On Roche m 511 analyzer, 'everything is done from the slide'

November 2018—*Roche Diagnostics will soon launch its m 511 analyzer for hematology laboratories. Krista Curcio, Roche technical marketing manager, hematology, told us, in a recent conversation with CAP TODAY publisher Bob McGonnagle, how and why the new instrument is different. "We're turning it upside down and going a different way," she said of the m 511. Here is more on the instrument Roche will launch before year's end.*

Roche has a different technology and it has a good pedigree in terms of image analysis and image recognition. Please outline the new Roche hematology technology and offering.

Curcio

When I'm talking to our potential customers or other medical technologists and technicians about it, the first thing I say is forget everything you know about how we've always done hematology because it's totally different. There's no impedance, no flow cytometry, no light scatter, all the things we've been so accustomed to in hematology for 40-plus years. We're turning it upside down and going a different way because everything is done from the slide. Think about that from a med tech perspective: When you run something on an analyzer, whenever we have questions about what the analyzer is telling us, we make a slide and put it under the scope. So I like to tell people we're using sort of a reference method. If you go back to the place we always go when we have questions, it is the slide, and that's where we're getting all our information.

Describe how it is that you, through the use of a slide and technology, are getting some of the answers we're used to getting from the traditional instruments in hematology.

The m 511 uses a technology called digital multispectral image analysis. It's using different wavelengths of light—red, blue, yellow, and green. By using those different light sources, it's able to recognize the different characteristics of the cells. So the first step under a low magnification process is using those different light sources to identify and count your reds, whites, platelets, and any nucleated reds that are present.

Then switching to high magnification, it's again using those light sources to differentiate the whites into their five normal types or into anything abnormal or unclassified. Using the blue light, which is specific for hemoglobin, we're able to determine our MCH measurement based on how much light the individual RBCs are absorbing. And then using all five light sources we are able to determine MCV based on how much of the light the individual RBCs are absorbing. With those numbers—MCV and MCH—we can calculate the rest of the RBC indices.

All this perception and analysis of colors is driven by a computer, correct? It's not visible to the naked eye.

Correct.

Apart from the technology as you roll this out—I realize it's a new rollout in North America but it's been in Europe for a while—how are customers reacting? What are the big concerns of customers in

hematology departments? What are their desires? And how does this product help fulfill their needs?
Of course, people who want to provide the best information they can to their clinicians for the patient are always cautious when it's something new. People want to see data to show that, yes, it really does work and we're going to give you information that's equivalent to what you're accustomed to seeing from a traditional hematology system. People are excited about it also, once the idea of how it's working clicks with them. Laboratorians are seeing the potential for this system and what it can do. Having the images available can provide a lot of benefit.

Because of our technology on the m 511, some types of challenging patient samples will be more easily analyzed in the laboratory, and technologists are excited about that possibility.

Will it be able to be incorporated into a core laboratory line?
It's a goal for the future. We have connectivity in development for the future, and it's definitely the direction we want to go.

The laboratory experts we spoke to and the other two manufacturers made a great issue out of the need to minimize manual differentials and to introduce rules—anything to make the entire process of analysis and reporting more efficient. Where does the manual differential, as we think about it traditionally, fit in with the Roche offering? Will there still be a need for manual differentials?
Initially people probably will want to go to the microscope, and that's always an option until people become comfortable with the technology and believe in it, because you can take that slide from the m 511 and look at it under a scope. I have not seen any instances at this point where we say you must always look at those particular slides. But I don't think we're at a point yet either where we would say, no, you never need to go to the scope again.

Is CellaVision a distant cousin to this technology?
The way it works is completely different. There's the digital imaging part of it where laboratories have over the years become more comfortable with using that technology. People who are comfortable with CellaVision would more easily adapt to the m 511, whereas people who haven't become comfortable with CellaVision yet might still find the digital part a little more challenging, or they might not be fully trusting of it yet.

There was discussion about rules and the release of results interfaced into the LIS and the EHR. I'm going to assume these are all issues Roche has solved or is in the process of solving as it gears up for the launch into North America, correct?
Yes. The system has onboard rules, so people could set up those rules similar to what they're accustomed to if they want to repeat a sample for a specific reason. We can configure those same types of rules. Everything can be sent directly to the LIS just like it can be done on any other analyzer.

I like to point out that just because we give you the images for every sample, you don't need to look at them. If it's something that's completely normal, you can release or autovalidate it into your LIS just like you would do from any other hematology analyzer.

You've been a hematology supervisor in the past. From your experience and now as you go around the country talking to people, what has surprised you in terms of what you're hearing from your counterparts who are still working in clinical laboratories in hematology departments?
This isn't anything new—it's been going on for several years—but I find it a little sad that we've lost a lot of the specialization we used to have in the lab. When I was in the lab we had people who were specialists in hematology, in chemistry, in blood bank. Because of how staffing's changed over the years, as things have gotten tighter, everyone's a generalist now. As a marketing person now, that can be beneficial because I'm offering technology that can help.

This change in staffing is part of the natural evolution in the environment, and to a large degree it's become a task of companies like Roche or Beckman Coulter or Sysmex, and others, to build that specialization and knowledge into their systems.
Yes, it really has. As the laboratory functions today, it doesn't allow for people to have that knowledge necessarily,

unless they do it on their own time.