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James H. Nichols, Mahesheema Ali, John I. Anetor, Li-Sheng Chen, Yu Chen, Sean Collins, Saswati Das, Sridevi Devaraj, Lei Fu, Brad S. Karon, Heba Kary, Robert D. Nerenz, Alex J. Rai, Zahra Shajani-Yi, Vinita Thakur, Sihe Wang, Hoi-Ying Elsie Yu, and Lindsey E. Zamora.

AACC Guidance Document on the Use of Point-of-Care Testing in Fertility and Reproduction.

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Guest: Dr. James Nichols is a Professor of Pathology, Microbiology, and Immunology, and is the Medical Director of Clinical Chemistry and Point-of-Care Testing at Vanderbilt University Medical Center in Nashville, Tennessee.

Randye 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, Randye Kaye. Point-of-care testing is continuously expanding due to its convenience, ease-of-use, and rapid result turnaround time relative to central laboratory-based testing. One particular area in which point-of-care testing is gaining popularity is the field of reproductive medicine. Point-of-care tests may predict ovulation, diagnose pregnancy, and identify premature rupture of membranes and fetal distress at birth.

Over the past few years, the AACC Academy has been working to update the Laboratory Medicine Practice Guidelines entitled Evidence-Based Practice for Point-of Care Testing, originally published in 2007. By publishing narrowly focused guidance documents on different areas of point-of-care testing, the Academy's most recent effort has focused on point-of-care testing for fertility and reproductive health. The Academy formed an expert committee to examine key clinical questions and published literature regarding the use of point-of-care testing in fertility and reproduction. The resulting document consists of expert opinion recommendations based on current peer reviewed literature. The document includes a discussion of the supporting literature for each recommendation as well as challenges and limitations.

The September 2022 issue of *JALM* includes the new "AACC Guidance Document on the Use of Point-of-Care Testing in Fertility and Reproduction," which is published as a special report. Today, we're joined by the guidance document's Chair, Dr. James Nichols. Dr. Nichols is a Professor of Pathology, Microbiology, and Immunology, and he is the Medical Director of Clinical Chemistry and Point-of-Care Testing at Vanderbilt University Medical Center in Nashville, Tennessee. Dr. Nichols, welcome.

Why did the AACC Academy choose to create a new document for point-of-care testing specifically in the areas of fertility and reproduction?

James Nichols: Sure. This is actually a revision of the reproductive testing section from the original Laboratory Medicine Practice Guidelines, LMPG, that were published in 2007. The panel of experts got together, decided that reproductive health and point-of-care testing was an important topic. There were some newer developments and we figured this was a great topic for revision.

Randye Kaye: All right, thank you. So tell me more about how the document was developed and what areas did the writing group decide to focus on?

James Nichols: Sure. So, I was a panel of academy members, so the AACC Academy, with expertise in point-of-care testing and laboratory medicine. We also recruited a couple of clinicians, emergency room, and OB-GYN, and we focused on reproductive health, specifically ovulation, pregnancy, premature rupture of membranes, and high-risk deliveries.

Randye Kaye: Okay. Now, I see in the document, it consists of several key recommendations. Can you tell me how the writing group came to consensus about the recommendations and how are they structured?

James Nichols: We asked clinically relevant questions and then went out and searched the literature to respond to those questions. So, the original draft was sent around to the committee members. Once we reached consensus, it was sent out for public comment, and it was reviewed by the AACC Academy Board of Directors. So, it went through several rounds of review and revision based on the response we got back from the general public.

Randye Kaye: Can you summarize some of those key recommendations?

James Nichols: Sure. With regard to ovulation, urine luteinizing hormone or LH tests are accurate and reliable predictors of ovulation and there are now home-based monitors that are popular for identifying the fertile window of the menstrual cycle. So, urine LH point-of-care testing as part of the procedures in various assisted reproductive technologies can facilitate fertility treatment. We then also focused on pregnancy point-of-care testing, recommended that it should be considered in clinical situations where rapid diagnosis of pregnancy is needed for treatment decisions, and the laboratory analysis cannot meet the required turnaround time. But there are some considerations regarding antigen excess, proteinuria, biotin, dilutional effects, and other sources for consideration of interference.

With regard to premature rupture of membranes, it is not recommended as an alone test. You should consider PROM, or premature rupture of membranes, only when there's clinical signs such as leakage of amniotic fluid from the cervical opening. And finally, we recommended that fetal scalp lactate testing is recommended over fetal scalp pH for the management of patients and delivery of fetuses with abnormal fetal heart rate. So, a couple of key important revisions and recommendations for those that are doing this type of testing.

Randye Kaye: Thank you for that summary. But what do you think the future holds for point-of-care testing in fertility and reproduction?

James Nichols: I think we're going to see more non-invasive testing, particularly the use of monitors, for instance for ovulation testing, and we're going to see an expansion of point-of-care, delivery of more testing closer to the patient.

Randye Kaye: All right, thank you so much for joining me today.

James Nichols: Oh great!

Randye Kaye: That was Dr. James Nichols from Vanderbilt University Medical Center, describing the *JALM* special report, "AACC Guidance Document on the Use of Point-of-Care Testing in Fertility and Reproduction." Thanks for tuning in to this episode of *JALM* Talk. See you next time and don't forget to submit something for us to talk about.