



Solutions for Women's Health

HPV Screening and Genotyping



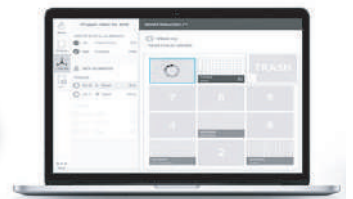
MAIS Robots



VitroCycler



HS12Auto



OVTS



Complete solution for HPV Screening and Genotyping

HPV Screening Real Time PCR Kit and HPV Direct Flow CHIP kit have been designed for the detection of 14 High Risk HPV genotypes and for the complete genotyping of 35 HPV genotypes respectively.

Both assays have been clinically validated for the detection of HPV genotypes associated with the development of cervical cancer.



UNG ENZYME
INCORPORATED TO
AVOID CONTAMINATIONS



INTERNAL
CONTROL



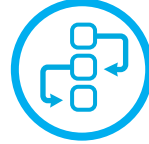
MULTIPLE
SAMPLE TYPES



FAST
RESULTS



FULL
AUTOMATION



TRACEABILITY

Screening of 14 High Risk HPV genotypes

HPV Screening Real Time PCR kit

HPV Screening Real Time PCR kit has been designed for the qualitative detection of DNA of 14 genotypes of the human papillomavirus (HPV) considered of high oncogenic risk (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).

The test allows the specific identification of HPV genotypes 16 and 18 and the simultaneous detection of genotypes 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68 at clinically relevant infection levels. It also detects the human beta globin gene as an internal quality control for the starting material and amplification.

In order to avoid contamination from previously amplified PCR products, the MMix contains the Uracil DNA glycosylase enzyme (Cod-UNG), which degrades all PCR products containing dUTP.

