Urinalysis: ‘a field with the potential to do more’: pathologist, two companies talk about urinalysis now and what’s needed

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December 2020—What *could improve urinalysis operations in your laboratory? That’s a question CAP TODAY publisher Bob McGonnagle asked Megan Nakashima, MD, of the Cleveland Clinic when she talked in October with him and two others: Carl Trippiedi of Sysmex and Matt Rhyner, PhD, MBA, of Beckman Coulter. Their conversation took place as CAP TODAY’s 2020 product guide to urinalysis instrumentation was taking shape. What they had to say follows.*

Carl Trippiedi, can you tell us about the important news announced in August, which was Sysmex’s involvement with the Siemens Healthineers urinalysis business?
Carl Trippiedi, group marketing manager, hematology and urinalysis solutions, Sysmex: It’s a slight change of role in the marketplace. For several years Sysmex has made the UF-Series available to Siemens, which had a series of high-volume urine chemistry analyzers. They would adjoin the two instruments and sell them under the Advia Urinalysis Workcell, or AUW.


Trippiedi

Sysmex introduced its latest urinalysis solutions in the United States in 2019. That included the UF-5000, which is our third-generation urine particle analyzer. In addition, there is the UD-10, a urinalysis digital imaging system, which reflexes off the UF-5000, and the urinalysis data manager, or UDM, the processing unit that connects the two.

Urinalysis instruments product guide

The new Sysmex introduction in 2019 is branded as the UN-Series, and it was designed with many of the same principles as the XN-Series in hematology. It is modular and scalable. If you think about integrated urinalysis in the high-volume clinical laboratory, what was missing was the urine chemistry piece. So a number of discussions took place about how Sysmex would address that. Then it was announced in August that Sysmex signed an exclusive agreement to distribute and service the Siemens Healthineers Clinitek Novus automated urine chemistry analyzer in both the acute-care hospital market and the reference laboratory market. It gives us the ability to add the Novus as a module to our UN-Series.

In past CAP TODAY roundtables, there’s been an emphasis on workflow and scalability solutions and, in the case of urinalysis and even hematology, reducing manual work. Matt

Rhyner, can you comment on the desire to integrate your urinalysis into one efficient system, with all elements in one place?
Matt Rhyner, PhD, MBA, VP and general manager of urinalysis, Beckman Coulter: There's a push to automate the field of urinalysis, especially around reduction of manual work and reviews and having that high-throughput system that can do a great job on both chemistry and sediment analysis.

We partnered with Arkray a couple of years ago to work with the iQ200 imaging system that has terrific technology that we call automated particle recognition. Within the broader Beckman Coulter community, we just launched the DxA 5000, and there are opportunities to integrate urinalysis into a total lab automation solution. We haven't done that yet, but there are more and more requests to understand the complete patient picture.

There are other opportunities to integrate urinalysis data with microbiology data to deliver better patient analysis.

Dr. Nakashima, can you comment on the move to integrate workflow and the move of urinalysis into high-volume laboratories that are good candidates for lab automation?


Dr. Nakashima

Megan Nakashima, MD, assistant professor of pathology, Cleveland Clinic Lerner College of Medicine, and staff hematopathologist, Cleveland Clinic: In terms of integrated workflow, we at the Cleveland Clinic main campus already have an automated system, so that change wouldn't impact us as much, and we have a low manual review rate. A lot of our volume is filtered in from the region, but we also have many outlying hospitals and clinics that have their own labs, so there is still a space where we need to have smaller instruments, and if they can be more efficient with that type of scalability, then that's attractive to a system. We are looking at total lab automation at the moment, and I'm not sure what benefits we would get from adding urinalysis to that system. The people I've talked to who have done this in other labs have, for the most part, kept urine off the main track, but it's something to think about.

Dr. Nakashima, in the next year if you could improve one or two things in the operations of the urinalysis you oversee at the Cleveland Clinic, what would those be? If I gave you a magic dipstick and you could wave it and solve two problems that are headaches now, what would you like to solve?
Dr. Nakashima (Cleveland Clinic): Our instruments break down frequently, and that's probably our major issue. It is a large-volume laboratory, so we push them pretty hard. The second thing would be more standardization of collection. For the most part, our preference is preserved urine or urine in preservative tubes and we don't always get them that way. Some of the analyzers are not approved for preservative samples. So if you don't have a high-complexity laboratory, you would not be able to run your samples that way. I wish the whole industry would move toward using preservative tubes

whenever possible.


