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CINtec PLUS Cytology: A New Biomarker-Based Triage in Cervical Cancer Screening

Welcome to ReachMD. This medical industry feature, titled “CINtec PLUS Cytology: A New Biomarker-Based Triage in Cervical Cancer Screening” is sponsored by Roche Diagnostics ‘doing now what patients need next’. This program is intended for physicians.

Here’s your host, Dr. Jennifer Caudle.

Dr. Caudle:
The Pap test has played a key role in reducing cervical cancer since its introduction in the 1940s. But like any test, it isn’t without its limitations, which is why in March 2020 a new cytology-based test was approved for the use in the United States that has the potential to change the way that we think about cervical cancer screening today.

I’m Dr. Jennifer Caudle, and joining me to discuss CINtec PLUS cytology test as a new tool for cervical cancer screening, is Dr. Ritu Nayar, Professor and Vice Chair of Pathology and Director for Cytopathology at Northwestern University and Northwestern Memorial Hospital in Chicago. Dr. Nayar, thanks so much for being here today.

Dr. Nayar:
It’s my pleasure. Thank you for having me.

Dr. Caudle:
Before we dive into the specifics of CINtec PLUS cytology, let’s talk about the history of the Pap test. Can you explain what led to the development of this new test and why it’s an important tool in cervical cancer screening today?

Dr. Nayar:
Sure. The Pap test has a rich history. In fact, it proved to be the most successful of cancer screening tests in the history of medicine, and its use significantly reduced both the morbidity as well as the mortality from cervical cancer, following its introduction into the screening programs in the United States in the 1960s.

The Pap test is a cytologic technique in which cells from the cervix or vagina are microscopically evaluated for cellular changes caused by HPV viral infection. Cytology involves firstly, looking for abnormal cells, then finding them, and then thirdly, but most importantly, grading the severity of the abnormality as either low-grade or high-grade. And it’s the high-grade changes that represent pre-cancer. They’re the changes that we want to find to prevent cancer.

However, the Pap test does have limited sensitivity for cervical precancer and less than optimal inter-observer reproducibility among both pathologists as well as among laboratories. This is why HPV co-testing and subsequently HPV primary screening were incorporated to improve the sensitivity of cervical cancer screening.

Additionally, with the increased uptake and success that HPV vaccination has had in the primary prevention of cervical cancer, the incidence of high-grade lesions has decreased, making it even harder to find and interpret precancer on a Pap test. It's like finding a needle in a haystack on cytology.

Dr. Caudle:
Now that we have a better understanding of what some of the limitations of the traditional Pap test are, can you tell us how CINtec PLUS cytology is different and how this new technology aims to overcome those challenges?

Dr. Nayar:

Yes, CINtec PLUS is a biomarker-based cytology test that was approved by the FDA in March 2020 for use in cervical cancer screening. The test uses a combination of two biomarkers – P16 and Ki-67 – and it represents a step forward in using molecular markers to more accurately detect transformed cells. Let's discuss the details using a stoplight analogy. The logic behind the stoplight analogy is in regards to the cellular function, which is altered by response to persistent high-risk HPV infection. Expression of the P16 biomarker indicates cell cycle arrest. You can think of this as a red light or a stop sign in the cell. P16 is expressed when the cell is trying to stop itself from replicating.

Expression of Ki-67 biomarker, on the other hand, indicates cellular proliferation. You can think of this as a green light, or "go signal" in the cell. In a normal cell, you can have expression of either P16 or Ki-67, but not both at the same time, as these two biomarkers are mutually exclusive. Thus, the co-expression of P16 and Ki-67 in the same cell indicates cell cycle deregulation and is a predictor of transforming HPV infection at the cellular level, or precancer. CINtec PLUS cytology therefore focuses on the objective detection of the molecular driving event behind the HPV transforming infection, rather than the more subjective morphologic manifestation of high-grade disease on cytology.

Dr. Caudle:
Now, what are the intended uses of CINtec PLUS cytology?

Dr. Nayar:
Firstly, as a triage test for women 25-65 years old who have a positive high-risk HPV test result using Roche's cobas HPV test platform. This would replace traditional Pap cytology in the current HPV primary screening algorithm. Its second approval is as an adjunct to HPV screening with the cobas HPV test in co-testing women aged 30-65 years, specifically for women who have a negative cytology and a positive high-risk HPV test.

Currently, when a co-test result is Pap negative and HPV positive, or when a reflex Pap that follows a positive primary HPV screen result is negative, patients are instructed to retest in 12 months. This may lead to potential loss of follow-up and uncertainty for patients who want immediate answers regarding their risk. The reality also is that they might be harboring precancer or they might be lost to follow-up. In fact, the repeat test compliance rate is only 59% according to a meta-analysis performed in over 13,000 patients in a randomized, controlled trial of primary HPV screening.

The use of CINtec PLUS cytology testing in these patients provides more definitive information about which HPV positive/Pap negative women may benefit most from immediate referral to colposcopy versus coming back for repeat testing. It does provide a clearer path forward for both physician and patient.

Data from the Improving Primary Screening and Colposcopy Triage, or IMPACT trial, shows that CINtec PLUS cytology can help find disease in women with discrepant screening results earlier and aid clinicians in making the right management decisions sooner.

Dr. Caudle:
For those of you who are just tuning in, you're listening to ReachMD. I'm your host, Dr. Jennifer Caudle, and I'm joined by Dr. Ritu Nayar to review CINtec PLUS cytology for use as a triage in cervical cancer screening.

So, Dr. Nayar, you just gave us some background on what this cytology test is, and who it's intended for. But now, I'd like to get your perspective on the impact of this technology. How do you see this test changing practice in cervical cancer prevention, and is there anything we should be aware of before implementing it?

Dr. Nayar:
Yes, CINtec PLUS cytology is a next-generation test. It uses objective biomarkers to provide more definitive results of precancer and helps avoid both undertreatment as well as overtreatment, and patients can be managed in a more timely manner to prevent the possibility of developing cervical cancer. This test requires nothing different really to be done on the part of the healthcare provider. Collection using liquid-based cytology is still the same as before, but your laboratory will need to make the test available to you before you can incorporate it into your clinical practice.

Dr. Caudle:
Now, unfortunately we're almost out of time, but before we close, Dr. Nayar, what do you want healthcare professionals to take away from this discussion?

Dr. Nayar:
I'd say do your own research. There are a number of peer-reviewed and published articles on CINtec PLUS cytology. Additional data, including that from the IMPACT trial will be forthcoming in the near future. CINtec PLUS cytology can address an unmet need in both primary HPV and co-testing screened populations for the laboratory, the clinician, and most importantly, the patient. And last but not the

least, foster collaboration with your testing laboratory. Let the lab know that you're interested in having this option to use this new test, because it can give you the ability to obtain more actionable screening results right away for your patient.

Dr. Caudle:
Well, considering the high prevalence and mortality associated with cervical cancer, it's important for us to stay on top of the latest screening technologies that are available to us, and I'd really like to thank my guest, Dr. Nayar, for helping us better understand this new cytology test in greater detail. Dr. Nayar, it was great speaking with you today.

Dr. Nayar:
It was a pleasure, thank you, Dr. Caudle.

Announcer:
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