Pharma Intelligence
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The Association of Molecular Pathologists (AMP) 2020 Annual Meeting

Coverage: November 19th, 2020

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One upside of the coronavirus pandemic is a higher profile for laboratory medicine specialists. During a session on laboratory workforce issues at the Association for Molecular Pathology (AMP) virtual meeting on November 19, a consultant explained what she thinks that will mean for staff shortages, which have been exacerbated by the combination of rising demand due to an increase in the elderly population and diminishing supply as healthcare professionals retire. This Informa Pharma Intelligence newsletter also includes summaries of abstracts about technical topics and solid tumors that were chosen by meeting organizers as having particular significance.

Will COVID help or hurt lab staff shortage?

The coronavirus is creating more stress for lab professionals, many of whom were already harried, but it is also creating opportunities to lure in new recruits and hopefully start to fill a big staffing gap, according to consultant Susanne Norris Zanto.

According to the U.S. Bureau of Labor Statistics, there were an estimated 337,800 jobs for clinical laboratory technologists and technicians in 2019, and this figure is projected to rise by 24,700 to 362,500 by 2029. That represents a 7% increase in the number of openings, compared with 4% for all occupations, the consultant noted.

The Health Resources and Services Administration (HRSA) National Center for Health Workforce Analysis is also projecting a big increase in the number of openings in the future, a trend driven by changing demographics, as the elderly population grows, and demand for new tests. HRSA foresees a 19% increase in demand for medical and clinical lab techs between 2016 and 2030.

Survey data from the American Society for Clinical Pathology (ASCP) show that the highest vacancy rates are found in phlebotomy (13%) and immunology (11.5%) and the lowest in point-of-care services (4%) and molecular pathology/diagnostics (5.7%). An 11.3% retirement rate over the next five years in molecular diagnostics, with more supervisors exiting than staff, Norris Zanto pointed out.

"This shows molecular pathology and diagnostics is still a fairly young field in the clinical laboratory. Probably more young people are gravitating to this and are not quite as ready for retirement as some of the other ones," said the consultant, who is based in Helena, MT.

While the number of accredited training programs for medical laboratory scientists (MLS) and medical laboratory technicians (MLT) dropped by 6.5% between 2000 and 2017, the number of graduates rose by 42% during the same period, suggesting greater efficiencies in training, she said. Nevertheless, there is still a lot of concern that there are not enough graduates to fill vacancies. Based on Bureau of Labor Statistics and current vacancy rates, 22,560 lab professionals would be needed in 2019, but only about 7,000 technicians and scientists would graduate that year.

Among other driving the imbalance between supply and demand, are the tendency for universities to close MLS and MLT programs to cut costs, lack of compensation for preceptors, and an increase in retirement rates, which range from 9.6% to 27.1% over the next five years according to ASCP survey data.

"We are losing a really good brain trust there," Norris Zanto said.

High vacancy rates have meant longer hours and less work/life balance for some in the field. ASCP surveys have shown high rates of job satisfaction, but also high rates of stress and burnout.

Potential recruits are likely to be shopping around to gain sign-on bonuses, higher salaries, student loan forgiveness, and other perks. Once employees are on board, labs can improve their odds at retention by offering flexible schedules, better pay, and support for education and training, she said.

COVID-19 creates the risk for even more stress and burnout, potentially worsening the staffing crunch, but could also drive interest in molecular pathology as a career. Norris Zanto flagged the *laboratorysciencecareers.com* website, which features work related to COVID-19 diagnosis prominently and has seen an uptick in page views since the pandemic.

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Stories about lab science have multiplied since the pandemic, including coverage of the shortage of medical lab scientists, she noted. Lab professionals can further raise the specialty's profile by blogging, writing opinion pieces and letters to the editor, and being interviewed on podcasts.

"At all times showcase the profession. Don't ever downplay. Don't say you are one of those nerds that lives in the laboratory," the consultant advised. "Talk about how wonderful it is to be a medical laboratory professional – that it is a vital and promising healthcare career."

Abstract ST80 (poster)

RNA stool test makes headway in colon cancer screening

A multi-target RNA stool test could one day find a place in the arsenal of options for colon cancer screening, based on positive preliminary results from a prospective study presented on November 19.

The study evaluated the investigational RNA fecal immunohistochemical test (RNA-FIT) prospectively in 1,305 patients, including a training set of 939 and a testing set with 366. Participants were recruited via social media channels and completed testing at home. Stool samples were tested in the laboratory of the test's developer Geneoscopy, a health startup based in in St. Louis, MO.

