PUBLICATION SUMMARY

Better Accuracy, Fewer Procedures: Real-World Validation of the Mia™ Comprehensive Cervical Cancer Test

Introduction

Decades of data support HPV-based screening as the preferred strategy for cervical cancer prevention. This large-scale Norwegian study evaluated the Mel-Mont Medical Proofer 7-Type HPV mRNA E6/E7 Test, one of the core molecular components of the Mia Comprehensive Cervical Cancer Test, which also includes the cobas® HPV DNA test and the Mia by XytoTest® sample collection kit.
The objective was to determine whether using mRNA testing to triage HPV DNA–positive women could improve positive predictive values (PPVs) and reduce unnecessary procedures compared with standard liquid-based cytology (Pap smears).

Key Insights

- **40%** fewer unnecessary colposcopies than Pap cytology.
- Higher specificity **(71% vs 48%)** and 1.5× improved predictive accuracy **(PPV 29% vs 19%).**
- Same sensitivity **(~73%)** for detecting true high-grade precancer (CIN2+).
- 7 high-risk HPV types (16, 18, 31, 33, 45, 52, 58) detected—responsible for **~90%** of cervical cancers worldwide.
- Demonstrates the value of combining HPV DNA and mRNA testing for better clinical clarity.

Study Design & Population:

- Participants: 58,029 women (ages 34–69) screened through Norway's national cervical program.
- HPV-positive cohort: 990 (5.6 %) tested positive by DNA assay; 962 had valid mRNA results.
- Endpoint: Histologically confirmed CIN2+ lesions.

Comparative Performance:

Decades of data support HPV-based screening as the preferred strategy for cervical cancer prevention. This large-scale Norwegian study evaluated the Mel-Mont Medical Proofer 7-Type HPV mRNA E6/E7 Test, one of the core molecular components of the Mia Comprehensive Cervical Cancer Test, which also includes the cobas® HPV DNA test and the Mia by XytoTest® sample collection kit.
The objective was to determine whether using mRNA testing to triage HPV DNA–positive women could improve positive predictive values (PPVs) and reduce unnecessary procedures compared with standard liquid-based cytology (Pap smears).

Measure	Cytology (Pap)	Proofer 7-Type HPV mRNA Test	Result
Sensitivity (CIN2+)	76%	73%	Similar ability to detect true precancer.
Specificity	48%	71%	Far fewer false positives.
Positive Predictive Value	19%	29%	1.5× higher predictive accuracy.
Colposcopies per CIN2+ case	5.2%	3.1%	≈ 40% reduction in unnecessary colposcopies.

Genotype Risk:
HPV types 16, 18, 31, 33, 45, 52, and 58 were the strongest predictors of CIN2+ lesions.
Detection of E6/E7 mRNA expression provided meaningful insight into active oncogenic infections, not just the presence of HPV DNA, improving risk stratification.

Conclusion

The Mia Comprehensive Cervical Cancer Test, integrating the Proofer 7-Type HPV mRNA Test, cobas® HPV DNA Test, and Mia by XytoTest® kit, achieves the same sensitivity as cytology while providing far greater specificity. This combination enables clinicians to focus on patients truly at risk, resulting in approximately 40% fewer unnecessary colposcopies, improved diagnostic confidence, and a better patient experience.

Citation

Sørbye SW, Falang BM, Antonsen M. Performance of a 7-Type HPV mRNA Test in Triage of HPV DNA Primary Screen Positive Women Compared to Liquid-Based Cytology. Journal of Molecular Pathology. 2023; 4(2): 69–80. https://doi.org/10.3390/jmp4020008