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HIGHLIGHTS

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LABS Undergoes Extensive Rebranding Effort

LABS, Inc., the Colorado-based laboratory that focuses on services related to organ transplantations and reproductive services, has chosen to rebrand, a relatively rare step among companies in the sector.

LABS replaced its old logo, a sketch of a beaker holding chemicals and its name in semi-serif fonts in earth tones. Now depicted in a much bolder black and blue scheme, the LABS' name is in a much larger black san-serif font that includes a molecular structure as part of the "A" and the motto "Realize The Potential" underneath.

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FDA Issues Guidelines on NGS-Based Tests

The U.S. Food and Drug Administration (FDA) has issued two sets of draft guidelines for next-generation sequencing (NGS). The guidance documents will likely be finalized later this year or in early 2017.

The reaction to the draft guidance, which total just 40 pages combined and were issued last month, has been mixed but seems to lack some of the teeth gnashing labs and the FDA have had over other regulatory issues.

One set of draft guidelines pertains to the use of NGS in in-vitro diagnostics for diagnosing germline diseases. The other set pertains to the use of genetic databases to support the clinical validity of NGS-based tests.

The FDA made clear that it considers NGS-based tests as a new form of class III medical device and should come under its scrutiny. However, it also put forth provisions for labs to obtain regulatory approval through the highly streamlined *de novo* process, which would also give many tests an exemption.

The proposed oversight of databases is broader. The FDA essentially has asked that the databases ensure patient confidentiality, do not contain redundant information that can lead to diagnostic errors, and that their managers are not engaged in professional conflicts of interest, among other recommendations.

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FDA Issues Guidelines on NGS-Based Tests, *from page 1*

"The FDA's job is to ensure that doctors and patients can depend upon the accuracy, reliability and clinical validity of these tests. It's our hope that this approach will achieve just that," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health.

The draft guidances underscore the uneasy relationship the FDA and the laboratory sector have had in recent years. The agency's current regulatory authority extends to point-of-care tests, which still remain a small sliver of the entire clinical testing business. But the sector and the FDA have butted heads repeatedly in recent years over the agency's attempt to more closely regulate laboratory-developed tests (LDTs). The lab sector has claimed that such regulation would be overly intrusive.

"ACLA continues to assert that laboratory developed tests (LDTs) are not medical devices, including those LDTs that utilize NGS technology."

— Alan Mertz, President, ACLA

But despite NGS-based tests being highly sophisticated themselves—representing a growing market worth billions of dollars a year in the United States alone—the lab sector is taking a fairly reserved position regarding the draft guidance documents.

The American Clinical Laboratory Association, perhaps the most powerful of the sector's lobbying groups, has suggested that the drafts are in the same category as the agency's desire to govern LDTs.

"ACLA continues to assert that laboratory developed tests (LDTs) are not medical devices, including those LDTs that utilize NGS technology," said ACLA President Alan Mertz. "While we recognize the FDA is looking for innovative solutions, these proposals show the inherent difficulty of attempting to shoehorn LDTs into medical device standards."

But Francis DeSouza, chief executive officer of Illumina, the San Diego-based laboratory and testing platform manufacturer, welcomed the moves by the agency,

"We support the proactive actions the FDA is taking to recognize the benefits of next generation sequencing and provide appropriately flexible and adaptive regulatory oversight of these tests, while accommodating the rapid evolution of NGS technologies," he said.

Takeaway: The laboratory sector, which has locked horns in recent years with the U.S. Food and Drug Administration, appears to be taking a more moderate, wait-and-see approach over its draft guidance for next-generation sequencing tests.

Trovagene Enters Into Pact With USC on Liquid Biopsy Test

Trovagene, the San Diego-based molecular laboratory, has entered into a deal with the University of Southern California's Norris Comprehensive Cancer Center to collaborate on creating a standard framework and best practices for the use of its Trovera assay for cancer detection.

The test uses circulating tumor DNA in a patient's urine sample in order to detect the presence of the disease, as well as provide a molecular profile suggesting specific courses of treatment.

> *"We look forward to working closely with clinicians and researchers at the USC Norris Comprehensive Cancer Center ... to further demonstrate the robustness and reliability of our technology in the identification of cancer mutations from urine."*
>
> — Mark Erlander, Ph.D.
> Chief Scientific Officer, Trovagene

"The clinical data Trovagene has presented and published thus far illustrate the tremendous promise of using urinary ctDNA as a noninvasive sample type to detect and monitor clinically actionable oncogene mutations, and provide essential molecular information about a patient's disease," said Stephen B. Gruber, M.D., director of the USC Norris Comprehensive Cancer Center, in a statement.

