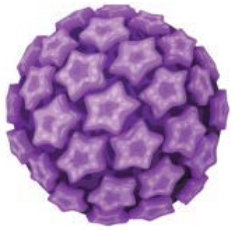
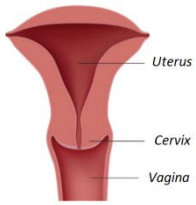
F-HPV Typing



Test to detect and typify Human Papilloma Virus (HPV)

Cervical cancer is the second most common cancer tumour in women worldwide, after breast cancer. More than 450,000 new cases are diagnosed per year and the mortality rate is a little over 50%. Unlike other types of cancer, cervical cancer affects a younger population, women between the ages of 30 and 60.

HPV is the main causative agent of cervical cancer. There are more than 100 types of HPV and approximately 25 of them affect both the female and male genital tracts, rendering cervical cancer the most prevalent sexually transmitted disease in sexually active people. Around 15 types of HPV have been classified as high oncogenic risk viruses, being found in more than 99% of cervical cancer cases.



Detection through screening techniques has become the main cervical cancer prevention tool. For the purpose of improving the sensitivity of conventional cytology screening, renowned national and international scientific associations recommend including HPV detection tests in cervical cancer screening programmes.

HPV and oncogenic risk

Not all women infected with high-risk HPV will go on to develop cancer. Most HPV infections spontaneously resolve due to immune system activity and, depending on the type of virus, tend to clear in a period of 8 months to 2 years.

In Spain, it is estimated that 5-10% of the population is infected, but only 10-20% of HPV infections are persistent.

HPV persistence is an essential factor for the development of high-grade intraepithelial lesions. Therefore, it is essential to be aware of the presence of the virus to prevent the development of this type of lesion.

The detection of the low-risk types 6 and 11 makes it possible to determine the cause of the development of most condylomata, or genital warts.

Scientific basis

HPV is detected and genotyped through multiplex fluorescent HPV typing, a new technique that consists of the specific amplification of 24 sequences contained in regions E6 and E7 of the virus's genome. These regions may be detected even when there is viral integration.

It is based on amplifying HPV DNA through multiplex PCR with 24 pairs of marked fluorescent primers, which specifically recognise **HPV** types **6, 11, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 42, 43, 44, 66, 26, 53, 70, 73 and 82** along with primers that recognise a human polymorphic sequence (STR) that is used as an internal control of DNA integrity and rules out the presence of PCR inhibitors.

Indications

It is especially indicated in the following cases:

- Primary cervical cancer screening in women age 30 and older, along with cytology.
- Patients with inconclusive cytology.
- Patients with mild- to moderate-grade pre-cancerous lesions, for the purpose of predicting its regression, persistence or progression.
- Patients who have been treated for cervical intraepithelial neoplasia (CIN) or cervical carcinoma, as part of their follow-up.

Interpretation of the results

Negative result

This means that none of the HPV types analysed were detected.

Positive result

This means that there is HPV infection. The report specifies the virus type that caused the infection.

In this case, the gynaecologist shall decide on the appropriate follow-up.

Requirements

It is not necessary to fast.

Sample: dry swab or fluid cytology with specific kit.

Documentation: Data collection application.

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