PUBLICATION SUMMARY

Fewer False Positives, Smarter Follow-Ups: The Value of the 5-Type HPV mRNA Test in Triage

Introduction

Women with minor cytological abnormalities (ASC-US or LSIL) often face unnecessary anxiety, repeat testing, or invasive colposcopies that reveal no disease. Selecting the right triage test can reduce overtreatment while ensuring that true precancers are caught early.
This Norwegian study compared a 5-type HPV mRNA test (PreTect HPV-Proofer®) that targets oncogenic activity with a 14-type HPV DNA test (cobas® 4800) to evaluate which method more accurately identifies women who truly need follow-up.

Key Insights

- Higher Specificity: The 5-type HPV mRNA test (PreTect HPV-Proofer®) showed 91% specificity vs. 84% for the 14-type HPV DNA test.
- Fewer Unnecessary Procedures: The DNA test triggered 57% more colposcopies than the mRNA test — with no increase in CIN3+ detection.
- Equal Detection of Serious Disease: Both tests detected the same number of CIN3+ (pre-cancer) cases.
- Improved Follow-Up Compliance: 81% of mRNA-tested women safely returned to routine screening vs. 71% in the DNA group.

Reduced Overtreatment: The mRNA test minimized detection of transient infections less likely to progress to cancer.

The study analyzed 564 women (ages 25-69) from the Norwegian cervical screening program with ASC-US/LSIL cytology. Both tests were evaluated for their ability to detect high-grade cervical lesions (CIN2+ and CIN3+).

Measure	HPV DNA (14-type)	HPV mRNA (5-type)	Clinical Meaning
Sensitivity (CIN3+)	100 %	100 %	Both detect true precancer equally well.
Specificity	84 %	91 %	mRNA test reduces false positives.
Positive Predictive Value (PPV)	13.5 %	19.5 %	mRNA test more accurately identifies true disease.
Colposcopy Rate	29 %	19 %	≈ 57 % fewer unnecessary procedures.
Return to Routine Screening	71 %	81 %	Better compliance and reassurance.

The mRNA assay detects E6/E7 oncogene expression from HPV types 16, 18, 31, 33, and 45 — the strains most responsible for cervical cancer progression. By focusing on viral activity rather than mere presence, the test distinguishes transient infections from those that are clinically relevant.

Introduction

The 5-type HPV mRNA test demonstrated the same disease-detection power as the 14-type HPV DNA test but produced fewer false positives and fewer unnecessary colposcopies.
For healthcare providers, this means more precise triage decisions, less patient anxiety, and improved screening efficiency — critical benefits for busy practices balancing accuracy, comfort, and cost-effectiveness.

Citation

Westre B., Giske A., Guttormsen H., Sørbye S.W., & Skjeldestad F.E. (2016). 5-type HPV mRNA versus 14-type HPV DNA test: test performance, over-diagnosis and overtreatment in triage of women with minor cervical lesions. BMC Clinical Pathology, 16(9). https://doi.org/10.1186/s12907-016-0032-x