CERVIVA Study[1]

HOLOGIC

42 Months of Data Analyzed

Head-to-Head Study Design

Aptima® HPV Assay vs. **cobas® HPV test**

10,150 Women Participated

Equivalent sensitivity. Improved specificity.

"Equivalent sensitivity, and a higher specificity of mRNA compared to DNA, was maintained when clinical performance was assessed in women under the age of 30 (25-29 years) and those 30 years and over."

HPV mRNA Demonstrated Equivalent Sensitivity to HPV DNA Testing:

Outcome	Aptima® HPV Assay (mRNA)	cobas® HPV test (DNA)
CIN2+ Sensitivity	**93.2%**	92.8%
CIN3+ Sensitivity	**94.6%**	94.6%

HPV mRNA Testing Had Significantly Higher Specificity Compared to HPV DNA Testing:

Outcome	Aptima® HPV Assay (mRNA)	cobas® HPV test (DNA)
CIN2+ Specificity	**84.0%**	80.8%
CIN3+ Specificity	**88.4%**	85.6%

Higher Specificity May Result in:

- **Fewer** false positives
- **Fewer** unnecessary follow-ups
- **Fewer** repeat visits
- **Reduced** colposcopy burden

"A higher positivity rate necessitates an increase in the number of triage tests for HPV-positive women, resulting in increased cost and burden on women having to attend for additional tests."

~30% Fewer False Positives

with **Aptima® HPV Assay** vs. cobas® HPV test

> *"...using mRNA GT as a triage approach could reduce colposcopy referrals while detecting the same amount of CIN2+ or CIN3+ compared to DNA HPV 16/18."*

>99% Negative Predictive Value

for **Aptima® HPV Assay**

> *"A negative HPV mRNA result gave good reassurance against high-grade disease..."*

Assay Design

HPV tests can detect a different target region of the HPV genome.[1]

Aptima® HPV Assay

Detects **E6** and **E7** mRNA by transcription mediated amplification (**TMA**)[1-2]

cobas® HPV test

Detects the **L1** region using **PCR**[1,3]

> *"Viral Integration into the host genome, which is associated with increased disease severity, can result in loss of the L1 region in addition to a reduction in the amount of DNA present in the cell. Whereas viral oncogene expression increases, thus increasing the amount of E6/E7 mRNA transcripts present in the cell."*

References: 1. White C, Reynolds S, Murphy K, Keegan H, Naik P, O'Brien R, Pilkington L, Sharkey Ochoa I, Glesson G, Russell N, Nuttall D, Tewari P, Wright F, O'Toole S, Sharp L, Flannelly G, O'Leary JJ, Martin CM; CERVIVA the Irish Cervical Screening Research Consortium. Performance of the HPV E6/E7 mRNA Aptima HPV assay combined with partial genotyping compared with the HPV DNA Cobas 4800 HPV test for use in primary screening: Results from the CERVIVA HPV primary screening study in Ireland. Int J Cancer. 2024 Jan 1;154(1):53-64. doi: 10.1002/ijc.34685. Epub 2023 Aug 26. PMID: 37632406. **2.** Apitma HPV Assay. US package insert AW-26045-001. Hologic, Inc.; 2023. **3.** cobas HPV Test. US Package Insert 05641268001-12EN. Roche Diagnostics; 2015.