

Case 2

Woman with alternating HPV positivity

Dr. Javier Cortés

- **Consults for a second opinion due to positive / negative results in recent years for HPV determination, with the last test one month ago positive for HPV 45.**

- **31 years of age. No children or previous pregnancies.**
- **Drinks alcohol.**
- **Open heterosexual relations. Sporadic use of condom.**
- **No relevant general pathological history.**
- **Not vaccinated against HPV.**

Action

- **A gynecologic examination is performed and a sample is obtained for HPV determination.**

- Clinically normal gynecologic examination.

- HPV Determination: **Negative for HR types.**

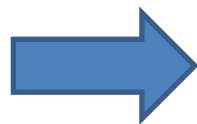
- Platform used: Cobas[®] 4800 HPV Test.

- **Vaccination with Gardasil 9[®].**
- **Preventive check-ups for cervical cancer in 5 years.**
- **Health check-up in one year or as needed depending on circumstances.**

HPV vaccination in adult woman

- Coverage in Spain in adult women: Below 1%¹

- Gardasil 9[®] efficacy²
- 95% CI

Gardasil 9[®]

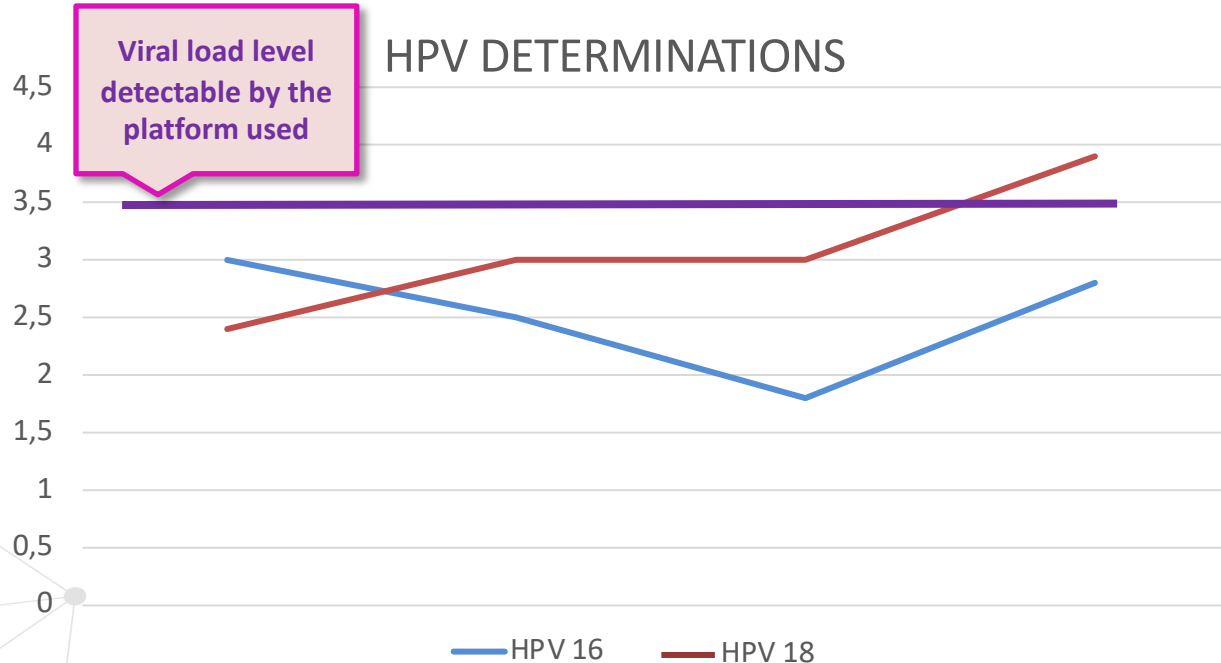
- CIN 2/3, AIS, Cervical Cancer, VIN 2/3, VaIN 2/3, Vulvar Cancer and Vaginal Cancer related to HPV 31, 33, 45, 52, 58:
 - 97.4 (85.0; 99.9)
- CIN 2/3, AIS related to HPV 16, 18:
 - 98.2 (93.5; 99.8)
- VIN 2/3 related to HPV 6, 11, 16, 18:
 - 100.0 (67.2; 100.0)
- VaIN 2/3 related to HPV 6, 11, 16, 18:
 - 100.0 (55.4; 100.0)
- Genital Warts related to HPV 6, 11, 16, 18:
 - 99.0 (96.2; 99.9)

1. Medical Departments of GSK and Merck. Personal communication.

2. https://cima.aemps.es/cima/dochtml/ft/1151007002/FT_1151007002.html

Not detecting HPV does not mean it is not there.

