

VitaSIRO *solo*TM HPV Assay Performance

In this study, 160 clinical specimens were tested using both the VitaSIRO *solo*TM HPV Assay and the Cepheid Xpert[®] HPV Assay for comparative evaluation. Among these, 13 specimens tested positive with the VitaSIRO *solo*TM HPV Assay, while 11 specimens were confirmed positive with the Cepheid Xpert[®] HPV Assay.

When all 160 specimens were analyzed, the VitaSIRO *solo*TM HPV Assay demonstrated excellent agreement with the Cepheid Xpert[®] HPV Assay, achieving a Positive Percentage Agreement (PPA) of 100% and a Negative Percentage Agreement (NPA) of 98.7% for both HPV 18/45 and other high-risk HPV (hr-HPV) groups. The Overall Percentage Agreement (OPA) was also 98.7%.

The two discordant specimens that tested positive with the VitaSIRO *solo*TM HPV Assay but negative with the Cepheid Xpert[®] HPV Assay were further analyzed by sequencing. Results confirmed that both samples were indeed positive for HPV: one was identified as HPV type 52, and the other as a HPV type 56/66 coinfection, suggesting a potential false-negative result from the Cepheid assay.

Since none of the clinical specimens contained HPV type 16, one of the most prevalent high-risk subtypes, a spiking study was conducted using SiHa cell lines (HPV16-positive) spiked into clinical sample matrices at three times the limit of detection (LoD) to simulate real specimens. The VitaSIRO *solo*TM HPV Assay successfully detected HPV16 in all conditions, regardless of whether the specimens were HPV-negative or contained HPV18/45 or other hr-HPV types.

Overall, these findings demonstrate that the VitaSIRO *solo*TM HPV Assay provides comparable or superior clinical performance to the Cepheid Xpert[®] HPV Assay, offering robust analytical sensitivity and accurate subtype identification across a broad spectrum of high-risk HPV types.

VitaSIRO *solo*TM HPV Assay Performance Summary in Clinical Endocervical Swab Samples Comparing to Cepheid Xpert[®] HPV Assay

	Cepheid Xpert [®] HPV Assay			
	HPV 16	HPV 18/45	Other hr-HPV	Negative
VitaSIRO <i>solo</i> TM HPV Assay				
HPV 16	0	0	0	0
HPV 18/45	0	2	0	0
Other hr-HPV	0	0	9	2
Negative	0	0	0	147
Positive Percentage Agreement (PPA)	-	100%	100%	-
Negative Percentage Agreement (NPA)	-	-	-	98.7%
Overall Percentage Agreement (OPA)	-	98.7%	98.7	-

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