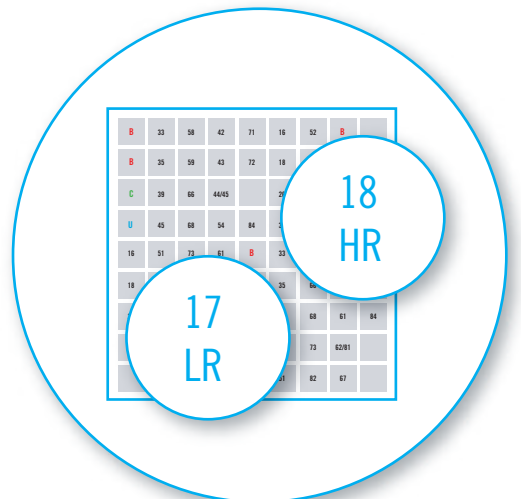


Genotyping of 35 HR and LR HPV genotypes

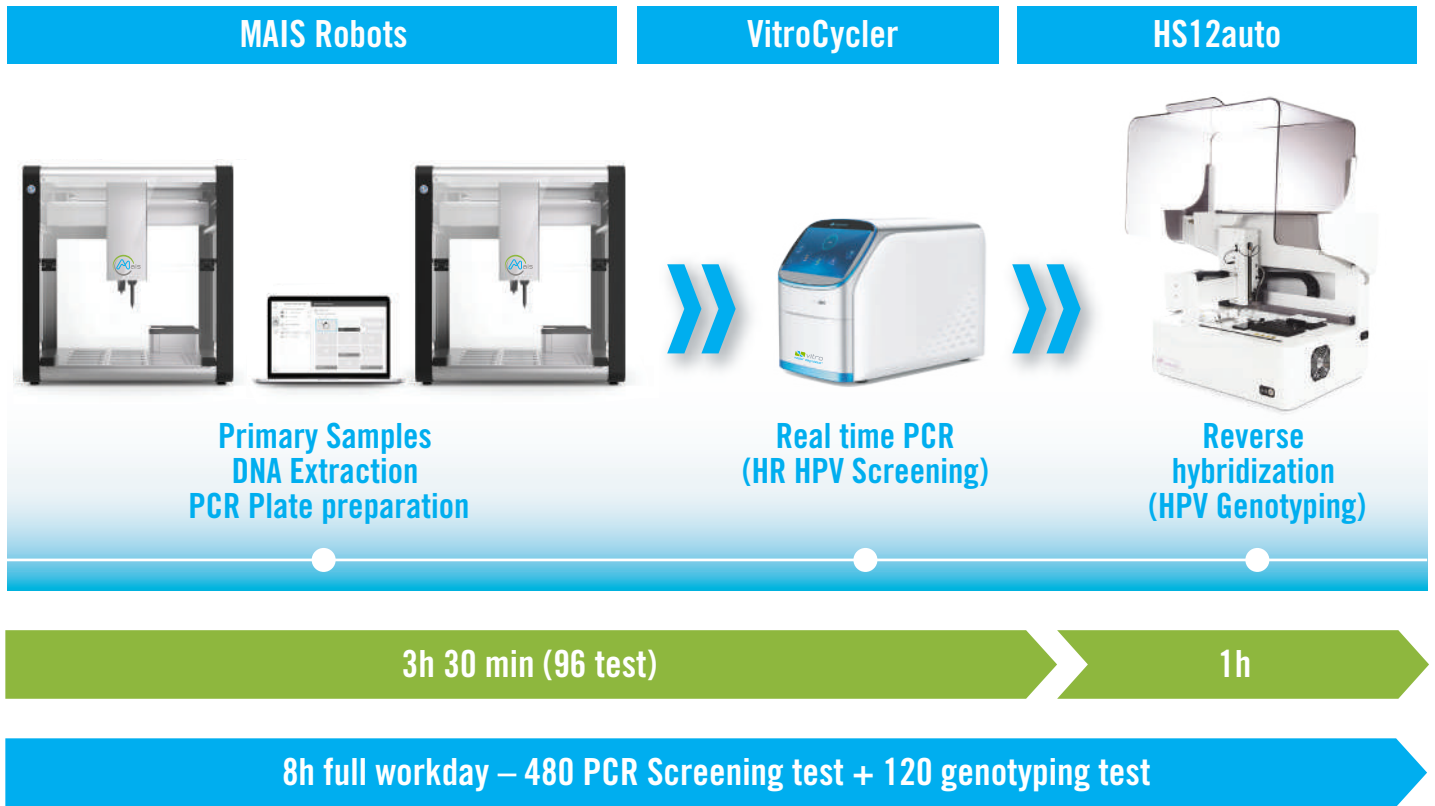
HPV Direct Flow CHIP

Kit allows for the detection of HPV and the simultaneous genotyping of 35 HR and LR HPV genotypes (HR: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73 and 82. LR: 6, 11, 40, 42, 43, 44, 54, 55, 61, 62, 67, 69, 70, 71, 72, 81 and 84).

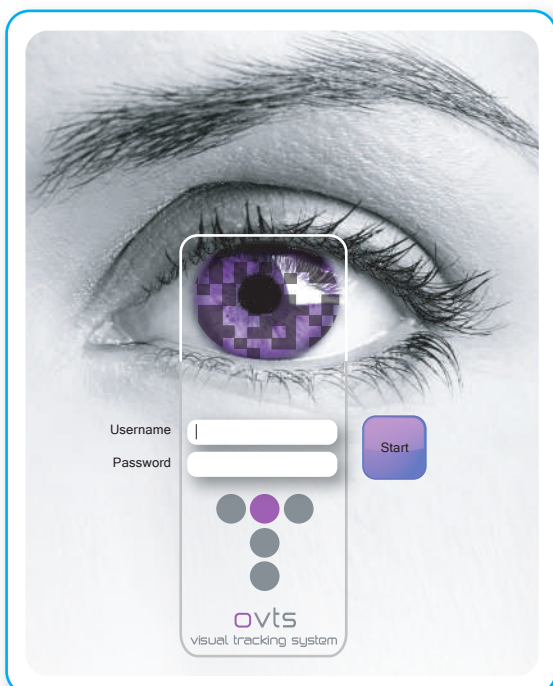
In order to avoid contamination from previously amplified PCR products, the MMix contains the Uracil DNA glycosylase enzyme (Cod-UNG), which degrades all PCR products containing dUTP.



