PUBLICATION SUMMARY

A New Way to Detect HPV Activity: How E6/E7 mRNA Testing Improves Cervical Screening

Introduction

Most HPV infections clear naturally. Traditional HPV DNA tests detect whether HPV is present, but cannot determine whether the infection is active or driving meaningful cellular change.
This patent introduces a molecular method for detecting E6/E7 mRNA expression, which appears only when HPV is actively promoting precancerous changes. This breakthrough laid the groundwork for modern mRNA-based HPV assays used in today's cervical cancer screening models.

Key Insights

- **Detects active, cancer-driving HPV infections** by measuring E6/E7 oncogene transcripts.
- **Improves diagnostic relevance** versus DNA-only testing, which detects presence but not activity.
- **Reduces unnecessary follow-ups by** distinguishing transient infections from progressive ones.
- **Supports earlier intervention** for women truly at risk for CIN2+ or CIN3+.
- **Forms the scientific basis** for mRNA technology within today's advanced cervical screening tests, including the mRNA component of the Mia™ Comprehensive Cervical Cancer Test.

1. What the Patent Introduces

The patent describes a laboratory method for detecting E6/E7 oncogene transcripts from high-risk HPV types. These transcripts are expressed only when HPV becomes active, making them a meaningful biomarker for clinically significant infection.

2. Why E6/E7 mRNA Matters Clinically

E6 and E7 oncogenes play a central role in cervical carcinogenesis by disrupting normal cell cycle regulation.
Detecting their expression allows clinicians to identify infections with true malignant potential, helping differentiate clinically relevant disease from harmless, transient HPV infections.

3. Advantages Over DNA-Based HPV Testing

The patent outlines several important improvements enabled by mRNA detection:

DNA HPV Tests	E6/E7 mRNA Detection
Detect only viral presence	Detect active oncogenic infection
High false-positive rate	Higher specificity
Cannot assess progression risk	Identifies biologic activity linked to disease

4. HPV Infection Risk Categories Based on mRNA Activity

Risk Category	HPV DNA Result	E6/E7 mRNA Result	Clinical Meaning	Recommended Interpretation
Low Risk / Transient Infection	Positive	Negative	HPV is present but not active. Most infections regress.	Routine screening per guidelines.
Elevated Risk / Possible Progression	Positive	Weak or Intermediate Signal*	Emerging biologic activity; may indicate early progression.	Closer follow-up per provider judgment.
High Risk / Active Oncogenic Infection	Positive	Positive	Active E6/E7 expression indicates HPV is driving cellular change.	Higher likelihood of CIN2+/CIN3+; refer as appropriate.
No Infection Detected	Negative	Negative	No evidence of HPV DNA or oncogenic activity.	Routine screening.

*Some assays include "weak/intermediate" thresholds depending on signal intensity.

Conclusion

This patent establishes the scientific foundation for mRNA-based HPV screening, demonstrating how E6/E7 detection provides more clinically relevant information than DNA testing alone.
By identifying active, high-risk infections, mRNA assays improve diagnostic specificity, reduce unnecessary colposcopies, and help clinicians focus on women who truly require intervention.
This approach is now central to modern cervical cancer prevention and diagnostic workflows, including the mRNA component of the Mia™ Comprehensive Cervical Cancer Test.

Citation

WO2003057914A2. Method for Detection of E6/E7 Transcripts from the High-Risk Human Papillomavirus Genotypes in Clinical Specimens. World Intellectual Property Organization (WIPO). Filed 2002; published 2003.