

# Advantages in choosing Vaginal Veil Collector **V-Veil UP2™**

## Comparison of effectiveness between **Vaginal Veil Collector V-VEIL UP2** and Endocervical Swab



**No. 1 in the world, in terms of efficiency\***

\* According to the study our veil collects with almost 200% more cells from the cervix area than the classical swab

**Self sampling vaginal veil collector V-Veil UP2** has almost twice the ability to detect high-risk oncogenic papillomaviruses (HPV-HR) by multiplex real-time PCR, compared to the standard swab sampling, performed by a gynaecologist or a nurse.

Discover all our  
scientific studies



Patents pending

**FOR HPV NATIONAL CAMPAIGNS**



Doctors



Clinics



Laboratories



Hospitals

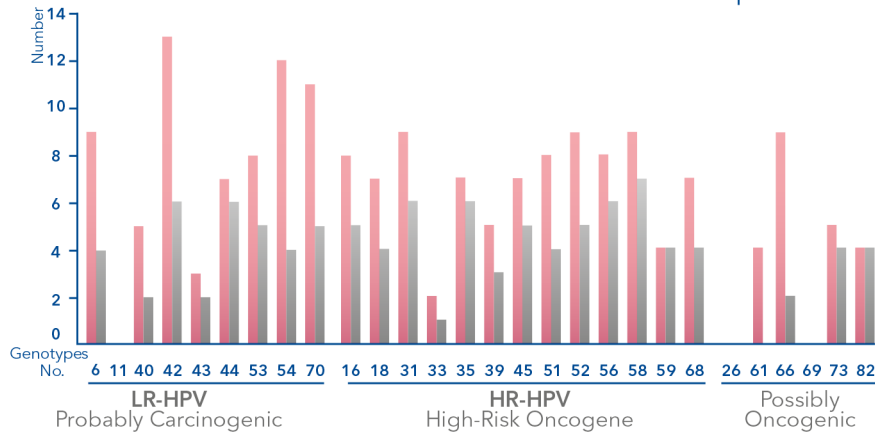
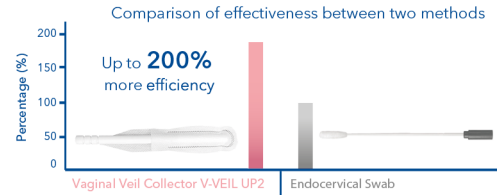


NGOs

# V-VEIL UP2™ STUDY IN GENERAL 253 FEMALE POPULATION: A prospective randomized non-inferiority trial

The graphic below compares the molecular detection of HPV genotypes performed from:

- Genital secretions self-collected by women themselves, using the **Vaginal Veil Collector V-Veil UP2**
- Genital secretions collected by a gynaecologist or a nurse, using an endocervical swab.



This study was performed on 253 adult women by the research team of the **Laboratory of Virology of the Hospital Georges Pompidou in France**. The veil detects 12 times more oncogenic HPV-HR than the use of a standard swab performed by a gynaecologist. (*Details on study*)

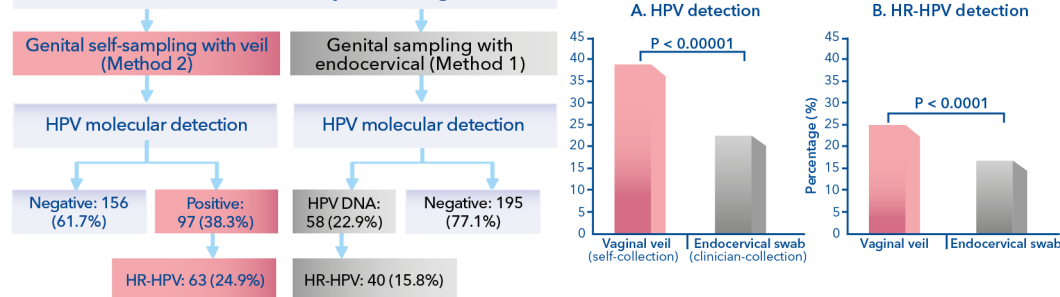
## RESULTS:

**High acceptability (≥96%)**, feasibility and satisfaction for veil-based genital self-collection.

**High accuracy:**

- Good agreement between veil-based self-collection and swab-based reference collection;
- Self-collection by veil was non-inferior to clinician-based collection for HR-HPV DNA molecular testing ( $P < 0.01$ );
- High sensitivity (95.0%; 95%CI: 88.3-100.0%) and specificity (88.2%; 95%CI: 83.9-92.6%).

