Automated molecular platforms: 3 companies on what's new and next

October 2018—CAP TODAY's *updated guide to the automated molecular platform market begins on page 45. Thirty-four platforms are profiled, with one new one: Hologic's Panther Fusion. Writer Valerie Neff Newitt talked with three of the 20 companies about what they introduced this year, what's to come, and more. "This is a dynamic and competitive industry. We are always asked to go faster, and that is what we are trying to do in terms of development," says Michelle Tabb, PhD, chief scientific officer, DiaSorin Molecular. Others seem to be doing the same.*

What did your company introduce this year, and/or what can we expect to see from your company in 2019?

Bryan Moore, PhD, director of marketing, molecular diagnostics, Roche Diagnostics: We introduced contamination-proof, validated preanalytics in three versions (Cobas p 312, p 512, and p 612), with differing amounts of "horsepower," now approved to be used upstream of molecular testing and even to be physically connected to our Cobas 6800 or 8800 system. Molecular has to handle a lot of sample types—swabs, urines, bronchoalveolar lavages, blood, and serum. Bringing automation into the lab to handle those and route them onto analyzers will be transformative for molecular labs.

In addition to having introduced a number of assays and reagents this year, we launched the Omni utility channel on the fully automated Cobas 6800 and 8800 systems. The Omni channel takes all the core reagents from our in vitro diagnostics, except primers and probes that a lab adds, into the cassette. Laboratory-developed tests can then be run in parallel on the same system as IVDs. Operationally this brings an incredible amount of automation to an LDT workflow on the same instrument on which routine molecular diagnostics are performed. This is a new approach to LDT testing, one that reduces manual steps.

We also introduced the next generation of our MagnaPure 24 system to automate the DNA or RNA extraction from various samples—tissue, blood, serum—for downstream lab-developed test applications.

On the software side, we have had continuous updates and improvements in connectivity. Labs want instruments to connect to their LIS and EMR, so they can pull patient information, set up work orders, and deliver results seamlessly, without manually transferring or typing anything in. Five years ago connectivity was still relatively new to molecular, but now every one of our Cobas 6800 and 8800 instruments is going into a connected system.

Wade Stevenson, senior vice president of global marketing, BioFire: For this year, we have submitted a pneumonia panel to the FDA that is under review. We are optimistic for a Q4 launch. Right now, the most common way to test for pneumonia can be slow and laborious. Our syndromic panel uses cutting-edge molecular biology to test for 26 common bacteria and viruses associated with pneumonia—18 bacteria, eight viruses—and seven antibiotic resistance markers. Having the resistance markers for pneumonia is unusual; we will be the first to offer that.

What makes the panel even better is that lab hands-on time is minimal. Sample prep and run setup time are down to about two minutes. The entire run takes about one hour. It will be game changing.

We expect this panel will have a huge impact on how lower respiratory tract infections are diagnosed and will change the way antibiotics are prescribed and how patients are managed. Because we can combine the most probable pathogens associated with a syndrome in a cost-effective manner, doctors won't have to order a test for just one pathogen; instead they can order a test for that entire syndrome.

Michelle Tabb, PhD, chief scientific officer, DiaSorin Molecular: Within the past year we launched Simplexa HSV 1 and 2 Direct with expanded claims—the only FDA-cleared HSV molecular test for cerebrospinal fluid and claims for all swab types, cutaneous and mucocutaneous. It is the most comprehensive coverage for molecular HSV testing on the market. Labs receive swabs from different body sites, cutaneous and mucocutaneous—wherever you could get a herpes lesion. Now clinical studies have shown that our product works beautifully for all those swab types.

We also have claims for all of the common transport media types that swabs show up in, so there are not a lot of limitations for the lab. Our customers wanted it, so we did it.

In 2019 we will launch an FDA-cleared product for detection of varicella zoster virus, which causes chickenpox and shingles. Shingles lesions can look a lot like HSV lesions. The VZV product will have the same kinds of sample claims as our HSV product (CSF as well as cutaneous and mucocutaneous swabs). We designed these products for use on a disk that runs up to eight samples at a time. If a lab gets an order to test both HSV and VZV, they can be run at the same time and on the same disk.

This year we attained CE marking for Simplexa Bordetella Direct. We expect to launch that with FDA clearance in the U.S. in 2019, along with the Simplexa Group B Strep Direct, if all goes as anticipated.

Because our system has user-defined, or open mode, it allows customers to develop LDTs. Toward that end, we offer a huge menu of primer pairs and have launched several new primer pairs this year. The first is *Pneumocystis jirovecii,* important because it is hard to culture this organism and it is a cause of pneumonia, especially in immune-compromised patients. Second, we have expanded our tick-borne bacterial detection offerings to include primer pairs for *Anaplasma, Ehrlichia*, and *Babesia.* We have seen an increase in tick-borne bacterial infections and co-infections in the U.S. and worldwide. These help our customers perform more sensitive detections using molecular means. It's an important step forward.

