

Xpert®
HPV**XPert® HPV****HPV**

Test Reagent Kit	Xpert HPV
Technology	Real time PCR
Targets E6/E7	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 Extraction	Automated/Integrated
Sample Type	Cervical cells collected in Preservcyt*
Sample types pretreated with GAA (glacial acetic acid)	Cervical cells collected in Preservcyt*
Precision Pipetting	Not required
Sample Volume	1 mL
TAT	<60 min
Hands-On Time	1 min

	Target	Copy level HPV DNA plasmids/ PCR reaction
Limit of Detection (LoD)	HPV 16,18,31,33,45,51,59	10
	HPV 35,52,56,68	15
	HPV 39,58	20
	HPV 66	30

Controls: Sample Adequacy (SAC)	✓
Controls: Probe Function/Detection (PCC)	✓

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
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Kit Storage	2-28°C
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Commercial Controls	Contact Cepheid Technical Support
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* Preservcyt® Solution (Hologic Corporation)

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

In Vitro Diagnostic Medical Device

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