

TRAINING MANUAL ON HIGH-RISK HUMAN PAPILLOMAVIRUS TESTING USING SELF-SAMPLING



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ABBREVIATIONS AND ACRONYMS

CHW – Community Health Worker

HCP – Healthcare Professional

HPV – Human Papillomavirus

hrHPV – High-risk Human Papillomavirus

HSIL – High-grade Squamous Intraepithelial Lesion

LMICs – Low- and Middle-income Countries

PRESCRIP-TEC – Prevention and Screening Innovation Project Toward Elimination of Cervical Cancer

INTRODUCTION

This training manual describes the process of high-risk human papillomavirus (hrHPV) self-sampling testing. The purpose of this manual is to provide information on hrHPV self-testing, specifically application instructions, types of self-swabs, benefits, contraindications to testing, and sampling transport and storage.

KEY MESSAGES ABOUT CERVICAL CANCER

- Globally, cervical cancer is the leading cause of cancer deaths in women.
- In 2018, an estimated 570,000 new cases of cervical cancer were diagnosed globally, propelling the disease to fourth place on the list of the most commonly diagnosed cancers in women.
- In low- and middle-income countries (LMICs), the overall incidence and mortality rates are higher than in high-income countries where screening programs have been implemented. LMICs accounted for nearly 90% of cervical cancer deaths worldwide in 2018.
- Several experts predict that the disease's global burden will continue to rise, with the number of new cases and deaths reaching an alarming 700,000 and 400,000 per year by 2030.
- Screening for hrHPV infection or premalignant lesions of the cervix is an effective way to prevent cervical cancer.

KEY MESSAGES ABOUT HUMAN PAPILLOMAVIRUS

- Cervical cancer is almost exclusively caused by a sexually transmitted infection – hrHPV.
- Human papillomavirus (HPV) is a common virus that infects both women and men. In most cases, the immune system clears the HPV infection within two years after acquisition.
- The vast majority of cervical cancer cases are caused by certain types of HPV.
- Cervical cancer has been linked to 14 of the more than 100 known HPV virus genotypes, which are referred to as hrHPV genotypes.
- Except for the cervix, HPV has also been linked to cancers of the anus, vulva, vagina, penis, and oropharynx.

TARGET GROUP

This manual is intended primarily for project participants, healthcare professionals (HCP), community health workers (CHWs), and project country representatives involved in the hrHPV self-testing.

WHAT IS CERVICAL CANCER SCREENING AND WHO IS ELIGIBLE FOR THE SCREENING?

Cervical cancer screening is used to detect changes in the cervix's cells that may lead to cancer. hrHPV self-sampling is an alternative to a clinician-collected cervical screening test for women and may be suitable for settings where sample taking by a clinician is unavailable or not desired.

All women who meet the project criteria for age groups (Table 1) and target audience and are willing to participate in the research are eligible for hrHPV self-testing.

Every woman participating in self-sampling in the PRESCRIP-TEC project **must sign an informed consent form**, be given clear information by the supervising HCPs or CHWs and have the ability to respond to questions or participate in an interview.

The screening will benefit women, particularly if the disease is detected and treated. They will also benefit from knowing that if no oncogenic human papillomavirus is detected, they are unlikely to develop cervical cancer.

Participants in this project may be concerned about cervical screening, necessitating special consideration in terms of reassurance and explanation of the screening procedure.

Self-sampling for hrHPV increases screening participation among previously unscreened women.

Table 1: Age target groups in project countries

Country	Target group
Uganda	30–49 years
Bangladesh	30–64 years
India	35–63 years
Slovakia	19–64 years

WHAT IS HRHPV SELF-TESTING?

hrHPV self-testing is a reliable alternative method for cervical cancer screening. An hrHPV test performed on a participant's vaginal sample has been shown to have the same sensitivity and specificity as those performed by a healthcare provider. Women should not be concerned about carrying out the sampling correctly, as a sample of vaginal cells even in the absence of cells from the cervix will suffice to determine whether the woman is infected with HPV.

The test examines a sample of cells to see if they are infected with a high-risk strain of HPV. Long-term infection of this type can cause changes in cervical cells that can lead to cervical cancer.

The test has the following characteristics:

- *convenience,*
- *cost-effective,*
- *privacy,*
- *ease of use.*

HOW IS A HRHPV SELF-SAMPLING TEST COLLECTED?

