Put It on the Board, 11/13

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Myriad's myRisk Hereditary Cancer improves colon cancer testing

Myriad Genetics presented last month new clinical data from a study with myRisk Hereditary Cancer, a 25-gene hereditary cancer panel, that showed a 60 percent increase in mutations detected in cancer predisposition genes in patients with a prior history of colon cancer, polyps, or both. Myriad presented this study and data from four others at the Collaborative Group of the Americas on Inherited Colorectal Cancer Annual Meeting in Anaheim, Calif.

One of the studies evaluated the mutation prevalence, using myRisk Hereditary Cancer, among cases referred for Lynch syndrome. The study presents data from two cohorts representing 1,133 patients diagnosed with colon cancer or colorectal polyps. The results demonstrated that 10 percent of patients had deleterious mutations in the traditional hereditary colon cancer genes, but an additional six percent had deleterious mutations in other genes. This represents a 60 percent increase in the number of patients detected with deleterious mutations in cancer predisposing genes.

The objective of another study was to better understand the prevalence of hereditary colon cancer mutations in patients who have abnormal histology, regardless of family history. About 13.9 percent (57/410) of patients with abnormal histology had a deleterious mutation. Among the patients who tested positive for a deleterious mutation, 77.2 percent (44/57) would not have met Amsterdam II criteria based on personal or family history for hereditary colon cancer testing if histology was not considered. These data support the use of histology to simplify patient selection for hereditary colon cancer testing.

Also in October, Myriad presented data at the American Society of Human Genetics annual meeting in Boston showing that myRisk Hereditary Cancer meets quality standards and provides clinical sequencing results equivalent to 99.99 percent accuracy.

"We've invested three years of research to optimize our Myriad myRisk Hereditary Cancer test, and the validation data show that Myriad myRisk Hereditary Cancer offers 99.99 specificity and sensitivity, which means it provides unprecedented quality and accuracy equal to the gold standard Sanger sequencing," Richard J. Wenstrup, MD, chief medical officer of Myriad, said in a statement.

Siemens offers HIV combo assay

The Siemens Healthcare Enzygnost HIV Integral 4 assay is an HIV combination test that detects both the HIV p24 antigen and HIV antibodies. In a study of 14,169 donor samples tested at three different blood banks, initial specificity was demonstrated at 99.94 percent.

Stefan Wolf, CEO, Hemostasis, Hematology and Specialty Business Unit, Siemens Healthcare, Diagnostics Division, said in a statement: "The increased sensitivity of the HIV Integral 4 assay enables clinicians to detect disease and initiate treatment earlier, and its high specificity provides our blood bank customers with confidence that the results are precise, enhancing the accuracy of their donor screening programs."

The new assay is available on the Siemens laboratory systems Quadriga BeFree and BEP.

MDxHealth's MGMT test in NCCN guideline, awarded tier 1 code

The technology underlying MDxHealth's PredictMDx for Glioblastoma test, used to identify patients most likely to respond to targeted therapy, is in the 2013 National Comprehensive Cancer Network senior adult oncology guideline, released Oct. 24 and published at www.nccn.org.

PredictMDx for Glioblastoma is an MGMT (06-methylguanine-DNA methyl transferase) test. The AMA CPT editorial panel awarded a tier 1 code, 81287, to MGMT methylation analysis following an application from MDxHealth. Tier 1 codes are assigned to report gene-specific and genomic procedures and are considered category 1 codes.

In the international prospective phase three (RTOG 0525) validation study, published in the Journal of Clinical Oncology (10.1200/JCO.2013. 49.6968), PredictMDx for Glioblastoma successfully identified newly diagnosed glioblastoma patients who are more likely to live longer and have a longer progression-free period after treatment with temozolomide.

