



Article:

Gregory J. Berry, et al.

Comparison of the Alere i and BD Veritor Assays for the Rapid Detection of Influenza A and B Viruses.

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Guest: Dr. Gregory Berry is assistant professor of Pathology and Laboratory Medicine at Hofstra Northwell School of Medicine in New York and assistant director of Infectious Disease Diagnostics at Northwell Health Laboratories.

Randy Kaye: Hello, and welcome to this edition of "JALM Talk" from *The Journal of Applied Laboratory Medicine*, a publication of the American Association for Clinical Chemistry. I'm your host, Randy Kaye.

The use of point of care testing in outpatient clinics and doctors' offices for patient management decisions is becoming more common. Although these tests are generally faster and more user-friendly than central laboratory equipment, they are still expected to have acceptable performance including accuracy, precision, sensitivity, and specificity for the analyte that they're measuring.

An article called "Comparison of the Alere i and BD Veritor Assays for the Rapid Detection of Influenza A and B Viruses," published in the May 2017 issue of JALM, compared the ability of two point of care devices to detect influenza A and B separately and quantitatively. These assays use different analytical techniques, where one is a rapid isothermal nucleic acid amplification assay, and the other is a chromatographic immunoassay. Samples with discordant results were subsequently analyzed using real time PCR.

The first author of this article is Dr. Gregory Berry, assistant professor of Pathology and Laboratory Medicine at Hofstra Northwell School of Medicine in New York and assistant director of Infectious Disease Diagnostics at Northwell Health Laboratories, and he's our guest for today's podcast. Welcome Dr. Berry.

Dr. Gregory Berry: Thank you.

Randy Kaye: To begin, why you don't just tell us a bit about your study?

Dr. Gregory Berry: So as you stated in your introduction, point of care testing is becoming increasingly more common, and these results have a direct impact on patient care decisions. Since the results of these tests are used to direct patient care, it is imperative that the results are accurate and reliable, and

that the studies are done to look at the performance of these assays. Our special interest was influenza point of care testing. We looked at two point of care tests on the market to detect influenza A and B viruses. These tests were the BD Veritor, which is a point of care test and is a more established chromatographic immunoassay in the realm of point of care testing, while the other, the Alere i, is a newer technology that uses nucleic acid amplification for pathogen detection. So our goal is to evaluate these assays and look at how the new molecular based Alere i assay performs in comparison to the BD Veritor immunoassay.

Randy Kaye: Okay. So now what new information do you think that the study is going to bring to the table for the clinics and the health systems trying to make a choice between these new molecular technologies and the rapid antigen test with which they're already familiar?

Dr. Gregory Berry: I think our study highlights a typical choice that's faced by clinics and health systems every day. And that choice is looking at two tests that seemingly do the same thing and then trying to make a decision to which one they're going to pick based on the various different factors that come into play, such analytical performance, ease of use, cost, and many other considerations.

In this case, our study compared the performance of these two tests over two consecutive influenza seasons, and found that the Alere i performed better in the detection of influenza A than the BD Veritor. The ability to detect the pathogen for which you're testing is of course one of the critical components to be considered when picking a new test. So that being said, we hope that the conclusions of our study can be used as part of an assay platform decision that a health system or a clinic would need to make.

Randy Kaye: Okay, make sense. I'd like to know though, you ran this test yourself, I understand? And two questions, do you find it easy to use? And also based on your experience and your observation, do you think it would fit well as a point of care test in the clinic?

Dr. Gregory Berry: Yeah. Actually, both assays were easy to use, but since the Alere i is the newer platform and it outperformed the Veritor in our study, I'll talk about the Alere specifically. Yeah, I did run the Alere i myself and I did find it easy to use. The design of the assay wasn't overly complicated and it's a quick set-up and a less than 15-minute results from the time of set-up to the time of result. So I think it would fit quite well in the clinic setting. One of the things that I found is the display screen on the instrument prompts the user to perform each necessary step, which I thought was a

real added plus and should really help clinic staff in running the test.

Randye Kaye: Okay, so molecular testing sounds like it has an advantage, especially in increased sensitivity over rapid antigen testing. But are there any drawbacks?

Dr. Gregory Berry: One big drawback is that molecular testing has a higher price in general and is typically higher than the test that it's looking to replace. So the cost is higher, but that being said, I know that the reimbursement rates have been adjusted to reflect this cost increase.

Also another point to consider is that more accurate test result should lead to better patient care. That's always the goal in this type of testing. So if we're using a better test that the cost factor is not as -- is maybe not as great.

Randye Kaye: Okay, that makes sense actually, but bearing all this in mind, what direction do you see point of care testing for infectious diseases going, over say the next five years?

Dr. Gregory Berry: So I'd say over the next five years, we're going to see a great deal more infectious disease testing. It's going to enter the point of care arena. I think that the convenience of the test results right at the patient's bedside or in the clinic during a sick visit really can't be denied. Those are huge perks to have the test result. Now that being said, test results obtained from point of care testing need to reach the same level of sensitivity and specificity as our current laboratory performed diagnostic test if they're ever to become the primary tool used in the diagnosis of any infection. Comprehensive evaluations of these types of point of care tests will really be key as we move forward.

Randye Kaye: Very interesting. Thank you so much for joining us today Dr. Berry.

Dr. Gregory Berry: It's my pleasure.

Randye Kaye: That was Dr. Gregory Berry from Northwell Health Laboratories talking about the JALM article, "Comparison of the Alere i and BD Veritor Assays for the Rapid Detection of Influenza A and B Viruses" for this podcast. Thank for tuning in for "JALM Talk." See you next time and don't forget to submit something for us to talk about!