

HPV Testing For Cervical Cancer Prevention

HPV testing is used for cervical cancer screening. There are several HPV testing products available. To aid decision making by cervical cancer program managers in selecting an HPV test for use in their programs, the following charts provide information on the main HPV tests available, along with their main characteristics.

TABLE 1. Test name, Company name, Regulatory Status, Type of assay and HPV Types detected.

TABLE 2. Format of results, Internal controls for sample adequacy, Collection media, Volume per test, Assay read-out, Equipment needed to process the test.

TABLE 3 Batch size, Processing time, Maximum number of tests processed in 8 hr day, Storage conditions and use of the platform for other tests.

For more information, go to [HPV Testing For Cervical Cancer Prevention](http://bit.ly/22TyIsP)
(<http://bit.ly/22TyIsP>)

HPV Testing - TABLE 1

HPV Test name	Company name	Regulatory Status	Type of Assay	HPV Types Detected
Cervista HPV HR	Hologic GEN-PROBE	FDA approved	Signal Amplification detects 14 high-risk types. (Invader method/ Fluorescence resonance energy transfer FRET)	14 high risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)
Cervista HPV 16/18	Hologic GEN-PROBE	FDA approved	Signal Amplification detects and differentiates HPV 16 and HPV 18. (Invader method/ Fluorescence resonance energy transfer FRET)	HPV 16; HPV 18
APTIMA HPV	Hologic GEN-PROBE	FDA-approved for ThinPrep	Transcription-Mediated Amplification (TMA) of mRNA E6/E7; amplicon with Hybridization Protection Assay (HPA)	14 high risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)
AMPLICOR HPV test	Roche	CE marked (not available in US)	Target amplification. (PCR/ Multiwell Plate hybridization, enzymatic color reaction)	13 high-risk genotypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68)
LINEAR ARRAY HPV Genotyping Test	Roche	NA RUO	L1 consensus PCR with Line-blot assay	37 HPV genotypes. Individual types
Cobas HPV test	Roche	FDA approved CE marked	Target amplification. Simultaneous detection of 14 high-risk types + specific genotyping information for types 16 and 18. PCR/ The detection of the amplicon is performed during thermal cycling using oligonucleotide probes labeled with four different fluorescent dyes	Channel 1 - HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68 Channel 2 - HPV 16 Channel 3 - HPV 18
Xpert HPV	Cepheid	CE marked	E6/E7 target amplification multiplex PCR	14 HR types(16,18,31,33,35,39,51,52,56,58,59,66 and 68)
BD HPV Onclarity Assay	BD	CE marked	E6/E7 DNA target amplification, real type PCR	14 HR types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)
Digene HC2 (Hybrid Capture 2) HPV DNA test	Qiagen	FDA approved	Full HPV genome detection by HC2 compared to PCR targeting L1	13 HR HPV Types 16,18,31,33,35,39,45,51, 52,56,58,59 and 68
HPV genotyping RH and LX kit	Qiagen		L1 consensus PCR with reverse Lineblot detection	16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82
careHPV test	Qiagen	Application submitted for WHO prequalification	Hybrid Capture 2 full-length RNA probes and signal amplification, chemiluminescence	14 HR types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)
OncoE6 Cervical Test	Arbor Vita Corporation	CE marked	Monoclonal antibodies in lateral-flow assay format to HPV 16/18 E6.	16, 18
Real TimeHigh-Risk HPV	Abott Molecular	CE marked	PCR	14 HR types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)
INNO-LiPA HPV Genotyping Extra*	Innogenetics	RUO	SPF Target amplification. Reverse hybridization line probe assay	6, 11, 16, 18, 26, 31, 33, 35, 39, 40, 43, 44, 45, 51, 52, 53, 54, 56, 58, 59, 66, 68, 69, 70, 71, 73, 74, 82
HPV DIRECT FLOW CHIP + E-BRID system	Master Diagnostic (TaKaRa Shuzo Co. Ltd.)		reverse dot blot hybridization	HPV6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73 and 82
PapilloCheck HPV-Screening	Greiner Bio-One	CE marked	PCR, amplicon hybridization on slide for type-specific detection	24 HPV types (6, 11, 16, 18, 31, 33, 35, 39, 40, 42, 43, 44, 45, 51, 52, 53, 56, 58, 59, 66, 68, 70, 73, 82)
PapilloCheck High-risk	Greiner Bio-One	CE marked	PCR, amplicon hybridization on slide for type-specific detection	14 HR types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)
HPV4A ACE Screening kit	Seegene	CE marked	PCR, Gel Electrophoresis	HPV 6, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, 82
Anyplex II HPV28	Seegene	CE marked	multiplex real-time PCR with proprietary detection system	Hr: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 73, 82 Lr: 6, 11, 40, 42, 43, 44, 54, 61, 70
Multimetrix Multiplex HPV Genotyping Kit	MIKROGEN (Germany) also Progen/Multimetrix		Gp5+/G6+ consensus PCR, Luminex	HPV 6, 11, 16, 18, 26, 31, 33, 35, 39, 42, 43, 44, 45, 51, 52, 53, 56, 58, 59, 66, 68, 70, 73, 82
CLART HPV 2	Genomica (Spain)	?CE marked	mult-plex PCR with visualization in low density arrays	35 low risk and high risk types (6, 11, 16, 18, 26, 31, 33, 35, 39, 40, 42, 43, 44, 45, 51, 52, 53, 54, 56, 58, 59, 61, 62, 66, 68, 70, 71, 72, 73, 81, 83, 84, 85, 89)
GenoFlow HPV Array	DiagCor (Hong Kong)		PCR, flow-through hybridization (cassette)	16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66/68,73, 82 6, 11, 40/61, 42, 43/44, 54/55, 70, 57/71, 72, 81, 84/26 plus universal HPV
fHPV Typing	molGENTIX (Spain)	CE marked	15 low risk and high risk types	HPV 6, 11, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68
Trovagene Urine-based HPV test	Trovagene & Strand Life Sciences (India)-kit under development, test currently performed by Trovagene laboratory		PCR	HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68
13 High-risk HPV Real-Time PCR kit	Hyribio		multiplex real-time PCR	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68
PreTect HPV-Proofer	NorChip AS		Multi-plex NASBA for HPV E6/E7 mRNA	HPV 16/18/31/33/45
CERVIMAX IHC/WB/FC/IC	VALDOSPAN GmbH		Antibodies E7	specialized kits for IHC, WB, FC, IF applications
NucliSENS easyQ	Biomereux	CE-IVD	NASBA amplification, real-time detection with molecular beacon probe	16, 18, 31, 33, 45
PapType	Genera Biosystems		PCR with labeled nucleotides on micro beads	6, 11, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68