"The publication of these results confirms the value of measuring the methylation status of the MGMT gene in a prospective manner," Prof. Monika Hegi, PhD, head, Laboratory of Brain Tumor Biology and Genetics, Neurosurgery, University Hospital of Lausanne, Switzerland, said in a statement. "The MDxHealth MGMT test was successfully carried out prior to patient randomization, which allowed for proper patient stratification. Newly diagnosed grade IV glioblastoma patients who have a methylated MGMT gene experience a survival and disease progression benefit from the current standard-of-care treatment." This study emphasizes the need, she said, to test glioblastoma patients for MGMT promoter methylation as a stratification factor in future clinical studies.

In other news last month, MDxHealth SA said its ConfirmMDx for Prostate Cancer test met all of the primary endpoints in the recently completed multicenter, blinded DOCUMENT (Detection of Cancer Using Methylated Events in Negative Tissue) clinical validation trial. Preliminary analysis of data verifies the test's high negative predictive value for ruling out the presence of prostate cancer and is a significant independent predictor of risk for men being considered for repeat biopsy.

The multicenter DOCUMENT study was conducted at five U.S. urologic centers. It involved analyzing tissue from initial negative biopsies and comparing assay results to cancer detection in subsequent biopsies within 24 months. ConfirmMDx for Prostate Cancer was used to analyze the epigenetic profile of prostate biopsy cores from 350 men screened by PSA. Results from the DOCUMENT study will be published after full analysis of the data is completed, according to the company.

MDxHealth SA has expanded access to ConfirmMDx for Prostate Cancer to an additional 50 million covered lives by signing agreements with health insurance providers FedMed and America's Choice Provider Network.

Quest acquires ConVerge

Quest Diagnostics has acquired ConVerge Diagnostic Services LLC from Water Street Healthcare Partners. The transaction includes ConVerge's laboratory in Peabody, Mass., and its patient service centers operating in Massachusetts, New Hampshire, and Connecticut.

ConVerge will operate as a wholly owned subsidiary of Quest Diagnostics, and its laboratory will operate as part of Quest's national laboratory network. Over time, the ConVerge laboratory is expected to be integrated into a laboratory facility Quest is building in Marlborough, Mass.

Financial terms of the transaction were not disclosed.

Illumina to acquire NextBio

Illumina has signed a definitive agreement to acquire clinical and genomic informatics company NextBio, Santa Clara, Calif. NextBio's platforms aggregate and analyze large quantities of phenotypic and genomic data for research and clinical applications.

"This agreement with NextBio demonstrates Illumina's unwavering commitment to drive the adoption of sequencing in new markets and vastly improve the genomic information workflow," Jay Flatley, Illumina president and CEO, said in a statement. Flatley added, "The combination of Illumina's BaseSpace cloud computing environment for next-generation sequencing with NextBio's platform for integrating patient data will allow us to

deliver solutions that seamlessly integrate the entire workflow from sample to result.”

Qiagen, Clovis to co-develop companion diagnostic

Qiagen has partnered with Clovis Oncology to co-develop and co-commercialize a companion diagnostic test to guide the use of CO-1686, a Clovis Oncology product candidate currently in clinical development. The Clovis drug candidate will initially target an unmet clinical need in patients with EGFR-driven non-small cell lung cancer for whom current EGFR-inhibiting drugs no longer control disease.

The diagnostic will build on Qiagen’s Therascreen EGFR RGQ PCR Kit, which the FDA approved in July as a companion diagnostic for use in the treatment of metastatic NSCLC in patients whose tumors have certain EGFR mutations.

The development plan for the companion diagnostic complements Clovis’ accelerated plan for CO-1686 development by potentially allowing a supplemental premarket approval filing for the diagnostic. Subject to regulatory approvals, Qiagen will be responsible for the global development and commercialization of the companion diagnostic, and Clovis will be responsible for the global development and commercialization of CO-1686.

PDI and Transgenomic team up

PDI and Transgenomic announced last month a long-term collaboration agreement to commercialize a molecular diagnostic test called CardioPredict. It’s a broad-based genetic assay that identifies gene variants that influence the effectiveness and safety of cardiovascular drugs.