Put It on the Board, 2/13

An estimate of specimen identification error

The frequency of occult type one specimen provenance errors (complete transposition between patients) and type two (contamination of the target patient's tissue with that of one or more unrelated patients) in 54 urology practices and surgical pathology labs was 0.26 percent and 0.67 percent, respectively, according to a study published last month. It's a prospective evaluation of almost 13,000 prostate biopsies in routine clinical practice, by John D. Pfeifer, MD, PhD, and Jingxia Liu, PhD, of Washington University School of Medicine and published in the *American Journal of Clinical Pathology* (2013;139:93–100).

The authors define a specimen provenance complication (specimen ID error) as the absence of any direct or indirect indication that a specimen switch or contamination may have occurred.

Strand Analytical Laboratories, Indianapolis, markets "know error," a system to detect occult specimen provenance complications in routine practice. Strand provided the authors with access to its data set from testing for occult SPCs in the setting of transrectal prostate biopsy performed to rule out adenocarcinoma of the prostate.

"The results of our analysis of this data set not only provide an estimate of the rate of occult SPCs in the United States but also demonstrate that errors occur across the range of practice settings and diagnostic laboratories," the authors write. Every urology practice setting and pathology lab type (for which at least 1,000 specimens were included in the data set) had a nonzero rate and at least one of each type of error, they say.

Overall, the mean frequency of SPCs across practice settings was 0.22 percent for transpositions and 1.69 percent for contamination.

Dr. Pfeifer and Dr. Liu cite six limitations of the data set, among them the following:

- Details of the testing paradigm were not standardized across practice settings, and the impact of the detected errors was unknown.

- The prospective short tandem repeat analysis was ordered as part of routine care by individual urologists and urology groups that chose voluntarily to implement the know error system; whether the self-selection introduced bias is unknown.

- It's unclear whether pairings of specific urologic pathology practices and specific pathology labs created workflows that introduced bias.

- The know error system itself, or associated awareness by the urology practices or pathology labs that their processes were under scrutiny, may have decreased the intrinsic rate of occult SPCs.

"It is unknown from our data set at which point in the test cycle (preanalytic, analytic, or postanalytic) the identification errors occurred…or, in most cases, whether mismatches were caused by misidentification errors relating to the reference specimen or the tissue biopsy specimen itself," the authors write. The QA and QC steps performed at Strand, they add, make it difficult to argue that the short tandem repeat test process itself was responsible for the errors.

Cepheid CT/NG test classified as moderate complexity

The FDA has categorized Cepheid's Xpert Chlamydia trachomatis/Neisseria gonorrhoeae test as moderate complexity under CLIA. Xpert CT/NG, which the FDA cleared on Dec. 27, runs on the GeneXpert system.

Xpert CT/NG incorporates several novel design features, David Persing, MD, PhD, Cepheid's chief medical and technology officer, said in a statement. "First, our research team used in silico approaches to uncover multiple genomic targets for improving the accuracy of both CT and NG detection. Second, we included a first-in-class sample adequacy control that we believe overcomes limitations of first-generation technologies and adds significantly to the interpretation of diagnostic results generated by the GeneXpert system."

The test's moderate-complexity classification is "a breakthrough for sexual health and STD prevention," Jeffrey D. Klausner, MD, MPH, professor of medicine, UCLA-David Geffen School of Medicine, Los Angeles, said in a statement. "The large number of moderate-complexity point-of-care laboratories that exist in U.S. hospitals and clinics can now offer rapid, highly accurate, and private same-day STD testing."

ARUP to offer Oncimmune early-stage lung cancer test

ARUP Laboratories on Jan. 9 announced it is entering into an agreement with Oncimmune USA to offer to ARUP's clients the EarlyCDT-Lung, a blood test that aids in the risk assessment and early detection of lung cancer. Patient blood samples sent to ARUP will be analyzed at Oncimmune's laboratory in metropolitan Kansas City.

Early CTD-Lung has a 93 percent specificity, seven times fewer false-positives and seven times better positive predictive value than CT, and greater than 91 percent accuracy, when considering a population with two percent prevalence of lung cancer (20 lung cancers per thousand), according to Oncimmune.

An audit of clinical data from the first 1,600 patients tested by EarlyCDT-Lung validates its utility to detect early-stage lung cancer and its overall performance, Oncimmune says. The Scottish government is conducting a 10,000-patient randomized clinical trial to validate the test's economic benefit in screening high-risk patients.

Hologic test cleared for detecting GI pathogens

The FDA on Jan. 17 cleared Hologic's Prodesse ProGastro SSCS assay, a real-time multiplex PCR test that provides qualitative results in four hours for five common bacterial pathogens associated with gastroenteritis.

ProGastro SSCS is for detecting and differentiating Salmonella, Shigella, and Campylobacter (C. jejuni and C. coli only, undifferentiated) nucleic acids and the Shiga toxin 1 (stx1) and 2 (stx2) genes.The assay is suitable for mid- to high-throughput settings.

ProGastro SSCS is optimized to use the same samples that physicians are collecting and labs are already accustomed to processing for stool culture, streamlining the transition to a molecular detection method.

IntelligentMDx to develop tests for Qiagen platform

IntelligentMDx on Jan. 7 entered into a multi-year development and license agreement with Qiagen to design, develop, and manufacture several undisclosed CE-marked and FDA-cleared diagnostic tests for use on Qiagen's QIAsymphony Rotor-Gene Q (RGQ) MDx automated platform.

The tests that IntelligentMDx is developing will be incorporated into Qiagen's menu of molecular diagnostic assays and be distributed worldwide by Qiagen. Qiagen has also retained the rights to assume manufacturing of the assays pursuant to volume considerations.

IntelligentMDx uses a proprietary bioinformatics platform to develop assays that can be formatted for a variety of real-time PCR platforms.

QIAsymphony is a laboratory automation system for molecular testing that incorporates all workflow steps from biological sample to result. The workflow solution consists of modules that can be used as standalone systems or

combined into the fully integrated QIAsymphony RGQ system.

Latest lab vacancy data in

Laboratories reported national vacancy rates of between seven and eight percent for nonsupervisory medical laboratory scientists last year, according to the findings of the ASCP 2012 vacancy survey.

M. Sue Zaleski, MA, HT(ASCP)SCT, 2011–2012 chair of the ASCP's Council of Laboratory Professionals, who helped construct the survey, was surprised at the survey's national and regional statistics.

"It shows national vacancy rates of about seven or eight percent for nonsupervisory personnel, which is lower than what we are experiencing in our region," Zaleski, who is the Lean management engineer in the Pathology Department at the University of Iowa Hospitals, said in a statement. "Our vacancy rates at the University of Iowa are running at about 10 to 11 percent."

Future ASCP vacancy surveys will include a breakdown of vacancy rates by state.

For the 2012 survey, seven new departments—core lab, lab safety, molecular biology/diagnostics, reproductive medicine and genetics, and specimen collecting—were added to the 10 lab areas surveyed in 2010.

Blood bank departments ranked the highest in the percentage of supervisory positions that have remained unfilled for more than six months, with 25 percent vacancy rates, followed by anatomic pathology, with nine percent rates.

The immunology and chemistry/toxicology departments had the highest overall percentage of employees expected to retire in the next 24 months, at 10 percent each. Cytogenetics and phlebotomy departments had the lowest such rates, with four percent each.

In the category of supervisor retirement rate, the hematology/coagulation departments ranked the highest, at 24 percent, and histology and molecular biology/diagnostics departments ranked the lowest, with four percent each.

The chemistry/toxicology and immunology departments led in the category of largest overall percentage of retirements by department, at 10 percent each.