Test	Hybrid Capture II	Cervista	cobas	Aptima	BD Onclarity
Manufacturer	Qiagen	Hologic	Roche	Gen Probe (Hologic)	Becton Dickinson
Year FDA approved for reflex HPV testing and HPV/ Papanicolaou cotesting	2001	2009	2011	2011	2018
Year approved for primary screening	N/A	N/A	2014 (ThinPrep only)	N/A	2018 (SurePath only)
Method	DNA (non-PCR based) Signal amplification: full genome probe	DNA (non-PCR based) Signal amplification: L1, E6, and E7 genes	DNA (PCR based) Target amplification: L1 gene target	mRNA (PCR based) Target amplification: *E6/E7* gene target	DNA (PCR based) Target amplification: *E6/E7* gene target
Genotypes detected	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 with genotyping of 16 and 18	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68; genotyping as separate test (16, 18/45)	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68; simultaneous, discrete identification of 16, 18, and 45
Clinical trial	ASC-US/LSIL Triage Study (ALTS), 2006 CAP	Cervista HPV HR	ATHENA[12]	CLEAR trial	Onclarity trial (baseline phase)[13]
Clinical validation	Extensive	Limited	Limited	Limited	Limited
Sensitivity for CIN2/3	63.6%–100%[2,14-24]	92.8%–100%[25]	71.1%–99%[2,15-21,26]	55.3%–100%[2,14,17-20,22-24,26-30]	85.7%–100%[18,31-33]
Specificity for CIN2/3	6.2%–98.4%[2,14-24]	—	24%–86.2%[2,15-21,26]	28.8%–99.2%[2,14,17-20,22-24,26-30]	17%–98.8%[18,31-34]
Built-in internal control	No	Yes (HIST2H2BE)	Yes (ß-globin)	Yes, an internal control transcript (HPV16 E6/7 transcript) is added to each reaction at the target capture step	Yes (ß-globin)