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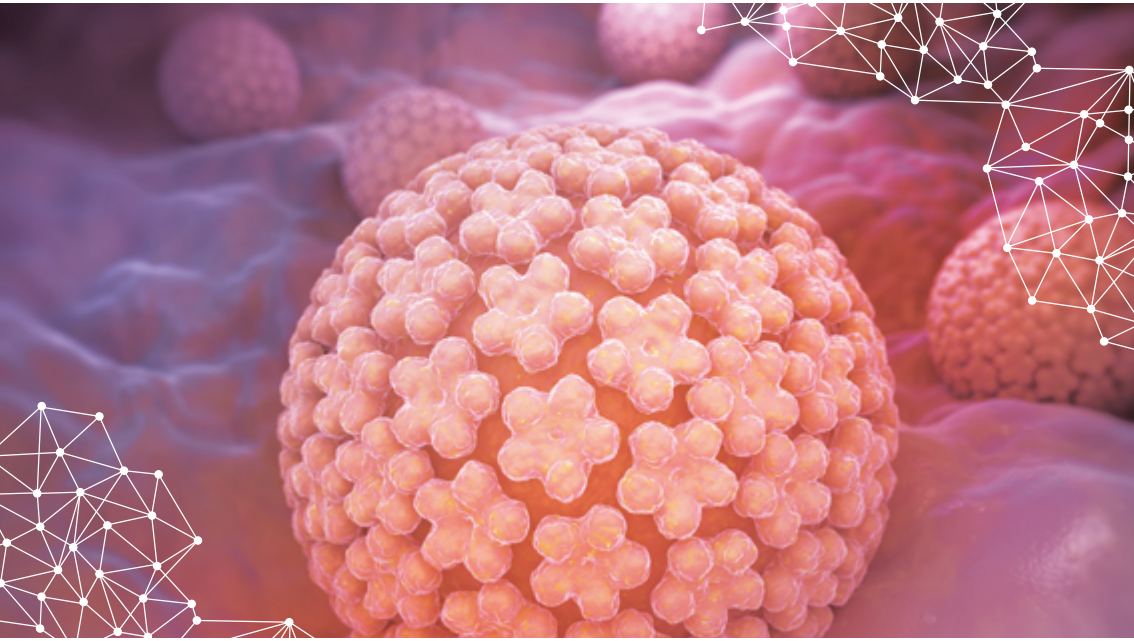


# Human papillomavirus

## and primary screening for cervical cancer

# Cervical cancer overview

Every year in the world:

**570 000**
**new cases of cervical cancer**[1]

**311 000**
**deaths from cervical cancer**[1]

**4th most common cancer among women**[1]

**45-55 ans**
**average age of onset**[2]

**Almost 90% of deaths occurred in low- and middle-income countries**[1]

**8 out of 10 women are exposed to the Human papillomavirus (HPV) in their lifetime**[2]

Cervical cancer is caused by the **presence** and persistence of certain HPV genotypes in the cervix.

The infiltrative cancer is preceded by cell transformations (= dysplasia = intraepithelial lesions) which are detectable by different tests:

- cytological examination (cervical screening).
- the HPV test.

Because of its slow evolution and the existence of curable pre-cancerous lesions, **cervical cancer can be detected at an early stage** and be **prevented by the detection of the lesions that precede it.**

It can therefore be regarded as a **preventable cancer**.

*[1] Ferlay J, Ervik M, Lam F, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2018). Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. https://gco.iarc.fr/today.*

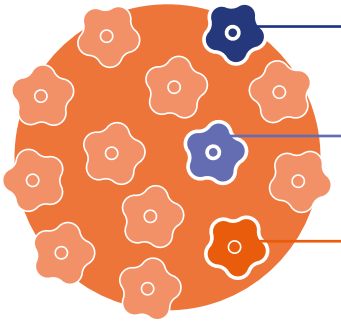
*[2] Source : Santé Publique France*

# HPV *(Human Papillomavirus)*

HPV has been implicated in 99.7% of cervical squamous cell cancer cases worldwide[3]. Among the 150 HPV genotypes, a distinction is made between **high carcinogenic risk** HPV's (HPV-HR) and **low carcinogenic risk** HPV's. 14 high carcinogenic risk HPV's are associated with cervical cancer (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68).

