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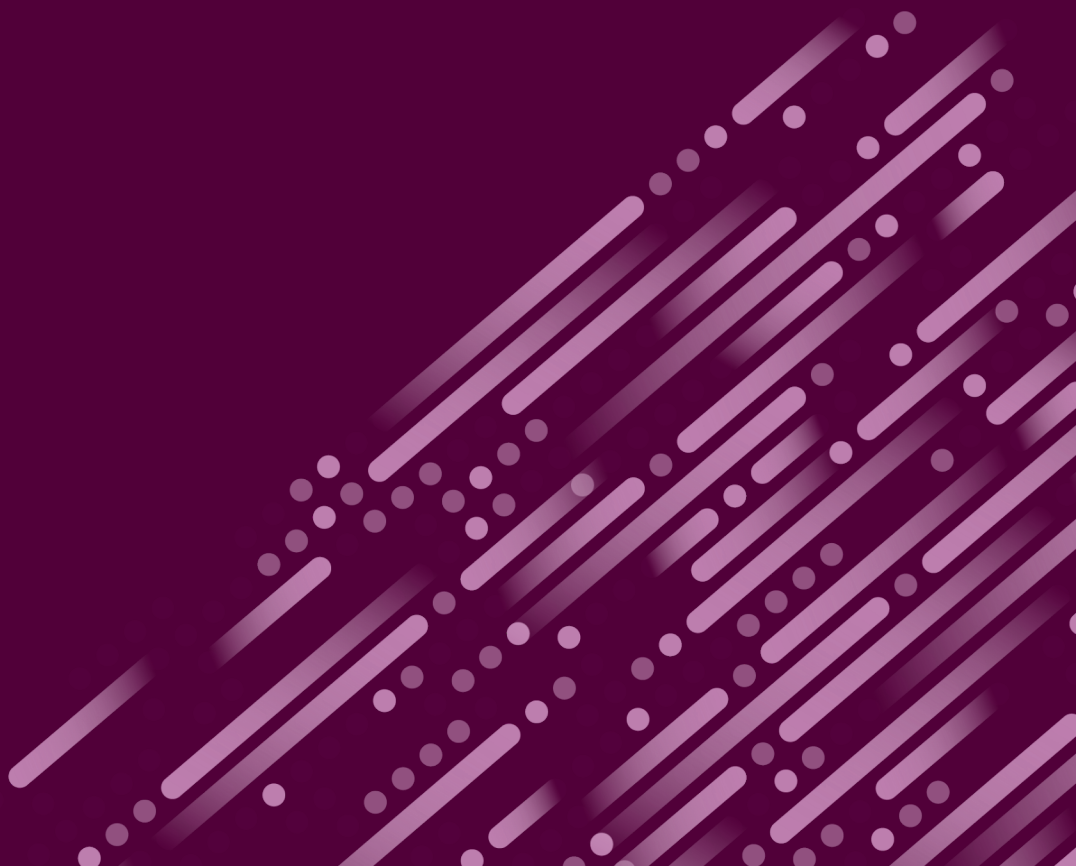
The Association of Molecular Pathologists (AMP) 2020 Annual Meeting

A Review



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Held in a virtual format this year, the Association for Molecular Pathology's (AMP) Annual Meeting & Expo featured scientific sessions, workshops, and advocacy sessions targeting issues at the heart of laboratory medicine practice during the COVID-19 pandemic. While many of the sessions were intriguing and insightful, Informa Pharma Intelligence has selected highlights from the conference that may be of particular interest to those working directly or indirectly in the pathology field.

Implementation Of Molecular Testing

On Monday November 16 Omai Garner, Associate Clinical Professor in the Department of Pathology and Laboratory Medicine at UCLA kicked off one of the scientific sessions by discussing testing errors in his timely presentation, Point-of-Care Testing for Microbiology in the Urgent Care.

In relation to Covid-19, there have been "relatively newsworthy large-scale problems with point-of-care testing," said Garner, which are important to add to the discussion around the most appropriate setting for point-of-care (POC) testing.

In 2000, the Center for Medicare and Medicaid Services (CMS) undertook a national survey of labs/offices performing waived POC tests. CMS directly observed 436 laboratories with certificates of waiver in eight US states. Tests consist of any of 56 tests granted "waived" status from Clinical Laboratory Improvement Amendments (CLIA). "Unfortunately, what they found were a large set of errors," said Garner, including test operator incompetence, non-adherence to procedure, and uncontrolled reagents and equipment.

