agreement to allow Biocare access to certain patents and materials related to p63 diagnostics in the research and IVD field. In parallel, Biocare and AsymmetRx Medical have settled their dispute as it relates to the p63 technology. As part of the settlement, Biocare has gained a worldwide license through Ventana to distribute p63 (4A4) mouse monoclonal primary antibody in both the research and IVD markets, and AsymmetRx has agreed to terminate all patent infringement litigation.

AsymmetRx holds the exclusive worldwide license under the Harvard Medical School patent filings for the use of the p63 antibody as an aid in the diagnosis of prostate and other cancers.