

Anyplex™ II HPV HR Detection is

clinically validated assay for primary cervical cancer screening¹⁾

Anyplex™ II HPV HR Detection meets the international consensus validation metrics for HPV DNA tests for cervical cancer screening¹⁾²⁾

Clinical Sensitivity & Clinical Specificity of Anyplex™ II HPV HR Detection

Category		Clinical Sensitivity	Clinical Specificity
Test population & number		60 samples with ≥ CIN2	816 samples with < CIN2
Result	Reference Test (GP5+/6+-PCR)	98.3% (59/60)	94.1% (768/816)
	Anyplex™ II HPV HR	98.3% (59/60)	93.6% (764/816)
Relative analysis to reference test		100%	99.5%
Requirements		≥ 90%	≥ 98%

► The clinical sensitivity and specificity for CIN2+ of Anyplex™ II HPV HR Detection were non-inferior to those of GP5+/6+-PCR.

Inter-lab agreement & intra-lab reproducibility of Anyplex™ II HPV HR Detection

Category		Intra-laboratory Reproducibility	Inter-laboratory Agreement ³⁾
Test population & number		505 samples	505 samples
Result	Agreement (95% CI)	96.0% (94.3~97.4)	96.8% (95.3~98.1)
	kappa value	0.91	0.93
Requirements	Lower 95% CI	≥ 87%	≥ 87%
	kappa value	≥ 0.5	≥ 0.5

► Anyplex™ II HPV HR Detection displayed sufficient intra-laboratory reproducibility and inter-laboratory agreement.

1) Hesselink AT et al. *Journal of Clinical Virology* 76:36-39 (2016)
 2) Meijer CJLM et al. *Int J Cancer* 124(3):516~20 (2009)
 3) Dr. Ronald Sahli in CHUV, Switzerland participated for inter-lab experiment

HP01-EN191114B-01

Anyplex™ II HPV28 Detection was proved its excellent performance in WHO evaluation

- Excellent genotype detection even in multiple infections
- Great sensitivity, specificity and inter-lab reproducibility

Percent proficient results of HPV types as claimed to be detected by test¹⁾

Type of HPV assay	Number of data sets	100% proficient	99-90% proficient	89-80% proficient	<80% proficient	Not proficient
All assays	148	89	14	9	5	31
Linear Array (Roche)	14	7	0	1	0	6
HPV Direct Flow-chip (Master Diagnostica)	14	9	0	0	0	5
GenoFlow HPV array (DiagCor)	14	13	0	0	0	1
Anyplex™ II HPV28 Detection (Seegene)	11	11	0	0	0	0
In-house PCR Luminex	8	3	1	1	0	3
In-house realtime PCR	8	4	0	1	1	2
In-house PGMY-CHUV	6	4	0	0	0	2
In-house blot	6	2	0	2	0	2
Papillocheck (Greiner)	5	4	0	1	0	0
Onclarity (Becton Dickinson)	5	5	0	0	0	0
CLART HPV 2 / 4 (Genomica)	4	0	1	1	2	0
Cobas 4800 (Roche)	4	4	0	0	0	0
InnoLiPA (Fujirebio)	4	1	2	0	0	1
PANA Realytper 1001 (Panagene)	3	0	3	0	0	0
PANArray Genotyping Chip (Panagene)	3	0	3	0	0	0
HybriBio 21 HPV (HybriBio)	3	3	0	0	0	0
RealTime HPV (Abbott)	3	1	0	2	0	0
In-house sequencing	3	0	0	0	0	3
HPV SPF10-LiPA25	2	0	0	0	0	2
HPV XpressMatrix™ (DNA laboratories)	2	2	0	0	0	0
Ampliquality (Analitica)	2	0	1	0	0	1
HybriBio 13 HR (HybriBio)	2	2	0	0	0	0
HybriBio 14 HR (HybriBio)	2	2	0	0	0	0
PANA Realytper 1002 (Panagene)	2	0	2	0	0	0
Optiplex (DIAMEX)	2	2	0	0	0	0
Other Commercial assays	14	9	1	0	1	3
Other In-house assays	2	1	0	0	1	0

100% proficiency in all tests performed by participants (11 labs worldwide)