**Included: 253 women** (35.0 years; range 25-65)



⚠️ ≈ 2 fold detection rates of cervical HPV DNA and high risk (HR)-HPV DNA by self-sampling with veil

# V-VEIL UP2™ STUDY IN 415 FEMALE SEX WORKERS: A randomized, non-blinded, non-inferiority trial among a high-risk population for HIV and HPV

**Sample size: 415 FSW** (mean age, 28.1 years)

**Intervention:** Unassisted veil-based self-sampling versus directly assisted veil-based self-sampling.

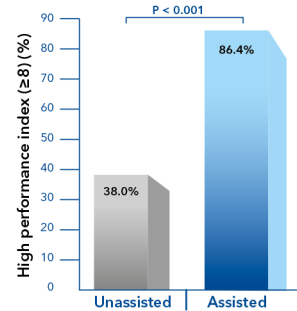
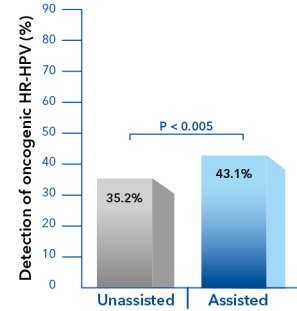
**Main outcome:** Veil-based self-sampling achievement using quantitative performance index (PI; 0 to 10; High ≥ 8; low ≤ 4; moderate: 5-7).

**Prevalences of HPV and HR-HPV infections at baseline:**

- 54% and 29%, respectively, mainly HPV-52 (14%), HPV-66 (10%), HPV-58 (9%);
- Only two-third of HR-HPV would be covered by Gardasil-9® vaccine.

**Intervention trial:**

- High acceptability (≥99%)** and satisfaction for veil-based genital self-collection at baseline;
- Performance index (baseline):** The variable "education level" associated with low performance [aOR: 2.6,  $P < 0.005$ ];
- Performance index (after intervention):**
  - Higher in directly assisted than in unassisted groups
  - [High PI in 86.4% of intervention group versus 38.0% of unassisted group; aOR 3.6,  $P < 0.001$ ];
  - The variable "education level" no more associated with low PI [aOR: 1.2, NS];
  - The variable "knowledge on genital self-sampling" associated with high PI [aOR: 2.9,  $P < 0.001$ ];
  - Directly assisted veil-based allowed to increase the performance of molecular detection of HR-HPV in self-collected genital secretions by 1.3-fold.



## V-VEIL UP2™ A PILOTE FEASIBILITY STUDY IN 57 MSM

**Sample size:** 57 MSM (mean age, 25.3 years); HIV-1: 68.9%

**High acceptability (≥93%)** for anal self-collection.

**High HPV anal carriage:** HPV and HR-HPV detected in 74.1% and 59.6% of study MSM, mainly HPV-35, HPV-58, HPV-59 and HPV-31.

**Multiple HR-HPV:** frequent in HIV-positive MSM (66%).

Only 65% of anal HR-HPV would be covered by Gardasil-9® vaccine.

MSM in Central Africa are at-risk of HIV and anal HR-HPV infections, with unusual and unique distribution of anal HR-HPV, frequently uncovered by Gardasil-9® vaccine.

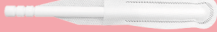



**Conclusions:**

- V-Veil UP2 collection device constitutes a simple, highly acceptable and powerful tool for self-collection of genital and anal secretions for further molecular testing, screening, genotyping and sequencing of an HPV genotypes including oncogenic HR-HPV.
- The device could be easily implemented in national programs for cervical cancer prevention (prophylactic vaccine and molecular diagnosis), care and research.

# Embrace the innovation of our veil

- offer women a better approach and use the best product available on the market!

## Advantages in choosing **V-Veil UP2™**

Comparison between 2 HPV TEST methods:	Veil UP2 Method	Endocervical Swab Method
<b>TIME GAINED</b>		
10-15 min: Administrative procedures and sending of samples	✓	○
3-5 min: Preparation & disinfection of the gynecological examination table	✓	○
8-12 min: A doctor to perform the test plus discussion	✓	○
1-2 min: A doctor to sign the prescription file	○	○
3-5 min: Table cleaning and disinfection	✓	○
<b>OTHER COSTS ELIMINATED</b>		
Sterile disposable vaginal retractor	✓	○
2 pairs of gloves for installation and after cleaning	✓	○
1 pair of gloves for the examination	✓	○
1 full set of disposable clothes for doctor	✓	○
1 Swab or brush	✓	○
1 HPV UP2 Veil	○	✓
1 Sterile transport tube	○	○

- ✓ The cancerous genome can be detected up to twice more with **V-Veil UP2** as compared to the classical method.
- ✓ The use of **V-VEIL UP2** reduces the total cost by 35-50%.
- ✓ Sampling for HPV testing using **V-VEIL UP2** does not require the presence of a doctor.
- ✓ With **V-VEIL UP2** the number of HPV tests to be done each day can increase.
- ✓ The patient appreciates a sampling method that respects her privacy.

Save more lives by using **V-VEIL UP2™**

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**MD** Class I  
In accordance with  
MDR 2017/745

**CE** **FDA** Approval  
soon

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