

V-VEIL UP²™ SELF-SAMPLING SOLUTION for HPV & STI DETECTION



UP2 RETROFITTER™ tube for V-Veil UP2™



Patent pending

V-Veil UP2™
SELF-SAMPLING VEIL COLLECTOR

UP2 Retrofitter™ TUBE

V-Veil UP2™ SCIENTIFIC STUDIES



hpv-veil.com

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V-Veil-UP Production, European company registered in EUDAMED as a producer of Medical Devices, Systems, and Kit Producers, and at NAMMD, manufactures and sells **V-Veil UP2™**, the best patented Self-Sampling Veil to detect HPV & STI and **UP2 Retrofitter™** Tubes.

FOR ALL WOMEN

- ✓ Safer, especially for those with lesions
- ✓ High acceptability ≥ 96%
- ✓ Easy to use
- ✓ Better screening approach



V-VEIL UP2™ AT GLANCE

- ✓ Self-Sampling Medical Device CLASS I according Regulation (EU) 2017/745 (CE mark under the responsibility of the manufacturer)
- ✓ Registered in EUDAMED (the European database of medical devices) and NAMMD (the National Agency of Medicines and Medical Devices of Romania).
- ✓ Produced in EN ISO 13485:2016 certified facility, in ISO 8 clean rooms.
- ✓ **V-Veil UP2™** is listed as medical device for self-sampling into technology landscape report of Unitaid *Screening precancerous lesions for secondary prevention of cervical cancer*.
- ✓ The self-sampling vaginal veil collector **V-Veil UP2™** has almost twice the ability to detect HPV-HR by multiplex PCR in real time, compared to standard swab.
- ✓ Specially adapted to women who feel discomfort during gynecological examinations, which may also be related to cultural or religious values.
- ✓ 97.1% acceptance rate on a panel of 253 women.
- ✓ The Patented Veil Technology can release 90.7% of DNA and 81.3% of Proteins. Other methods of self-sampling are extremely FAR from this efficiency.

IF MORE DNA IS RELEASED, MORE LIVES WE SAVE!

- ✓ The stability of the **V-Veil UP2™** collected sample in dry media (without any kind of liquid) at temperatures between 4 to 40°C is 30 days and at 50°C is 7 days.
- ✓ This Veil Technology is being used WORLDWIDE by a PCR equipment manufacturer.
- ✓ **V-Veil UP2™** devices have multiple patent applications and patents pending on several continents.

For orders, please contact us at contact@vvup.org



V-VEIL UP2™

The self-sampling vaginal veil **V-Veil UP2™** is a class I, non-sterile, UVC disinfected medical device, for the collection of secretions, various fluids and substances from the human vaginal cavity and cervix, for diagnosis by laboratory tests.

POSSIBLE ANALYSES with V-VEIL UP2™

HPV genotyping Vaginal Microbiome

- Chlamydia trachomatis
- Neisseria gonorrhoeae
- Ureaplasma parvum/
Ureaplasma urealyticum
- Mycoplasma Genitalium
- Mycoplasma hominis
- Trichomonas vaginalis
- Gardnerella vaginalis
- Herpes Simplex virus 1
- Herpes Simplex virus 2
- Syphilis (Treponema pallidum)



Our products are available in:

- individual packaging;
- collective packaging of 250 pcs.;
- bulk of 1000 pcs.



The 28mm veil can be used to keep medicine/drugs in the vaginal cavity, for a higher efficiency and minimize leaking accidents.

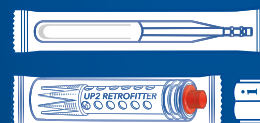
BUY
For personal use



Discover all our
KITS



V-Veil UP2™ KIT 1.3 14mm Self-Sampling Veil



Content

- 1 Vaginal Veil Collector V-Veil UP2™
- Instructions for use
- 1 UP2 Retrofitter™ Tube

V-Veil UP2™ KIT 4.3 14mm Self-Sampling Veil



Content

- 1 Vaginal Veil Collector V-Veil UP2™
- Instructions for use
- 1 UP2 Retrofitter™ Tube
- 1 safety bag UN3373
- 1 courier bag.

OTHER PRODUCTS:

KIT 1.1 and **KIT 4.1**, are also available, with 1 regular container for storage and transport of samples.

V-VEIL UP2™ KITS are self-sampling procedure packs used to collect secretions, various fluids and substances from the vaginal cavity and cervix, for diagnosis by laboratory tests.

