Molecular testing platforms a land of plenty

Anne Ford

October 2013—If you've ever seen what happens when someone accidentally puts regular liquid soap in a dishwasher, you'll have a good mental image of just how vigorously the automated molecular testing market is bubbling over with new assays. HCV genotyping, rifampin resistance, group A Streptococcus—vendors are pouring these and many other tests into a market that, by all accounts, is more than eager for them.

"The molecular testing market will continue to grow at double-digit rates for the next three to five years," says Sarah Lewis, Meridian Bioscience marketing communications manager. Her prediction is supported by the breadth of offerings in this month's product guide to automated molecular platforms.

Take Cepheid, which reports that it has more than a dozen molecular assays—among them HPV, HIV, HCV, and HBV—in the development stages. Introduced in the last year are the Xpert MTB/RIF test, which enables detection of Mycobacterium tuberculosis and rifampin-resistance mutations in two hours; the Xpert CT/NG test, for 90-minute detection and differentiation of Chlamydia trachomatis and Neisseria gonorrhoeae; and the Xpert GBS LB test, for point-of-care antepartum group B streptococcal disease screening.

Why so many new offerings? In part, says Cepheid chief medical and technology officer David H. Persing, MD, PhD, because of the increased number of laboratories that are bringing molecular testing in-house for the first time, and doing so on smaller systems.

"In these cases, the driver for a system placement may be a single test on the menu," he explains. "For instance, we are seeing system placements for CT/NG testing in large ob-gyn offices with moderate-complexity physician office laboratories. Previously, these labs were sending out their CT/NG molecular testing with average turnaround times of two to three days. They now capture revenue from the testing because they do it themselves and offer results in 90 minutes." Other examples, he adds, are the placement of smaller systems for stat influenza, enterovirus, or TB testing for patients admitted through the emergency room.

Abbott, too, has expanded its test menu, with new assays introduced this year for HCV genotyping, vancomycin-resistant enterococci, and influenza A/B and respiratory syncytial virus, all for its automated m2000 molecular testing system. The next 12 months are expected to bring a test for Clostridium difficile, as well as an HSV-1 and HSV-2 assay. These assays will round out the system's menu, which includes HIV-1, hepatitis B and C viral load, and a chlamydia/gonorrhea combination test. Abbott's aim, says Mike Rowan, director, global marketing, is to expand its menu and instrument solutions "to ensure laboratories of any size are able to consolidate infectious disease testing on a single platform and automate the complex and manual steps associated with molecular diagnostics."

Also in the next year, BioFire Diagnostics intends to launch its Film-Array gastrointestinal panel, a 23-target panel that will allow users to test for bacteria, viruses, and parasites that cause infectious diarrhea, with results in about an hour directly from stool in transport media. The panel will be a followup of sorts to the company's 27-target Film-Array blood culture identification panel, which tests for common antimicrobial resistance genes associated with MRSA and VRE and for the blaKPC gene, and which was introduced in June.

Nanosphere product manager Zack Crowther isn't surprised to see more targeted multiplexed panels on the market. "We've seen that trend emerge over the past few years," he says, adding that at the same time, vendors must take customers' financial concerns into account, and that bigger isn't always better. "Our customers want tests that target organisms and genetic markers; that provide high-value, clinically actionable information to physicians; and that offer a rapid format and exceptional level of accuracy without breaking the budget." With the reimbursement landscape shifting, he notes, hospitals are scrutinizing any new testing to be sure it has a positive

impact on patient care, lowers costs for the hospital, or both. That's why, he says, "Nanosphere carefully evaluates the size and scope of each new multiplexed panel we develop for the Verigene system."

Last year, Nanosphere introduced a gram-positive blood culture test that simultaneously identifies 12 bacterial targets and three antibiotic resistance markers. The new blood culture test joins FDA-cleared assays for C. difficile and respiratory viruses as part of the Verigene system's test menu. The coming year, Crowther says, will see the introduction of multiplexed molecular tests for enteric pathogens, gram-negative blood cultures, yeast blood cultures, and respiratory pathogens.

The efficiency gains are what drives the growing demand for multiplex tests and streamlined workflow, says Roche Diagnostics marketing director Chris Norris. The FDA recently approved a new, more efficient workflow process for Roche's three-in-one Cobas HPV test, allowing sample processing from the primary sample collection vial after it has been used for cytology (Pap) testing. This means, Norris says, that labs can load the same vial used for a ThinPrep Pap test directly onto Roche's Cobas 4800 system for high-risk HPV and individual HPV 16 and 18 genotype testing. New from Roche last fall was the first FDA-approved test for quantifying DNA of cytomegalovirus, intended for use as an aid in managing solid-organ transplant patients who are undergoing anti-CMV therapy.

The past year has seen two new assays from Meridian: the Illumigene Group A Streptococcus test and the Illumigene Mycoplasma test. The former, says the company, increases detection of positives by more than 53 percent over traditional culture in symptomatic patients, while the latter detects Mycoplasma pneumoniae in throat swab and nasopharyngeal swab specimens. Tests for pertussis, chlamydia/gonorrhea, herpes simplex virus I and II, Giardia, E. coli, and malaria are in the works.

In addition to the companies bringing forth new assays, a few have launched—or are about to launch—new automated molecular platforms. Siemens, for example, is looking forward to the introduction into the U.S. of its Versant kPCR Sample Prep system (not in the guide), which is already available outside the U.S. Senior global product manager Ellen Sampson says the system will automate the extraction of DNA and RNA from 20 types of samples and have flexibility to be able to extract between one and 96 samples in a single batch run. The Siemens system is also under clinical investigation to assess the automated extraction of nucleic acids from clinical samples for HCV genotyping.

New and already available from HTG Molecular Diagnostics: the Edge RNA analysis system, dubbed by company president TJ Johnson as "the only automated RNA analysis platform that never requires RNA extraction and delivers multiplexed results on a multitude of biological samples in less than 24 hours." HTG, he adds, is preparing an FDA submission for its first IVD assay and plans to release several probesets for immunotherapy research, mismatch repair, and DLBCL cell of origin. "We will also be introducing capability for the measurement of expressed mutations and gene fusions with probesets for BRAF v600E mutation and ALK fusion," he says.

New to the molecular platforms product guide this year (in addition to HTG's system) is Life Technology's QuantStudio Dx Real-Time PCR instrument and Great Basin's Portrait PA500 benchtop analyzer. The FDA last month granted 510(k) clearances to Quidel's molecular influenza A+B assay and its molecular RSV+hMPV assay, both for use on the QuantStudio Dx.

GenMark reports that it is developing a next-generation sample-to-answer system. "Our initial menu will target infectious disease testing and includes RVP, sepsis, a gastrointestinal infection panel, and HCV genotyping," says president and CEO Hany Massarany. "We remain confident that we will bring to market the most competitively differentiated sample-to-answer system, and we're on track to complete its development in the second quarter of 2014."

CAP TODAY's guide to automated molecular platforms consists of the systems from the aforementioned manufacturers as well as from AutoGenomics, Hologic/GenProbe, Qiagen, BioMérieux, and BD Diagnostic Systems. Companies supplied the information listed. Readers interested in a particular system should confirm it has the stated features and capabilities.

[hr]

Anne Ford is a writer in Evanston, Ill.