Put It on the Board, 8/16

LabCorp will acquire Sequenom

Laboratory Corp. of America and Sequenom have entered into a definitive agreement and plan of merger under which LabCorp would acquire all of the outstanding shares of Sequenom in a cash tender offer for $2.40 per share, or an equity value of $302 million, which represents a total enterprise value of about $371 million, including net indebtedness.

"This is exactly the kind of strategic acquisition that LabCorp seeks," David King, the company's chairman and CEO, said in a statement. Sequenom was the first laboratory to offer a clinically validated noninvasive prenatal test, MaterniT21, and has performed more than 500,000 tests to date, King said. "Sequenom's proven best-in-class technology and strong research complement LabCorp's extensive women's health offering, providing patients and physicians with one source for the most complete range of testing options in women's health, including NIPT and reproductive genetics." The acquisition is expected to close by year's end.
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New York ends state PT services

Starting in January, the New York State Department of Health allowed laboratories operating in the state to use other CMS-approved proficiency testing providers to meet the state's PT requirements. Many laboratories chose to do so, said a July 22 letter to lab directors from Derek Symula, PhD, director of the Wadsworth Center PT Program, and Stephanie Shulman, MPH, MS, MT(ASCP), director of New York's Clinical Laboratory Evaluation Program.

"After evaluating the effects of the new policy for the first half of 2016, we will discontinue the remaining NY [state] clinical laboratory PT programs," they wrote in the letter. "Effective Dec. 31, 2016, New York State will no longer provide clinical laboratory proficiency testing. Instead, we will expand our current process for reviewing results and scores from other PT providers, following a model similar to Washington state, the other CLIA-exempt state."

The letter stresses that the state's PT requirements still apply to proficiency testing offered by other providers.
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St. Jude lands CAP ISO 15189 accreditation

The St. Jude Children's Research Hospital Department of Pathology has received accreditation to the ISO 15189 standard under the CAP's 15189 Accreditation Program. St. Jude is the first children's hospital in the nation to be accredited under this program.

"This CAP accreditation recognizes St. Jude's commitment to providing the highest standards of quality for our patients and their families," pathology chair David Ellison, MD, PhD, said in a statement. "We are honored to receive this accreditation, and I congratulate the department's hard work and dedication that has helped us reach this milestone."

CAP 15189 complements CAP accreditation and is a voluntary, nonregulatory accreditation to the ISO 15189:2012 Standard, as published by ISO.
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Epigenomics' DNA test included in CRC guideline

Epigenomics, the German-American cancer molecular diagnostics company, announced that the U.S. Preventive Services Task Force has included Epi ProColon in its new recommendation statement for colorectal cancer screening, published in JAMA (USPSTF, et al. 2016;315[23]:2564–2575). The USPSTF is the first American guideline body to recognize this colorectal cancer screening test after its recent FDA approval, the company said.

In the recommendation, the USPSTF names Epi ProColon (referred to as the SEPT9 DNA test) as one of several screening tests for the detection of early-stage colorectal cancer. The use of screening tests such as Epi ProColon is recommended in adults between ages 50 and 75. The USPSTF acknowledged there is no one-size-fits-all approach to colorectal cancer screening. Instead of emphasizing specific screening approaches, the new guideline focuses on the importance of patient participation in CRC screening, without recommending for or against any particular method. However, only methods with substantial scientific evidence were included in the task force's review of available tests.

Epigenomics said it expects that the new USPSTF recommendation will contribute to higher CRC screening rates, which have been stagnant over the past years. The American Cancer Society and other medical guideline bodies pursue a colorectal cancer screening goal of 80 percent of eligible patients.
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OSU to deploy Inspirata digital pathology solution

Inspirata has been selected to provide a digital pathology workflow solution at the Ohio State University Comprehensive Cancer Center–Arthur G. James Cancer Hospital and Richard J. Solove Research Institute and the Department of Pathology, located at the OSU Wexner Medical Center in Columbus. The solution Inspirata will create for the OSUCCC-James combines whole-slide imaging with viewing software and imaging analytics within an integrated system that uses sophisticated algorithms.

The scope of the engagement spans all of the hardware, software, and services necessary to support an end-to-end pathology workflow solution. This includes deploying a bank of Philips Ultra Fast Scanners and its Image Management System and EMC Converged Infrastructure and providing the staffing needed to digitize the institution's retrospective and prospective glass pathology slides. It also includes installing Inspirata's Digital Pathology Cockpits, which is a desktop system designed to enable the pathologists to review cases, view digitized histology slides and other diagnostic images, share pathology and radiology images for second opinions, and report their findings to treating physicians—all from within the single sign-on, encrypted device.
Inspirata says its cockpits will be fully compatible with the relevant clinical systems of the OSUCCC-James so pathologists can easily access comprehensive information about the patient's previous diagnostic testing and

results.
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Mindray's clinical chemistry analyzer cleared

Mindray and MedTest jointly announced they have received 510(k) clearance from the Food and Drug Administration to market and sell the new Mindray BA-800M Clinical Chemistry Analyzer.