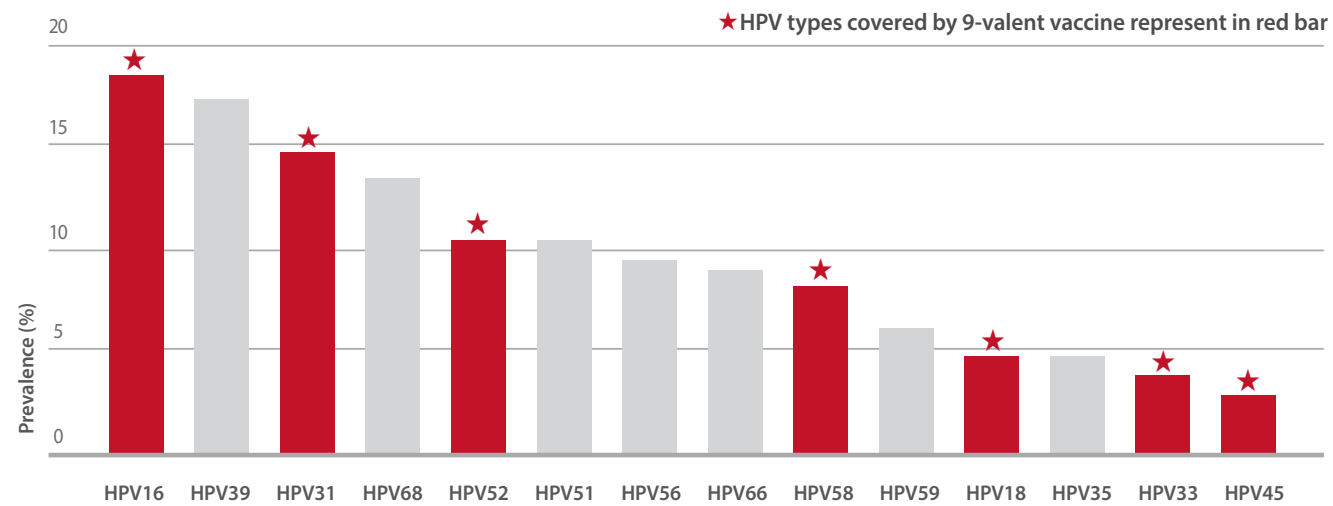
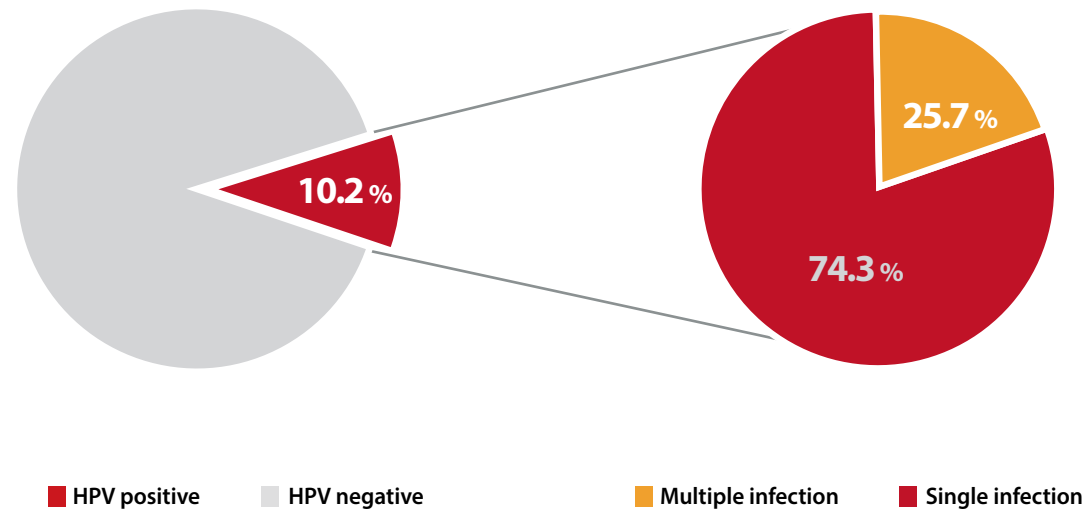
► Information of participants

- Total number of participants : 121 laboratories
- Distributions : Europe (70), America (14), Western Pacific (25), South East Asia (8), Africa (3), Eastern Mediterranean (1)
- Total number of datasets : 148

Anyplex™ II HPV HR Detection is a successfully implemented for the largest Cervical Cancer Screening

- HR-HPV genotyping Cervical Cancer Screening in European populations
- Tested 105,458 women in Northern Portugal
- Provides critical data which impact program management and vaccine policy

