Panel explores urinalysis solutions, rules, POC testing

December 2019—What do users of urinalysis systems want? According to those in the know, the answer is instruments that are scalable and modular, maximize automation, reduce hands-on time, improve workflow, and more. CAP TODAY publisher Bob McGonnagle convened a panel in October to discuss these topics and other aspects of urinalysis testing. On the panel were Megan Nakashima, MD, of Cleveland Clinic; Michelle Dumonceaux, of Beckman Coulter; Maya Daaboul, of Siemens Healthineers; and Jason Anderson, MPH, MT(ASCP), of Sysmex. What they said follows.

Dr. Nakashima, in these discussions, we tend to focus on three areas: workflow, the importance of scalability for instrument solutions across a wide network and of maximizing automation, and reducing manual tasks, in part due to labor shortages. Are these factors applicable in the urinalysis area?

Megan Nakashima, MD, staff hematopathologist, Department of Laboratory Medicine, Cleveland Clinic: Absolutely. Those are things that I consider when I'm looking at urinalysis instruments.

Can you expand on reducing manual examination? What are you doing in the clinic to eliminate that bottleneck?

Dr. Nakashima (Cleveland Clinic): We have an automated microscopy system that does the dipstick, reads it, and then reflexes to the microscopic analysis if needed. The only time manual work is needed is if results from the automated microscopy are unclear or the sample volume or type is not sufficient for the automated analyzer.

Michelle, are you, at Beckman Coulter, hearing these same themes from your customers as you discuss your solutions with them?

Michelle Dumonceaux, senior manager of product management and global marketing, urinalysis, Beckman Coulter: Yes, those are the three top items we discuss from a global perspective: workflow, scalability, and reducing tech hands-on time. The market continues to move toward full automation with efforts to greatly reduce microscopic work. This all moves toward standardization between technologists and laboratories. Ideally we want to minimize the number of times the sample is handled while providing consistent results quickly.

Urinalysis instrumentation interactive guide
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What are one or two of the highlights or initiatives at Beckman Coulter to help solve some of these issues?

Michelle Dumonceaux (Beckman Coulter): Our instruments use digital flow morphology with auto particle recognition. We can autoclassify 12 particle types with 27 subcategories with onscreen digital imaging to reduce the need for manual review.

We look at the holistic problem: What do customers need as health care continues to evolve? The needs of customers in the United States vary a little from customer needs viewed from a global perspective. So we also need to consider how we can meet global needs as best as possible.

Maya, I'm assuming you're hearing many of these same themes from Siemens Healthineers' customers and potential customers. How is Siemens fulfilling the needs of folks in the urinalysis

market?

Daaboul

Maya Daaboul, global marketing manager of centralized urinalysis-POC, Siemens Healthineers: I agree mainly with the three pain points you brought up: workflow, scalability, and reducing manual work. And I would like to add standardization as well, as we hear more about it from our high-volume labs. They want to make sure they have standardized processes and results. From Siemens' perspective, by offering a solution such as the Clinitek AUWi Pro system, which combines the Clinitek Novus chemistry analyzer and Sysmex UF-1000i flow cytometry analyzer, we provide our customers with an integrated system that—like Dr. Nakashima mentioned—reflexes from the chemistry into the sediment and, by doing so, reduces the need for the operators to do that manual work while maintaining a standardized workflow.

Do you envision this reflex capability from chemistry into the urinalysis and flow cytometer occurring on an automated line?

Maya Daaboul (Siemens Healthineers): The Clinitek AUWi Pro is an integrated system between the chemistry and sediment parts. We have also been working with our lab-diagnostic counterparts in Siemens to have a solution partially or fully on an automation track.

Jason, what can you tell us about Sysmex's approach to these challenges in urinalysis raised by your customers?

Jason Anderson, MPH, MT(ASCP), manager of product-urinalysis solutions, Sysmex: We hear the same things from our customers—workflow, scalability, modularity, maximizing automation, reducing manual processes—themes that are important to laboratories dealing with staffing shortages, increasing workloads, and budget constraints. By pairing the accuracy, precision, and standardization of fluorescent flow cytometry particle counting with digital imaging, the new Sysmex UN-Series is a unique solution that helps address these challenges that laboratories are facing. For example, our system is modular and scalable, which allows us to tailor a configuration that best suits the workflow needs of our customers. In addition, the reflexive and complementary combination of technology allows labs to harness the walkaway efficiency of automated particle counting via flow cytometry but still allows for reflexing to digital image review for those abnormal samples that require it. The result is less "screen time" and more freedom to address other critical laboratory tasks.

As we all know, urinalysis is one of the more tedious areas in the clinical lab, in part because of the high testing volumes. It doesn't have the caché of the advanced-technology tests we associate with next-generation sequencing, or other types of tests that might be top of mind to people looking for new laboratory technologies. Dr. Nakashima, do you think that the clinical yield of urinalysis can be improved through some new directions in testing, perhaps new product innovation?