Workflow



OVTS: Full traceability along the whole process



- ✓ Real-time visualization and monitoring of each element.
- ✓ Graphic illustration of all processes.
- ✓ Results Interpretation.
- ✓ Boosts Productivity .
- ✓ Easy connection to Thermocyclers, HybriSpot and MAIS instruments.
- ✓ Direct control of MAIS robots without the need for additional intermediate applications.
- ✓ Connection to any LIS system.

Excellent clinical data

HPV Screening PCR Real Time and HPV Direct Flow CHIP kits show excellent sensitivity and specificity.

Concordance between HPV Screening Real Time test kit (HPV S) and the COBAS HPV test (COBAS) for the detection of HPV 16 and 18 genotypes and HPV HR genotypes										
Number of cases with +/- results for each kit of the total cases analyzed (N = 377)										
Genotype HPV	HPV S +	COBAS +	HPV S + / COBAS +	HPV S + / COBAS -	HPV S - / COBAS +	HPV S - / COBAS -	Concordance %	KAPPA INDEX	STANDARD DEVIATION	C.I. 95%
HPV 16	130	128	127	3	1	246	99	0.976	0.012	0.953-0.999
HPV 18	33	32	32	1	0	244	100	0.983	0.017	0.95-1.016
Other HR HPV	186	191	181	5	10	181	96	0.92	0.02	0.88-0.96

*All samples analyzed with HPV Screening Real Time and cobas® HPV Test with known cytohistopathological Dx are included.

Concordance between the HPV Direct Flow CHIP (FLOW CHIP) and COBAS HPV test (COBAS) kits for the detection of HPV 16 and 18 genotypes and HPV HR genotypes										
Number of cases with +/- results for each kit out of the total cases analyzed (N = 139)										
Genotype HPV	FLOW CHIP +	COBAS +	FLOW CHIP + / COBAS +	FLOW CHIP + / COBAS -	FLOW CHIP - / COBAS +	FLOW CHIP - / COBAS -	Concordance %	KAPPA INDEX	STANDARD DEVIATION	C.I. 95%
HPV 16	35	36	35	0	1	103	99	0.81	0.019	0.944-1.018
HPV 18	8	8	8	0	0	131	100	1	0	1.00-1.00
Other HR HPV	56	58	53	3	5	78	94	0.881	0.041	0.801-0.961

*All samples analyzed with HPV Direct Flow and cobas® HPV Test with known Cyto-histopathological Dx are included.

References

REFERENCE	DESCRIPTION	FORMAT
MAD-003949M	HPV Screening PCR Real Time	100 Tests
MAD-003930MU-HS24-24/48	HPV Direct FLOW CHIP	24 / 48 Tests
MAD-003930MH-24/48	HPV Direct Flow CHIP Hybridization Reagents	24 / 48 Tests

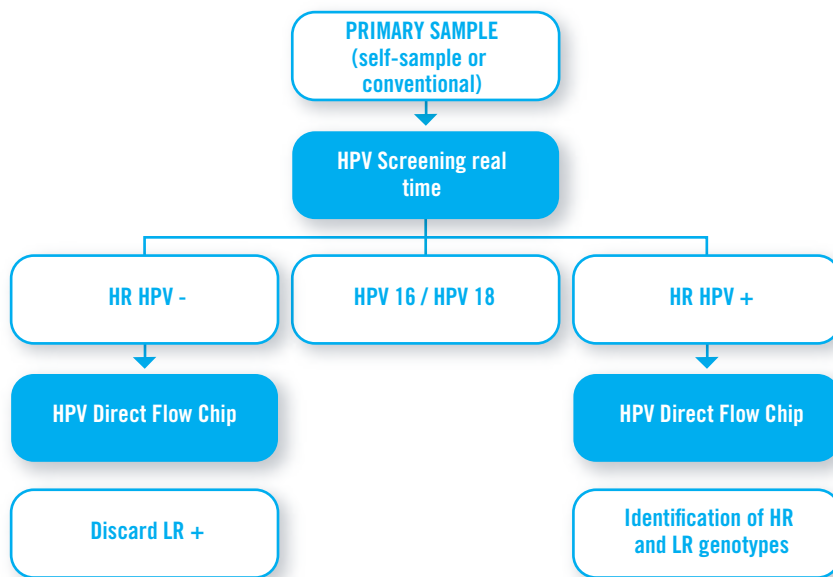
REFERENCE	DESCRIPTION
VIT-MAIS	MAIS System
VIT-HS12A	HybriSpot 12 PCR AUTO
VIT-VITROCYCLER	Thermocycler Vitrocycler

HPV detection and genotyping. Global solution

The HPV Screening and Genotyping kits are optimized for use with both traditional cervical samples and self-samples.