HPV-HR is the main risk factor for the occurrence of cervical cancer.

## Distribution of different HPV types associated with cervical cancer :



**HPV HR: 16, 18[4]**
Responsible for 70% of cervical cancer

**HPV: 31, 45, 52, 33[2]**
Responsible for 20 % of cervical cancer

**HPV: 56, 58, 59, 66, 68, 35[2]**
Responsible for 7 % of cervical cancer

**Infection with HPV occurs via sexual contact. HPV-HR infections are extremely frequent but usually regress spontaneously**. It is the persistence of the virus, the reasons for which are still poorly understood, that is responsible for the later occurrence of cancers.

In the absence of the virus in a woman, the risk of cervical cancer is minimal. The negative predictive value of HPV testing is therefore close to 100%. The prevalence of HPV infection varies with age, peaking between the ages of 20 and 30 when it reaches 20% of the population (it is <10% after the age of 30)[2].

*[2] Rapport HAS juillet 2019. Évaluation de la recherche des papillomavirus humains (HPV) en dépistage primaire des lésions précancéreuses et cancéreuses du col de l'utérus et de la place du double immuno-marquage p16/Ki67*

*[3] Walboomers, J. M. M., M. V. Jacobs, M. M. Manos, F. X. Bosch, J. A. Kummer, K. V. Shah, P. J. F. Snijders, J. Peto, C. J. L. M. Meijer, and N. Munoz. 1999. Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. J. Pathol. 189:12-19*

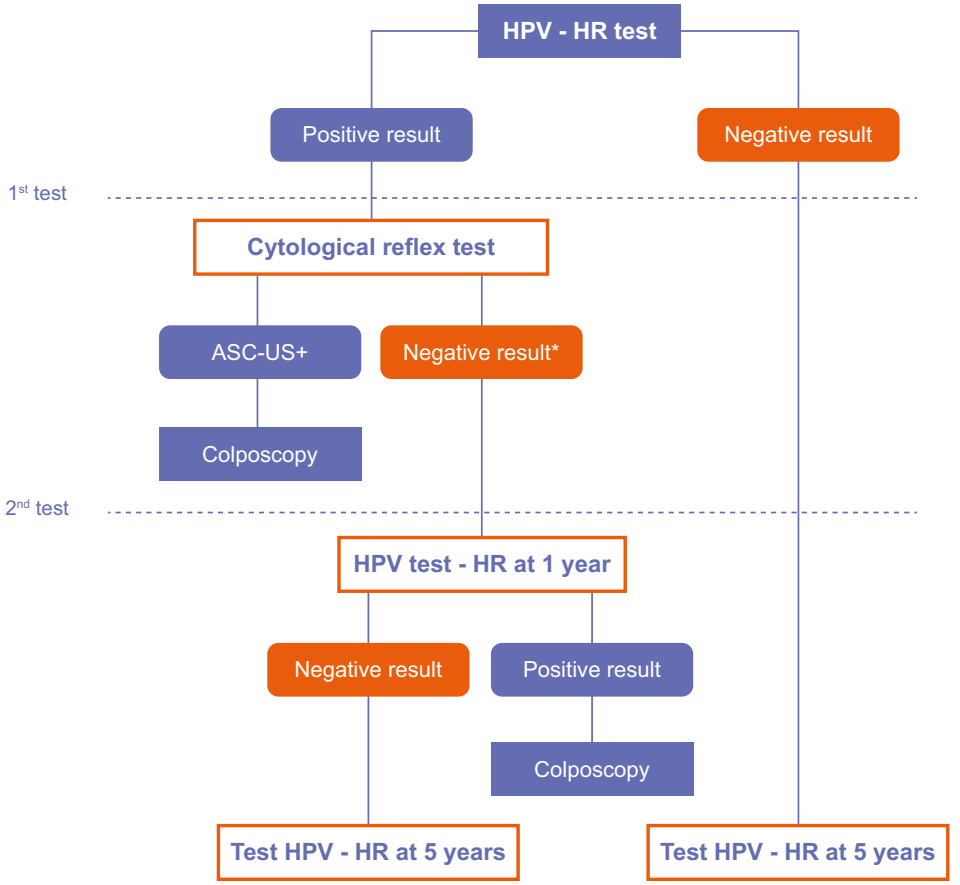
*[4] Papillomavirus humain (PVH) et cancer du col de l'utérus (who.int)*