Dr. Nakashima (Cleveland Clinic): I think so. One thing that can be difficult in the interpretation of urinalysis is that some clinicians forget that the UA dipstick is meant to be sort of a screening test. Some clinicians—when you report, for example, in specific units—believe that the result you're giving them is precise. I've had clinicians say, "Can we stop ordering urine protein by chemistry and just use the dipstick?" Considering the types of targets they're looking for, I don't think just a dipstick is necessarily precise enough to guide them. So, in terms of expanding the scope of what can be done by basic urinalysis, I'm not sure we need to go much further unless the

technology improves to the point where the results are reliably precise.

Let me ask our experts from the three companies: Do you hear from customers that they have difficulty communicating with their clinicians the value of urinalysis as a screening test, as opposed to a confirmatory-type diagnostic test?

Dumanceaux

Michelle Dumonceaux (Beckman Coulter): Yes, that is something we hear. We get a lot of requests about what is the specificity, sensitivity—how customers can tweak it and make more decisions off it. We have to constantly remind them that it is a screen. We find people are utilizing a feature on our instrument, which is our urine culture indicator checklist, which combines the urine chemistry and some of the particle tests of urine microscopy, to help decide if samples should go to microbiology for culture testing.

Jason Anderson (Sysmex): Semiquantitative result information and subjective particle identification by nature come with challenges when compared to quantified methods. From my experience, clinicians have found value in the insights provided by automated urinalysis analyzers, such as the UN-2000, notably with RBC, WBC, and bacteria enumeration, assisting the clinician in the diagnostic pathway. Our customers have shared with us that they greatly value the standardized quantified results that fluorescent flow cytometry brings to patient care in their facilities.

Maya, I'm hearing that urinalysis might be ripe for additional studies into its value and into areas of rules, standardization, and interpretation. Do you believe that to be the case based on dealing with Siemens' customers?

Maya Daaboul (Siemens Healthineers): It depends on where on the globe they are located. The system is used for screening. However, when you have a flow cytometry-based instrument, you can significantly reduce urine culture in the lab due to the technology precision. There are always going to be areas in the lab where the skills of the operators need to still be used; therefore, we need to free their time wisely. So, yes, I agree that it is a screening analyzer and that customers basically want to see a reduced urine culture rate.

Some of you mentioned testing rules. Are the rules in urinalysis changing, and are those rules being reflected in some of the instrument and laboratory information system interfaces?

Maya Daaboul (Siemens Healthineers): The rules are never the same from one lab to the other. They're dependent on patient population, for one, depending on the lab processes and how they want to reflex, for instance. But at a higher level, some things remain common. When the system uses a flexible and customizable software, which is what we have on the WAM middleware solution on the Clinitek AUWi Pro system, for instance, we can meet the various customer rules. This allows the application personnel from Siemens to work with the customer to understand their needs, to write rules, and to implement them in the software. For instance, if blood is negative on the Clinitek Novus chemistry analyzer, yet RBCs are seen on the sediment analyzer, the user would want to have this result flagged, and a simple rule can be created in the system. Examples of rules that may be different from one lab to the other could be rules to reflex to urine culture or rules to reflex to sediment.

Dr. Nakashima

Dr. Nakashima (Cleveland Clinic): I would totally agree with that. Even within the Cleveland Clinic, we have a urinalysis instrument in the main lab, as well as a dedicated urinalysis lab within our Glickman Urological and Kidney Institute. And we have different rules because those two patient populations are quite different. We have also conducted studies that found that different manufacturers' strips show varying levels of sensitivity and specificity for things like finding blood or bacteria, however, so laboratories may want to do internal studies before instituting a workflow heavily based on reflex testing. Interestingly, a few years ago, we were asked to start a reflex urinalysis-to-culture workflow because of the issue of how much catheter-associated UTIs are being tracked in the hospitals, and the clinicians don't use it very much, so I'm not sure what that says about those types of rules.

Jason, please comment on some of these different rules seen in different parts of a health care system.

Anderson

Jason Anderson (Sysmex): Flexibility is a very important consideration when it comes to creating decision and reflex rules in urinalysis. Customers need to be able to easily create rules that standardize patient care and have access to expert resources to optimize their rules and enhance their workflows as needed. Whether it be more standardized rules like reflexing to visual sediment examination based on a positive dipstick result, or creating cross-check rules to evaluate result discrepancies, the system should be flexible to accommodate laboratory need. As a reflex-based system, the urinalysis data manager on the UN-2000 provides a user interface that allows customers to easily create and customize rules that standardize the urinalysis testing process and create workflow efficiency.

Michelle, please comment on the same question from the perspective of Beckman Coulter.

Michelle Dumonceaux (Beckman Coulter): I completely agree with Maya and Jason in terms of the flexibility that's needed and the standardization that is not necessarily seen throughout the various labs. Urology, oncology, and the ED have somewhat different parameters for what they're looking to test and why they're testing a urine sample.

At Beckman Coulter, we offer a software solution called iWARE that provides flexibility for the laboratory. It is designed to streamline the technical and clinical validation procedures by consolidating all processes into a single system. It also minimizes the number of computers required to manage each data release point. Laboratories can use iWARE to customize rules based on test type, result value, patient demographics, and more. It helps provide flexibility and define when to reflex to microscopy.

