

Test Reagent Kit	Xpert HPV	
Catalog Number	GXHPV-CE-10	
Technology	Real-time PCR	
Targets	HR HPV (14 type screen); HPV 16 and HPV 18/45 call-out only HR HPV screen with 16 HPV and 18/45 type call-out	
Batch or On-Demand	On-Demand	
Minimum Batch Size	1	
Sample Types	Cervical cells collected in Preservcyt*	
Sample Types Pretreated with GAA (glacial acetic acid)	Cervical cells collected in Preservcyt*	
Sample Extraction	Automated/integrated	
Precision Pipetting	Not Required	
Sample Volume	1 mL	
TAT	56 minutes	
Controls: Sample Adequacy (SAC)	✓	
Controls: Probe Function/Detection	✓	
Limit of Detection	Target	Copy level HPV DNA plasmids/PCR reaction
	HPV 16,18,31,33,45,51,59	10
	HPV 35,52,56,68	15
	HPV 39,58	20
	HPV 66	30

Cervical specimens in Preservcyt

Clinical Performance Relative To ≥ CIN2 Disease Status[^]

Sensitivity 90.9%

Specificity 43.5%

Clinical Performance Relative To ≥ CIN3 Disease Status[^]

Sensitivity 94.5%

Specificity 41.3%

Sample Stability in Preservcyt	2–30 °C/6 months after date of collection
Kit Storage	2–28 °C
Commercial Controls	Refer to Package Insert or Contact Cepheid Technical Support

* Preservcyt[®] Solution (Hologic Corporation)

[^] Point estimates for performance in a colposcopy referral population. For details, refer to Package Insert.

CE-IVD. In Vitro Diagnostic Medical Device. Not available in all countries. Not available in the United States.

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