



VisionArray®

Arrays for DNA analysis

Genotyping of Human Papillomavirus

VisionArray® HPV

Your Complete
Solution from
DNA Extraction
to Analysis!

Simultaneous Detection of 41 HPV Types

High Sensitivity – Easy to Handle

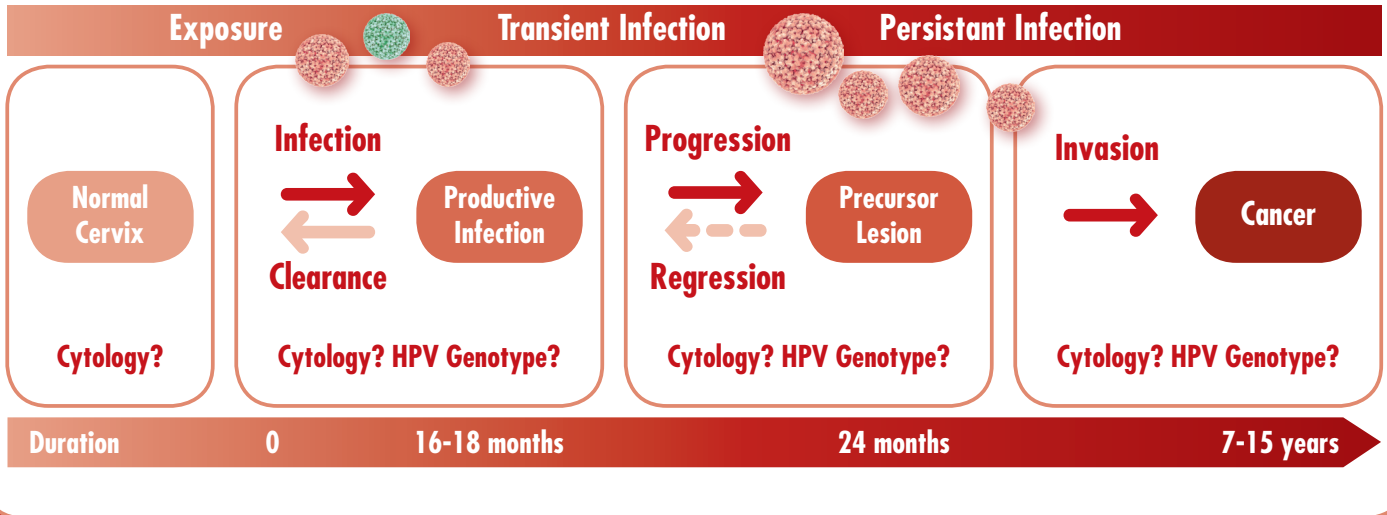
ZYTOVISION
Molecular diagnostics simplified

Importance of HPV Testing

The human papillomavirus (HPV) has been conclusively identified as the major risk factor for cervical cancer. It is the third most common cancer in women worldwide, with an estimated number of 530,000 new cases and 280,000 deaths each year. Over the last years the relevance of HPV in the history of oropharyngeal cancers has become more and more important which is indicated by a dramatically risen number of cancers of the oral cavity and pharynx linked to HPV.

Cervical Cancer Progression

Initial HPV infection requires virion integration into the basal epithelial cells. Whereas most HPV infections are transient and are cleared by the immune system, infection with HPV high risk types may lead to cancer when infection persists.



VisionArray® HPV Chip – Fast and Reliable Genotyping

The VisionArray® HPV Chip 1.0 is intended to be used with the VisionArray® Analysis Package for the qualitative detection and genotyping of PCR amplificates of 41 clinically relevant HPV genotypes.

