Put It on the Board, 8/15

To meet TAT goals, Vanderbilt builds ED lab

In a move expected to help meet accreditation standards on testing turnaround times for stroke and chest pain patients, Vanderbilt University Medical Center's emergency department will gets its own satellite laboratory this month. The 333-square-foot space—dubbed "the nest" for its small size—comes after years of struggle with the turnaround time demands for certification as a Joint Commission Comprehensive Stroke Center and accreditation as a Chest Pain Center by the Society of Cardiovascular Patient Care.

"We've been tackling this for many, many years. I've been there for eight years and pretty much since the time I got there we were meeting with the ED to try to tackle this issue," Alison Woodworth, PhD, said during her presentation last month at the American Association for Clinical Chemistry Annual Meeting in Atlanta. She is medical director of Vanderbilt's ED laboratory and also medical director of esoteric chemistry.

Dr. Woodworth

The accreditation standards can be exacting. The Joint Commission's stroke protocol, for example, seeks an order-to-result TAT of 45 minutes or less for complete blood and platelet counts, troponin, creatinine, electrolytes and vitamin K, and PT/INR. Chest pain center accreditation, meanwhile, requires an order-to-result TAT of 60 minutes or less for baseline troponin testing when done on core laboratory instrumentation, or within a half-hour if performed using point-of-care equipment.

How to meet these goals, while also hitting analytical quality standards, requires a careful consideration of different factors, Dr. Woodworth said. These include who will operate the tests; how specimens are labeled, accessioned, and processed; and what mix of core, satellite, and POC testing to employ. Nationwide, there has been a major shift to POC testing for troponin I, she noted. Of about 3,000 laboratories surveyed in 2005, less than 10 percent offered POC testing for the cardiac marker. By 2014, more than 40 percent did.

At Vanderbilt, a level-one trauma center, Dr. Woodworth and her colleagues opened a temporary ED laboratory in February 2013 to improve turnaround times. Staffed by medical technologists, the lab included an Abbott i-Stat for troponin I and creatinine POC testing, Stago coagulation for PT/INR and PTT, and a Sysmex 2000 for CBC tests. The ED staff performed the i-Stat basic metabolic panel for stroke protocol patients.

By May 2013, the Vanderbilt team was able to deliver stat whole-blood troponin results within 45 minutes of receipt in lab nearly 100 percent of the time. But there were struggles with turnaround times on potassium and other plasma chemistry tests sent to the main laboratory, with the percentage completed within one hour of lab arrival dipping to 60 percent by May.

In September 2013, Vanderbilt implemented a new automated chemistry line and a new laboratory information system on the same day.

"That was a crazy day," Dr. Woodworth said. "Now it has been two years and we're finally digging out. We continued to have turnaround time delays, because Vanderbilt had a lot of IT stuff that was homebrew that, when we turned to Cerner, we didn't even realize was there. We had a lot of problems to deal with, and as we started, our turnaround times plummeted. But, one by one, problems were solved and turnaround time improved." By the time the temporary ED lab was closed last fall to make way for the permanent laboratory, the Vanderbilt team was hitting the one-hour-or-less mark on plasma chemistry turnaround times more than 80 percent of the time.

Also making life more difficult was the decision, made by clinical and administrative teams, to require ED laboratory professionals to match specimens to requisitions. "That did not work," Dr. Woodworth said. "Best practices, of course, state that nursing or whomever is collecting the specimen should match the specimen tube with the requisition at the collection site."

Even with approval to build a permanent ED laboratory, clinicians' entire lab test wish-list could not be accomplished in the small space provided. Try to imagine fitting four analyzers, storage space including refrigeration, and a clean and dirty sink in 333 square feet. It could not be done, no matter how many drawings were made. Out went the urine analyzer and the coag analzyer, and urine hCG and PT will be done
at the bedside with POC testing equipment.

Winning support for the emergency department laboratory at Vanderbilt was the result of years of close collaboration with ED clinicians, Dr. Woodworth said.

