

Clinical Performance Summary of GeneNav™ HPV qPCR Kits

A prospective clinical study was conducted to evaluate the performance of the GeneNav™ HPV qPCR Kits for screening patients with ASC-US cytology results to determine the need for referral to colposcopy. All women (21 years or older) with cytology results of ASC-US during routine cervical cancer screening procedures were invited to participate in the study prior to learning their HPV status. For women who consented, their initial residual ASC-US cervical specimens were subsequently obtained for GeneNav™ HPV qPCR testing. All patients who consented to the study underwent colposcopic examination. Investigators and patients remained blinded to the patient’s HPV status until after completion of the colposcopic procedures, to avoid bias. Colposcopically directed histological specimens were examined by pathologists who were also blinded to the patient’s HPV status. 1,245 women age 21 and over with ASC-US results were ultimately enrolled in the study.

Results

Table 1: GeneNav™ HPV qPCR Kit Results as Compared to Colposcopy/Central Histology Results among Women with ASC-US Cytology

GeneNav HPV qPCR Kit	Central Histology				Total
	Normal	CIN1	CIN2	≥CIN3	
HPV HR Positive	254	110	31	16	411
HPV HR Negative	548	22	3		573
Total	802	132	34	16	984

Table 2: Clinical Performance Summary of GeneNav™ HPV qPCR Kits as Compared to Colposcopy/Central Histology Results (≥ CIN2) among Women with ASC-US Cytology

Sensitivity	94.0% (47/50)	95% CI: 87.4% - 100%
Specificity	61.0% (570/934)	95% CI: 58.0% - 64.0%
PPV	11.4% (47/411)	95% CI: 8.3% - 14.5%
NPV	99.4% (570/573)	95% CI: 98.8% - 100%
Disease Prevalence	4.7% (47/984)	

Table 3: Clinical Performance Summary of GeneNav™ HPV qPCR Kits as Compared to Colposcopy/Central Histology Results (≥ CIN3) among Women with ASC-US Cytology

Sensitivity	100% (16/16)	95% CI: 100% - 100%
Specificity	59.2% (573/968)	95% CI: 56.1% - 62.3%
PPV	3.9% (16/411)	95% CI: 2.0% - 5.8%
NPV	100% (573/573)	95% CI: 100% - 100%
Disease Prevalence	1.6% (16/984)	