# The HPV test

## New prescribing procedures for HPV testing

Since July 2019, Eurofins Biomnis has offered the HPV test for primary screening of precancerous and cancerous uterine lesions in women.

**Algorithm for the triage of women aged 30 to 65 with HPV testing for primary cervical cancer screening** (see picture from WHO organization) :**




*Negative result for intraepithelial or malignant lesion

***In France*

# Test performance

## Targeting specific areas

Real-time PCR - Alinity m Abbott HR HPV AMP Test

Amplification of HPV-HR viral DNA (L1 region)

## Specific detection of genotypes 16, 18, 45 and detection of two pools:

| | | | Pool 1 | Pool 2 |
|---|---|---|---|---|
| 16 | 18 | 45 | 31, 33, 52, 58 | 35, 39, 51, 56, 59, 66, 68 |
| ✓ | ✓ | ✓ | ✓ | ✓ |

HPV-HR 16,18 responsible for 70% of CCU cases
HPV-HR 45 responsible for 6% of CCU cases

Importance of specific genotyping of the most carcinogenic genotypes

# Sensitivity / specificity

**100% clinical sensitivity** for **CIN3+** detection*

**99% clinical sensitivity** for **CIN2+** detection*

**93,8 % clinical sensitivity** for detection of **<CIN2***

** Source : Clinical and Analytical Evaluation of the Alinity m HR HPV Assay within the VALGENT-3 Framework (Évaluation clinique et analytique du test HPV Alinity m HR dans le cadre de VALGENT-3).*

## Detection techniques

- Detection of 14 HPV-HR
- Nucleic acid extraction and automated real-time PCR
- Presence of an internal cellularity control - ensures that a sample is present, minimising false negative results.

## Vaccination

Prevention of cervical cancer is based on vaccination, which prevents infection by the HPV's included in the vaccine. These vaccines have no proven therapeutic efficacy on existing lesions and do not protect women who are already infected.

The WHO recommends vaccinating girls between the ages of 9 and 14, when most have not yet begun sexual activity.

Some countries have also started vaccinating boys, as vaccination prevents genital cancers in both men and women.

Recommendations from the French Public Health Council (HAS) states that "in the current state of knowledge, screening for cervical cancer remains recommended in vaccinated women with the same methods as for unvaccinated women."

# Practical details

## Sample

- **Eurofins Biomnis codes :**
- **HPV:** primary screening in women between 30 and 65 years of age
- **HPV2:** HPV test secondary to a smear test or as a follow-up to treatment
- **HPVPV:** primary screening in women aged between 30 and 65 on vaginal self-sampling
- **Recommended transport methods:**
  Endo-exocervical swabs in PreservCyt® medium (Cytyc), SurePath® (TriPath Imaging Inc), Floqswab® swab for vaginal self-collection
- **Transport and conservation conditions:**
  Ambient temperature and refrigerated temperature
- **Turnaround time for results:** 3 days
  upon reception at Eurofins Biomnis

## Find out more

**International Division**

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DS6-INTGB - January 2024