Trovagene has entered into collaborations with the University of Michigan and the University of California at San Diego regarding the development of assays to detect and assess specific forms of cancer.

"We look forward to working closely with clinicians and researchers at the USC Norris Comprehensive Cancer Center ... to further demonstrate the robustness and reliability of our technology in the identification of cancer mutations from urine," said Mark Erlander, Ph.D., Chief Scientific Officer at Trovagene, in a statement. "Our collaboration is focused on conducting several novel studies that have potential to improve the standard-of-care for cancer treatment, and to accelerate adoption of our noninvasive tests into clinical practice."

Takeaway: Trovagene has continued to enter into deals to further develop and standardize urine-based cancer assays.

Singulex Test Could Wind Up Targeting Heart Disease Treatments

An assay developed by a California-based laboratory that determines the levels of troponin could be used as a marker for declining cardiac heath.

That's the conclusion of a new study published in the *Journal of the American College of Cardiology* about a molecule-counting test developed by Singulex. The study involved the testing of more than 4,100 blood samples of patients considered to have stable coronary artery disease.

Those patients who had higher levels of troponin—a protein released into the body as the result of coronary damage—and underwent intensive therapy that included statins and other treatments saw their risk for cardiovascular death or heart failure drop by 3.5 percent. By comparison, those patients who only underwent statin therapy had just a minor decrease in such risks.

"Our findings support the potential broadening of a paradigm from viewing cardiac troponin solely as a transiently elevated diagnostic marker in the setting of acute injury to also using the information as a marker of ongoing heightened cardiovascular risk," said Marc P. Bonaca, principal investigator of the study, in a statement. "This knowledge is particularly relevant in stable patients with ischemic heart disease, among whom there may be opportunities for more intensive preventive therapy."

Singulex focuses on testing related to cardiac health, and has five proprietary assays, including single molecule counting.

Takeaway: The Singulex assay could be used as a way to guide more intensive and effective treatments for patients who have stable forms of heart disease.

Inside The Lab Industry

Pathology, Lab Communities Weigh In on Proposed MACRA Rules

Last year the long-maligned Sustainable Growth Rate payment formula was replaced with the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), a system where providers are paid in part based on the quality of care they deliver.

"This is the biggest change in how physicians are paid ... since the creation of DRGs," said Emily Volk, M.D., a pathologist and chief quality officer for the Baptist Health System in San Antonio who also sits on the board of governors for the College of American Pathologists.

MACRA won't be fully implemented until 2019 at the earliest (and likely later than that), but the U.S. Department of Health and Human Services released draft regulations for how the new law would be implemented earlier this year. The agency received nearly 4,000 comments on the proposed regulations from members of the public. The vast majority were physicians, but a handful were pathologists or groups representing that medical specialty as well as laboratories.

The sector is taking a fairly cautious wait-and-see attitude. The CMS will take months digesting the comments it received (although hundreds of them were template submissions from members of the Texas Medical Association). It will likely be the end of the year or even 2017 before the final regulations are announced.

"I'm not getting exorcised about it right now," said Barry Portugal, president of Health Care Development Services, a Florida-based consulting firm to pathology practices.

MACRA – The Current Rundown

- Applies to all providers who bill the Medicare program $10,000 a year or more.
- Budget-neutral incentives and penalties will be applied for each provider (for every dollar paid out in incentives, a dollar will be deducted via a penalty). The incentives and penalties will start at 4 percent of Medicare revenue in the early years, eventually growing to a maximum of 9 percent a year.
- Smaller providers will likely qualify for the Merit-Based Incentive Payment System (MIPS), and will have their performance judged on six quality and outcomes-based objectives (half of their final performance score), with the other half of the score weighted on the cost of delivering care, clinical practice improvement activities and advancing care information.
- Pathologists will qualify for at least eight measures, all holdovers from the 2016 Physician Quality Reporting System measures (among them breast cancer resection pathology reporting; immunohistochemical evaluation of HER2 for breast cancer patients; and Barrett's esophagus).
- Many pathologists will likely be classified as non-patient facing specialists, meaning some of their performance measures may be weighted differently than clinicians who regularly interact with patients.
- Larger providers will likely qualify for alternate payment models (such as ACOs, although CMS estimates fewer than 4 percent of providers will be participating in this category).