HPV Testing - TABLE 2

HPV Test name	Format of result	Internal Control for Sample Adequacy (if yes, specify)	Collection media/volume per test	Assay Read-out (automated, manual-visual, manual-screen)	Platform/Equipment needed to process the test
Cervista HPV HR	Positive, negative, indeterminate	Yes, human HIST2H2BE	ThinPrep, 2 mL	software processing of fluorescent signal	Thermal cycler, fluorescence plate reader, PC with Call Reporter software
Cervista HPV 16/18	Positive, negative, indeterminate	Yes, human HIST2H2BE	ThinPrep, 2 mL	software processing of fluorescent signal	Thermal cycler, fluorescence plate reader, PC with Call Reporter software
APTIMA HPV	Negative, positive, invalid	Yes. Non-infectious RNA transcript (more like external control)	1 mL ThinPrep (2000 processor) Pap Test vials containing PreservCyt Solution. Specimens processed using the ThinPrep 3000 processor or other instruments have not been evaluated	RLU from Luminometer	Tigris or Panther system
AMPLICOR HPV test	positive, negative	Yes, human beta-globin	0.25 mL ThinPrep, SurePath (Validated on common liquid based cytology media)	Absorbance	Thermocycler, Amplicor hybridization/detection unit
LINEAR ARRAY HPV Genotyping Test	positive/negative for each of the types	Yes, β-globin	Thin-Prep 1 mL (can be adapted for any DNA extract from STM, SurePath, FFPE)	manual visual	Thermocycler, waterbath, shaker, automated hybridization (for high throughput)
Cobas HPV test	High-risk HPV positive/negative. Separate HPV16 and 18 results optional in the same test	Yes, β-globin	PreservCyt, 1 mL (adaptable to other specimen types with input adjustments)	automated	automated extractor (cobas 4800x) and RT-PCR detection unit (cobas 4800z)
Xpert HPV	HPV 16 and HPV 18/45 in two distinct detection channels. HPV 31, 33, 35, 39, 51, 52, 56, 58, 59, 66 and 68 in a pooled result	Yes	PreservCyt® Solution, 1 mL		cartridge processor
BD HPV Onclarity Assay	16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 - pooled as well as individual types 16, 18, 31, 45, 51, 52 and type groups 33/58, 56/59/66, 35/39/68	Yes, beta globin	0.5 ml LBC media (BD SurePath™, Hologic PreservCyt®) BD Onclarity cervical brush	automated	BD Viper LT System
Digene HC2 (Hybrid Capture 2) HPV DNA test	high-risk HPV positive/negative	No	HC2 Specimen Collection Device (cervical brush and STM). PreservCyt Solution or BD SurePath (only CE-IVD mark)	automated signal detection and RLU cut-off setting	orbital shaker, plate washer, luminometer
HPV genotyping RH and LX kit	positive/negative for each of the types	Yes, B-Globin	STM or PreservCyt	Manual, visual	manual: waterbath, orbital shaker automated: ProfiBlot 48T (Tecan)
careHPV test	qualitative (pos/neg for hr HPV)	No	careHPV Collection Medium (50 µl)	Automatic (plus/minus display on Test Controller)	Test Controller, Luminometer, shaker, magnetic plate holder
OncoE6 Cervical Test	positive or negative by type	Yes (no indicated)	“Dry” Polyester tipped cervical swab (“Dacron” swab). PreservCyt (“Thinprep”) media. Self collection (for example, via “Delphi Screener”)	Visual readout	~ 1 meter of bench space; Small non-refrigerated microcentrifuge; slow tube rotator (AC or battery) P1000 / P200 pipettors, pipet tips, gloves, kim wipe, etc.