Prevalence of High-Risk HPV and multiple infection¹⁾



1) Sousa H et al. (2019) Papillomavirus Research 8:100179

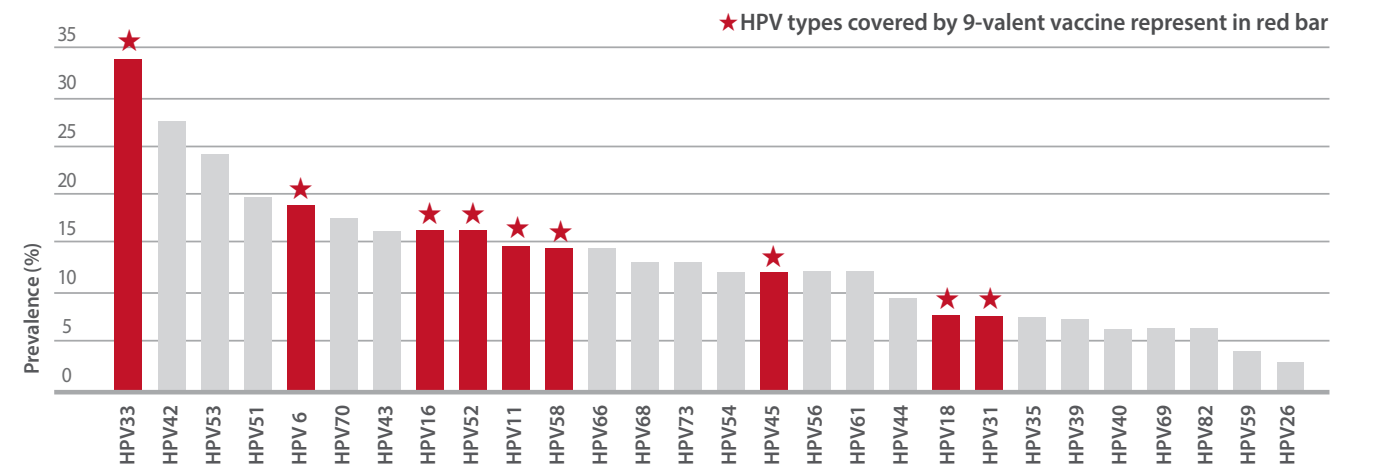
Anyplex™ II HPV28 Detection provides reliable outcomes even with extra-cervix samples

- Studies of diverse specimens (Anal, Oral, etc) depending on customers' need
- HPV types other than HPV16/18 are predominant in extra-cervical sites

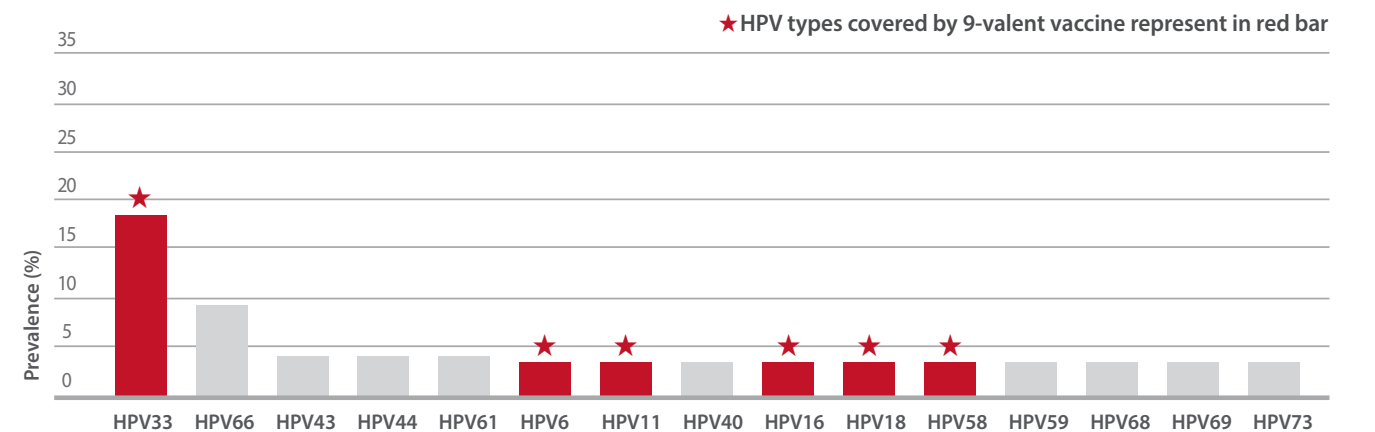
Anal & Oral specimens in HIV-negative MSM group in France¹⁾

All HPV prevalence were detected 93.4 % and 33.9%, in Anal and Oral specimen, respectively. HPV 33 was most detected in both specimens (31% in Anal; 16% in Oral).

Prevalence of HPV genotypes in Anal



Prevalence of HPV genotypes in Oral



1) RSM Bouassa et al. (2019) Open Forum Infectious Diseases 6(9):ofz291