- ✓ Suitable for all national HPV detection campaigns.
- ✓ Very practical for NGOs that organize HPV screening campaign, especially in Muslim or hard to reach communities.
- ✓ The use of this veil makes it possible to almost double the detection capacity of HPV-HR by multiplex PCR in real time compared to a standard swab method.
- ✓ Suitable for laboratories that want to have the best product and save money.
- ✓ The only self-sampling veil with scientific studies that show good results, with or without medical assistance.
- ✓ **V-Veil UP2™** is simple, safe, and respects the privacy of all women.
- ✓ For women as final user, the KIT 4.1 and KIT 4.3 are available for on-line buying, in EU, at test-hpv.shop

For orders, please contact us at contact@vvup.org

V-Veil UP2™



UP2 RETROFITTER™ TUBE

GROUNDBREAKING WORLDWIDE MEDICAL DEVICE INNOVATION

Reduced risk of pre-analytical error and ease of use for automation

The self-sampling medical device **V-Veil UP2™** can be used with its patented, next generation **UP2 Retrofitter™** tube, which allows the laboratory to use this primary tube with the collected sample, directly in the PCR automation system, without the need for an intermediate tube and another barcode.

UP2 Retrofitter™ creates free empty space, in which the pipette of the preanalytical robot can be easily introduced, thanks to the same length and internal diameter of standard hemolysis tube provided.



UP2 RETROFITTER™ TUBE HOW IT WORKS

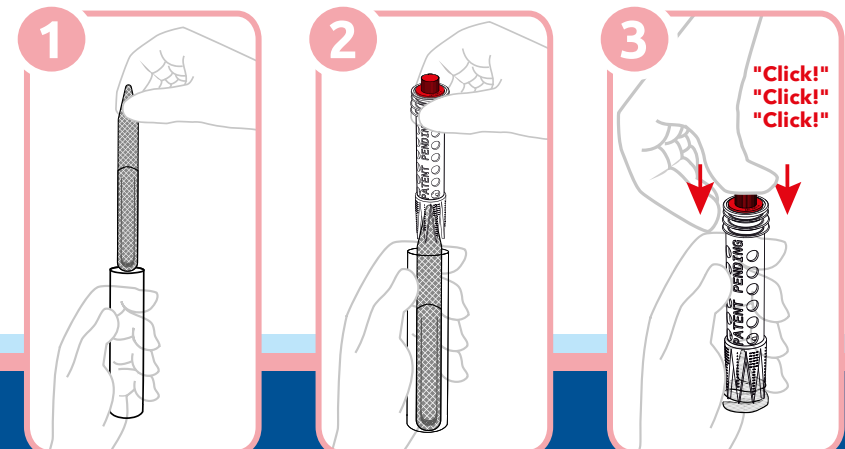
The patient puts her sampling in the tube, then pushes it totally inside with the **UP2 Retrofitter™** provided to her. After the veil is fully inserted, the patient presses the cap until a “CLICK” is heard three times, to completely close the sample. The veil is captured between the wall of the tube and the wall of the **UP2 Retrofitter™**, leading to a large free space, like a normal empty tube.

PATIENT ADVANTAGES:

1. This patent pending technology allows the patient to use **V-Veil UP2™**, probably the No. 1 self-sampling device, in terms of efficiency, to detect HPV-HR (see international studies published).
2. The self-sampling **V-Veil UP2™** Vaginal Veil Collector it is easy, safe and provides more accurate results.

PATIENT'S STEPS:

1. Insert the collected sample **veil** into the dry tube provided.
2. Insert **UP2 Retrofitter™** in the tube, over the Vaginal Veil Collector.
3. Press the **UP2 Retrofitter™** cap 3 times, to fix it inside the tube.



UP2 RETROFITTER™ TUBE

HOW IT WORKS

LABORATORY STEPS:

Once the laboratory receives the **UP2 Retrofitter™** Tube, with the collected sample, the laboratory technician:

1. Removes the red cap.
2. Adds 5ml of neutral liquid or PCR compatible, reaction interference-free elution media, on the dry tube. TE buffer (1X) pH 8.0 for molecular biology.
3. Makes a rotation movement of the tube, to mix the liquid.
4. Vortexes the tube for 1 minute.
5. Inserts the tube directly in the automate, for the next step, which requires the use of the pipette.
6. When this is finished, puts on the green cap (standard size hemolysis cap tube to mark that the sample was tested).