The BA-800M analyzer, for mid- to high-volume laboratories, produces 800 photometric test results per hour with an overall throughput of 1,200 tests per hour with ISE. The sample delivery module has a sample capacity of 440 positions, providing large-volume laboratories hours of unmanned operational time. The reagent consumption design of this analyzer minimizes reagent usage per test and reduces the reagent bottle dead volume. Advanced features of the analyzer include continuous reagent loading, reagent bubble detection, water quality monitor, one-key stat touch button, probe liquid level detection, and sample probe clot and collision recovery.

MedTest is the exclusive U.S. distributor of the BA-800M including manufacturing and distribution of reagents, calibrators, and quality control products for the general chemistry and urine drugs-of-abuse screening markets.
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Successful Keytruda trial stopped early

The KEYNOTE-024 trial investigating the use of Merck's Keytruda (pembrolizumab) in patients with previously untreated advanced non-small cell lung cancer whose tumors expressed high levels of PD-L1 (tumor proportion score of 50 percent or more) met its primary endpoint. In the trial, Keytruda was superior compared with chemotherapy for both the primary endpoint of progression-free survival and the secondary endpoint of overall survival, Merck said in a statement. Based on these results, an independent data monitoring committee has recommended that the trial be stopped and that patients receiving chemotherapy in KEYNOTE-024 be offered the opportunity to receive Keytruda.

"We believe that the KEYNOTE-024 results have the potential to change the therapeutic paradigm in first-line treatment of non-small cell lung cancer," Roger Perlmutter, MD, PhD, president of Merck Research Laboratories, said in a statement. "We look forward to sharing these data with the medical community and with regulatory authorities around the world."

The safety profile of Keytruda in this trial was consistent with that observed in previously reported studies in patients with advanced NSCLC. Results from KEYNOTE-024 will be presented at an upcoming medical meeting. KEYNOTE-024 is a randomized, pivotal, phase three study (Clinical Trials.gov, NCT02142738) evaluating Keytruda monotherapy compared with standard of care platinum-based chemotherapies in the treatment of patients with advanced NSCLC.
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Top court clarifies autopsy's place in Texas law

The Texas Supreme Court has decided, in the case of *Christus Health Gulf Coast v. Carswell*, that a hospital-provided autopsy falls under the scope of the state's medical liability statute. The plaintiff, Linda Carswell, alleged that professionals at Christus St. Catherine Hospital in Katy, Tex., defrauded her by refusing to request that an autopsy for her husband—who died as a hospital inpatient—be performed by the county medical examiner's office. The autopsy was instead performed by a hospital-contracted pathology group. Carswell's attorneys alleged this was done as part of an effort to hide some medical error-related cause of death.

A jury sided with Carswell on the fraud claim, but Christus Health appealed, arguing the case should fall under the

Texas Medical Liability Act, which sets a two-year time limit on claims that the plaintiff failed to meet. The matter went to the state's top court and was watched closely by Texas pathologists and legal experts concerned the case might adversely affect physicians performing autopsies (see "Case raises uncertainty on autopsy's legal status," CAP TODAY, March 2016, page 70).

Carswell's attorneys argued that once a patient dies, he is no longer covered by the state's medical liability statute, stating colorfully that "a corpse is not a patient." But in the court's opinion, justice Phil Johnson wrote that the statute is sufficiently broad to cover the alleged activities at issue in the case.

"Even if persons can no longer be patients after they die, a question we need not decide today, the inquiry does not end there," he wrote. The Texas Medical Liability Act "does not limit its reach to persons receiving or having received health or medical care—it applies to 'claimants.' . . . The professional or administrative services underlying the Carswells' complaint were directly related to the improper health care they alleged Jerry Carswell received, or health care they alleged he should have received but did not." The complete opinion is available at http://bit.ly/texasruling. *—Kevin B. O'Reilly*
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EUA for Siemens Zika assay

The Food and Drug Administration has granted Siemens Healthcare Diagnostics an emergency use authorization for its real-time PCR Zika virus assay, the Versant Zika RNA 1.0 Assay (kPCR) Kit.

The molecular test is validated for plasma, serum, and urine (collected alongside a patient-matched serum or plasma specimen) from individuals meeting CDC Zika virus clinical criteria and/or CDC Zika virus epidemiological criteria, and is designed to run on the Siemens Versant kPCR Sample Prep automated platform, along with several commercially available thermal cyclers. The assay must be run by laboratories in the United States that are certified to perform high-complexity tests or by similarly qualified non-U.S. laboratories.
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