Put It on the Board, 5/16

FDA approves Abbott companion diagnostic for CLL

The Food and Drug Administration has approved a companion diagnostic to identify patients with B-cell chronic lymphocytic leukemia who may be eligible to receive a targeted therapy.

Abbott's Vysis CLL FISH Probe Kit received FDA premarket approval as the first companion diagnostic to detect deletion of the *TP53* gene to identify patients with CLL for whom treatment with AbbVie's Venclexta (venetoclax) drug is indicated.
Deletion of the *TP53* gene and several other markers tested with the Vysis CLL test are associated with poor prognosis or patient outcomes and low response rates to standard treatment for CLL.

About five percent of people with CLL have a TP53 deletion at diagnosis, but for patients with relapse or refractory CLL, the prevalence of *TP53* deletion can be as high as 50 percent.

The National Comprehensive Cancer Network recently updated its non-Hodgkin's lymphoma guidelines, which include CLL, and recommend FISH testing, such as Abbott's Vysis CLL FISH probes, at diagnosis and at relapse to help in selecting treatment options.

SelectMDx study published in *European Urology*

MDxHealth announced that data validating the clinical performance of the SelectMDx for Prostate Cancer test were published in April in *European Urology*.

The study, conducted across six institutions in the Netherlands, was designed to identify methods to improve the detection of clinically significant or aggressive prostate cancer at an early, more treatable stage.

Urine samples from two prospective, multicenter studies (n=905) were collected after digital rectal examination to measure the mRNA expression levels of the SelectMDx genes, which were previously identified for their ability to detect aggressive prostate cancer. These results were combined with standard clinical risk factors. An algorithm was developed in a training cohort and validated in an independent cohort. The SelectMDx risk score resulted in an improved identification of men at risk for harboring aggressive prostate cancer, significantly outperforming PSA and PCA3, with an area under the curve of 0.90 and a negative predictive value of 98 percent for clinically significant prostate cancer, according to a company statement. In addition, SelectMDx resulted in the highest reduction of unnecessary biopsies in men with no or indolent prostate cancer, the statement said.
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Quest Zika test authorized for emergency use

Quest Diagnostics received an FDA emergency use authorization for the Zika Virus RNA Qualitative Real-Time RT-PCR test. Quest's Focus Diagnostics subsidiary developed the test. The CDC recommends RT-PCR testing during approximately the first seven days of symptom onset for certain patients.
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Epigenomics receives FDA approval for Epi proColon

The FDA has approved Epi proColon, a blood-based colorectal cancer screening test from Epigenomics AG, a German-American molecular diagnostics company.

Epi proColon will be made available in the United States under a joint commercialization agreement with the company's strategic partner Polymedco. It is indicated for colorectal cancer screening in average-risk patients who choose not to undergo colorectal cancer screening by guideline-recommended methods such as colonoscopy and stool-based fecal immunochemical tests.
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Leica to collaborate on companion diagnostic

Leica Biosystems and Merrimack Pharmaceuticals are partnering to develop companion diagnostic assays, and the initial focus of their work will be an assay for Merrimack's seribantumab, or MM-121.

Seribantumab, an investigational therapy, targets ErbB3, a cell surface receptor activated by the ligand heregulin.[hr]