Source: Centers for Medicare & Medicaid Services

Inside The Lab Industry

For the moment, Portugal said he is most concerned about the record-keeping required for quality measures, particularly for smaller practices.

"It's a (challenge) keeping track of all of that work and trying to statistically infer how well you're doing," he said.

"Pathologists for years have been making contributions to delivering value, but the current program was designed with primary care physicians in mind and not our group."

— Emily Volk, M.D.

Concern About Smaller Practices

The consensus among many in the health care industry is also that smaller or solo medical practices will be overwhelmed by the many reporting requirements.

"All of the items in MACRA and going back to the (Affordable Care Act) have the secondary impact of increasing administrative costs," Volk said. "Does this hit a smaller practice more than a larger one? No doubt that it does."

CAP represents the group of laboratory-oriented clinicians who will be most impacted by the rule. It submitted 27 pages of comments, one of the lengthiest documents submitted by commenters.

The organization wants an expansion of potential quality measurement categories for pathologists and a minimization of clinical practice improvement activities until more specifics for meeting the objectives are created.

"Pathologists for years have been making contributions to delivering value, but the current program was designed with primary care physicians in mind and not our group," Volk said.

Both Volk and Portugal suggested that pathologists might be measured in areas such as blood management and conservation, as well potentially reducing duplicative testing.

Perhaps most importantly, CAP wants a liberalization of the definition of non-patient facing physicians to automatically default pathologists to that category, where scoring is weighted in a manner more favorable to clinicians that don't regularly interact with patients. Under the current proposal, physicians or group practices qualify for a non-patient facing designation if they have less than 25 patient encounters a year.

"If there is a change in someone's status (late in the year), it would be difficult for them to retrospectively meet the reporting requirements," Volk said.

Quality Improvement Possibilities Seen

COLA, the laboratory quality and safety organization, sees a potential opportunity in MACRA to improve the objectives of its mission.

Inside The Lab Industry

"There are opportunities to expand and improve upon the rule's existing list of clinical practice improvement activities to recognize the significant impact laboratory medicine plays in the delivery of quality care," said COLA Chief Executive Officer Douglas Beigel.

Of particular interest is the measurement category known as clinical practice improvement activities, which would comprise 15 percent of a clinician's score for an incentive or penalty.

"A CPIA that focuses on enhancing practice safety in waived testing through educational support, training and practice management tools will undoubtedly make a clear impact on the quality of care received by patients by encouraging clinicians to take a closer look at the existing waived testing practices," Beigel said.

Another area where a CPIA would make sense is in improving quality control during the pre-analytic phase of testing. According to Beigel, up to 68 percent of all testing errors occur during this phase.

"A CPIA that highlights initiatives focused on quality control measures and proper training for the entire care team will help to enhance practice safety," he said.

Takeaway: The laboratory/pathology sector has taken its first look at the proposed MACRA regulations and has asked for relatively few changes so far.

The Laboratory Sector Weighs In On Proposed MACRA Regulations

American Clinical Laboratory Association

"We suggest CMS formally seek input from the laboratory industry in the future, either directly, or through laboratory associations such as the American Clinical Laboratory Association. More than 70% of medical decisions made by physicians are based on laboratory findings, yet labs are often not consulted regarding critical interoperability decisions. For example, CMS removed laboratory results as a Meaningful Use measure before the Lab Result Interface interoperability standard ONC named for meaningful use certification could be fully deployed. Laboratories invested significant resources developing this interface to help EHR vendors achieve MU certification but few vendors actually deployed this interface, even though they may have certified a product."

College of American Pathologists

"The CAP is looking forward to continued engagement with the CMS on this challenging program in order to determine how to measure appropriately providers who typically do not furnish services that involve face-to-face interaction with patients, including pathologists. The CAP believes considerable accommodations or alternate measures will be necessary to meet this clause."

COLA

"We believe MACRA has the potential to achieve many important aligning objectives across the healthcare field through its innovative incentives program."

Quest Diagnostics

"CPOE only requires the provider enter the order into the EHR and not the transmission of the order to the laboratory. We suggest that CMS consider changing the rule and the Laboratory Order Measure to require the transmission of laboratory orders to external labs and that (the) ONC name a standard for this exchange."

