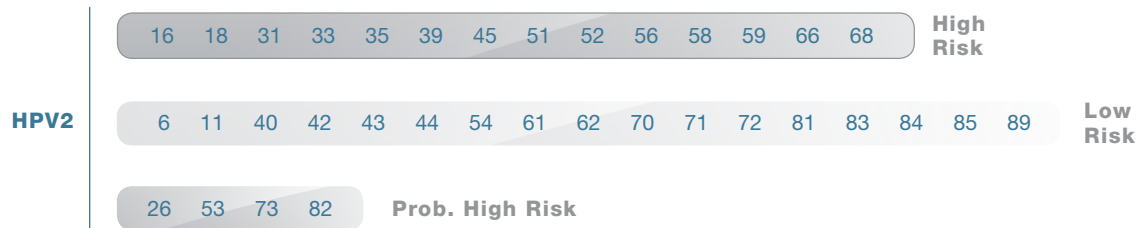




# CLART<sup>®</sup> HPV 2

## Genotyping Human Papillomavirus

### ● GENOTYPES DETECTED :



▶ 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

### ● IMPORTANCE OF HPV GENOTYPING :

- ▶ Genotyping allows simultaneous detection of single infections or co-infections.
- ▶ Provides information about HPV prevalences, specially among already vaccinated cohorts.
- ▶ Enables the early detection and patient follow up, essential for cancer prevention.
- ▶ Allows studies about HPV types and their distribution in rectal, pharyngeal and cervical cancer.

### ● FEATURES :

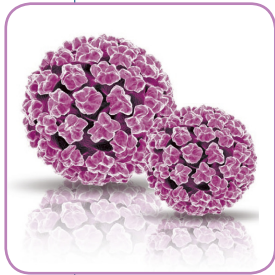
- Is a full genotyping assay used in HPV screening programs worldwide thanks to GENOMICA's automated system (autoclart<sup>®</sup> and autoclart<sup>®</sup> plus).
- Detects and genotypes 35 different HPV types, including HR and LR in one assay.
- Kits are validated for automatic and manual extraction of LBC, Swabs and FFPE tissues.
- High sensitivity and specificity. Clinical validation performed.
- Three quality controls included per sample:
  - **Genomic DNA control:** validates the extraction performance.
  - **Amplification control:** check the proper performance of the visualization reagents provided with the kit.
  - **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 a working day.
- Compatible with any GENOMICA automation system.

#### DATA MANAGEMENT :

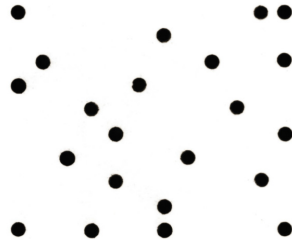
- Automatic reading and interpretation of results (CAR<sup>®</sup>).
- User-friendly report format (html, bmp).
- Samples are processed individually and three complementary reports are generated.
- Printable, exportable and storable reports.



REPORTING RESULTS :



Report and image obtained by CAR® reader.



C3

Result view <b>CLART® HPV2</b>		AT code: 50516
		Rev. 16oct3
Sample reference:	3	
Array ID:	000000050516 (C1)	
Analysis type:	tmb end point detection	
Date and time:	Fri Jan 14 15:25:36 2011	

Virus	Result	Controls
Type 6	Negative	Passed
Type 11	Negative	Passed
Type 16	Negative	Passed
Type 18	<b>Positive</b>	Passed

ORDERING REFERENCES AND CONTACT DETAILS :

CLART® HPV2 Extraction

48 tests: AT-1105-48

CLART® HPV2 Amplification

48 tests: AT-1106-48-MT

CLART® HPV2 Visualization

48 tests: CS-0208-48

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2. "External quality assessment for molecular detection of human papillomaviruses". *Journal of Clinical Virology* 48 (2010) 251-254.
3. "Human Papillomavirus 2 Assay Compared With the Hybrid Capture 2 Test". *Journal of Medical Virology* 2011 83:272-276 (2011).
4. "Identification of Multiple HPV Types on Spermatozoa from Human Sperm Donors". *PLOS ONE*. March 2011, Volume 6, Issue 3, e18095.
5. "Human papillomavirus genotype distribution among French women with and without cervical abnormalities". *Int J of Gynecol & Obstetrics* 2011, Vol 114, Issue 2, Pag116-119.
6. "Prevalence of Human Papillomavirus Infection in Women in Portugal. The CLEOPATRE Portugal Study". *Int J Gynecol Cancer* 2011;21: 1150Y1158.
7. "Detection and genotype distribution of human papillomavirus (HPV) DNA in Danish colorectal carcinoma patients". Poster presented at the 28th IPVc, Puerto Rico, 2012.
8. "Human Papillomavirus Type Distribution in Cervical Intraepithelial Neoplasia Grade 2/3 and Cervical Cancer in Portugal. A CLEOPATRE II Study". *Int J Gynecol Cancer* 2013;23: 500Y506.
9. "Patterns of cervical coinfection with multiple human papilloma virus types in a screening population in Denmark". *Vaccine*, Volume 31, Issue

CLART® HPV2: Essential features of CLART® HPV2 are protected by Patent Families of International PCT Patent applications WO2007017699 and WO2011116797.

CLART® HPV2 kit, accomplish with all the normatives described in EU 98/79/EC for IVD.