Real TimeHigh-Risk HPV	Pooled for any type, identification of 16 and 18	Yes, human beta-globin	PreservCyt, Sure Path, Abbott Cerci-Collect (400 µL)	automated	Abbott m2000rt, m2000 System software
INNO-LiPA HPV Genotyping Extra*	positive/negative for each of the types	Yes, MHC gene	various	manual, visual (software available Liras)	Thermocycler, waterbath, shaker, automated hybridization (for high throughput)
HPV DIRECT FLOW CHIP + E-BRID system		Yes ("housekeeping human gene fragment")	Cytological swabs in PBS, cervical cells in liquid cytology media (any), FFPE tissues	automated signal detection with hybriSpot 24, manual read with hybriSpot 12	Thermocycler. Microcentrifuge. Thermostatic bath or heating block. DNA flow/chip processor: hybriSpot 12 (semiautomated) or hybriSpot 24 (automated)
PapilloCheck HPV-Screening	individual type identification	Yes (human gene ADAT1)		automated (scanner)	Extractor, thermocycler, hybridization chamber, waterbath, CheckScanner
PapilloCheck High-risk	individual type identification	Yes (human gene ADAT1)		automated (scanner)	Extractor, thermocycler, hybridization chamber, waterbath, CheckScanner
HPV4A ACE Screening kit	positive/negative separately for HPV6/11, HPV16, HPV18 or other high risk types	Yes	Thin-Prep, SurePath	manual (bands on gel)	Thermocycler, capillary gel electrophoresis
Anyplex II HPV28	positive, negative for individual types, with high, intermediate and low titers	Yes	Thin-Prep, SurePath	automated, software interpretation	Nimbus IVD (DNA extractor), STARlet (liquid handler), CFX96 (real-time thermal cycler)
Multimetrix Multiplex HPV Genotyping Kit	positive, negative for individual types	No (only negative and hyb control)	Liquid-based cervical cytology specimen	automated (luminex)	thermomixer, heated incubator, Luminex LX100
CLART HPV 2	type-specific identification	Yes, human CFTR gene	liquid cytology, swabs, paraffin-embedded tissue	automated (image analysis with SAICLART)	Thermocycler, microcentrifuge, extractor, thermoblock, CAR (Clinical Arrays Reader) or autoclart
fHPV Typing		Yes, human STR			
Trovagene Urine-based HPV test			Urine, 30 ml		
13 High-risk HPV Real-Time PCR kit	Quantitative detection of 13 High Risk HPV types	Yes	ThinPrep or SurePath, 1 mL	manual read out of real-time plots from software	DNA extraction equipt, Thermal cycler
PreTect HPV-Proofer	type-specific identification	Yes, mRNA from human U1 snRNP protein A (U1A)	Exfoliated cervical cells in PreTect, ThinPrep or SurePath (volume/test not specified)	Automated software required	Fluorescent reader and PreTect analysis software package
CERVIMAX IHC/WB/FC/IC		no		manual, visual	
NucliSENS easyQ	positive/negative for the 5 hr types	intended for cervical specimens collected in PreservCyt	automated, pos neg call	Real-time NASBA Amplification Platform	
positive/negative for each type		Yes	ThinPrep 800µl	flow data interpreted by "Qplot software"	Flow cytometer

