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This medical industry feature, titled "Respiratory Testing Challenges in the Ongoing Pandemic" is sponsored by Cepheid. This program is intended for physicians, laboratorians, and all frontline healthcare workers.

Here's your host, Dr. John Russell.

Dr. Russell:
As COVID-19, respiratory syncytial virus, and the flu present with similar symptoms, symptomatic differentiation and quick diagnosis are vital to determining the correct patient pathway in minimizing viral spread. This is ReachMD and I'm Dr. John Russell.

Joining me to take a look at challenges in respiratory testing during the COVID-19 pandemic is Dr. Greg Berry. Dr. Greg Berry is an Associate Professor of Pathology and Cell Biology at the Columbia University Vagelos College of Physicians and Surgeons. He is Co-director of Clinical Microbiology Service, an Associate Director for the CALM Center, the Center for Advanced Laboratory Medicine at New York Presbyterian Columbia University, Irving Medical Center in New York, New York.

Dr. Berry, thanks for being here, today.

Dr. Berry:
Thank you. It's a pleasure to be here.

Dr. Russell:
So Dr. Berry, what key clinical challenges do you anticipate seeing as we head into this year's respiratory season?

Dr. Berry:
Well, that's an interesting question and I'll tell you why. Because, while COVID-19 has been a major issue over the last 18 months and we've basically been focusing on COVID-19 testing, it's really clear that the other respiratory viruses have not really gone anywhere and basically, we're gonna start to see a resurgence of some of them. That's quite clear with RSV right now as we see a national surge in RSV cases. It's also true that as we move into flu season, flu A and flu B typically have a seasonality we're moving right into that season now. So as you see social distancing start to change, masking requirements start to change, and other things that are at play, and now 18 months in, I think that it's gonna be definitely a challenge when you have a symptomatic patient in front of you and you have to, determine whether that patient has COVID-19 or has one of these other respiratory viruses. Because as we know, symptomology really is not useful in telling the difference. Really, it falls back on diagnostic testing, to make that assessment.

Dr. Russell:
So Dr. Berry, we certainly hear a lot about the evolution of the virus. How is Cepheid gonna evolve as there are new strains with some of the new technologies they're coming up with?

Dr. Berry:

You know, that's interesting because as we've watched now the progression of these different variants, there's a lot of talk lately about the delta variant, but I mean that it's pretty clear to everybody that this won't be the last variant that is going to make front row and center as we watch the evolution of this virus continue. And what Cepheid has done is they actually added a third gene target to the assay in order to make sure that as they move forward, they at least have a potential to identify some of these variants by basically picking different targets and having at least three targets in their assay. So, if one of the targets or two of the targets gets affected by the next variant XYZ, they will still be able, hopefully, to detect the virus because of this extra target that's been added to the assay.

Dr. Russell:
So, with the diagnostic changes in mind you just mentioned, what value do you see in multiplex respiratory testing during this year's flu season?

Dr. Berry:
I think multiplex testing is gonna be very valuable because, as I had said before, I mean, COVID-19 is, clearly here to stay for a while if not for always, right? The other respiratory viruses that were always present are still gonna be here, which means when we look at patients who are symptomatic moving into the flu season, we're gonna need to have the ability to actually differentiate between a COVID-19 infection and infection with, for example, influenza, right, or RSV, or some of the other viruses that you would typically see, but specifically influenza and RSV.

Dr. Russell:
For those just tuning in, you're listening to ReachMD. I'm Dr. John Russell and today I'm speaking with Dr. Greg Berry about respiratory testing amid the COVID-19 pandemic. Before the break, we spoke about the upcoming respiratory season and the role diagnostics will play. Let's get more specific and talk about Cepheid's 4-in-1 respiratory test.

So Dr. Berry, now that we've got a good understanding of the upcoming respiratory season and the role of diagnostics and how important they are, let's take a look at a specific test, Cepheid's 4-in-1 respiratory test. Dr. Berry, what can you tell us about this?

Dr. Berry:
So, the Cepheid Xpert® Xpress actually tests for four different pathogens, SARS-CoV-2, influenza A, influenza B, and RSV. And so, this is an all-in-one test that's basically what's called a cartridge-based sample-to-answer assay, which means that you take the patient's specimen, you load it into an individual cartridge, which is the cartridge for that patient test, and then that goes onto the instrument. And this is actually a molecular-based assay that because of that really benefits from having that nucleic acid amplification that leads to the increase sensitivity and specificity that really is helpful, especially with respiratory tests, as well as many other infectious disease tests.

Dr. Russell:
So, for the Cepheid's 4-in-1 Xpert® Xpress test, you're at a university teaching center in New York City, I'm a primary care doctor, is this something that's more tailored for the university centers, or is it going to be something that someone like myself could use in their office?

Dr. Berry:
Yeah, I think that's a great question because in a way, it's actually even more tailored for use in your office versus here because here, I have a staff of molecular technologists who work in a laboratory every

day. This test was really designed to, while it can function quite well in this environment, it also has been designed to actually work at the point of care, closer to patients and really be able to flourish and work just as well in that environment as it does in a laboratory-based environment. This and other molecular tests that are designed for point of care really have been driving in that direction.

Dr. Russell:
So Dr. Berry, if I'm gonna be using this in my office, what's gonna be the turn-around time before I can tell someone that they don't have COVID?

Dr. Berry:
So, you know, while molecular tests that are lab-based typically take hours to run which is much quicker than previous technologies, like cell culture or something like this, the assays in the lab take a few hours to run typically, this test is actually available for if it's a SARS-CoV-2 result, it's available within 25 minutes and if it's a flu/RSV result, or any other positive result, basically the assay ends at 36 minutes and also at 36 minutes you know if it was negative. So, best case scenario is 25 minutes, worst case scenario is 36 minutes. Well under an hour to have these, kind of molecular-based sensitive specific results.

Dr. Russell:
So, there's lots of other tests out there, how does Cepheid's solution differ from some of the current testing methods that I might have in my office or other clinicians might have in their offices?

Dr. Berry:
That's a great question because most of the time when we think of point of care testing, infectious diseases specifically, we're really thinking about what used to be called rapid antigen tests, right? Which rapid antigen tests basically look at the surface of the virus and whatever amount of virus you have there, it can either detect that virus or not, based on whatever quantity is in the patient's specimen. The big difference with molecular assays, Cepheid included, are that they amplify the patient's specimen and they actually amplify the nucleic acid that's present in that patient's specimen. So, you can take a virus that is in a very small quantity, right, and when you go through that amplification of its genome, you can actually detect it, even if it was there in a very small quantity, which means your sensitivity goes way up compared to a rapid antigen test.

Dr. Russell:
Before we close, Dr. Berry, what impact do you think Cepheid's Xpert® Xpress test will have on patients and providers for the respiratory season?

Dr. Berry:
I would say that going back to your earlier question about the last 18 months, I think that it has been a race to try to get enough testing, in place, in order to make sure that we can actually test all the patients that need to be tested for SARS-CoV-2, but now, also for the other pathogens like influenza A, like influenza B, like RSV. So, I think that tests like this, molecular tests that are highly sensitive and specific really play a major role in making sure that we have enough testing capability to make sure patients get the tests that they need. And this is definitely a step in the right direction.

Dr. Russell:

Well with those considerations in mind, I wanna thank my guest, Dr. Berry for helping us to better understand the role of multiplex testing and how it serves us during the respiratory season and the ongoing COVID-19 pandemic.

Dr. Berry, thank you so much for being here, today.

Dr. Berry:
Thank you, Dr. Russell, it was a true pleasure.

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