●		+	6	11	16	18	26		●
		31	33	34	35	39	40		
42	43	44	45	51	52	53	54	55	56
57	58	59	61	62	66	67	68a	68b	69
70	72	73	81	82 IS39	82 MM4	83	84	90	91
35	34	33	31	26	18	16	11	6	+
54	53	52	51	45	44	43	42	40	39
68a	67	66	62	61	59	58	57	56	55
		81	73	72	70	69	68b		
●		91	90	84	83	82 MM4	82 IS39		

High Risk HPV Types detected by the VisionArray® HPV Chip

16	18	31	33	35	39
45	51	52	56	58	59

Probably High Risk HPV Types detected by the VisionArray® HPV Chip

26	34	53	66	67	68a
68b	69	70	73	82 (IS39)	82 (MM4)

Low Risk HPV Types detected by the VisionArray® HPV Chip

6	11	40	42	43	44	54	55	57
61	62	72	81 (CP8304)	83 (MM7)	84 (MM8)	90	91	

■ High Risk	■ Low Risk
■ Probably High Risk	■ Guide Dots/Positive Control

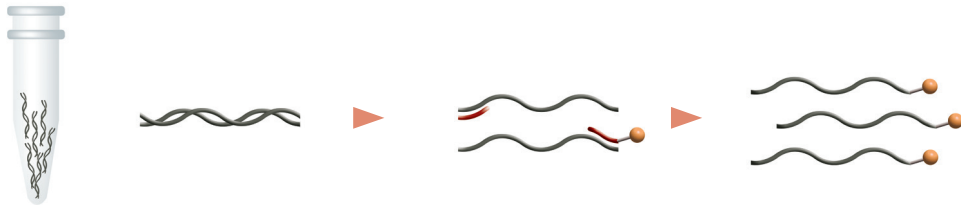
1. Sample Collection

For the detection of HPV genotypes with the VisionArray® HPV system the following raw material can be used for DNA extraction:

- Formalin-fixed, paraffin-embedded (FFPE) tissue samples
- Cervical swab/brush specimen
- Liquid based cytology specimen (ThinPrep®)

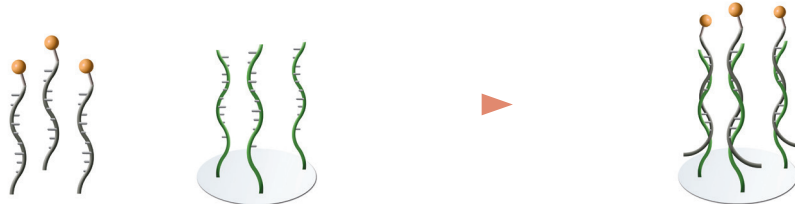
2. Detection & Differentiation of 41 HPV Types

Step 1: Amplification and Labeling in a PCR



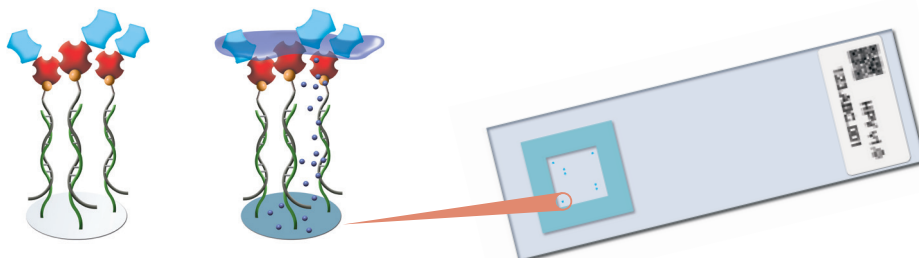
Biotinylated primers are used to amplify and label different sections of the L1 region of the HPV genome. The human HLA-DQA1 gene is also amplified and serves as a PCR positive control and as a genomic control.

Step 2: Hybridization on the Glass Chip



After amplification, the biotinylated sequences hybridize to complementary DNA capture sequences on the glass chip.

Step 3: Detection and Visualization



Specifically bound and biotinylated sequences are visualized by secondary marking with a streptavidin-peroxidase conjugate and a staining with tetramethylbenzidine. After color development, evaluation is performed using the VisionArray® Analyzer Software.