How do we bring the quality of POC up to that standard you would expect from a clinical laboratory? Garner asked. "The point-of-care market is growing," he emphasized. "People want tests as quickly as possible from a results perspective. The tests are getting better and better. The sensitivity and specificity are achieving a level comparable to a clinical laboratory when performed correctly."

From an oversight perspective, the laboratory should be the owners of point-of-care testing across the system, he said, adding that a UCLA committee, it looks at the determination of medical need and appropriateness of testing, evaluation and selection of methods and instrumentation, establishment of policies and procedures, maintenance of test quality, training and competency assessment of personnel, and regulatory compliance as the pillars of how to perform POC testing the best way possible.

UCLA's POC management program for its 200 outpatient clinics aims to ensure quality across the health system, develop standardized workflows to ensure reliability, operator training, and quality control. It also allows for new test evaluation and comprehensive POC test launch. "If you're considering launching Covid-19 testing your infrastructure needs to be very strong," advised Garner.

Garner discussed the advent of POC molecular testing, brought about by false positives when quick turnaround tests were used. In January 2015, the FDA granted its first CLIA waiver to a nucleic acid-based test, the Alere i Influenza A&B. A few months later, Roche received a CLIA waiver for the cobas Liat System for Strep A. By the end of the year, Alere i Strep A, Roche cobas Liat influenza A & B, and Cepheid' s Xpert Flu+RSV Xpress had also received CLIA waiver. "We're very excited about this at UCLA," he said.

POC molecular infectious disease tests should be compared to the laboratory gold-standard and evaluated both for accuracy and workflow, which Garner stressed was essential for the roll out and use of these tests. Establishing quality POC testing across a health system with multiple clinics requires standardization of test platforms, workflows, QC, and operator training/competency, he said, adding that the volume of POC testing can vary dramatically amongst clinics. He warned that manual test resulting can lead to clinical confusion and transcription errors, recommending connectivity if possible.

"For the first time in history, molecular assays are being used in POC, and the results are available in about 20 minutes," said Raquel Martinez, System and Core Laboratory Director of Clinical and Molecular Microbiology at Geisinger Health System. "This is really exciting, but it is also really scary. No disrespect to non-laboratorians performing these tests, but from a laboratory perspective it is difficult to think of a non-laboratorian performing what is traditionally a laboratory test." There are so many ways for molecular tests to go wrong, but the real issue is that the laboratory is not in control and cannot oversee the assays, Martinez added.

She discussed the way in which Geisinger had driven the change from the laboratory to improve outpatient impact. It had identified the overcrowded emergency departments as a major problem, and to help with patient management it offered a faster assay with quick results. It hoped to improve microbial stewardship, faster length of stay, and a lowered overall cost.

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Geisinger stopped performing rapid antigen testing in 2013 and moved to molecular testing. “We knew we needed speed, we needed to reduce our collect-to-result time,” recalled Martinez. “With molecular tests comes cost and that is listed as the number one roadblock for many laboratories. Implementation can also be difficult if you don’t have personnel to perform the testing and if the transport is significantly delayed, the benefit is lost,” she explained.

When deciding to implement a new assay there are some key considerations, Martinez advised. Think about the type of laboratory you are, what platforms you use, who gets the test and when, where is the test performed, who is doing the testing, and what resources you need. She also advised considering how your decision to move to molecular testing will affect your stakeholders.

Covid-19 has made the continuity of the molecule POC difficult, with only four out of 23 urgent care sites still operational due to the biosafety risk posed by the pandemic. Covid has also meant shortages in reagents, staffing and supplies. Throughput is also an issue because of the increased demand for testing, Martinez said, and the lack of automation with these testing platforms.

Geisinger is currently planning its dedicated mobile site for infectious disease testing. Martinez said she believed portable devices are on the horizon and will soon be widespread.

Thinking Ahead To A Biden Administration

A new administration in the White House under President Joe Biden could bode well for clinical laboratories, experts said during a panel session November 17 organized by the AMP’s Economic Affairs Committee.

The panel session focused on lab economics amid COVID-19. The public health emergency declared by the US Department of Health and Human Services (DHHS) is set to expire on January 20, following a 90-day extension. That end-date will likely be extended again based on the current state of the pandemic, with reports of mounting cases and hospitalizations around the country at the cusp of the holiday season. Even after the public health emergency ends, there will be likely be a need to extend coverage and payment policies for several months, said session moderator Erika Miller, Senior Vice-President at CRD Associates, in Washington, DC.