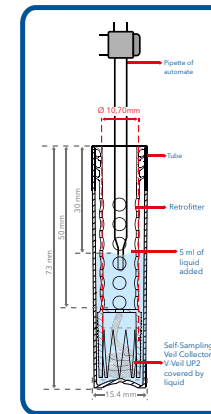
See use instructions



UP2 RETROFITTER™ TUBE ADVANTAGES

The patented technology **V-Veil UP2™** with **UP2 Retrofitter™** Tube, is suitable for all clinics, hospitals and laboratories, as it offers:

- **Efficiency**
- **Neutrality with respect to molecular biology reagents**
- **Compatibility with all HPV PCR Kits on the market**

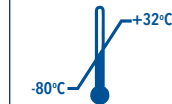


V-Veil UP2™ with it's **UP2 Retrofitter™** Tube, is safe and provides a more accurate result.

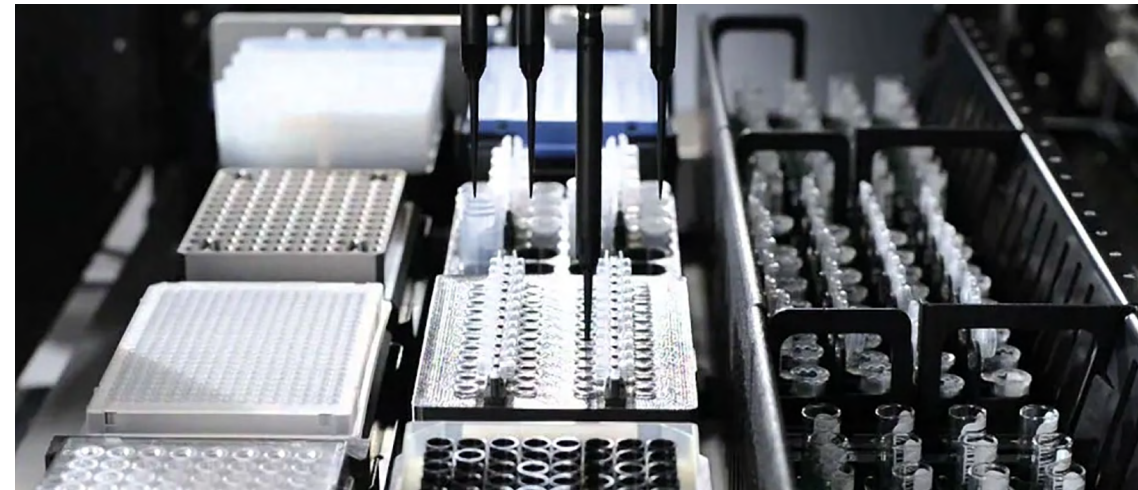
LABORATORY ADVANTAGES:

- ✓ Safer
- ✓ Faster
- ✓ No contamination
- ✓ Economic
- ✓ Ready for extraction

Size compatible with frozen storage boxes



Patent pending



For orders, please contact us at contact@vvup.org

WHY USE V-VEIL UP2™

1

The Veil Technology releases all the biochemical molecules (90.7% DNA and 81.3% Proteins) contained in a woman's genital secretion. **V-Veil UP2™** is up to 20% more efficient than swab.

**Better release of genital secretion:
If more is released, more lives we save!**

2

A clinical field research study* of 253 female participants, conducted by the European Hospital Pompidou (Paris) - using Seegene™ reagents - demonstrates that collecting female genital secretions using **V-Veil UP2™**, a self-sampling device offered by V-Veil-UP Production, **detects up to 2 times more HPV than swab.**

*Study published in scientific journals and medical congresses, available on the website hpv-veil.com

**Improved detection performance for oncogenic HPVs:
If more is detected, we save more lives!**

3

V-Veil UP2™ is listed as a self-sampling device, into the category of sample collection for HPV testing and emerging self-collection strategies in Unitaïd technology landscape report: **Screening and treatment of precancerous lesions for secondary prevention of cervical cancer.**

UNITAID report



PATENTED TECHNOLOGY FOR HPV & STI

4

The patented, **next-generation primary tube with UP2 Retrofitter™** allows laboratories to use the primary tube, containing the **V-Veil UP2™** self-sampling device, directly with a preanalytical robot, without the need for an intermediate tube and barcode. Direct use of the primary tube is optimal for HPV and STI molecular testing.

Ease of use in terms of automation: Faster and more economical! Reduced risk of pre-analytical error.