3. Workflow Schedule

This is a condensed protocol for the VisionArray® method and should not replace the instruction for use!



0 Min.



PCR

- For the PCR the *VisionArray® Primer Kit 2.0* is used
- The master mix is prepared by using the *dNTP/dUTP Solution*, *HPV Primer Mix 2.0*, *VisionArray® PreCise Taq Polymerase*, *VisionArray® Uracil-DNA Glycosylase* and the corresponding reaction buffers
Alternatively: The VisionArray® HPV PreCise Master Mix can be used
- DNA sample is added to the master mix



30 Min.



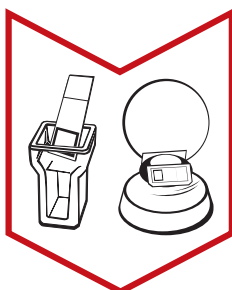
Hybridization

- PCR product and *Hybridization Solution* are mixed well
- Mix is applied onto the *VisionArray® Chip*

Duration: 30 min



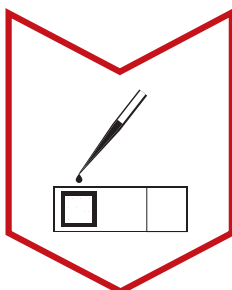
50 Min.



Stringency Wash

- Unbound DNA fragments are removed using *1x Wash Buffer*
- Drying of *VisionArray® Chip* by centrifugation

Duration: 2 min



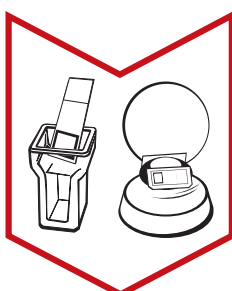
Detection

- Marking of biotinylated sequences using the *Detection Solution*
- Visualization is performed by applying the *Blue Spot Solution*

Duration: 17 min



60 Min.



Wash

- Removing of the *Blue Spot Solution* by washing with *1x Wash Buffer*
- Drying of *VisionArray® Chip* by centrifugation

Duration: 2 min



Analysis

- Chips are scanned with *VisionArray® Scanner 8100*
- Automated analysis is performed by using the *VisionArray® Analyzer Software*

Duration: 10 min

Quick & easy 1 hour protocol · Automated user-friendly evaluation within a few minutes

