Put It on the Board, 2/17

LabCorp to purchase Mount Sinai's outreach laboratories

In the latest chapter of hospitals exiting the laboratory outreach business, Mount Sinai Health System in New York City agreed in January to sell its outreach operations to LabCorp.

Mount Sinai grew dramatically in 2013 through the merger of Continuum Health Partners and Mount Sinai Medical Center, creating a system with seven hospitals in three New York City boroughs. A pathologist and observer of the local laboratory sector suggested Mount Sinai considered the outreach business a distraction from its primary task of operating its hospitals.

"The thought may have been that they wanted to sell everything, lock, stock, and barrel," said the observer, who requested anonymity. That observer added that continued downward pressure on reimbursement for outpatient testing may have been another driver behind the decision.

According to a joint statement issued by LabCorp and the hospital system, LabCorp would take over seven patient service centers currently operated by Mount Sinai, giving the national lab 127 such centers in the metropolitan New York City area. LabCorp will offer clinical pathology testing, including cytology and cytology-related molecular testing. The parties said they are also "vigorously exploring opportunities to collaborate on projects involving companion diagnostics, clinical trials, and medical education."

One source indicated Mount Sinai's outreach operation could have an annual volume of more than 5 million tests and revenue of roughly $50 million.

"We are confident this transaction will provide great benefits for our patients and physicians and allow Mount Sinai to continue to invest in our core strategic programs," Donald Scanlon, Mount Sinai chief financial officer and chief of corporate services, said in a statement. "LabCorp's proven track record of service excellence, breadth of diagnostic capabilities, and cost-efficiency will benefit our community now and in years to come."

Robert Boorstein, MD, PhD, a pathologist who serves as the medical director at Lenco Diagnostic Laboratory in Brooklyn and is a consultant to other labs, believes such sales could make it harder for hospitals to claim clinical and economic superiority over standalone labs.

"The trend of outsourcing [lab services] by prominent academic institutions to commercial ones undercuts the argument that they have greater quality than commercial labs and thus should command higher fees," he said.

Dr. Boorstein and the anonymous observer agree that many hospitals and health care systems with outreach businesses have difficulty quantifying their profitability—another reason behind such a sale.

LabCorp and Quest Diagnostics have been active in the outreach acquisition business in recent years, with the companies scoring significant deals in California, Massachusetts, and Connecticut.

Quest announced last month that it will work with Montefiore Health System in New York to perform a portion of Montefiore's low-complexity diagnostic tests in the Quest Teterboro, NJ, laboratory. The remainder of the laboratory testing will continue to be performed at Montefiore hospitals under the direction of the Montefiore and Albert Einstein College of Medicine Department of Pathology.

The Mount Sinai transaction has received clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and is expected to close by the end of this quarter, LabCorp said. —*Ron Shinkman*
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Philips and Illumina to offer integrated genomics solutions for oncology

Royal Philips and Illumina announced a collaboration that aims to integrate Illumina's sequencing systems for large-scale analysis of genetic variation and function and Philips' IntelliSpace Genomics clinical informatics platform, and to coordinate marketing and sales of the resulting solutions. They will also seek to collaborate on clinical research with health systems in the U.S. that want to develop precision medicine programs in oncology.

The two companies say they will work together to provide new solutions aimed at acquiring, analyzing, annotating, and interpreting genomic data in oncology cases. Illumina's BaseSpace Sequence Hub connected to its instruments will acquire the data, which will be processed through Philips' IntelliSpace Genomics solution for oncology. This solution will combine data from multiple sources—radiology, immunohistochemistry, digital pathology, medical records, and lab tests—and deliver a consolidated dashboard view. The system will support researchers in developing insights more efficiently and will ultimately support lowering the cost of health care and improved health outcomes, according to the companies.

Laboratories that adopt the solution will be able to integrate sequencing data with information from multiple data sources (e.g. imaging, pathology, and laboratory). They will also have ready access to advanced analytics, deep learning technologies, and available reference literature, guidelines, and evidence in a single view.
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Werfen, IL acquire Accriva

Accriva Diagnostics announced a definitive agreement with Werfen, a privately held medical diagnostics firm headquartered in Barcelona, Spain, and its subsidiary Instrumentation Laboratory, headquartered in Bedford, Mass., in which Werfen and IL have acquired all shares of Accriva. The transaction was closed on Jan. 19.

The Accriva portfolio, consisting of point-of-care diagnostic products for coagulation and antiplatelet therapy response, will allow IL to establish a market-leading position in hospital-based POC hemostasis testing, expand its position in POC critical care testing, and complement its leadership in the hemostasis laboratory segment, according to the companies.

Accriva Diagnostics will become part of IL and continue operating out of its existing San Diego facility.
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Abbott granted EUA for molecular Zika test

The Food and Drug Administration has authorized for emergency use the Abbott RealTime Zika test to detect Zika virus in whole blood (when collected alongside a patient-matched serum or plasma sample). This is the first molecular test made by a commercial manufacturer authorized to detect Zika in whole blood samples.

In other news, Abbott reports that it has been awarded a contract by the U.S. Defense Advanced Research Projects Agency to develop a testing panel for Zika and multiple tropical fever pathogens for use on a mobile platform to meet the needs of testing in rural and remote areas. And through a grant from the U.S. Agency for International

Development, Abbott is exploring the development of a serology test that does not cross-react with other tropical disease antibodies.
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Guideline now out on CRC molecular biomarker testing

A new clinical practice guideline on molecular biomarker testing for patients with colorectal cancer was published online Feb. 6 in the Archives of Pathology & Laboratory Medicine and three other journals.

The CAP and the American Society for Clinical Pathology, Association for Molecular Pathology, and American Society of Clinical Oncology collaborated to develop the "Molecular Biomarkers for the Evaluation of Colorectal Cancer" guideline.

"Realizing that molecular diagnostics is a rapidly evolving field of medicine, the collaborating organizations of CAP, ASCP, AMP, and ASCO are committed to updating this guideline routinely in order to capture and make recommendations for new discoveries in the field," Stanley R. Hamilton, MD, of the University of Texas MD

Anderson Cancer Center, said in a statement. He was co-chair of the project on behalf of the CAP.

The other co-chairs were Antonia R. Sepulveda, MD, PhD, of Columbia University, on behalf of the AMP; Carmen Allegra, MD, of the University of Florida Health Cancer Center, on behalf of ASCO; and Wayne W. Grody, MD, PhD, of UCLA School of Medicine, on behalf of the ASCP.

Twenty-one guideline statements were established—eight recommendations, 10 expert consensus opinions, and three "no recommendations"—based on evidence from a comprehensive literature review.

The guideline was published online in the *American Journal of Clinical Pathology, Journal of Molecular Diagnostics,* and *Journal of Clinical Oncology in addition to the Archives.*[hr]