The HPV Screening PCR Real Time and HPV Direct Flow CHIP kits help to:

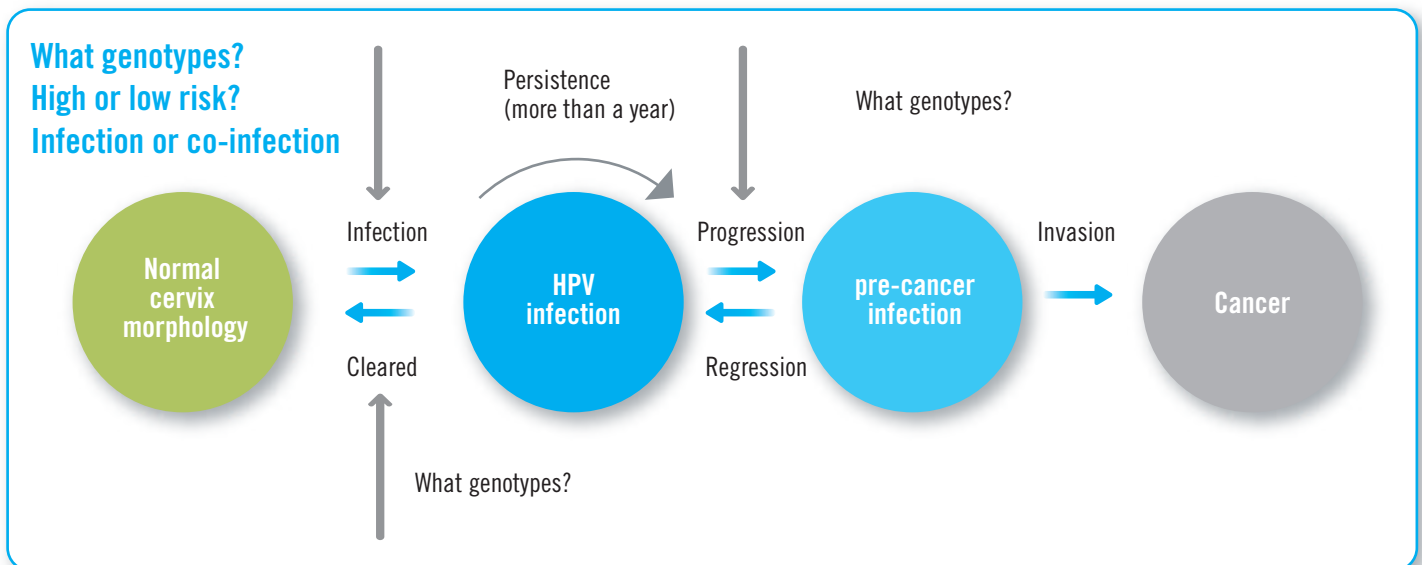
1. Establish a risk threshold.
2. Find an alternative scenario.
3. Improve the diagnostic algorithm by identifying HPV genotypes, including those that are covered by vaccines.



When do you recommend genotyping guides?^(2,3)

In women older than 30 years with a negative cytology and positive results.

Natural History of HPV Infection ⁽¹⁾



(1) Shiffman M et al. The promise of global cervical cancer prevention. N Engl J Med 2005; 353:2101-2104.

(2) American Society for Colposcopy and Cervical Pathology. 2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors. J Low Genit Tract Dis. 2013 Apr;17(5 Suppl 1):S1-S27.

(3). Cervical Cancer Screening for Individuals at Average Risk: 2020 Guideline Update from the American Cancer Society. CA Cancer J Clin. 2020 Sep;70(5):321-346.



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