Put It on the Board, 3/17

LabCorp to acquire PAML

LabCorp, Providence Health & Services, and Catholic Health Initiatives announced Feb. 23 they have entered into a definitive agreement for LabCorp to acquire all of the ownership interest in Pathology Associates Medical Laboratories, LLC, which is owned by Providence and CHI.

In addition to PAML, LabCorp will acquire PAML's interest in five joint ventures: Colorado Laboratory Services, Kentucky Laboratory Services, MountainStar Clinical Laboratories, PACLAB Network Laboratories, and Tri-Cities Laboratory.

"This signature transaction strengthens LabCorp's relationships with anchor health systems and expands LabCorp's geographic presence into important markets," David King, LabCorp chairman and chief executive officer, said in a statement.

PAML and its joint ventures provide laboratory services in California, Colorado, Idaho, Kentucky, Montana, Oregon, Utah, and Washington. PAML's headquarters are in Spokane, Wash.

The hospital co-owners of Colorado Laboratory Services (Lakewood), Kentucky Laboratory Services (Lexington), and PACLAB Network Laboratories (Renton, Wash.) have agreed to sell their joint venture interests to LabCorp.

The hospital partners in MountainStar Clinical Laboratories (Salt Lake City) and in Tri-Cities Laboratory (Kennewick, Wash.) continue to evaluate future options for their ownership of the joint venture, which may include a sale to LabCorp.

After the staged transactions have been completed, Providence, CHI, and the hospital joint venture owners will continue to provide all existing inpatient hospital laboratory services. LabCorp will then continue to provide the outreach testing services and reference laboratory services now provided by PAML and the joint ventures that are part of the overall transactions. The transactions do not include any PAML joint venture services in California.

The parties anticipate that transaction closings will begin this year and continue into 2018.
[hr]

Brahms PCT approved as aid in antibiotic stewardship

BioMérieux received 510(k) clearance from the Food and Drug Administration for the expanded use of its Vidas

Brahms PCT, an automated assay measuring procalcitonin levels, to help clinicians make decisions about the use of antibiotics in two clinical situations: lower respiratory tract infections and sepsis.

It's the first test to use PCT as a biomarker to aid in antibiotic management decisions.
In the case of patients with lower respiratory tract infection, Vidas Brahms PCT will aid physicians in decision-making to safely reduce overall antibiotic use. In the case of sepsis patients, it will aid physicians in deciding when antibiotics can be safely discontinued.
[hr]

CAP selects FIGmd to develop Pathologists Quality Registry

The CAP has selected FIGmd to develop the first pathologist-specific clinical data registry. Designed for pathology practices, this registry will ease compliance with quality reporting requirements and provide a simplified mechanism pathologists can use to improve quality and to meet the requirements of the Medicare Quality Payment Program, or QPP.

The CAP's aim is to ensure that pathologists can comply with new value-based payment models such as those enacted as part of the Medicare Access and CHIP Reauthorization Act, or MACRA. The CAP has submitted an application to the Centers for Medicare and Medicaid Services for approval and authorization of the registry as a reporting option in Medicare's QPP.

The registry, set to launch at the CAP annual meeting in October, will include 16 measures. Eight of those measures are the current Physician Quality Reporting System measures developed by the CAP. The fall launch will precede the 2018 MACRA performance period to ensure pathologists qualify for payment bonuses under Medicare's Merit-based Incentive Payment System.

"We chose to workwith FIGmd based on their experience with medical specialty societies and medical professional associations and their innovative approach to making data collection meaningful. They are known for developing registries that are simple to implement and easy to use," CAP president Richard Friedberg, MD, PhD, said in a statement.
[hr]

Novartis to sell Genoptix

Private investment firms Ampersand Capital Partners and 1315 Capital announced they have partnered with a management group to acquire the commercial laboratory of Novartis subsidiary Genoptix.

Genoptix provides hematology and solid tumor molecular profiling and offers clinical trial services such as assay and companion diagnostic development to biopharmaceutical partners. Novartis acquired the company in 2011 for $470 million.
[hr]

Horizon launches multiplex I cfDNA reference standard

Horizon Discovery Group launched its first HDx cfDNA (cell-free DNA) reference standard in synthetic plasma.

cfDNA-based diagnostics are at a particularly high risk of error, and an assay may be required to identify as few as 50 copies of a target sequence that has already undergone DNA damage. This is further complicated by the highly variable amount of cfDNA present in a sample from patient to patient.

Laboratories must therefore extract and reliably quantify as much cfDNA as possible. Horizon's new Multiplex I cfDNA Reference Standard Set in Synthetic Plasma directly addresses this problem by allowing users to control for

the entirety of their workflows, from sample extraction to result reporting, interrogating the sources of variability at each step so they can address them.

Developed using clinically relevant mutations, the Multiplex I cfDNA Reference Standard Set in Synthetic Plasma contains eight cancer-relevant mutations including *BRAF, EGFR, KRAS, NRAS*, and *PIK3CA* at five percent, one percent, and 0.1 percent allelic frequencies (RUO only).
[hr]

FDA grants PMA approval for Aptima HCV assay

The Food and Drug Administration has granted PMA approval for Hologic's hepatitis C virus assay for quantitation of HCV viral load and confirming active HCV infection on the fully automated Panther system.

The Aptima HCV Quant Dx assay uses real-time transcription-mediated amplification. In addition to an HIV-1 viral load assay, the Panther menu includes tests for chlamydia, gonorrhea, trichomoniasis, and HPV.
[hr]

DiaSorin launches *C. diff* molecular test in the U.S.

DiaSorin received clearance from the Food and Drug Administration to market its Simplexa *C. difficile* Direct assay. The assay, first launched outside of the U.S. in late 2016, was developed by DiaSorin Molecular to be run on the Liaison MDX. It is a scalable benchtop instrument able to provide real-time PCR results for quantitative, qualitative, multianalyte, and sample-to-answer detection needs.[hr]