



# CLART<sup>®</sup> HPV4, HPV4S & HPV4SHR

Genotyping of Human Papillomavirus (liquid cytology and swab without DNA extraction and FFPE tissues with extraction).

## GENOTYPES DETECTED:

HPV4	HPV4SHR	16 18 31 33 35 39 45 51 52 56 58 59 66 68	High Risk
	HPV4S	16 18 31 33 35 39 45 51 52 56 58 59 66 68	High Risk
		6 11	Low Risk
			40 42 43 44 54 61 62 71 72 81 83 84 85 89
		26 53 70 73 82	Prob. High Risk

○ Oncogenic risk classification according to:

Bouvar d V, Baan R, Straif K, Grosse Y, Secretan B, El Ghissassi F et al.  
A review of human carcinogens -Part B: biological agents. Lancet Oncol 2009;10(4):321-322

## GENOTYPING:

### HPV4

- Full genotyping of HR and LR genotypes.

### HPV4S

- Full genotyping of HR plus 6 and 11 genotypes.

### HPV4SHR

- Genotyping of High Risk genotypes.
- Aimed for HPV screening programs worldwide.

## FEATURES:

- Detects and genotypes different HPV types, including HR and LR in one assay.
- Sample processing without any need of DNA extraction. Validated for Dry Swab, Hybrid capture, Cell Suspension (ThinPrep & SurePath).
- Sample processing with need for DNA extraction: FFPE Samples.
- High sensitivity and specificity.
- Flexibility in the number of samples. From 4 to 96 in the same analysis.
- Each HPV genotype is detected in duplicate/triplicate.
- Results are obtained within 4 hours.
- Compatible with any GENOMICA automation system (ACT<sup>®</sup>, ACP<sup>®</sup>).
- Three quality controls included per sample:
  - **Genomic DNA control:** validates the proper performance of the extraction process.
  - **Amplification control:** allows detection of inhibition of the PCR reaction.
  - **Biotin markers:** validate the proper performance of the visualization process.

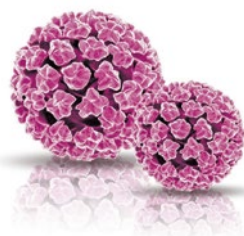


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## DATA MANAGEMENT:

- Automatic reading and interpretation of results (CAR®, ACP®).
- User-friendly report format (html, bmp).
- Samples are processed individually and three complementary reports are generated.
- Printable, exportable and storable reports.

## REPORTING RESULTS:



- Report and image obtained by CAR® reader.



Virus		
Virus	Result	Controls
6 (LR)	Negative	Passed
11 (LR)	Negative	Passed
16 (HR)	<b>POSITIVE</b>	Passed
18 (HR)	Negative	Passed
20 (PHR)	Negative	Passed

## ORDERING REFERENCES:

### CLART® HPV4

IVD product for the detection and identification of 35 genotypes of the Human Papillomavirus:

- Amplification 48 tests: AT-0115-48
- Genotyping 48 tests: CS-0215-48

### CLART® HPV4S

IVD product for the detection and identification of 16 genotypes of the Human Papillomavirus:

- Amplification 48 tests: CS-0116-48
- Genotyping 48 tests: CS-1215-48

### CLART® HPV4SHR

IVD product for the detection and identification of 14 genotypes of the Human Papillomavirus:

- Amplification 96 tests: CS-0116-96-PL
- Genotyping 96 tests: CS-1215-96

## BIBLIOGRAPHY:

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- Calleja-Macías, I.E., Villa, L.L., Prado, J.C. et al. "Worldwide genomic diversity of the highrisk human papillomavirus types 31, 35, 52, 58, for close relatives of human papilloma virus type 16". Journal of Virology. 79, 13630-13640 (2005).
- Chranioti A., Spathis A., Aga E., Merustoudis C. Pappas A., Panayiotides I. and Karakitsos P. "Comparison of two commercially available methods for HPV Genotyping: CLART HPV2 23 and Linear Arrays HPV Genotyping Test". Analytical and Quantitative Cytopathology and Histopathology. Volumen 34, number 5, October 2012.
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CLART® HUMAN PAPILOMAVIRUS 4 or CLART® HPV4 is under protection of 2 patent families corresponding to International PCT Patent Applications WO2007017699 and WO2011116797, which comprise national and regional members in different territories, including granted patents in Spain, Germany, Denmark, France, Italy, Sweden, Russia, Mexico, China and Israel, and patent applications under prosecution in Brazil and Canada.



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