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We know President-elect Biden is committed to science and evidence-based policies and this can be expected to factor heavily into decisions about extensions, said Miller, adding that it is not going to be like "flicking the light switch" off. Miller also expects a different and more pro-testing posture from Biden compared with the last four years.

In a plan to combat COVID-19 published on his website *joebiden.com*, the president-elect called for an urgent and robust national response to the pandemic and placed heavy emphasis on testing. Among other things, the plan backs "wide availability of free testing" and the "elimination of all cost barriers to preventive care and treatment for COVID-19".

The meaning of "free" is likely that testing is available, with no constraints on supply and for patients getting screened, said Jay Patel, Vice-Chair of New Codes and Pricing on AMP's Economic Affairs Committee. Supply chain issues could still benefit from greater coordination and payers may face pressure to maintain open coverage policies, said Patel.

Miller sees a lot of opportunities for change in the new year. The AMP has been heavily focused on coding and reimbursement issues during the pandemic and it would like to see a change to a new US Centers for Medicare and Medicaid Services (CMS) policy on COVID testing reimbursement. As of January 1, a new healthcare common procedure coding system (HCPCS) policy for high throughput COVID-19 testing is set to take effect. To qualify for a higher rate, the majority of a lab's tests must be turned around within 48 hours of specimen collection. Panelists noted that supply chain issues make the turnaround time target difficult to achieve and that there are also administrative burdens associated with compliance. There will now be an opportunity to weigh in on this with a new administration, Miller said.

Similarly, Pranil Chandra, Vice-Chair of Coverage Decisions on the Economic Affairs Committee, said that he sees an opportunity to focus on areas that are working well but also on opportunities for better coverage and pricing policies. Issues need to be framed in a manner that demonstrates the impact on patient care as well as effects on laboratories doing testing around the country, said Chandra, who is Chief Medical Officer of Genomic and Clinical Pathology at PathGroup in Brentwood, TN.

Several different options should be made available to clinicians, including panel tests that incorporate COVID-19. The pandemic provides an opportunity for education on the value of these tests and to promote better coverage policies, Chandra said.

Covid-19 Molecular Testing: Experiences From The Field

On Tuesday 17, in a discussion-based format, four expert clinical microbiologists from academic, reference, and public health laboratories discussed the challenges and triumphs associated with SARS-CoV-2 molecular testing during the COVID-19 pandemic.

In an enlightening session, Teresa Karre of the Nebraska Methodist Hospital and Medical Center, Anthony Tran of the District of Columbia Department of Forensic Sciences, Beth Marlowe from Quest Diagnostics, and Michael Bachman of the University of Michigan shared their experiences.

The panelists began by discussing the lead up from hearing of the disease to testing. Bachman described having to wait to decide which assay would be the best way forward for testing. “On February 29th when we knew there was a pathway to do testing, we tried to assess what was the quickest way to get that done. It was clear to us that the CDC assay was the best way to go, with IDT producing those reagents at scale,” he recalled.

Marlowe of Quest Diagnostics identified the challenges of finding enough reagents to satisfy the FDA to create a test. Her laboratory in California partnered with a sister laboratory in South Korea, which sent extract from patients. “If it hadn’t been for that we would not have been able to get the tests up as quickly as we did, even though we had asked for help from others,” she said.

All panelists agreed that their laboratories were not prepared for the wave of testing that came to them. Tren of the District of Columbia Department of Forensic Sciences only had a team of 24 when Covid hit. Karre of Nebraska Methodist Hospital said that pre-Covid its monthly molecular volume was about 2000 a month, this has now more than doubled she said. “Its been really challenging. We’ve had to shift a lot of staff from our core lab to our molecular area to manage that.” Bachman said that the University of Michigan used its m2000 platforms for a lot of the testing. In August 2019 the staff using that system were doing around 400 tests a week, in August 2020 they were performing 6,300 tests a week, a 15x increase for that group.

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Scaling up testing is not something you take lightly, said Marlowe, discussing the challenges of meeting the two-day turnaround time, the logistics of transporting specimens and remaining accurate. On March 9, Quest, which uses the Roche system, could manage a throughput of 2000 tests a day. Today, it can handle 200,000 a day across the system.