Women can easily collect an hrHPV sample themselves by following the 11 steps illustrated below:

The instructions for use must be carefully followed.



STEP 1: You will be given a package by the HCP or CHW. A swab may differ from the ones shown here.

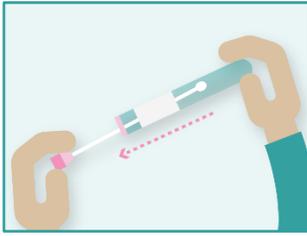


STEP 2: Wash your hands before removing the hrHPV self-sampling kit from its packaging. Make sure your hands are clean and dry.



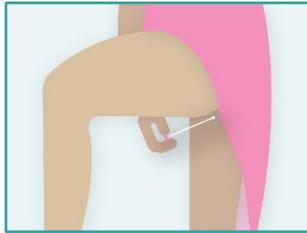
STEP 3: Make sure you know which end of the swab can be held (Tip A) and which end is for taking the sample before you open the package (Tip B).

If you are unsure which end is which, seek advice from the HCP or CHW.



STEP 4: Remove the swab from the packaging by twisting the cap.

Avoid touching Tip B, which will be inserted to collect the sample. Do not put the swab down.



STEP 5: Undress from the waist down. Find a comfortable position, for example lying down on a cushion (with your buttocks on a cushion), knees bent and legs spread open or standing upright with one foot on a chair.

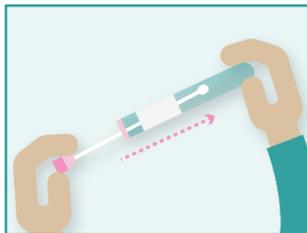


STEP 6: Gently spread your vaginal opening with one hand and insert the swab into the vagina.

Insert the swab about 5 cm (half the length of your finger) into the vagina, or to the breaking point if there is one, aiming for your lower back. This is similar to how a tampon would be inserted.



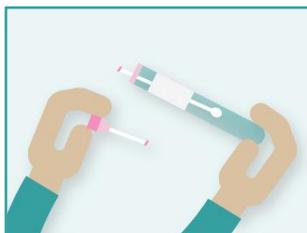
STEP 7: Gently rotate the swab 5 times (20–30 seconds) to collect cells.



STEP 8: Slowly remove the swab from the vagina and place it in the collection tube provided. Tightly screw the cap back on.

*In case of the swab with liquid transport medium – rinse in the collection medium by pressing the bottom of the collection tube several times.

*See subchapter What kind of self-collected vaginal swabs can be used?



*In case of the swab with a breaking point – place the swab inside the vial after collecting the specimen and breaking the handle at the breakpoint (do not cut the swab handle with scissors).

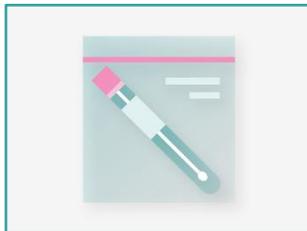
*See subchapter What kind of self-collected vaginal swabs can be used?



STEP 9: After collecting your specimen, discard any remaining packages/broken-off swab handle.



STEP 10: Wash your hands with soap and water.



STEP 11: Return the package to the assigned personnel.
The date and time of sample collection is noted.

If the participant is experiencing pain or brisk bleeding, please advise stopping the sampling immediately and informing the assigned personnel about this issue.

WHERE TO COLLECT HRHPV SELF-SAMPLING TEST?

1. at home,
2. at clinics/camp settings (the area with privacy, where the woman will feel comfortable).
3. Requirements in those areas include:
4. bed/cot/chair (easier access for inserting the swab),
5. bin to waste disposal,
6. provision for hand wash.

WHO SHOULD NOT UNDERGO HRHPV SELF-SAMPLING TEST?

Self-sampling should NOT be offered to:

- pregnant women,
- women with possible symptoms of cervical cancer (intermenstrual bleeding, postcoital bleeding, blood-stained underwear, lower back/pelvic pain or offensive watery discharge),
- women who have had a hysterectomy,
- a history of the high-grade squamous, intraepithelial lesion (HSIL) of the cervix.

If possible, taking the sample during the monthly period of women should be avoided.

WHAT INFORMATION SHOULD BE PROVIDED TO WOMEN?