THE IMPORTANCE OF VIRAL LOAD



The importance of viral load

- **The viral load of HPV has a lower diagnostic precision than that reported for other screening tests for detecting HPV³.**
- **However, it can be useful to understand fluctuation in detection and to measure the capacity of HPV integration⁴.**

3. Malagón T.: Viral load of human papillomavirus types 16/18/31/33/45 as a predictor of cervical intraepithelial neoplasia and cancer by age. *Gynecol Oncol.* 2019; 155: 245–253.

4. Cao M.: Increased High-Risk Human Papillomavirus Viral Load Is Associated With Immunosuppressed Microenvironment and Predicts a Worse Long-Term Survival in Cervical Cancer Patients. *Am J Clin Pathol.* 2019. pii: aqz186. doi: 10.1093/ajcp/aqz186. [Epub ahead of print]

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HUMAN PAPILOMAVIRUS DETERMINATION – RESULT REPORT

Name:

Indication: Dr.

Record No.:

TECHNIQUE

Cobas 4800® for detection of DNA from high-risk HPV types 16 – 18 – 31 – 33 – 35 – 39 – 45 – 51 – 52 – 56 – 58 – 59 – 66 – 68 at relevant levels of clinical infection

RESULT



Reported by Dr.

Palma, 2 April 2019

Dr. Cortés Laboratory
Alfonso el Magnánimo 29, 07004 Palma
Telephone +34 971498781 – e-mail cortes@oceas.es

An essential requirement: The use of a validated test for HPV⁵

We will make clinical decision based on the result:
it must be obtained through a reliable technique.

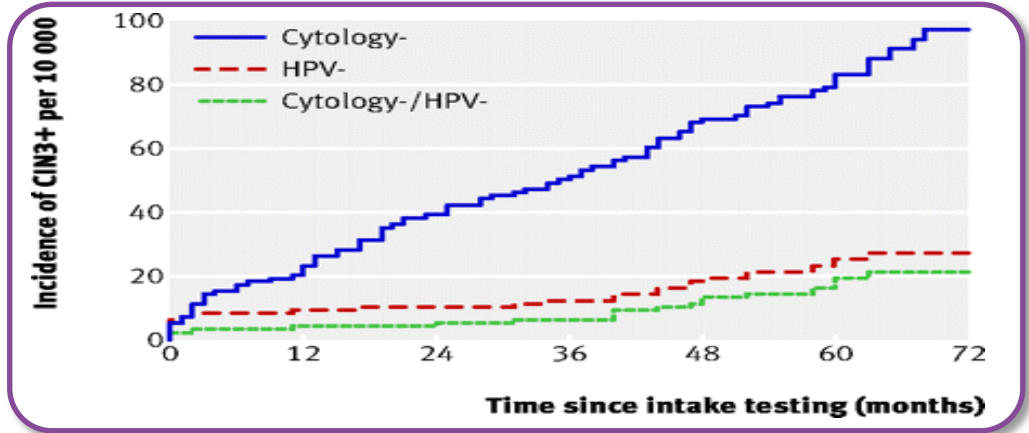
HPV

1. Hy Clinical validation of full genotyping CLART[®] HPV4S assay on SurePath and ThinPrep
2. Ce collected screening samples according to the international guidelines for human
3. Co papillomavirus test requirements for cervical screening. BMC Cancer. 2020 May 6;20(1):396.
4. Ap
5. **BD Onclarity HPV Assay[®]. Benton, Dickinson & Company**

5.Meijer CJ.: Guidelines for human papillomavirus DNA test requirements for primary cervical cancer screening in women 30 years and older. Int J Cancer 2009;124:516-20

Preventive check-ups for cervical cancer in 5 years?

Negative predictive value of the HPV test



Dillner J.: BMJ 2008;337:a1754

330,790 women ≥ 30 years of age. Risk of CIN3+ at 5 years:

HPV - 0.17%

HPV - / Cyto - 0.16%

The double test does not improve the results

Preventive check-ups for cervical cancer with HPV - every five years Annual health check-up

- **Over the last fifty years gynecologists have successfully instilled in women the culture of the “Annual Health Check” (Well-Woman Visit).**
- **Routinely associated with certain procedures, the annual health check should be adapted in its content to new evidence personalized to suit the woman.**
- **The excellent habit of the annual health check should not only be preserved but strengthened, guiding women to a gynecological health exam⁶.**

6. Cortés J.: La Prevención del Cáncer Ginecológico en la Asistencia Privada [The Prevention of Gynecological Cancer in Private Health Care].
Prog Obstet Ginecol 2017; 60: 160 – 175.

What condition must an HPV determination test meet to be used in clinical practice?

- 1. Acceptable cost.**
- 2. Be validated.**
- 3. Speed of report issuance.**

If an HPV determination is negative, what is the correct interpretation?

- 1. There is no HPV.**
- 2. HPV is not detected.**
- 3. HPV is not detected at a clinically relevant level.**

The negative predictive value for HSIL in a negative HPV test is:

1. 88%.
2. 68%.
3. 48%.