CLART® HPV4

Non-extraction system using liquid-based cytology and swabs samples

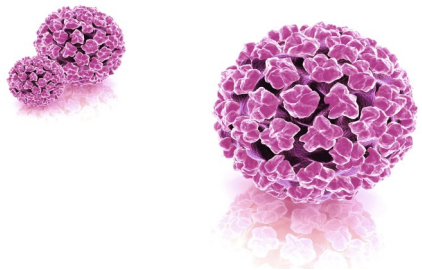
High Risk	16 18 31 33 35 39 45 51 52 56 58 59 66 68
Probable High Risk	26 53 73 82
Low Risk	6 11 40 42 43 44 54 61 62 70 71 72 81 83 84 85 89

Complete panel of genotypes detected by CLART® HPV4

MOLECULAR DETECTION OF 35 GENOTYPES OF HPV

- MULTIPLEX PCR.
- LOW-DENSITY ARRAY-BASED DETECTION
- RESULTS IN 4 HOURS FROM DRY SWAB/LIQUID BASED CYTOLOGY
- AUTOMATABLE SYSTEM. MINIMAL SAMPLE MANIPULATION

- Wide range of validated samples, including paraffin-embedded tissues.
- Clinically validated. High sensitivity and specificity.
- Several built-in quality controls in each test ensure both the presence of the sample and proper amplification.
- Simultaneous detection of co-infections within a single sample.
- Flexibility in sample throughput. From 4 to 96 samples in a single run.
- Automatic result interpretation. Reports in digital format (HTML).
- Traceability of results.
- IVD

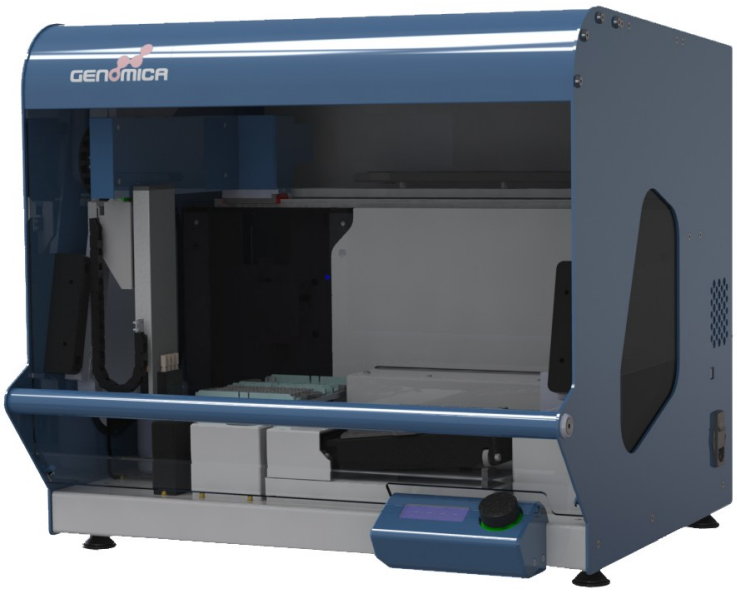


The genotype matters:

- The oncogenic potential and persistence of the infection vary significantly among different subtypes.
- HPV 16 increases the risk (PPV) of detecting a CIN2+ lesion.
- HPV 33 and HPV 31 have a higher risk (PPV) of CIN2+ than HPV 18.
- Genotyping allows:

  Patient follow-up and evaluation of vaccinated populations.
  Detection of ecological shifts in the absence of HPV16 and 18.
  Reduction of overtreatment caused by low-risk HPV types.

- Effective as a test of cure following LEEP.



autoclart® automatic processor

References:

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

2. *Clasificación riesgo oncogénico según Muñoz et al.,* N. Engl. J. Med. 348:518-527 (2003 Cancer Epidemiol Biomarkers Prev. 2006 May;15(5):908-14.

3."*The Influence of type-specific human papillomavirus infections on the detection of cervical precancer and cancer: A population-based study of opportunistic cervical screening in the united states*". Int J Cancer. 2013 Nov 14. doi: 10.1002/ijc.28605.

4."*Clinical Performance of the CLART Human Papillomavirus 2 Assay Compared With the Hybrid Capture 2 Test*". Journal of Medical Virology 83:272–276 (2011).

5."*Prevalence of Human Papillomavirus Infection in Women in Portugal The CLEOPATRE Portugal Study*". Int J Gynecol Cancer 2011;21: 1150Y1158.

6."*Patterns of cervical coinfection with multiple human papilloma virus types in a screening population in Denmark*". Vaccine, Volume 31, Issue 12, 15 March 2013, Pages 1604–1609.