Source: Regulations.gov

LABS Undergoes Extensive Rebranding Effort, *from page 1*

The company also slightly tweaked its mission statement. It now reads, "enabling customers' safe and timely decisions by delivering the highest quality, most accurate laboratory services."

LABS new logo

LABS old logo

According to Kimberly Elliott, LABS' vice president of sales and marketing, "we really wanted to bring forward the culture and ... mission and make it fresh, bright and bold."

Elliott said the rebranding has been nearly a year in the making and was in the planning process prior to the appointment of Gregory D. Clark, as chief executive officer in March. Clark previously served as a vice president with PAML in Spokane, Wash., overseeing operations of its national esoteric reference laboratory.

"The rebranding starts with our desire to transform LABS into a global market leader by expanding the boutique and specialty services we provide, while increasing the markets we serve," Clark said.

Francis noted that the rebrand is *"an expensive proposition, and LABS, Inc. felt it was worth the resources to update their mission, tagline and logo to show the world they are a global market leader in their niche field of transplantation testing services."*

Peter Francis, president of Clinical Laboratory Sales Training, a Maryland-based consulting firm, observed that rebrandings in the lab sector have been few and far between. The only one that he can recall is Metpath rebranding to create Quest Diagnostics, which it did primarily to better absorb the acquisition of SmithKline Labs.

Whether or not such a rebranding can boost sales remains to be seen, according to Francis. But he did observe that "employees can easily become reinvigorated with a new look—along with top-down positive messaging. Sales people, in particular, should gain a rejuvenated psyche," he said.

The changes are coming just before LABS opens a new testing facility on the West Coast. Neither Clark nor Elliott was willing to disclose any specific information about the new facility, which will be used primarily to reduce transportation and turnaround times for organ transplantation and other testing in the western U.S. LABS currently operates a 30,000 square-foot facility adjacent to its headquarters in Centennial, Colo., and a smaller laboratory in the Philadelphia area.

Francis noted that the rebrand is "an expensive proposition, and LABS, Inc. felt it was worth the resources to update their mission, tagline and logo to show the world they are a global market leader in their niche field of transplantation testing services."

LABS, which is a non-profit subsidiary of allograft firm Allosource, currently has just under 150 employees. Clark declined to provide any specific testing volumes for the business other than to say they were stable and that year-over-year revenue growth was "acceptable."

Takeaway: LABS, Inc. has expended significant resources to rebrand just before an operational expansion, a rare move for commercial laboratories.

INDUSTRY BUZZ

RealTime Laboratories Offering Direct-To-Consumer Mycotoxin Test

Texas-based RealTime Laboratories has decided to offer its mycotoxin test directly to consumers.

The test is used to determine the level of exposure individuals have had to mold. Some forms of mycotoxin poisoning can lead to respiratory distress, memory loss, seizures and even death.

"This is an important test for the health of individuals who are or may have been exposed to a home or building, which is harboring mold, particularly water-damaged buildings," said RealTime Chief Executive Officer David Murcott in a statement. "Direct access testing simplifies the process significantly for consumers."

The urine-based test costs $699. Consumers in 26 states can order the testing kit and return it to RealTime's lab in Carrollton, Texas. The company claims a turnaround time within 10 days, and test results are sent by encrypted email.

RealTime is not without controversy. Although it focuses on mold exposure, the Centers for Disease Control and Prevention (CDC) has not issued any data about the trending of reported cases of exposure, suggesting such cases are fairly isolated. An article published last year by CDC physicians in the agency's *Morbidity and Mortality Weekly Report* evinced extreme skepticism about using urine-based mycotoxin testing.

"CDC does not recommend biologic testing of persons who work or live in water-damaged buildings nor routine environmental sampling for mold," the article said. "To identify possible mold contamination, visual inspection is the first step."

RealTime's medical director, pathologist Dennis Hooper, M.D., practiced at Los Angeles County King-Drew Medical Center in the 1990s. Hooper drew close scrutiny in a 2004 *Los Angeles Times* investigation of shoddy care provided at the hospital, including his repeated misdiagnosis of patients, including oncology cases. The reporting led to Hooper resigning from a subsequent job at a hospital in San Antonio and being placed on five years of probation by the California Medical Board in 2006.

RealTime's spokesperson did not respond to phone calls and an email requesting comment.

Takeaway: RealTime's urine-based mycotoxin test is being offered directly to consumers, but questions have been raised about the necessity of such an assay.

References

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