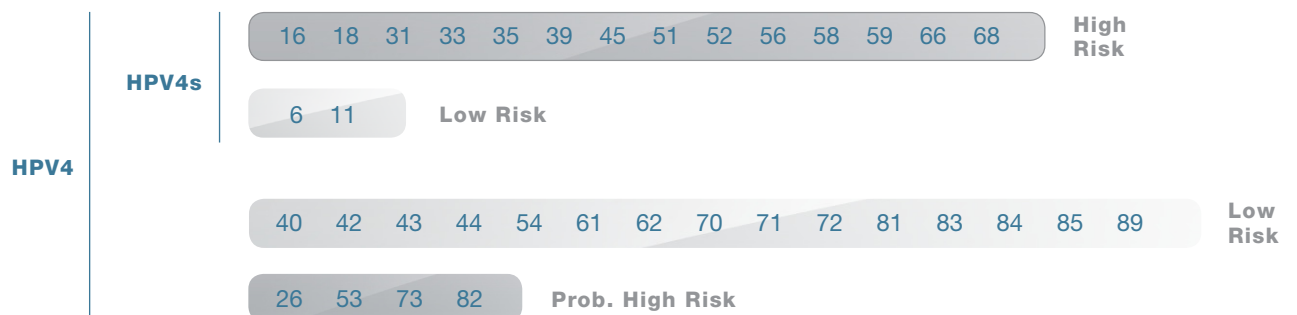




CLART[®] HPV4 & HPV4s

Genotyping of Human Papillomavirus without DNA extraction from liquid cytology and swab.

● GENOTYPES DETECTED :



► Oncogenic risk classification according to:
 Bouwar 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.
- 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 is validated for Dried Swab, Digene STM and Cellular Suspension.
- High sensitivity and specificity.
- Clinical validation performed.
- Three quality controls included per sample:
 - **Genomic DNA control:** validates the extraction performance.
 - **Amplification control:** avoids false negative results.
 - **Biotin markers:** check the proper performance of the visualization reagents provided with the kit.

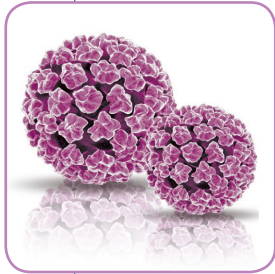
- Each HPV genotype is detected in triplicate avoiding unspecific bindings.
- Results are obtained within 4 hours.
- Compatible with any GENOMICA automation system.

DATA MANAGEMENT :

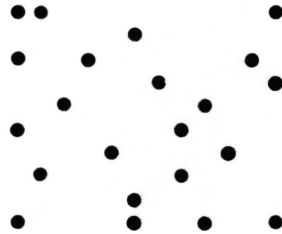
- Automatic reading and interpretation of results (CAR[®]).
- User-friendly report format (html, bmp).
- Samples are processed individually and three complementary reports are generated.
- Printable, exportable and storable reports.



REPORTING RESULTS :



► Report and image obtained by CAR® reader.



B1

Result view		Assay ID: 50213
CLART® HPV4		Rev: 13ac.12
Sample reference	2	
Array ID	0000000050213 (B1)	
Date and time	Thu Apr 07 14:07:37 2016	
Virus		
Virus	Result	Controls
6 (LR)	Negative	Passed
11 (LR)	POSITIVE	Passed
16 (HR)	Negative	Passed
18 (HR)	Negative	Passed
26 (PHR)	Negative	Passed

ORDERING REFERENCES AND CONTACT DETAILS :

CLART® HPV4

Amplification 48 tests: AT-0115-48

Genotyping 48 tests: CS-0215-48

CLART® HPV4s

Amplification 48 tests: CS-0116-48

Genotyping 48 tests: CS-1215-48

■ Parque Empresarial Alvento. Edificio B.
Vía de los Poblados, 1. 1ª Planta.
28033 Madrid (Spain).

■ Tel.: +34 91 674 89 90

■ Fax: +34 91 674 89 91

■ info.genomica@genomica.com

BIBLIOGRAPHY :

1. Bosch, F.X., Lorincz, A., Muñoz, N., Maijer, C.J.L.M. and Shah K.V.: "The causal relation between human papillomavirus and cervical cancer". *J. Clin. Pathol.* 55, 244-265 (2002).
2. Calleja-Macias, 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).
3. 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 PAPILLOMAVIRUS 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.