The public health laboratory in DC was already running a lot of emerging infectious diseases tests, Tran explained, and was running around 2000 tests. It now runs around 100,000 tests a week and is running 4000-5000 molecular tests a week for SARS-CoV-2. Its more than 20x what the lab was originally running pre-Covid. It was able to hire a large, contracted workforce to meet the demand. It was also the only public health laboratory that didn't have a e-TOR (electronic test ordering and reporting) system, so every person had to fill out a manual test request form which would have to be downloaded off the lab website, sent in and a faxed result would be sent. During the pandemic it launched three web-based e-TOR systems. "I'm very proud of the team that they were able to do that in a very short amount of time, throughout all the IT issues the city had with regards to VPN access and external access for folks into the firewall," Tran said. "People don't give it much thought but in a government institution there are lots of obstacles to go around."

"We're moving so fast, if we just had a little time to stop and think about how to manage this a little smarter, we could make up for the allocations or try to get through the volumes. Its really challenging, said Quest Diagnostic's Marlowe.

The panel was asked if this experience has improved or impaired their ability to direct their lab. Marlowe opined that this has been an opportunity to highlight the profession, and what happens in a laboratory, as well as testing as a part of the continuum of care. "I'm really hoping something positive can come from this whole experience," she said.

"Other areas of the lab have suffered because so much of our focus has been on this," said Karre. "It's difficult to keep up with your normal director duties when you're managing a crisis. But in other ways we've come together as a team in a more effective way than I've seen before, so in some ways I believe it has improved my director capabilities."

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Point Counter Point: Clinical Metagenomics Is Worth the Juice

Metagenomics, the study of genetic material recovered directly from environmental samples, has pros and cons for laboratories and health systems, and experience is growing with effective deployments. Experts hashed out the potential wins and losses during a Point/Counterpoint panel session on November 18.

Laying the ground rules for the panel session, moderator Erin Graf, of the Mayo Clinic Arizona, explained that for the discussion, metagenomics would be defined as "unbiased sequencing of DNA and in some instances RNA from a variety of patient sample types and for different clinical indications in order to determine presence of an possible infectious agent or agents."

What could be the potential downsides of next-generation sequencing (NGS) for pathogens? Cost is a biggie. For example, if a sequencing test costs $2,000 but 14 patients need to be screened to get one clinically meaningful or actionable result, that is a total cost of $28,000, Graf posited. Most of these tests are being sent out and assuming no reimbursement, the lab would have to absorb the costs.

Taking the con side of the debate on metagenomics, the University of Pittsburgh's Stephanie Mitchell said that her experience with the technology was that findings were typically negative and ultimately had no impact on care. The experience, however, did spur good conversations with clinicians about the advantages and limitations of sequencing in the context of infectious diseases. Mitchell also flagged disappointing specificity as a major limitation and noted the risk for false positives leading clinicians down a rabbit hole instead of paying attention to symptoms.

When a new platform is introduced, testing protocols may not be in place yet for appropriate use, said Debra Palazzi, Chief of Pediatric Infectious Diseases at Texas Children's Hospital in Houston, which offers plasma-based metagenomics. Clinicians may be prone to ordering NGS when conventional testing can deliver results and delivering them faster, she commented. And as opposed to substituting for other tests, the NGS is adding to the number of tests, she added. The effect on overall costs is an open question; from 3-50 tests have been ordered per month and staff are in the process of analyzing data, Palazzi said.

Although the session, which ran 90 minutes, included many pros and cons, a general message emerged that NGS can be valuable for some patients and that mastering appropriate use is a work in progress.

Palazzi recalled that testing helped solidify the diagnosis of brain abscess caused by *Bacillus megaterium* in a premature infant, which then enabled delivery of targeted therapy and a conversation with family about expectations for clinical outcomes.

Clinical utility really needs to be considered thoughtfully when ordering a test, said Steve Miller, Director of the Clinical Microbiology Laboratory at the University of California San Francisco (UCSF), which has fully validated metagenomic sequencing, starting with cerebrospinal fluid samples. Ordering clinicians should make sure the patient has a high likelihood or a reasonable likelihood of having an infection, said Miller, adding that at UCSF all test orders are reviewed to ensure they meet clinical criteria for best use.

