Put It on the Board, 9/13

FDA clears Vitek MS

BioMérieux has been granted FDA 510(k) de novo clearance for Vitek MS, the first clinical mass spectrometry MALDI-TOF-based system available in the U.S. for rapid identification of disease-causing bacteria and yeast.

To gain FDA clearance, BioMérieux submitted data from a multi-center study consisting of 7,068 clinical isolates. Vitek MS accuracy was compared with 16S ribosomal RNA gene sequencing for the following categories of microbial pathogens: anaerobic bacteria, Enterobacteriaceae, gram-positive aerobes, fastidious gram-negative bacteria, gram-negative non-Enterobacteriaceae, and yeast. The overall accuracy of Vitek MS compared with nucleic acid sequencing for these organisms was 93.6 percent.

“In the battle with infectious diseases, time is a luxury we don’t have. MALDI-TOF will have one of the greatest impacts on clinical microbiology since the use of molecular amplification methods for the identification of pathogens,” Christine C. Ginocchio, PhD, MT(ASCP), senior medical director and chief, Division of Infectious Disease Diagnostics, North Shore-LIJ Health System Laboratories, and professor, Hofstra North-Shore LIJ School of Medicine, said in a statement.

For some organisms, she says, the savings in time before clinicians have the results will be 24 hours. “For other more difficult organisms, it could be 48 or even 72 hours.”

Dr. Ginocchio describes the reproducibility of the results with Vitek MS as “exceptionally accurate.”

“Studies that were done in the trials where it was tested at three different laboratories by different technicians on different days showed that the same result was obtained in probably greater than 99 percent of the tests that were performed,” she says.

Researchers from Washington University School of Medicine decided to put Vitek MS to a rigorous test by analyzing a 10-year collection of clinical samples that was initially difficult to identify with traditional methods.

“The question was, if we tested these organisms with MALDI-TOF MS, how would we do?” Carey-Ann Burnham, PhD, assistant professor of pathology and immunology at Washington University School of Medicine and medical director of microbiology at Barnes Jewish Hospital, said in the statement. “So we pulled these samples from the freezer and the answer was very exciting. Nearly all of the isolates were able to be identified with high accuracy in a matter of moments using a single method: MALDI-TOF MS.”

Rapid pathogen ID study wins pharmacy innovation award

A study conducted by the Pathology and Genomic Medicine and the Pharmacy departments at The Methodist Hospital in Houston has been selected for the Award for Innovation in Pharmacy Practice by the American Society of Health-System Pharmacists Foundation.

The aim of the study, titled “Integrating rapid pathogen identification and antimicrobial stewardship significantly decreases hospital costs,” was to determine whether mass spectrometry coupled with antimicrobial stewardship provides a substantially improved alternative to conventional laboratory methods. The study is in this month’s Archives of Pathology & Laboratory Medicine and was reported in the January 2013 issue of CAP TODAY (“Triple play in lab’s MALDI-TOF efforts”).

The award, given annually, is for an outstanding contribution to the biomedical literature that describes an innovation in pharmacy practice in hospitals or health systems.

“The goal of integrating rapid diagnostic microbiology laboratory techniques (ie, pathogen identification and susceptibility testing) with antimicrobial stewardship practices was to improve outcomes among hospitalized

patients with gram-negative BSIs [bloodstream infections]," write the authors. The average turnaround time for final culture identification and antimicrobial susceptibility results during the intervention period was a day faster compared with the preintervention study group—24.4 versus 47.1 hours. The targeted antimicrobial therapy given earlier led to shorter lengths of stay, lower mortality rates, and reduced health care expenditures.

ACOs and the threat of liability

The hundreds of health systems that have adopted the ACO model are taking on new liability risks thanks to a "new dimension of medical malpractice liability that goes hand in hand with the cost containment charge: the claim that the ACO's actions or policies prioritized cost savings over patient safety, contributing to the patient's harm," say the authors of a July 10 *JAMA* Viewpoint (310:141–142).

H. Benjamin Harvey, MD, JD, of the Department of Radiology, Massachusetts General Hospital, and I. Glenn Cohen, JD, of Harvard Law School, write in "The looming threat of liability for accountable care organizations and what to do about it" that the ACO will walk the "same precarious line between cost savings and patient care" as managed care organizations in the 1990s. MCO member lawsuits alleged negligent medical decisions stemming from the MCOs having prioritized their financial success over the health of their members.

The Supreme Court in 2004 gave MCOs some immunity against these types of state law tort claims "by recognizing federal preemption (ie, that federal law blocked enforcement) of these claims for employer-provided health insurance plans subject to the requirements of the Employee Retirement Income Security Act (ERISA)," the authors write. ACOs, they say, will generally not have the benefit of ERISA, "nor are they slated to get comparable federal liability protections."

ACOs have advantages over MCOs for containing costs without negatively affecting care, the authors say, pointing to the mandatory quality and outcomes standards common to shared-risk contracts and the lessons learned from the MCO experience, better patient-related analytics, and more control over physician behaviors.

What do they say ACOs can do? For now, they can buy managed care errors and omissions insurance as partial protection, match care algorithms to published guidelines or evidence-based medicine, and "be cautious when implementing incentive-based compensation that ties a substantial portion of physicians' income to their ability to reduce patient care costs."

Congress could amend ERISA such that its protections for employer-provided plans apply equally to ACOs and MCOs, though many would argue, they say, that ERISA protections went too far.
Another option: Establish safe harbors in the form of best practices relating to compensation structures and the use of evidence-based medicine, with ACOs that meet the safe harbor requirements receiving protection from state law tort claims.

Xifin acquires PathCentral

Xifin has acquired the product and service assets and related intellectual property of PathCentral, which provides AP Anywhere, a cloud-based anatomic pathology and molecular diagnostics laboratory information system.

PathCentral also provides an online information exchange and global digital consultation forum (PathCentralPro.net) that enables pathologists to collaborate worldwide using digital pathology technology, social media, and LIS functionality in a single cloud-based platform.

"The acquisition of PathCentral expands our technology platform and advances Xifin's vision of the open, secure exchange of diagnostic, financial, and clinical information," Lâle White, CEO of Xifin, said in a statement.

BioMérieux acquires BioFire

BioMérieux has entered into an agreement to acquire BioFire Diagnostics.

BioFire’s FilmArray is a key asset in the development of BioMérieux’s franchise in infectious disease diagnostics, which accounts for 85 percent of sales in clinical applications. On the basis of ongoing R&D, FilmArray should make it possible to detect more than 70 disease agents responsible for respiratory, gastrointestinal, and blood infections within the next three years, according to a statement from BioMérieux.