5

V-Veil UP2™ self-sampling device does not require transport fluid**, and the collected sample can be stored up to 30 days at room temperature, between 4 to 40°C, and 7 days at 50°C. This system enables us to respond officially to national HPV or STI screening campaigns.

**It is not recommended for the patient to use collection tube with transport fluid without the supervision of a professional.

**Regulatory compliance for HPV & STI testing campaigns.
Neutrality with respect to molecular biology reagents used.
Compatibility with all HPV PCR kits on the market.**

Advantages



V-VEIL UP²™ SELF-SAMPLING for HPV & STI SCIENTIFIC STUDIES



SUITABLE FOR:



Doctors



Clinics



ONGs



Laboratories



Hospitals



National Campaigns



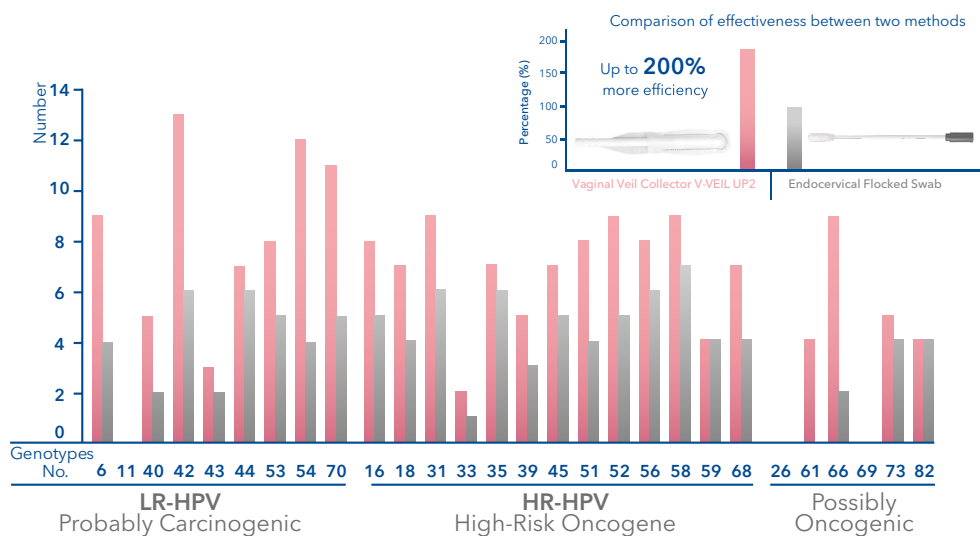
V-VEIL UP2™ STUDY IN GENERAL 253 FEMALE POPULATION

A prospective randomized non-inferiority trial

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 gynecologist. (*Details on study*)

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

- Genital secretions self-collected by women themselves, using the **V-Veil UP2™**
- Genital secretions collected by a gynecologist or a nurse, using a standard swab



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

Genital self-sampling with veil (Method 2)

HPV molecular detection

Negative: 156 (61.7%) Positive: 97 (38.3%)

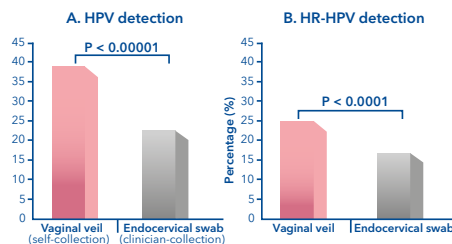
HR-HPV: 63 (24.9%)

Genital sampling with endocervical (Method 1)

HPV molecular detection

HPV DNA: 58 (22.9%) Negative: 195 (77.1%)

HR-HPV: 40 (15.8%)



COMPARISON OF EFFECTIVENESS BETWEEN V-VEIL UP2™ and ENDOCERVICAL SWAB

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%)
- ✓ High specificity (88.2%; 95%CI: 83.9-92.6%).