Dr. Rhyner

Dr. Rhyner (Beckman Coulter): The preservative tube issue is complex. The preservatives themselves can play with urine chemistry results, and that's the heart of the issue. As to the approval and what will be accepted from the regulatory agencies, it's not all the manufacturer's decision. The FDA has a lot to say about what it considers to be interfering substances. That's where I would leave it from my perspective: It's something we want to expand, but we need to work closely with the regulatory agency because the agency has a definitive point of view.

Dr. Nakashima, does that mean you would have to set up some of this as a laboratory-developed test?
Dr. Nakashima (Cleveland Clinic): Yes, that is what we've had to do at some sites.

We had so many issues because you can never really tell what happened to a urine sample. You either run it in one hour or you hope someone refrigerated it, and that's just too much variability. We could either reject all these samples or use preservatives, so that's why we've made that move.

An LDT application may be easy for the Cleveland Clinic but not for a lot of other labs. Carl, can you comment on this?
Carl Trippiedi (Sysmex): Matt mentioned it was a complex situation and I'm going to add another layer of complexity—the tube manufacturers, because they use different preservatives and different manufacturing techniques, it does become a challenge. But we know and understand what the market needs and that is to be able to use a preservative tube. So where tube manufacturers are developing their own standards and their own validations, our industry will need to continue working with both the regulatory bodies and with the collection tube manufacturers to find a resolution.

Carl and Matt, can you comment on data handling in integrated urinalysis systems? Are you happy with the data handling to date? Could it be improved? What couple of things could make everyone's life easier from the data reporting point of view?
Carl Trippiedi (Sysmex): Data handling is improving. With our new UN system, we do have a single point for data handling and that's the urinalysis data manager. The UDM is a single interface to a lab information system through an LIS vendor. As much as the data can be analyzed and reported in one place at one time, it is best for the customer. That's what customers have told us is a product requirement—one we're trying to meet.

Dr. Rhyner (Beckman Coulter): One nice attraction of a fully integrated workcell is you get the chemistry and the cross peer results. There are opportunities to do more networking. There's greater opportunity, as Carl said, to connect more fully with the LIS. In terms of what the data is, in the future it can get much better at more certainty around the particle classifications that can be reported, and perhaps new types, new particles could be expanded. Urinalysis is a lot different than it was when it was all manual review, but there's still progress to be made. It's probably not as advanced as some

other parts of the laboratory.

Dr. Nakashima, what can you tell us about data handling?
Dr. Nakashima (Cleveland Clinic): We do use an integrated workcell and it transmits data pretty well to our LIS. We're also now going through the pain of an LIS conversion.

There's always the issue of whether you want the perfect final answer to be transmitted or if you want kind of raw data or if you have middleware to handle that. I haven't done enough of this hands on to have an opinion about which of those things is best, but things can always be better.

Dr. Nakashima, could a better, quicker use of urinalysis lead to improved antibiotic stewardship?
Dr. Nakashima (Cleveland Clinic): The chem strip can be negative in someone who does have a UTI, so unless we were to find a new marker, I don't think that would be entirely possible. It is if someone is nitrate positive; then they know what to do with that.

Any comments in closing?
Dr. Rhyner (Beckman Coulter): Urinalysis is a field that has the potential to do more than it does today. Interesting solutions will come to market and you will see more near patient care as the diagnostics field expands.

Carl Trippiedi (Sysmex): I agree, and I would add that clinical laboratories need an efficient way to continue to turn out results. By utilizing data and reflexing, labs will become more efficient with the newer-generation analyzers that are now on the market.

Dr. Nakashima (Cleveland Clinic): I agree with both. Anything that can reduce manual work is welcome in any part of the laboratory. A dream for the future would be to have a smaller-scale automated instrument, which I know would be difficult. But I hope the companies will keep that in mind going forward.

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