Immunocompromised patients may be hard to diagnose, with hidden sources of infection they are unable to clear and could benefit from testing. A negative NGS result in an immunocompromised patient could also have a positive impact on patient care by ruling out certain classes of infections, allowing clinicians to investigate other causes of disease.

There may also be clinical utility for detection of novel or re-emerging organisms. In one case, metagenomics enabled the diagnosis of a transplant patient with symptoms of encephalitis and meningitis as well as liver abnormalities with Saint Louis encephalitis, which was thought to be absent in California and Arizona, Miller said.

An Insight Into Developing The Cancer Dependency Map

William Hahn of the Dana-Faber Cancer Institute spoke on Friday November 20 about defining a cancer dependency map. Applying precision cancer medicine requires an understanding of somatic alterations and their consequences in tumors. Dr Hahn's presentation described his team's efforts to comprehensively map genes required for the fitness of human cancers using genome scale genetic approaches.

"No longer is cancer a question of asking what the possible mutations are, it is really knowing what mutations occur and knowing when they occur. And that changes the way we think about cancer research," he said. The ability to find mutations easily has also transformed cancer care, he continued.

The current challenges in precision medicine are two-fold, he explained. Firstly, for most tumors we don't know how to read the cancer genome, secondly, drugs are available to target a limited number of vulnerabilities. Dr Hahn and his team have been looking at this problem from a reverse engineering point of view using genetics. He has been using functional approaches to cancer phenotypes; gain of function using the ORF library and loss of function using CRISPR-Cas9.

Dr Hahn's team firstly looked at the TP53 allele to map out why the mutations occur, then looked at the oncogene KRAS. They took the wildtype KRAS allele and introduced mutations in every position in a saturated way, looking to see which alleles would transform cells. Data found that there are around six positions that clearly mutated and had function in transforming cells.

"Having this knowledge will allow us to know the consequences of each set of alleles as we find them in the tumor, but also allows us to anticipate resistance as we make drugs," explained Dr Hahn. He floated the idea that this system could be used on all cancer genes. He is currently working with the Broad Institute on an ambitious project which, he said, goes further than has been gone before. "This is dependent on making very robust assays to assess gene function," he said.

The team has been looking at ways to have an assay that is not dependent on bespoke assays to readout gene function. It has been questioning if it is possible to capture meaningful phenotypes with "general" assays, and which phenotypes might be amenable. Signatures can predict complex phenotypes, he said. And while several approaches to this are complementary, how would this be done to scale?

Single cell sequencing can identify impactful variants. This experiment has now been used on hundreds of alleles, said Hahn, and now is the time to figure out whether this can be scaled to do saturation for any gene. "The saturation mutagenesis program allows us to answer a clinical need of understanding variants of unknown significance. The current technology will allow analysis of dozens of genes, but there are now ways to do this on a much larger scale," explained Hahn.

What if we used systematic studies without focusing on particular genes, he asked, identified by genome sequencing studies? To answer this, Hahn and his team have created the Cancer Dependency Map. “The idea is to take molecular and genetic information of cell lines and tumors, models of those tumors and then perturb them with small molecules or genetics with the idea that, at scale, this would give us a comprehensive map of what genes and pathways are required for particular subsets of tumors.”

Hahn started this project because he was “increasingly impatient” with the usual way of looking at genome scale studies. He wanted to focus on the unknown. To do this he had to find a lot of cell lines, of which he now has 1600. Researchers at the Broad Institute had been developing new patient-derived models, and between the amount of cell lines and the new models, “our hope is to cover the lineages and the micro mutational spectrum that exist in tumors,” Hahn explained.

The cancer dependency map will be most helpful for a subset of cancer cell lines, but not all, he said. It is the preferential dependencies that are going to be most insightful, he explained. All the molecular information and preferential dependencies taken are predictive models created to predict which cell lines are dependent of particular genes, and what other features line up. “Much to my surprise mutation is not the best predictor of dependency, but gene expression” said Hahn.

All data is available on *depmap.org*

Notable Abstracts

Abstract G13

Universal Genetic Testing Broadens Catch In Cancer Patients

Universal genetic testing has the potential for detection of findings beyond what is possible through screening based on selection criteria enshrined in clinical guidelines, Memorial Sloan Kettering researchers reported in a study presented on November 17.

The study was featured in a session highlighting four abstracts that were determined to have significant value by the AMP’s leadership in genetics. Researchers compared two different approaches to testing in patients evaluated

for cancer at the Memorial Sloan Cancer Center between 2015 and 2020, with a range of tumor types represented (breast, ovarian, colorectal, pancreatic, and prostate).