Discover all our scientific studies

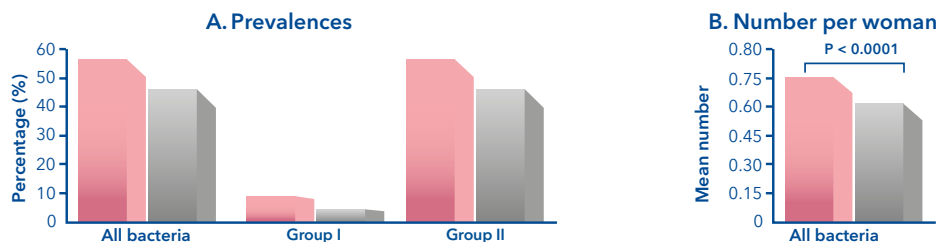
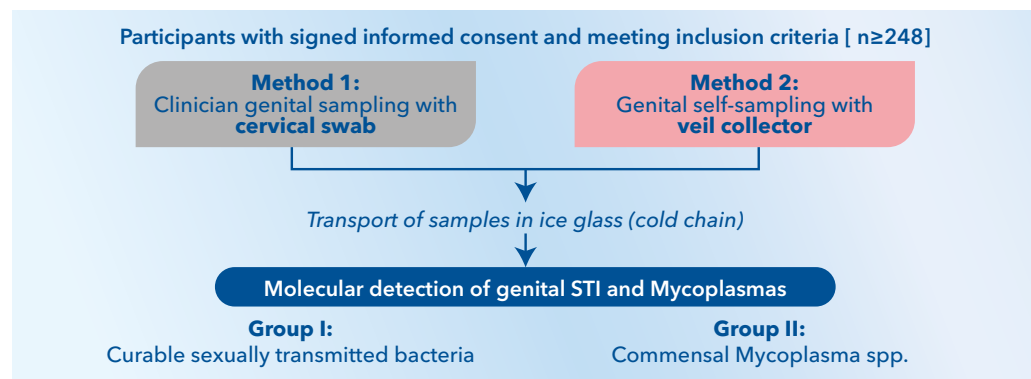


⚠ ≈ 2 fold detection rates of cervical HPV DNA and high risk (HR)-HPV DNA by self-sampling with veil

V-VEIL UP2™ STI & GENITAL MYCOPLASMAS STUDY

by Multiplex Real-Time PCR, using a Self-Collection Veil,
among Adult Women in Sub-Saharan Africa

The cross-sectional study was carried out to assess the performance of **V-Veil UP2™** as a genital self-sampling device, to collect genital secretions for STI diagnose by molecular biology, as compared to reference clinician-collected genital specimens, in adult African women.



The results showed high accuracy of the **veil-based genital self-collection**, which was non-inferior to clinician-based collection as reference for genital bacteria DNA molecular testing, with "almost perfect" agreement between the two collection methods, high sensitivity and specificity.

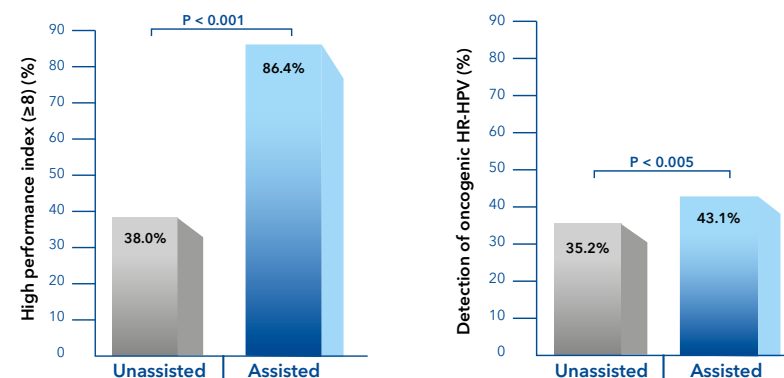
Outstandingly, **the mean number of detected genital bacteria was significantly higher when using veil-based collected genital secretions than clinician collected cervical secretions by swab.**

Self-collection of genital secretions using the **V-Veil UP2™** device is a **simple and powerful tool to collect genital secretions** for further molecular testing and screening of genital microorganisms and could be easily implemented in the national prevention programs.

Veil-based self-sampling is equivalent to swab for the molecular detection of bacterial sexually transmitted infections and genital bacteria.

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:

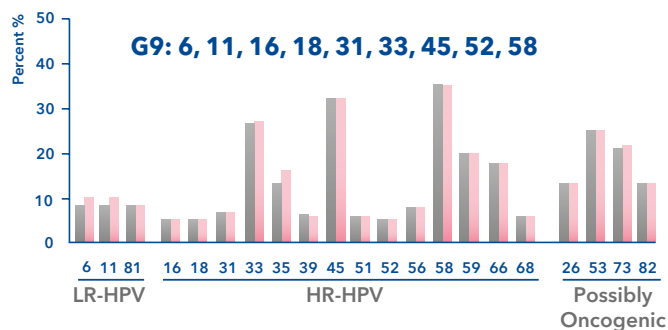
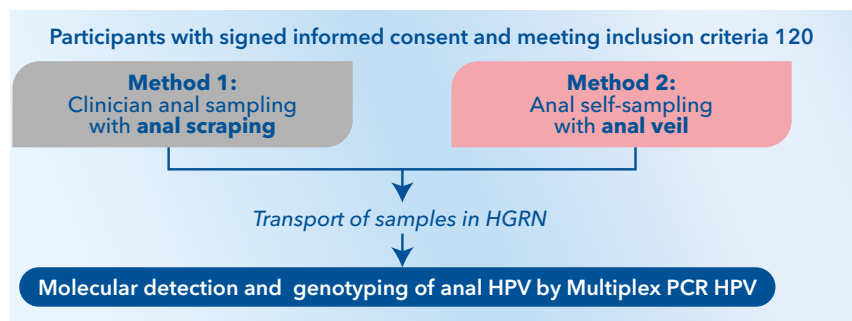
- ✓ 54% and 29%, respectively, mainly HPV-52 (14%), HPV-66 (10%), HPV-58 (9%);
- ✓ Only two-third of HR-HPV would be covered by Gardasil-9© vaccine.

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™ ANAL STUDY using the Anal Self-Collected Veil among 120 MSM in CHAD Africa

After eligibility assessment, participants were randomized between anal scraping collected by medical staff and anal self-sampling by veil, and the two sampling methods were taken 2 hours apart. The acceptability, practicability and satisfaction questionnaires were completed after self-collection and anal scraping.



Usability of anal veil (94%):

No difficulties to read the instructions or discomfort in using the anal veil

Satisfaction of anal veil (96%):

Because higher privacy

V-VEIL UP2™ A PILOT FEASIBILITY STUDY IN 57MSM

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.

STUDIES CONCLUSIONS

✓ These observations in the field highlight the high burden of cervical and anal HR-HPV infection in various high-risk populations.

✓ **V-Veil UP2™** devices are simple, highly acceptable and powerful tools for self-collection of genital and anal secretions for further molecular testing and screening of HR-HPV that could be easily implemented in national programs for cervical and anal cancer prevention (prophylactic vaccine and molecular diagnosis) and care in Africa.





General conclusions:

The veil is adapted as medical device to self-collect female genital and anal secretions, as well as secretions for biochemical dosages, molecular detection and genotyping of various STI microorganisms and oncogenic HPV.



EMBRACE THE INNOVATION OF OUR PRODUCTS

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

Comparison between 2 HPV TEST methods:	V-Veil UP2™ Method	Endocervical Swab Method
TIME GAINED		
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	✓	○
MONEY GAINED		
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	○	○
The sterile transport tube	○	✓

With **V-Veil UP2™**

- ✓ The cancerous genome can be detected up to twice more, compared to the classical method.
- ✓ The total cost decreases by 35-50%
- ✓ The self-sampling veil collector **V-Veil UP2™** does not require the presence of a doctor to perform the HPV prelevement.
- ✓ The number of HPV tests to be done each day can increase.
- ✓ The patient appreciates a sampling method that respects her privacy.

COMING SOON PRODUCTS

UP2 Retrofitter™ tube with pierceable aluminium foil, without cap, for manual processing or automation (DNA or Cytology).

- ✓ Licence, OEM, custom size on demand.
- ✓ Pre-order reservation possible at each exhibition where **V-Veil UP Production** is participating.

Micro ECONOMIC automation assey, which removes 24 caps from our new **UP2 Retrofitter™** tube, fills the tube with 5ml liquid and also does the vortexing, all in just 2 minutes.

- ✓ Compatible with the 24 tubes rack and the small 16 tubes rack
- ✓ Licence, OEM, custom size on demand.
- ✓ Pre-order reservation possible at each exhibition where **V-Veil UP Production** is participating.

**Offer women a better approach
and use the best product available on the market!**



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MD Class I
In accordance with
MDR 2017/745

CE

IVD Class A
In accordance with
IVDR 2017/746

FDA Approval
soon





SAVE MORE LIVES BY USING V-VEIL UP²™



V-Veil UP²™, the self-sampling kits for HPV and STI with the new **UP² Retrofitter™** tube can be also purchased directly via **Seegene™**

For orders, please contact:
contact@vvup.org or **nbd@seegene.com**

For personal use, in EU, order at: **test-hpv.shop**



hpv-veil.com

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