Study participants had the investigational test as well as colonoscopy, which is the gold standard for detection of colon cancer. Efficacy was assessed based on the ability to detect cancer and high-risk adenomas relative to colonoscopy.

Study results were presented by Erica Barnell, Ph.D., the company's cofounder and chief science officer during an AMP meeting session highlighting abstracts on solid tumors research of particular significance. In the training set, the RNA-FIT test's sensitivity was 100% for colon cancer, 58% for high-risk adenomas, and 20% for other precancerous lesions. This sensitivity profile was achieved with an 85% blended specificity for hyperplastic polyps and no findings on colonoscopy, Barnell noted.

In the testing set, the RNA-FIT test demonstrated sensitivity of 100% for colon cancer, 60% for advanced adenomas, and 25% for other precancerous lesions. The blended specificity rate for hyperplastic polyps and no findings on colonoscopy was 84%.

Since only five cancers (.5%) were detected in this prospective study, company researchers sought to substantiate their findings by adding 17 samples from patients diagnosed with colon cancer. Out of 22 positive samples, the FIT-RNA test detected 21, including all known stage I and II cases.

The FIT-RNA test is being positioned as a low-cost, more convenient option than colonoscopy, which is highly sensitive for detection of cancer and advanced adenomas, but requires uncomfortable prep for bowel clearing, as well as sedation. Noninvasive, low-cost fecal assays, including a DNA test, are available, but these tend to be less sensitive than colonoscopy for cancer detection and much less effective when it comes to adenomas and other precancerous lesions, she noted.

Geneoscopy's test screens for eight biomarkers for RNA, which the company says delivers more information than DNA. With colon screening uptake lagging behind mammography for breast cancer and Pap smears for cervical disease, the company sees room in the market for an effective noninvasive test. Barnell noted during her AMP presentation that the company succeeded in recruiting its target population for the study. Out of 1,305 recruited, 21% had an income lower than $30,000 per year and 24% received health insurance through public programs.

The FIT-RNA test has breakthrough device status with the U.S. Food and Drug Administration (FDA) and is currently undergoing analytical verification and clinical validation.

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Abstracts TT10 and TT06 (posters)

How EGFR blood tests stack up in lung cancer

Three different blood testing methods for EGFR driver mutations are effective and similar for guiding use of targeted drug therapies in non-small cell lung cancer (NSCLC) patients, according to a study presented on November 19.

The study, which was supported by a research grant from Roche and AstraZeneca, evaluated the following methods for determining tyrosine kinase inhibitor sensitizing and resistance mutations in circulating tumor DNA (ctDNA) of NSCLC patients:

- next-generation sequencing (NGS)-based Avenio expanded kit (Roche);
- MassARRAY-based UltraSEEK panel (Agena Bioscience); and
- real-time quantitative polymerase chain reaction (qPCR)-based Cobas EGFR mutation test (Roche)

All three tests were effective for testing EGFR variants, with concordance of 83.3%, reported Lei Zhang, postdoctoral fellow at the University of Alberta in Canada, who presented results during a session highlighting four significant technical abstracts at the AMP meeting. Zhang noted that Roche's Avenio expanded kit had the highest sensitivity and that the company's Cobas real-time qPCR assay had the fastest turnaround time. Based on the results, hybridization capture-based NGS technology is looking very attractive for biomarker testing in ctDNA in NSCLC patients on targeted therapies, Zhang concluded.

In another study presented during the same session, Chris Karlovich, Ph.D., associate director of the Molecular Characterization (MoCha) Lab at the Frederick National Laboratory for Cancer Research reported similar molecular profiling results for a blood test as with tumor tissue testing in 25 patients with late-stage EGFR-mutant NSCLC.

For the study, tissue testing was performed with a comprehensive genomic profiling assay and blood testing was conducted with the MoCha ctDNA test. Both were large panels based on Illumina's TruSight Oncology 500 research use only assay

"High concordance was observed between matched tumor and plasma, with 87% of somatic variants identified in the tumor also identified in plasma," Karlovich reported.

Variants with potential to cause resistance that were identified in plasma included ERBB2, MDM2 amplifications, and an EGFR L718Q mutation.

Karlovich also reported 67% concordance for tumor mutational burden (TMB) measures on plasma and tissue samples, but acknowledged inclusion of just a small number of patients with very high TMB as a limitation of the research.