Put It on the Board, 4/17

At OSU, Inspirata completes deployment of WSI scanners, launches Consultation Portal

Inspirata has completed what it describes as the largest single-site deployment of whole slide image scanners at the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (The James) and the Department of Pathology, both located at Ohio State University Wexner Medical Center, Columbus.

The Scan Facility includes Philips IntelliSite Digital Pathology Solution with eight IntelliSite Ultra-Fast Scanners and other specialty scanners located on- and off-site for remote microscopy, frozen section scanning, and large format slide scanning. These specialty scanners include devices from Huron and Sakura, among others.
Anil Parwani, MD, PhD, director of digital pathology at The James, said in a statement, “We are truly excited to be the first pathology department in the country to implement this type of robust, end-to-end digital pathology solution and the benefits it will ultimately provide to our patients.” Dr. Parwani is vice chair and director of anatomic pathology at Ohio State University College of Medicine Department of Pathology.

In other news, Inspirata announced its launch of a cloud-based, HIPAA-compliant Consultation Portal that is customizable for sending and receiving institutions. The portal enables the receiving institution’s pathologists to review digital pathology images and case details on complex cases uploaded from partner institutions anywhere in the world. The consulting pathologist can then review the case and communicate with the sending physician via email alerts and messages, including providing amendments after the case is signed out.

Partner institution physicians who want to submit a case for review can log in to their institution’s portal to create and manage cases for consultation, identifying the type of subspecialist review required and/or selecting the subspecialty pathologist they want to review their case. They then upload whole slide image files along with other diagnostic images, case notes, and additional relevant patient information and files. The portal provides email alerts and messaging options for two-way communications between both physicians. Payment can be made within the Consultation Portal on a per-slide or per-case basis through an integration with Payum or through the consulting institution’s billing system.

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FDA clears DxC 700 AU chemistry analyzer

Beckman Coulter Diagnostics announced FDA clearance and the U.S. commercial launch of its DxC 700 AU chemistry analyzer. The company says the new system brings together the capabilities of two Beckman Coulter products—the design of the DxC analyzer and the throughput and workhorse capabilities of the AU analyzer—into one standardized platform to meet the needs of mid- to high-volume clinical laboratories.

The DxC 700 AU chemistry analyzer reduces the number of test-processing steps by 30 percent, according to the company, as well as the total cost of ownership by using fewer consumables compared with other industry same-class systems. The system uses concentrated reagents, long-lasting ion-selective electrodes, and non-disposable cuvettes.
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IncellDx releases OncoTect iO Single Cell PD-L1 assay

IncellDx has released its OncoTect iO Quantitative, Single Cell PD-L1 Assay, for research use only. The test kit includes labeled antibodies to PD-L1 and CD45, CD8, and CD3 cell subsets plus a DNA dye for cell cycle and quantitative detection of PD-L1 expression in non-small cell lung cancer tissue.

Single cell preparations from tumor tissue are first prepared using the IncellPREP (IVD) Single Cell Tissue Kit, then processed using the OncoTect iO kit. PD-L1 is quantified on immune and tumor cells, including tumor cells in different phases of the cell cycle, using flow cytometry.

The company said the kit can be used on numerous sample types including FNA, core biopsies, and blood and different tumor types including lung, bladder, and head/neck cancers.
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Qiagen launches JAK2 test

Qiagen launched its Ipsogen JAK2 RGQ PCR Kit, which was cleared by the Food and Drug Administration as a qualitative IVD test for the detection of the JAK2 V617F/G1849T allele in genomic DNA extracted from EDTA whole blood. The JAK2 assay is processed on Qiagen's Rotor-Gene Q MDx system.

Qiagen says its Ipsogen JAK2 assay is the first FDA-cleared kit for the JAK2 V617F mutation, important for the diagnosis of polycythemia vera, according to the 2016 WHO classification of myeloid neoplasms.

