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Study Supports Screening with Pap+HPV Together™ as Best Way to Detect Cervical Cancer & Pre-Cancer

Co-testing with Pap+HPV Together™ results in significantly fewer false-negative results than either test used alone 1

A new cervical cancer screening study demonstrates that Pap+HPV Together™ (co-testing) remains the most effective strategy for detecting high-grade cervical lesions[1,2,] Hologic, Inc. (Nasdaq: HOLX) has announced. The study, published this month in *Cancer Cytopathology* , a peer-reviewed journal of the American Cancer Society, also showed no significant difference between the sensitivities of the Pap and HPV tests when either was used alone as a primary screening method.[1]

- **Study details[1]:** The authors, from Houston Methodist Hospital, evaluated a database with 130,648 Pap test results. Of these patients, 47,499 were screened with Pap+HPV Together and 1,654 underwent follow-up biopsies. The HPV test results were performed using the cobas® HPV test and cobas® 4800 System from Roche Diagnostics, while the Pap tests were performed with the ThinPrep® Pap test (a liquid-based test) from Hologic or the SurePath™ liquid-based Pap test from BD Diagnostics.

  Key takeaways[1]: The study confirmed that screening with Pap+HPV Together detected more cases of pre-cancer and cancer than either test used alone. Pap+HPV Together missed significantly fewer cases of high-grade cervicovaginal lesions – only 1.2 percent – compared to either the cobas HPV test (8.7 percent) or the Pap test (9.1 percent) when used alone. Further, when used alone as primary screening methods, sensitivity results for the cobas HPV test and the Pap tests were comparable, according to the study.

The researchers concluded, "Our data strongly support the view that currently, cytology-HPV co-testing is the best strategy for screening women who are 30 years old or older."

"With data continuing to mount that screening with Pap+HPV Together is more effective than screening with either HPV or Pap alone in women over 30, the clinical benefit of continuing the co-testing strategy is clear," said Edward Evantash, M.D., Medical Director and Vice President of Medical Affairs, Hologic. "This study underscores the value of real-world data in accurately reflecting test performance as compared to clinical trial results alone."

The Pap test performance in the study aligned with the College of American Pathologists (CAP) benchmarking database, demonstrating that when cytology performance is on par with U.S. national averages, co-testing

performance is optimized.

The study further supports current consensus guidelines from multiple organizations, including the American Congress of Obstetricians and Gynecologists, which recommends screening for cervical cancer with a Pap test and an HPV test together for women ages 30 to 65.[3]

"All women deserve the best possible protection against cervical cancer, which is once again proven to be the use of Pap and HPV tests together," said Evantash. "Offering HPV-alone screening would be a step backward and unnecessarily put women's lives at risk."

The new study corroborates previous research, including the largest retrospective cervical cancer screening study conducted in the United States, the 2015 Quest Study.[2] The Quest Study found that Pap+HPV Together identified more cervical pre-cancer and cancer than either test used alone,2 and demonstrated that one in five cases of cervical cancer was missed with HPV-alone screening.[2*]

About Pap+HPV Together

Both Hologic's ThinPrep® Pap test and its Aptima® HPV Assay are the market-leading products for cervical cancer screening in the U.S. To learn more about the importance of screening with Pap+HPV Together using an mRNA-based test like the Aptima HPV Assay, visit www.PapPlusHPV.com.

References

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