Automated molecular platforms — the latest on two dozen

Kristen Eberhard

October 2015—CAP TODAY's automated molecular platforms product guide begins on page 31 and features 26 platforms from 18 companies. Faster turnaround times and higher throughput are among the capabilities that manufacturers are touting.

New to the market is BioMérieux's EasyStream, which was first installed in Europe in 2014 and sold in the U.S. this year. EliTech Group, new to the product guide, introduced its Elite InGenius this year.

BioFire Diagnostics in February received FDA clearance and CE IVD marking for its FilmArray 2.0 system. The FilmArray 2.0 processes up to 175 samples per day. Each system includes the computer, printer, and optional FilmArray rack and accommodates one to eight random-access Film-Array units. The system is also capable of connecting to laboratory information systems.

Automated molecular platforms product comparisons

BioFire submitted in April a de novo FDA clearance for the FilmArray Meningitis/Encephalitis (ME) Panel, used to test cerebrospinal fluid for the 14 most common pathogens (six bacteria, seven viruses, one fungus) responsible for community-acquired meningitis or encephalitis.

Great Basin in June received FDA clearance for its second sample-to-result molecular assay, an antepartum screening for group B streptococcus. The company submitted in August a 510(k) application for the first multiplex panel on its menu, Staph ID/R Blood Culture Panel, and is finalizing its 510(k) application for the Great Basin Shiga Toxin Direct Test.

Great Basin expects to submit three additional assays for 510(k) clearance in the first half of 2016. "We are also engineering a platform upgrade to our Great Basin analyzer for delivery in mid-2016. The new design will allow for higher testing throughput in a smaller footprint with a shortened time to result," says Brittney Kennedy, director of marketing communications.

Meridian Bioscience received FDA clearance in July for its Illumigene HSV 1&2, a qualitative in vitro diagnostic test for the direct detection and differentiation of herpes simplex virus types 1 and 2 in cutaneous and mucocutaneous lesion specimens, to be run on its Illumigene molecular platform. "Results are available in less than one hour to reduce turnaround time, eliminate send-out costs, and aid in same-day diagnosis, treatment, and counseling of patients," says Mike Shaughnessy, executive vice president and president of Meridian Global Diagnostics.

Meridian Bioscience is developing a malaria assay for the Illumigene platform. The goal of the Illumigene Malaria concept, Shaughnessy says, is to "address current diagnostic challenges such as simplification of sample preparation from blood, reagent stability under ambient conditions, ease of use for the end user, and affordable pricing." Meridian has partnered with the CDC on this project, and worldwide market entry is planned for early 2016.

Dako, an Agilent Technologies company, added its Omnis instrument, introduced in 2013, to this year's product guide. The company released its IQFISH fast hybridization buffer as a standalone product, which enables a four-hour sample-to-result workflow for fluorescence in situ hybridization experiments. "Traditionally, a FISH experiment takes two days," notes Dako senior product marketing manager Nicole Wootton. Agilent Technologies now offers a portfolio of SureFISH DNA probes, which provide "high-quality staining with minimal background, due to their synthetic nature and true repeat-free designs," says Rebecca Brandes, global marketing director.

CAP TODAY's guide to automated molecular platforms consists of the systems from the aforementioned manufacturers as well as those from Abbott, AutoGenomics, BD Diagnostics, Cepheid, Focus Diagnostics, GenMark Diagnostics, Hologic/Gen-Probe, HTG Molecular, Nanosphere, Qiagen, Roche, and Thermo Fisher. Companies supplied the information listed. Readers interested in a particular system should confirm it has the stated features and capabilities.

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