HPV Testing - TABLE 3

HPV Test name	Batch size - specimens per run	Total processing time (Time to result)	Maximum number of tests processed in 8 hr day	Storage Conditions Assay reagent stability/storage requirements	Other tests that can be processed using the same platform
Cervista HPV HR		6-7 hours (with 4 hour "walk away" time)		-30°C and -15°C.	Cervista HPV16/18
Cervista HPV 16/18				-30°C and -15°C.	Cervista HPV HR
APTIMA HPV	TIGRES: 100 to 250, PANTHER: 180			Aptima reagents: 2°C to 8°C and 15°C to 30°C ThinPrep: 2°C to 30°C for up to 60 days	Trichomonas, HSV1, -2,
AMPLICOR HPV test	96 well plate			Reagents 2°C to 8°C	HIV, CT/NG
LINEAR ARRAY HPV Genotyping Test				4°C	
Cobas HPV test	8, 24 48, 72 or 96 samples	5 h/94 samples		4°C	HSV1 and 2 MRSA/SA Test, EBV, HIV, CMV, VZV WNV and others
Xpert HPV	1 - 80	1h	471	Kits stored 2-28 C Transport at 2-30 C Store 2-30 C for up to 6 months after collection	trichomonas, clamydia
BD HPV Onclarity Assay	1-46 samples		120	30 days-30° C (SurePath, PreservCyt, co-collection device) 12 months-30° C (extraction and PCR reagents)	CT/GC (planned HSV1&2, Trichomonas)
Digene HC2 (Hybrid Capture 2) HPV DNA test	88 samples	6-7 h for 88 samples, manual (4.5 – 5.5 hours for 352 using RCS automated platform, according to slides)		HC2 kits should be stored at 2-8°C STM samples can be stored for: Up to 2 weeks at room temperature Up to an additional week (3 weeks total) at 2-8°C Up to three months at -20°C PreservCyt specimens may be held for up to 3 months at 2-30°C	HPV HR/LR Test CT/GC assay
HPV genotyping RH and LX kit				all reagents at 2-8°C	
careHPV test	80	2.5 h	240	careHPV Test kit between 4°C and 25°C. Clinical specimens in careHPV Collection Medium between 15°C and 30°C for 14 days or between 2°C and 8°C for 30 days	No
OncoE6 Cervical Test	15+	2.5h	45+	24 months at 15-25°C (no cold chain required) Shorter term elevated temperature storage (> 30°C) permissible Leftover sample can be stored for years at neg. 70°C	
Real TimeHigh-Risk HPV	24 to 96				
INNO-LiPA HPV Genotyping Extra*	20			neg 20° and 4°C	
HPV DIRECT FLOW CHIP + E-BRID system	24 rx			PCR reagents at -20°C, Hybridization reagents at 2 8°C	-
PapilloCheck HPV-Screening	12 to 48	5 hours			
PapilloCheck High-risk	12 to 48	5 hours			
HPV4A ACE Screening kit	48	6,5	96	PCR reagents at -20 C	
Anyplex II HPV28	48	6.5 h	96	PCR reagents at -20 C	no
Multimetrix Multiplex HPV Genotyping Kit	94		188	neg 20° and 4°C	
CLART HPV 2					CMA (KRAS, BRAF, PI3K, NRAS, iKRAS); STIs; PneoMVlr; PneumoCLART bacteria; ENTHERPEX (HSV and enterovirus); EnteroBac; SeptiBac
GenoFlow HPV Array			64		
fHPV Typing		4h			
Trovagene Urine-based HPV test					
13 High-risk HPV Real-Time PCR kit	96	3 h	192	-20°C	
PreTect HPV-Proofer					
CERVIMAX IHC/WB/FC/IC					
NuclISENS easyQ	\$48	2 h	192		
PapType					