

‘Staff love the change’: moving to MLS and why it matters

written by CAP TODAY
September 18, 2022

September 2022—Never a better time than now to switch from the medical technologist job title to medical laboratory scientist. So says John Waugh of Henry Ford Health System, where the job title was formally changed. “Because our people are scientists,” he explains. Waugh and other Compass Group members met online Aug. 2 with CAP TODAY publisher Bob McGonnagle, where they talked about the job title and testing for monkeypox.



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From the President’s Desk

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September 2022—Like so many pathologists, I have been keeping a close eye on the VALID Act, which would create a new framework for FDA oversight of laboratory-developed tests (LDTs). As I write this, the VALID Act has been voted out of a Senate committee and now awaits further action by the full Senate. I have heard from some pathologists and laboratorians who are concerned about this legislation and about the CAP position on it since the Senate HELP Committee released a draft on May 17, 2022. If you have not followed this bill and the issues of LDT oversight, allow me to offer some context. Regulatory oversight of LDTs has been in active discussion since 2008 when the FDA intervened with a national reference laboratory that was selling a test that had been developed at a prestigious university to identify high-risk women who might have ovarian cancer. Patient advocacy groups had raised a concern because several women had undergone unnecessary prophylactic bilateral oophorectomy based on this LDT. In response, the FDA expressed concern about the public harm, and the reference laboratory pulled the test from the market.

[Clinical pathology selected abstracts](#)

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September 2022—Clinical laboratory workforce shortages are an issue, in large part because it is difficult to find qualified testing personnel. Pathology residents present a solution to this problem because MD and DO residents who have current training certificates or medical licenses and who are trainees in pathology or other specialties can qualify to perform high-complexity testing.

[Anatomic pathology selected abstracts](#)

written by CAP TODAY
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September 2022—Hypergastrinemia states, such as achlorhydria from gastric mucosal atrophy or a gastrin-producing tumor, have been associated with the development of enterochromaffin-like cell hyperplasia and gastric neuroendocrine tumors.

[Pathology informatics selected abstracts](#)

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September 2022—Artificial intelligence in pathology has progressed recently, with at least four machine-learning algorithms classified for clinical use in the United States. While many challenges of implementing AI in pathology labs are well documented, one area that has not received much study is how an AI algorithm designed to augment pathologist performance will impact pathologists' clinical decisions.



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[Molecular pathology selected abstracts](#)

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September 2022—The widespread availability of next-generation sequencing-based somatic mutation analysis of solid tumors has led to the routine identification of patients eligible for FDA-approved targeted therapies, including immunotherapies. However, validated targeted therapies are available for only a small number of mutations, thereby preventing many patients from realizing the benefits of these life-extending modalities. With a focus on reducing the gap in eligibility for targeted therapy, the authors conducted a large-scale retrospective analysis of interactions between mutations, drug responses, and long-term cancer survival outcomes. They performed the analysis using the nationwide U.S.-based Flatiron Health-Foundation Medicine clinicogenomic database. The authors analyzed data on more than 40,000 patients from approximately 280 cancer clinics.

Q&A column

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Q. The laboratory at which I work uses two proficiency testing programs—from the CAP and an alternate provider—for dermatologists who perform fungal smears. Our laboratory administers challenges for both programs every six months. The dermatologists have variably passed and failed challenges from both programs such that the record of satisfactory challenges alternates between the CAP and the alternate provider’s programs. Is our approach allowed? Do we need to stick with a single PT provider for one year before switching? [Read answer.](#)

Q. Should flow cytometry be used to test a cerebrospinal fluid specimen with known or suspected Creutzfeldt-Jakob disease? Our hospital administration is pushing to run such samples. I think the testing should not be done because it would contaminate the instrument and potentially endanger the flow techs. [Read answer.](#)

Newsbytes

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September 2022—Do you want to play a role in solving a problem or improving a process in your laboratory via machine learning or artificial intelligence but don’t know where to begin? If so, take some time to learn, listen, share, and, perhaps, have a cup of coffee, says Scott Doyle, PhD, biomedical

engineer at the State University of New York at Buffalo.



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[Put It on the Board](#)

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September 2022—The Food and Drug Administration on Aug. 11 granted accelerated approval to Enhertu for adult patients with unresectable or metastatic non-small cell lung cancer whose tumors have activating *HER2* (*ERBB2*) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy. Enhertu (AstraZeneca and Daiichi Sankyo) is the first drug approved for *HER2*-mutant NSCLC.



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[FDA clears DiaSorin Simplexa COVID-19 test](#)

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Sept. 14, 2022—DiaSorin received 510(k) clearance from the FDA for its Simplexa COVID-19 Direct kit.



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