All HCPs, CHWs, and other field workers should be aware of the main aspects of the procedure. HCPs should be able to address any questions or concerns that participants may have, as well as respond appropriately and effectively to any new situations that may arise.

Additional information should be provided, as follows:

- details on the supplies used in hrHPV self-testing,
- precise instructions to enable the woman to undertake a self-test,
- instructions for providers in accepting a self-swab, labelling the collection tube, sending and transporting.

WHAT KIND OF SELF-COLLECTED VAGINAL SWABS CAN BE USED?

For hrHPV detection, two types of vaginal samples can be used: a DRY swab and a WET swab (the type is always indicated on the package). A dry swab is put into a dry container after taking a vaginal swab. A wet swab is put into a container that contains a collection medium. For wet swabs, it is important to rinse the swab in the medium. See in Table 2 the types of platform, swab and medium used in individual project countries.

Table 2: Types of used platform, swab and medium per project country

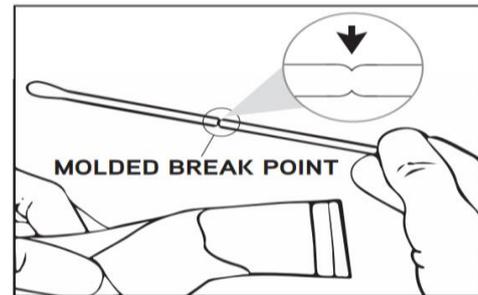
Country	Platform	Swab	Medium
Uganda	GeneXpert®	FLOQSwab®	PreservCyt®
Bangladesh	GeneXpert®	FLOQSwab®	PreservCyt®
India	GeneXpert® cobas®	FLOQSwab®	MSwab® PreservCyt® cobas®
Slovakia	cobas® 4800	FLOQSwab®	MSwab® cobas®

The vaginal FLOQSwab® intimate collection device is used for hrHPV self-sampling. These swabs are sterile, safe, and process-ready, and they are available in two variants (WITH and WITHOUT a breaking point) (Picture 1 and Picture 2).



Picture 1: Example of a swab with a marked breaking point

Source: copangroup.com



Picture 2: Example of a swab with a molded breaking point

Source: copangroup.com

It is critical that the instructions for collecting the hrHPV self-sample are simple, preferably with visual aids (see step by step instructions above). An important step in the self-sampling process is explaining to the participants how to collect their own samples using the manufacturer's instructions.

If participants are having difficulty taking the sample or would like to explain the instructions further, field workers should assist them with their best knowledge. They should also explain the significance of hrHPV testing to the woman, as well as the implications of the results, and ensure that the woman understands the explanation.

Obtaining a kit that includes a single-use swab as well as a collection tube is required for self-sampling.

WHAT TO BE CAUTIOUS OF?

1. The instructions for use must be followed carefully.
2. This product is intended for single use only – reuse is not permitted.
3. Not suitable for any other use than the intended one.
4. Not suitable to use if there is evidence of damage or contamination to the product (for example, if the swab tip or swab shaft is broken, the expiration date has passed or the swab kit is open).
5. Before collection, do not bend or shape the swab. Excessive force, pressure, or bending when collecting swab samples from patients may result in accidental breakage of the swab shaft.
6. All specimens must be handled and disposed of with appropriate precautions as clinical waste.

If the participants inadvertently touch Tip B, they can still take a sample.

If the participants inadvertently drop Tip B on a dry clean surface, they can still take a sample.

If the participants accidentally drop the Tip B or the swab on a wet or dirty surface, it is advised to request a new swab kit.

HOW SHOULD A HRHPV TEST BE STORED AND TRANSPORTED?

Storage and transport of the HPV specimen depends on the medium used in the individual project countries (Table 3).

Table 3: Storage and transport specifics of collected cervical specimen according to used medium

Medium	Storage temperatures	Storage time
MSwab®	20–25°C	processed within 14 days
	4°C	processed within 21 days
	-20°C	processed within 6 months
PreservCyt®	2–30°C	for up to 6 months after the date of collection
cobas®	2–30°C	for up to 6 months after the date of collection
dry swabs	20–25°C	maximum duration of 7 days
Cervical specimens can be transported at 20–30°C.		

ACKNOWLEDGMENT

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The manual was written with the assistance and guidance of a group of healthcare professionals, laboratory technicians, and people with hands-on experience with hrHPV self-testing.



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