Automation, standardization lead the way in urinalysis

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December 2017—Smaller-scale technology and standardization are just some of what laboratories need, and it's where the companies that make urinalysis analyzers are in part focusing their work. CAP Today spoke with three of the five whose analyzers are profiled on the following pages.

"Our strategy is to continue to build out our urinalysis portfolio to serve each urinalysis market segment," says Jessica Donlan, Arkray marketing and application manager. Customers are looking for one vendor to supply all urinalysis needs, she says. "Visual read all the way to total lab automation. They also want a single strip strategy, which helps streamline purchasing."

Arkray's most recent launch, in 2016, was the Aution Eleven AE-4022 semiautomated urine chemistry analyzer, a standalone analyzer for use in mid- to high-volume laboratories that can also serve as a backup for fully automated urine analyzers. (The Aution Hybrid AU-4050 is Arkray's fully automated and integrated chemistry and sediment analyzer.) At 8.3 inches wide, the AE-4022 maximizes laboratory space, Donlan says, and can be transported easily. Identical strip pad technology used across all Arkray platforms makes it possible for laboratories to standardize results within a health care network, she says.

Leslie Williams, senior product manager for Sysmex urinalysis, says the prime objective for any urinalysis vendor is to eliminate the need for manual microscopy. "That would require refinement of existing technologies to improve the images themselves, enhance any classification or grouping performed by the device, and perhaps provide the user the option to focus up or down on an image as you would with a microscope to get a better view of the cell," she says.

Sysmex's urinalysis system, the UF-1000i, can operate as a standalone fully automated urine sediment analyzer or as part of an integrated system with Siemens Healthineers' Clinitek Novus automated urine chemistry analyzer. The UF-1000i uses fluorescent flow cytometry technology for quantitative cell counts for RBC, WBC, epithelial cells, and bacteria and to flag for the presence of crystals, yeast-like cells, small round cells, sperm, and mucus.

In addition to measuring the fluorescence of each cell, the UF-1000i measures forward scatter, which represents the amount of time each particle takes to move through the flow cell, as well as side scatter, which identifies the internal complexity of the cell. When the sample analysis is complete, Williams says, algorithms in the software interpret the scatterplots for each cell type to determine the final quantitative count.

"The UF-1000i can detect as few as five bacterial particles in a urine sample to give clinicians early indication there may be a urinary tract infection," she says.

Market research points to further integration of instrumentation and a slight downward trend in standalone systems, Williams says. Other market trends? "IT solutions and middleware. The same type of advancements we've seen in hematology: managing reporting and alerts and callbacks, and reruns and flags for pathological elements. I can see all of those having a future in urinalysis," she says.

"The challenge is being able to package the technology in smaller pieces," Williams adds, "while keeping the pricing competitive, and that's not always possible."

The need for automation and standardization is the main trend, says Jason Weshler, Siemens Healthineers' director of marketing and business for end-to-end solutions. The Clinitek Novus analyzer combines dry-pad urine chemistry technology and a cassette test format to ensure standardized testing with other Clinitek analyzers.

Weshler says a few "game-changing innovations" went into the Novus platform, released in 2015.

“First, we changed the way reagents are run on an automated analyzer. We use cassettes with individual cards, fully self-contained, including an RFID tag for traceability. The cassettes eliminate the need to align test strips. We use a cutting-edge digital camera to take seven images of the urine chemistry strip; algorithms are then applied to check the pad for humidity exposure and to detect red blood cells.”

The AUWi Pro, also released in 2015, combines the Novus with the Sysmex UF-1000i.

“We’re seeing growth in the fully automated space,” Weshler says, but point of care, too, is growing. “The hub and spoke of our hospital network either wants point of care or full automation.”

The five companies whose analyzers are profiled supplied CAP TODAY with the data on the following pages. Readers interested in a particular system should confirm it has the stated features and capabilities.
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