Qiagen reported that the clinical performance of the Ipsogen JAK2 assay was evaluated during a multicenter, international, prospective, interventional study. The study demonstrated 94.6 percent sensitivity and 98.1 percent specificity for the diagnosis of PV, together with a 100 percent positive percentage agreement and a 99.4 percent negative percentage agreement to bidirectional sequencing.
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AMP issues guidelines for NGS oncology panel validation

The Association for Molecular Pathology published on March 22 "Guidelines for validation of next generation sequencing (NGS)-based oncology panels: a joint consensus recommendation of the Association for Molecular Pathology and College of American Pathologists."

"In this era of precision medicine, NGS has quickly become the method of choice for detecting multiple somatic

variants, diagnosing disease, and predicting response to targeted therapies. However, the required analytical validation process remains challenging," Lawrence Jennings, MD, PhD, attending pathologist at Ann and Robert H. Lurie Children's Hospital of Chicago, said in a statement. "AMP convened and led a multidisciplinary subject matter expert working group with liaison representation from CAP to summarize current knowledge, expose challenges, and provide guidance on how to best validate these tests to ultimately improve patient care." Dr. Jennings was chair of the NGS Validation Working Group of the AMP Clinical Practice Committee.

The AMP is in the process of providing a series of guidelines designed to improve the entire NGS workflow. The latest report addresses NGS test development, optimization and familiarization, and best practices for establishing test performance characteristics. The recommendations emphasize the critical role of the molecular laboratory director in establishing and using an error-based approach for patient risk management.
The full report is at http://dx.doi.org/10.1016/j.jmoldx.2017.01.011.

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Siemens receives FDA premarket approval of HCV genotyping test

The Food and Drug Administration has granted premarket approval for the Versant HCV Genotype 2.0 Assay (LiPA) from Siemens Healthineers.

The assay identifies all six genotypes and subtypes 1a and 1b. In particular, the inclusion of the HCV Core region allows for accurate differentiation of subtypes 1a and 1b, as well as determination of genotype 6. A single-step RT-PCR kit that can be used on commonly available thermocyclers provides ease of use and increased laboratory efficiency, according to the company.
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Promega has compact CE

Promega has announced the development of a benchtop capillary electrophoresis instrument in collaboration with Hitachi High-Technologies. The Spectrum Compact CE System meets small batch and single sample needs in DNA analysis and performs sequencing and fragment analysis.

The Compact CE system makes it possible for laboratories of all sizes to carry out single nucleotide polymorphism, PCR sizing and microsatellite analysis, de novo sequencing, NGS validation, and mutation detection. The benchtop CE instrument runs up to 32 samples at once and features four-capillary, six-dye detection along with an integrated touchscreen for instrument operation.

"This opens new possibilities to scientists seeking high-quality DNA detection on a smaller scale," says Doug Storts, Promega's head of research–nucleic acid technologies. The system is expected to be commercially available in the second half of this year.
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Volunteers needed in Liberia

Pathologists Overseas and the American Society for Clinical Pathology are seeking board-certified MD cytologists and credentialed cytotechnologists for deployment to Liberia in West Africa to assist with clinical service, teaching, and training of the Liberian workforce in diagnostic pathology services.

Liberia is engaged in a workforce development program in all health sectors through a World-Bank–funded program led by Mt. Sinai Hospital of New York City. The program will bring volunteers across all health care specialties to Liberia for short- and long-term visits to train staff and provide clinical support. The goal is a self-sustaining health care workforce in Liberia. For pathology, the initial approach is through cytology using FNA to

gather data on epidemiology of disease and provide diagnostics for treatment. The program is expected to evolve to include standard histology services within the first year.

Pathologists Overseas is recruiting in-country volunteers in parallel with ASCP, which is helping to build physical infrastructure, including anatomic pathology laboratories, telepathology services, and technical support. Pathology volunteers will be asked to visit for at least two weeks (four to six weeks preferred). Housing, local transportation, and licensing costs are covered; airfare is the volunteer's expense (a 501(c)(3) letter for tax purposes can be provided).

If interested, please send email to emily@pathologistsoverseas.com.

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