

Guide to urinalysis instrumentation

It is arguably the oldest discipline in pathology, but that title likely would not be enough to generate sentimental feelings among those at the receiving end of a urinalysis test. Yet urinalysis is a Cinderella of sorts: morphing from visual observation, to taste testing, to manual dipstick tests, to sleek, state-of-the-art instrumentation that can measure numerous substances.

Showing off their features on the following pages are 10 urinalysis instruments that, collectively, represent CAP TODAY's first urinalysis systems product guide. The guide focuses on fully automated and semiautomated urine chemistry and microscopy/sediment instrumentation. We determined what information would be relevant to you, the reader, in part by discussing with industry representatives what we should ask and how to ask it. A special thank you to the product specialists at Arkray, Roche, and Siemens and to our trusted CAP TODAY informatics experts, Raymond D. Aller, MD, and Hal Weiner, for their guidance. And an enormous thank you to Leslie Williams, at Sysmex America, for her invaluable assistance each step of the way. We would appreciate feedback and suggestions on how to improve future editions of the guide.

But first writer Anne Ford reports what a few company representatives say about how urinalysis technology fits into laboratory automation and the importance of urinalysis. —Kimberly Carey, managing editor, kcarey@cap.org

December 2015—Not everyone shares Lauren Foohy's idea of a good time, and she knows it.

"Performing urine sediment analysis under a microscope—I thought it was fun," Foohy says with a laugh. She spent 10 years in the laboratory before ultimately becoming senior director of global marketing for point-of-care urinalysis and diabetes at Siemens Healthcare, Point of Care Diagnostics. "I just always thought it was fun to figure out, 'What are these cells I'm looking at? Red cells, white cells, casts, crystals, amorphous phosphates, bacteria?' It wasn't often you'd see a parasite, so it was always a big deal when you did, and everybody would be screaming, 'Look at this!'"

"I loved doing it," she continues. "But as fewer and fewer people are going into the medical technology field, it's more difficult for lab managers and directors to find people who are trained to do urinalysis via microscopy and who want to do it." That, she adds, is in part why demand for automation has increased.

But even as demand rises, "there seems to be variation in how urinalysis technology fits into full automation," says Leslie Williams, urinalysis product manager for Sysmex America. "There are some urinalysis systems that have been incorporated into large automation systems, but I am not sure how common that is in practice. Usually customers will take our UF-1000i fully automated urine sediment analyzer and put it on an automation line, and then put the urine chemistry analyzer at some other point further down the line and run them that way. Our distributor, Siemens, sells the UF-1000i as part of an integrated urinalysis system, the Clinitek AUWi Pro automated urine workstation."

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That workstation, Foohy says, has been available in the United States since the beginning of the year and is also for sale in Canada and Japan. "Siemens connects the UF-1000i with our Clinitek Novus urine chemistry analyzer [via] a track that moves racks of urine tubes throughout the system," she explains. "There is no doubt that automation requires a greater upfront investment...but it pays off in shorter turnaround times, speed to diagnosis, and staffing within the lab. At the end of the day, if you don't have the laboratorians to do the testing manually,

you really don't have a choice. Even some of our smaller-volume customers want to go to full automation."

The Clinitek Novus automated urine chemistry analyzer, which was also introduced this year, can be loaded with up to 200 samples at a time. "The nice thing about all of our reagents is that we make them all in the same plant, and they're all the same chemistries," says Foohey. "So the chemistry that makes up a ketone pad for visual reading is the same technology that is in our high-volume Clinitek Novus analyzer, so you get very consistent results regardless of where you're running the product."

Arkray, too, has been focusing on the marriage of automation and urinalysis. "Laboratories are seeking automation solutions to decrease manual tasks such as urine microscopy without compromising quality," says marketing manager Jessica Donlan, MLS(ASCP). "Automated urinalysis minimizes hands-on time, standardizes results, and gives laboratorians the flexibility to multitask." Arkray sells the Aution Hybrid AU-4050 fully automated and integrated urine chemistry and sediment instrument as well as the Aution Max AX-4030 fully automated urine chemistry instrument.

The urinalysis market, in general, "is growing globally at about two percent for the urine chemistry side," says Foohey. "But when you look at the combined automated urine chemistry and sediment market, it's growing at more like four to five percent."

Stressing the ongoing need for urinalysis—automated or not—Foohey adds that, "Globally, there are more than 1 billion people at risk for kidney disease, with one risk factor being [age] over 60 years," she says. "And this is a very easily performed test. All you need is some urine, a cup, and a urine strip, whether the physician is in the outback of Australia, or the most remote parts of Canada, or Tierra del Fuego in South America."

Williams agrees. "I think a lot of people have fallen into the trap of thinking, 'It's just urine,'" she says. "But if you really pay attention to what urinalysis results are telling you, specifically to what you find in the urine sediment, then I think you can appreciate that urine is still as relevant as it's ever been."

She points to the trend toward identifying biomarkers for kidney disease. "There have been several of these identified, but the medical community can't seem to come to a consensus on which one is best for which condition. Once they identify a marker and can align it with a specific disease state, that's going to be a new avenue for urine testing."

Also supporting the growth of urinalysis, Williams says, is the trend toward increased screening for urinary tract infections, particularly those associated with catheter use. "It's more important than ever for hospitals to catch infection early, so they can prove that a patient did not develop a hospital-acquired infection," she says. "Otherwise, they run the risk of losing the reimbursement for the entire stay. And quite often those patients are not symptomatic, and if you let a UTI go undetected, it can lead to sepsis. Using available urine testing to make sure you capture these infections early is becoming more important as health care starts to focus on patient outcomes and test value versus the traditional pay-for-service model."

In CAP TODAY's guide to urinalysis instrumentation are products from the aforementioned manufacturers and from Beckman Coulter and Roche Diagnostics. Companies supplied the information listed. Readers interested in a particular product should confirm that it has the stated features and capabilities.

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