We are also launching offerings for atypical pneumonia (not caused by *Streptococcus pneumoniae*) this year. The new primer pairs are for *Chlamydophila pneumoniae* and *Mycoplasma pneumoniae* and *Legionella* species, all of which will be available before the end of 2019. Those three together provide nice coverage of these other bacteria that are difficult to detect using culture or serology and are more easily detected using molecular means.

What is the one (or two) most important thing readers should know about your system(s)?
Dr. Moore (Roche): The first key point for the Cobas 6800/8800 system is it is self-contained for DNA extraction, PCR setup, and real-time PCR for IVDs and LDTs, yet it is a moderately complex system. When you eliminate human steps and automate with preanalytics and an analyzer, as we have done, you can achieve a moderately complex level of instrumentation, which enables the lab to be more flexible in how it uses its labor to run its systems.

Second, our system is designed to allow laboratories to consolidate their highest volume of FDA-approved and -cleared tests, as well as all their LDTs, on a single moderately complex instrument. Customers tell us this is of great value to them.

Stevenson (BioFire): Our standard line is fast, easy, comprehensive, and allows labs quickly and easily to test for a comprehensive set of pathogens.

Dr. Tabb (DiaSorin Molecular): First, we are committed to growing our menu. We have a system that has a small footprint, and we are committed to bringing up more assays that can be run on it. Second, we have unique flexibility. By changing a disk within the same system and the same software, our system can run the full gamut from the most highly complex LDT (that the user has to validate) or the most easy-to-use CLIA moderate-complexity IVD that is FDA cleared.

What molecular testing market changes does your company foresee, if any?
Dr. Moore (Roche): Two things driving market dynamics are consolidation and decentralization, going on in parallel. This means if there is a patient intervention that can achieve good outcomes by quick action, testing necessarily gravitates closer to the patient and out of the lab. That is the decentralization pull.

At the same time outpatient-based screening and monitoring tests are being consolidated to improve efficiencies. Certainly within laboratories, there are efforts to choose a single platform to accomplish much of the core molecular testing, whether FDA approved or LDT. There are now options to consolidate that testing.

Stevenson (BioFire): The continued adoption of syndromic testing is a trend. Now about 1,500 hospitals in the U.S.

are doing syndromic testing; that number has grown 20 to 30 percent every year. Our compound annual growth rate over the past five years has been about 98 percent a year. We anticipate growth will continue. Hospitals and health systems increasingly understand the value of rapid syndromic testing.

Dr. Tabb (DiaSorin Molecular): We have noticed that despite lingering questions about whether the FDA will eventually regulate LDTs, concern seems to have stabilized for now. Labs still want to develop their own LDTs and need components, like primer pairs, to support that. Especially in lower-volume esoteric testing, as in infectious diseases, companies will not bring that type of testing all the way through the FDA process. It is much too burdensome and expensive.

What is your company hearing from its customers, in terms of laboratory needs and wants?
Dr. Moore (Roche): We see that labs, microbiology labs in particular, are going through significant transformation and incorporation of innovation. But how can those molecular micro labs get true sensitivity results back to the health care providers so they know a patient is not just infected with this bacterium that is resistant to XYZ drug but also exactly what they can treat with? Labs tell us that's what doctors want to know.

So far, this is a need that is not quite being met. It is an area we are pursuing heavily with a technology called Smarticles, which will provide molecular phenotyping. Smarticles will be able to identify a bacterium and determine what it is most sensitive to from an antibiotic standpoint. It is an automated technology we are maturing and will bring out on an instrument called VivoDx, a new benchtop analyzer to be used within the microbiology lab. (Smarticles is in development and not yet available.)

Additionally, we continue to bring out a healthy pipeline of IVD tests to expand the menu on existing platforms so labs can continue to consolidate testing. However, there seems to be additional appetite from our customers to do LDT applications, and customers' interest drives our investments in our products.

Stevenson (BioFire): We hear from labs that they are continually challenged to do more with reduced resources. Budgets and lab workforces are shrinking, but oddly enough health care institutions are still asking for faster turnaround times, more accurate tests, and better services. Technology is helping by making it possible to provide faster, more comprehensive testing services. Our customers want cutting-edge molecular technology to offer improvements over culture in terms of sensitivity and specificity.

Dr. Tabb (DiaSorin Molecular): In general we've seen a continual drive for molecular diagnostics. People want those specialized targets, and they keep increasing their molecular menu offering. The switch from culture-based methods to molecular is still happening. We hear, "Give me more molecular."

We are listening to our customers about problems they have in the lab, such as pathogens that are difficult to culture, and trying to bring products to the market that will help them accordingly. We plan to continue to offer more primer pairs to support our customers' LDT efforts, and keep our IVD pipeline as hot as possible.

Finally, the big thing customers continue to ask for is more automation, often with onboard extraction. Labs are cognizant of technician injury, risk points, and efficiencies in the lab, and automation delivers on all counts. We are exploring how to offer more automated solutions in the various situations where they are needed. If customers need it, we will find a way to provide it.