In one cohort of 4,120 patients, selection for genetic testing was done in the traditional way, that is based on clinical and family history, and screening focused on a set of known genes. In the other cohort, which included 9,341 cancer patients, all underwent testing for 76 or 88 genes known to be associated with predisposition for a wide array of cancer types.

Researchers compared the positivity rates associated with the two approaches and noted additional findings that surfaced through broader genetic testing. Results were reported at the AMP meeting by Ozge Ceyhan Birsoy, a clinical molecular geneticist at Memorial Sloan Kettering.

Researchers reported similar positive rates for most tumor types, for example the positivity rate for pathogenic or likely pathogenic variants in breast cancer patients was 7.5% and 9.6% with broad, unselected testing. Birsoy noted during her presentation that there were differences in patient numbers. For example, when it came to breast cancer, 3,341 patients had targeted testing compared with 2,249 who had the universal approach. But for colon cancer, only 252 had targeted testing compared with 2,060 universal.

In the cohort of 9,341 patients who had universal testing, the researcher reported that 9.1% had pathogenic or likely pathogenic variants that would not have been picked up in a targeted panel test. And of those with additional findings beyond a targeted panel test, 4.6% had variants in a gene of high or moderately high penetrance, Birsoy reported. In a small number of cases, patients had findings on broad testing that could lead to changes in treatment, that is for prophylactic treatment.

The results come at a time of growing debate about how broad testing should be in cancer patients and when universal, unselected testing is appropriate. However, questions remain about how viable universal testing is from an economic point of view and how to address the risk of detecting and acting upon variants of unknown significance.

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Abstract ID27

Blood Test Helps Pinpoint Cause Of Pneumonia

A microbial cell-free DNA sequencing blood test was helpful for diagnosing invasive mold infections in pneumonia patients, with potential to cut down on invasive procedures, researchers for Karius reported on November 17.

The test is an iteration of a microbial cell-free DNA sequencing test for more than 1,000 pathogens developed at Karius, of Redwood City, CA. During an AMP session highlighting four abstracts deemed to be particularly significant by infectious disease leadership at the meeting, Karius Chief Scientific Officer Timothy Blauwkamp explained that the test had been optimized for diagnosing invasive mold infections, which present challenges for detection.

Blauwkamp presented data for a subset of 68 hematopoietic stem cell transplant patients with pneumonia from a previously reported study. Standard workup for pneumonia patients with suspected mold infections includes invasive bronchoalveolar lavage (BAL) procedures or lung biopsies that pose risk for complications in immunocompromised patients.

The retrospective study compared the blood test on stored samples to results from a range of BAL tests individually and as a composite. They also tested specificity used in 19 controls with pneumonia caused by bacteria or viruses as well as blood from 684 donors presumed to be healthy.

In the 68 patients, 191 invasive tests had been conducted, or about 2.8 per patient. The blood test gave the same result as findings from up to eight invasive tests in 72% of patient cases. Sensitivity was like that of each BAL test individually. Specificity for the blood test was 100% in the control patients and 97.4% in the reference dataset.

Turnaround time for the blood test is 48 hours, whereas the results from multiple BAL and culture tests can take a week or more to receive, he noted. There are also potential cost savings if invasive procedures could be reduced, considering that they involve specialized surgical care, anesthesia, and operating room time.

However, it was acknowledged that a lot more data are needed to prove the hypothesis that redundant invasive tests could be eliminated. The company is currently evaluating the test in a prospective multicenter study of pneumonia in immunocompromised patients.

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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 attractive for biomarker testing in ctDNA in NSCLC patients on targeted therapies, Zhang concluded.

In another study presented during the same session, Chris Karlovich, 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 high TMB as a limitation of the research.

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, the company's Co-Founder 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.

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The FIT-RNA test is being positioned as a low-cost, more convenient option than colonoscopy, which is sensitive for detection of cancer and advanced adenomas, but requires uncomfortable prep for bowel clearing, as well as sedation. Non-invasive, 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 pre-cancerous 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 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 US Food and Drug Administration (FDA) and is currently undergoing analytical verification and clinical validation.

There is every hope that AMP's annual expo will be hosted in person in 2021. All presentations from 2020 will remain available to delegates until February 15.