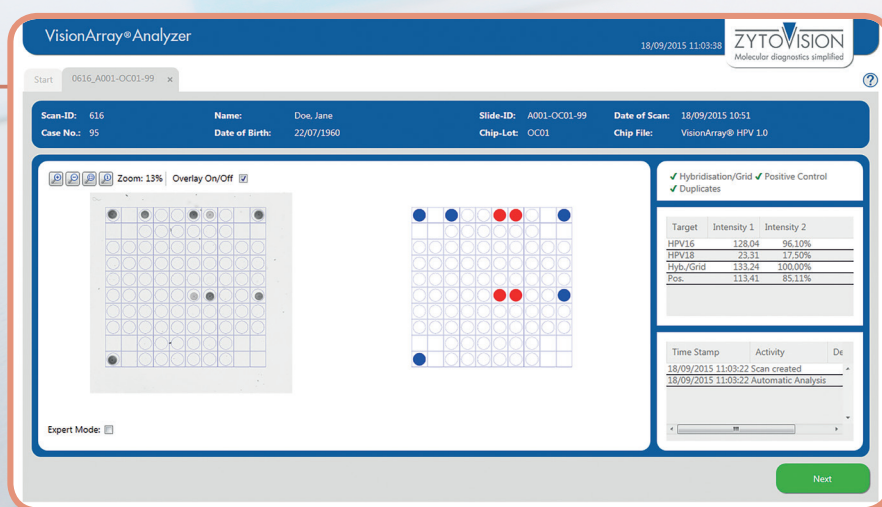
HPV Tests in Comparison

Assay	Genotyping	Co-infection	No. of CE-IVD HPV Types	Sensitivity* (copies/reaction)
Anyplex™ II HPV28 Detection	✓	✓	28	≥ 50
Cervista® HPV HR	–	–	14	≥ 1.250
CLART® HPV (3, 4)	✓	✓	35	≥ 10
cobas® HPV Test	HPV 16 + 18	HPV 16 + 18	14	≥ 150 copies/ml
digene® HC2 HPV DNA Test	–	–	18	≥ 3100
INNO-LiPA® HPV Genotyping Extra II	✓	✓	32	≥ 20
VisionArray®	✓	✓	41	≥ 50

* Sensitivity data are according to the respective instruction for use

VisionArray® – At a Glance

- Simultaneous genotyping of 41 different HPV types – all certified for *in vitro* diagnostic use
- All capture sequences and positive controls are set up on the VisionArray® Chip as duplicates
- High sensitivity and specificity
- Quick & easy 1 hour protocol
- Automated evaluation using the VisionArray® Analyzer Software – simple visualization & quick analysis in just a few minutes



VisionArray® HPV Chips



Prod. No.	Product	Tests
VA-0001-10	VisionArray HPV Chip 1.0 CE IVD Incl. 10 pieces	10
VA-0001-50	VisionArray HPV Chip 1.0 CE IVD Incl. 5x 10 pieces	50
VA-0002-10	VisionArray HPV High Risk Chip 1.0 CE IVD Incl. 10 pieces	10
VA-0002-50	VisionArray HPV High Risk Chip 1.0 CE IVD Incl. 5x 10 pieces	50

VisionArray® DNA Extraction, PCR, and Detection



Prod. No.	Product	Tests
VI-0001-50	VisionArray FPPE DNA Extraction Kit Incl. Paraffin Dissolver; Tissue Lysis Buffer; Decrosslink Buffer; DNA Wash Buffer; Proteinase K; Proteinase K Buffer; Elution Buffer; Columns; Collection Tubes	50
VI-0002-50	VisionArray Cytology DNA Extraction Kit Incl. Pre-Lysis Buffer; Cell Lysis Buffer; DNA Wash Buffer; Proteinase K; Proteinase K Buffer; Elution Buffer; Columns; Collection Tubes	50



Prod. No.	Product	Tests
VP-0001-50	VisionArray HPV Primer Kit 2.0 CE IVD NEW Higher Sensitivities Incl. HPV Primer Mix 2.0; dNTP/dUTP Solution	50
VE-0001-100	VisionArray PreCise Taq DNA Polymerase CE IVD Incl. VisionArray PreCise Taq DNA Polymerase; Reaction Buffer, 10x; PreCise MgCl ₂ , 25 mM	100
VE-0002-100	VisionArray Uracil-DNA Glycosylase CE IVD Incl. VisionArray Uracil-DNA Glycosylase (UDG); UDG Reaction Buffer, 10x	100
ES-0007-50	VisionArray HPV PreCise Master Mix CE IVD NEW Containing HPV Primer Mix 2.0; dNTP/dUTP Solution; VisionArray PreCise Taq DNA Polymerase; Reaction Buffer, 10x; PreCise MgCl ₂ , 25 mM; VisionArray Uracil-DNA Glycosylase	50



Prod. No.	Product	Tests
VK-0003-50	VisionArray Detection Kit CE IVD Incl. Hybridization Solution, 1 ml; Detection Solution, 5 ml; Blue Spot Solution, 5 ml; 100x Wash Buffer, 250 ml	50
E-4051-1	Mini Slide Centrifuge	

VisionArray® Analysis Package



Prod. No.	Product
E-4060-1	VisionArray Analysis Package CE IVD Incl. Scanner 8100; Slide Holder; Hand Scanner; PC with preinstalled VisionArray Analyzer Software; USB-Hub; External Hard Drive; Computer Mouse

CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.