"To make a huge investment like this, to move forward, the request cannot come from the laboratorians alone," she said. "You have to get together with your ED medical director team, and you need to agree together on what is the best fit for your turnaround time and your analytical quality needs. We're so fortunate that the medical directors of our ED really understand the analytical quality aspects of this. . . . So, the request, when it went to administration, was supported from all different directions—from the ED to the lab. That's what was required for the success of the project."
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Sunquest, TriCore partner

Sunquest Information Systems has announced a strategic partnership with TriCore Reference Laboratories to jointly develop diagnostic laboratory software to support population health, precision medicine, and integration pathology. Development efforts will include new technologies for improved data analytics in connected, multiorganization environments.

The co-developed solutions will be leveraged in one of TriCore's reference laboratories that will serve as the innovation center for commercial-grade diagnostic methods, operations, and technology.
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FDA clears and waives Theranos' HSV-1 test, system

Theranos has received the FDA's clearance of its test system and test for herpes simplex 1 virus IgG, and also received a CLIA waiver from the agency allowing use of the system outside traditional laboratories. The company

said the FDA's decision provides independent validation of its patented fingerstick and venous blood-testing technology and the system on which the HSV-1 IgG test is run.

The 510(k) clearance includes the use of Theranos' nanotainer tubes for tests run by this method, which allow samples to be collected from a few drops of blood. The Theranos system, including Theranos' device, analytical software, and nanotainer tubes, has been fully validated and cleared for use with this test method.

Theranos provided data to the agency on its test systems and methods, its chemistry, its hardware, and its software in the company's foundational system and LDT application. Specifically, Theranos provided study data from 818 subjects of varying age and ethnicity, demonstrating that its system could be run accurately using only a fingerstick as well as a traditional venous draw across large numbers of Theranos devices, all compared against an FDA-cleared, commercially available reference method.

The CLIA waiver will allow the HSV-1 test and system to be used in Theranos Wellness Centers in Arizona, California, and Pennsylvania. The FDA's determination came after review of data showing that the test and underlying Theranos system perform at least as well in the field with nonlaboratory personnel as by trained operators in a traditional laboratory setting.

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Bio-Rad introduces fifth-generation HIV test

Bio-Rad Laboratories has announced the U.S. introduction of the BioPlex 2200 HIV Ag-Ab assay, a fifth-generation multiplex diagnostic test for use on the BioPlex 2200 automated platform.

The FDA gave premarket approval for the BioPlex 2200 HIV Ag-Ab kit, already offered in Europe. The assay is designed to simultaneously detect and differentiate HIV-1 p24 antigen, antibodies to HIV-1 (groups M and O), and antibodies to HIV-2 in human serum or plasma. In the U.S., it is approved for diagnostic testing, including for use with pregnant women and patients as young as two years old. The test also can be used for organ-donor screening.

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Qiagen's EGFR kit approved for use with Iressa

Qiagen has received premarket approval of its Therascreen EGFR RGQ PCR kit as a companion diagnostic to guide the use of AstraZeneca's Iressa (gefitinib) in the treatment of patients with advanced or metastatic non-small cell lung cancer. The test can help identify NSCLC patients who have tumors that are positive for EGFR mutations and therefore are eligible for treatment with AstraZeneca's drug.

Along with the Therascreen EGFR test to analyze tissue from lung tumors, the FDA approved Iressa for first-line treatment of NSCLC in patients identified with the aid of an FDA-approved companion diagnostic.

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Orchard Software launches analytics unit

Orchard Analytics, a new business unit of Orchard Software, provides analytics services and advanced training to support pathologists, laboratory leaders, and administrators in learning to use health care data from disparate sources to improve care and reduce costs.

The first in-person training class is scheduled for Oct. 19–22 in Indianapolis. The training will be led by unit director and pathologist Brad Brimhall, MD, MPH, professor of pathology and medicine and senior consultant for enterprise data warehouse and clinical analytics at University of Mississippi Health Care.

More information, including white papers and case studies demonstrating the real-world value of laboratory data analysis, is available at www.orchard analytics.com.
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