One thing we mentioned at the outset was scalability, and this goes across many testing disciplines, whereby you have a concentrated core lab-like operation for high-volume testing—automation is

maximized, labor is minimized in relation to the volume of testing that's done—yet we still see a great deal of testing in offices and clinics. Do we have that same distribution in urinalysis, or is there something unique about the way urinalysis testing is evolving?

Dr. Nakashima (Cleveland Clinic): I think that scalability is very important if you're dealing with a large system that, as you were saying, has a core lab, as well as smaller facilities. For example, I'm medical director for urinalysis at this main hospital but also lab director at several smaller sites. If you want to truly harmonize your reporting and testing, you would want to have a scalable system.

One thing that we haven't really addressed and is not my area of expertise is point-of-care testing. Our ED does point-of-care urinalysis, and when they send it to the lab, they send it to always get microscopy because they already know that the chemistry's abnormal.

Are you happy with the quality of that result and that request, or do you think they often are overcalling the need for microscopy?

Dr. Nakashima (Cleveland Clinic): I think most of the results end up being positive, and it's not a huge burden to the laboratory. So it's probably helpful for them to screen out some of the samples they're not as worried about.

I realize that all three companies represented have people who do a lot with point-of-care testing. You may or may not be particularly conversant with the point-of-care part of urinalysis, but let me ask you, Jason, if you would agree that there's still a considerable amount of point-of-care testing done in urinalysis.

Jason Anderson (Sysmex): Absolutely, especially when it comes to urine chemistry strip testing. In the future, laboratory systems will continue to value and even demand scalable standardized urinalysis testing solutions that work in harmony from the bedside to the core lab.

Michelle, what are your thoughts on urinalysis at the point of care?

Michelle Dumonceaux (Beckman Coulter): When you look at the broad spectrum of urinalysis, manufacturers are trying to develop a solution that can be used from point of care—even from having testing done in the home—up to a high-volume reference lab. So there is a need for consistency across all spectrums, so when the clinician interprets the tests, there are consistent results and standardization. But the technology is very different from a visual read strip all the way up to a fully automated, and you've got smaller types of analyzers in between. So how do you bridge these in? That is a challenge we continue to assess.

Maya, I know Siemens has a dedicated point-of-care testing division. Does urinalysis have a home in that part of Siemens Healthineers?

Maya Daaboul (Siemens Healthineers): This is our favorite topic at Siemens—point-of-care testing and end-to-end solutions. We have 75-plus years of innovation in urinalysis testing, from the very first manual strips. We understand that our customers are looking for scalability of results, same reference range, same quality of results, and same performance whether the patient is in a small clinic with a satellite lab or in a large hospital. By having an end-to-end solution, from the single visual-read manual strips all the way to our Clinitek Advantus and Clinitek Novus analyzers found in the central lab, our customers basically get the same results on all platforms. The same dry pad chemistry is being used on every test no matter the setting. We even have incidents where Clinitek Novus was placed in the ER.

Jason, Michelle, and Maya, do you have any final thoughts you'd like to share with our readers about this topic of urinalysis?

Jason Anderson (Sysmex): Standardization is critically important in all testing processes, and urinalysis is no exception. In addition to benefiting from a highly standardized flow cytometry and digital imaging-based urinalysis solution, customers can benefit from the BeyondCare quality monitor, an innovative quality management software

program that can help laboratories standardize and streamline their urinalysis quality control processes, simplify record-keeping, and enhance compliance activities. It's exciting to see urinalysis technology evolve, and I look forward to the future innovations that will continue to enhance patient care.

Michelle Dumonceaux (Beckman Coulter): We're trying to reduce subjectivity. We utilize digital flow morphology with auto particle recognition to classify different particles based on size, shape, contrast, and texture. We have software solutions that can assist with rule writing to offer flexibility for the lab. In addition to testing a urine sample, laboratories can run body fluids on our analyzer.

Maya Daaboul (Siemens Healthineers): My final thought is that we need to continue listening to our customers and understanding their needs so we can build products that meet those needs. We are committed to investing in urinalysis, whether in North America or outside, by providing various platforms and listening to our customers' suggestions for short-term updates as well as long-term changes and solutions.

Dr. Nakashima, as you know, urinalysis may be the oldest type of laboratory test. Do you have final comments about urinalysis testing and the role it plays in the life of the laboratory and the health of patients?

Dr. Nakashima (Cleveland Clinic): Going back to what you were saying earlier, we probably do have more things that we could find out from urinalysis, with or without microscopy, that could have clinical impact. But what we're lacking in somewhat is prospective studies because, as you alluded to, it's not an "exciting" field. It's not as "sexy" as NGS, for example. So if we really want to push that envelope, we have to get people more interested in doing prospective projects.

I'd also like to say that the use of urine preservative tubes has in many ways become standard, just because of the distances some of these samples have to travel and the inability in many cases to document proper specimen storage—i.e. refrigeration. And I've noticed that a lot of the manufacturers have been validating their instruments on nonpreserved urine. I hope that moving forward, they will consider that most samples coming into a laboratory are going to be in preservative and take that into account with their validations.