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Navigating How the Updated ASCCP Guidelines Can Work for You

Announcer:
Welcome to ReachMD.

This medical industry feature, titled “Navigating How the Updated ASCCP Guidelines Can Work for You,” is sponsored by Roche.

Here’s your host, Dr. Mary Katherine Cheeley.

Dr. Cheeley
The American Society for Colposcopy and Cervical Pathology, otherwise referred to as ASCCP, released an update to the enduring guidelines of 2019 for the management of cervical cancer screening, for the first time addressing dual-stain. What’s new? And what do these changes mean for you and your patients?

This is ReachMD, and I’m Dr. Mary Katherine Cheeley. Joining me to discuss the updated ASCCP guidelines for cervical cancer screening management is Dr. Leigh Cantrell. She’s a medical physician, as well as having her MSPH. She’s a fellow of the American College of Obstetrics and Gynecology. She’s an OBGYN who specializes in gynecologic oncology.

Dr. Cheeley:
Dr. Cantrell, welcome to the program.

Dr. Cantrell:
Thank you so much for having me. I’m happy to be here.

Dr. Cheeley:
The updated ASCCP guidelines now address the use of dual-stain technology. As you know, CINtec *PLUS* Cytology is the only approved dual-stain triage test on the market. For those who may be unfamiliar, can you describe what the CINtec *PLUS* Cytology dual-stain triage test is?

Dr. Cantrell:
Absolutely. So, CINtec *PLUS* Cytology is a test of the co-expression of p16 and Ki-67 and confirms the presence of a transforming HPV infection and defines patients with high-risk cervical disease. It has high specificity to rule out disease without sacrificing sensitivity.

Dr. Cheeley:
Thank you for that summary. Now, can we discuss the updated ASCCP guidelines?

Dr. Cantrell:
Absolutely. Today we’ll address the recommendations aligned with the intended use of CINtec *PLUS* Cytology test.

Dr. Cantrell:
A combination of dual-stain and limited genotyping provided by the screening HPV test is acceptable for triage of individuals who test positive for HPV. If using dual-stain to triage HPV-positive test results with limited genotyping, colposcopy, is recommended for individuals who test positive for HPV16 or 18. For individuals who test positive for the pool high-risk 12 other genotypes, colposcopy is recommended when dual-stain is positive, and one year return is recommended when dual-stain is negative.

Dr. Cantrell:
As mentioned previously, all HPV16 and 18-positive individuals should be referred to colposcopy until additional data for the safety of

HPV16-positive or HPV18-positive and dual-stain-negative individuals becomes available. Women with the other 12 high-risk HPV types should be managed according to risk, and this is in accordance with dual-stain intended use.

Dr. Cheeley:
Thank you, Dr. Cantrell. Now, what do the guidelines say about dual-stain within the co-testing setting?

Dr. Cantrell:
Perfect. In a co-testing setting, dual-stain is acceptable for triage of individuals with HPV-positive test results and negative for intraepithelial lesion or malignancy, also known as NILM or normal cytology.

Dr. Cantrell:
If using dual-stain to triage HPV-positive co-testing results of normal cytology with limited genotyping, colposcopy is recommended for individuals who test positive for HPV16 or 18. For individuals who test positive for the pool of high-risk 12 HPV other genotypes with normal cytology, colposcopy is recommended when dual-stain is positive, and one year return is recommended when dual-stain is negative.

Dr. Cheeley:
So, Dr. Cantrell, can you break this down for us a little bit? What's the bottom line or the take-home point of these guidelines?

Dr. Cantrell:
Absolutely. So, per the ASCCP, dual-stain is an acceptable option for the triage of HPV-positive screening results in both the primary and co-testing screening pathway.

Dr. Cheeley:
For those just tuning in, you're listening to ReachMD. I'm your host, Dr. Mary Katherine Cheeley, and today I'm speaking with Dr. Leigh Cantrell about the use of dual-stain in the recently updated ASCCP cervical cancer management guidelines.

Dr. Cheeley:
So, Dr. Cantrell, we spoke a little bit earlier about CINtec *PLUS* Cytology, what that test is, and how dual-stain is addressed in the updated ASCCP guidelines, but I kind of want to bring this a little closer to home. What do these new guidelines mean for clinicians like you?

Dr. Cantrell:
Right. Great point. So, this is the first time dual-stain is included in the ASCCP guidelines.

Dr. Cantrell:
These updates provide clearer evidence-based recommendations for cervical cancer screening and management. The use of dual-stain testing can enhance the detection of high-risk cases and allow for more accurate identification of patients who need further evaluation and treatment. This can lead to improved patient outcomes by facilitating earlier intervention and reducing unnecessary procedures for those patients at lower risk.

Dr. Cheeley:
That all sounds great. What does this mean for our patient?

Dr. Cantrell:
Right. So, the increased use of dual-stain triage among HPV-positive patients will result in a decrease in the number of HPV-positive patients who are unnecessarily referred to colposcopy. It will also reduce the time to CIN2 and 3 diagnoses as compared to triage with cytology alone.

Dr. Cheeley:
What are the specific, approved scenarios where the CINtec *PLUS* dual-stain triage test can be used?

Dr. Cantrell:
In the setting of positive high-risk HPV (non-16/non-18), dual-stain is used to triage either to colposcopy if CINtec*PLUS* Cytology is positive or one year follow-up if CINtec *PLUS* Cytology is negative.

And for HPV16 and 18 positive results, patients should be sent to Colposcopy without cytology.

Dr. Cheeley:
Can you talk a little bit more about primary HPV screening and what exactly it is?

Dr. Cantrell:

Sure. Primary HPV screening is a cervical cancer screening algorithm that starts with a molecular test for high-risk HPV genotypes. It identifies the highest risk subtypes of HPV16 and 18 and then a pool of 12 other high-risk HPV genotypes.

Dr. Cantrell:
After a positive high-risk HPV test, if the high-risk HPV genotypes 16 and 18 are specifically identified, these cases are sent directly to colposcopy. If the high-risk HPV subtypes are in the pool of 12 others, these cases can be triaged with dual-stain in order to determine the risk for high-grade disease. If dual-stain is positive, then these patients proceed to colposcopy. If dual-stain is negative, the patient can safely be triaged for follow-up in one year.

Dr. Cheeley:
Thank you for explaining that. That was really helpful.

Can you tell us about a case example in which CINtec *PLUS* dual-stained triage test was used in the setting of primary HPV screening?

Dr. Cantrell:
Certainly. A 40-year female patient hasn't had a cervical cancer screening since her last childbirth about ten years ago.

She had HPV primary screening, which resulted positive for high-risk HPV 12 other, not 16/18.

Her clinician requested the CINtec *PLUS* Cytology dual-stain triage test, which returned positive. She was then sent to colposcopy, which confirmed CIN3 dysplasia.

If her CINtec *PLUS* Cytology dual-stain triage test had come back negative, then she could have returned for a follow-up in one year for reevaluation and been spared the colposcopy.

Dr. Cheeley:
I think that's a great way to round out our discussion on this topic, and I agree. Clinical examples make all the difference in the world.

I want to thank my guest, Dr. Leigh Cantrell, for helping us better understand the updated ASCCP cervical cancer screening guidelines and how the CINtec *PLUS* Cytology dual-stain triage test fits into these guidelines.

Dr. Cantrell, it was great speaking with you today.

Dr. Cantrell:
Well, thank you for having me. It was great to be here.

Announcer:
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