

HPV screening & treatment solutions guide

This guide from the Partnership for Supply Chain Management (PFSCM) provides The Global Fund to Fight AIDS, Tuberculosis and Malaria's Principal Recipients (PRs) with a comprehensive overview of products available for human papillomavirus (HPV) sample collection, screening, and treatment of cervical precancerous lesions. All are available for procurement via wambo.org. The products included are aligned with World Health Organization (WHO) guidelines and compatible with leading diagnostic platforms.

Background

Cervical cancer remains one of the leading causes of cancer-related deaths among women in low- and middle-income countries (LMICs), accounting for about 94% of the 350,000 global cervical cancer deaths in 2022. The primary cause is persistent infection with high-risk HPV types, particularly HPV 16 and 18, which are responsible for about 70% of all invasive cervical cancers. Over 150 HPV types exist, but only a subset are considered high-risk for cancer development.

HPV, transmission, and disease progression

HPV is sexually transmitted, and nearly all sexually active individuals will acquire it at some point in their lives. Most HPV infections resolve on their own, but persistent infection with high-risk types can lead to precancerous changes in cervical

cells. If undetected and untreated, these changes may progress through stages, moving from low-grade lesions to high-grade lesions (which are precursors to cancer), and eventually to invasive cervical cancer. In immunocompetent women, this progression can take 15 to 20 years. However, for women with weakened immune systems, such as those living with HIV, the progression is faster, typically within 5 to 10 years.

Risk factors and vulnerable populations

The main risk factors for cervical cancer include:

- ▶ Persistent infection with high-risk HPV types.
- **Early initiation of sexual activity** and having multiple sexual partners can increase exposure to HPV.
- Smoking which weakens the local immune response.
- Immunosuppression, particularly due to HIV infection, raises the risk of HPV.

Women living with HIV face a higher risk of developing cervical cancer, being six times more likely to do so compared to HIV-negative women. HIV weakens the immune system, making it harder to clear HPV infections and accelerating the progression from HPV infection to cancer. This is particularly significant in sub-Saharan Africa and LMICs where both HIV and HPV are highly prevalent.



WHO cervical cancer elimination targets

The WHO has set ambitious global targets to eliminate cervical cancer as a public health problem. These include vaccinating 90% of girls with the HPV vaccine by age 15, screening 70% of women with a high-performance test by ages 35 and 45, and ensuring that 90% of women identified with cervical disease receive appropriate treatment. Achieving these targets will significantly reduce cervical cancer incidence and mortality worldwide.

WHO RECOMMENDATIONS FOR CERVICAL CANCER SCREENING, TESTING, AND TREATMENT

Timely access to reliable HPV diagnostics, sample collection tools, and treatment is essential in supporting countries to meet their elimination goals.

WHO emphasizes the use of molecular testing as a cornerstone for cervical cancer prevention, highlighting its superior sensitivity and specificity compared to traditional methods like cytology or visual inspection with acetic acid (VIA). Below are the key recommendations:

Primary Screening



HPV DNA TESTING: Recommended as the primary screening method for detecting high-risk HPV types associated with cervical cancer. This approach is preferred over VIA or cytology due to its higher reproducibility and ability to identify women at risk earlier.



TARGET POPULATION AND FREQUENCY: All women should be screened at least twice in their lifetime (at ages 35 and 45) with a high-performance HPV test. More frequent screening (every five years for women aged 30-65) is encouraged where resources allow.



SELF-COLLECTION: WHO endorses self-sampling for HPV testing. Self-collected samples are as accurate as clinician-collected ones and help increase screening uptake by offering privacy and convenience, particularly in low-resource settings.

Screen-and-treat approach



For women who test positive for high-risk HPV, WHO recommends immediate treatment of precancerous lesions using methods like thermoablation or cryotherapy. Loop Electrosurgical Excision Procedure (LEEP) may be necessary for larger lesions. Women living with HIV should be screened earlier and more frequently due to their higher risk of progression.

Screen, triage, and treat approach

In this approach, treatment decisions follow a positive primary screening test and a subsequent positive triage test, which may or may not involve a histologically confirmed diagnosis. While colposcopy with biopsy and histopathological examination are valuable for diagnosis, this guideline also accommodates triage strategies that don't rely on these potentially challenging-to-implement procedures.



Decision-making for ablative treatment: Visual Evaluation vs. VIA as screening

Thermal ablation is recommended for treating precancerous cervical lesions (CIN) in women who test positive for HPV or VIA and qualify for this treatment. WHO advises thermal ablation (or cryotherapy) as the primary option, while Large Loop Excision of the Transformation Zone (LLETZ) or LEEP can be alternatives for those not eligible for ablation.

When deciding on ablation after a positive HPV test, it is crucial to differentiate between two processes: Visual Evaluation for treatment eligibility and using VIA as a primary screening tool.

- In the HPV screen-and-treat approach, women who test positive for HPV undergo a visual evaluation to assess their eligibility for ablation. Only those who meet specific visual criteria receive treatment, while others may be referred for further procedures.
- In the HPV screening strategy, VIA acts as a secondary test where HPV-positive women who also test positive with VIA may be treated with ablation, while those who are HPV positive but VIA negative are monitored instead. This process minimizes unnecessary treatments and improves patient outcomes.



PRODUCT CATALOG: cervical cancer screening and treatment solutions available through PFSCM

This section provides a comprehensive catalog of cervical cancer screening and treatment solutions available through PFSCM.

PRs can utilize this resource to identify and procure the necessary supplies, equipment, and test kits to implement cervical cancer prevention programs effectively. Each product listing includes relevant details to facilitate informed procurement decisions.

Sample collection devices

Sample collection is a critical component of effective HPV testing. PFSCM provides validated collection kits tailored to each diagnostic platform and test protocol.

TABLE 1: HPV collection devices & mediums

Manufactfurer	PFSCM SKU	Product Name	Product Type	Platform/Test Compatibility	
Abbott	106047	Abbott Cervi-collect Specimen Collection Kit	Collection Device and Mediums	Abbott m2000 (RealTime HR HPV)	
	106249	Alinity m Cervi-collect Specimen Collection Kit	Collection Device and Mediums	Alinity m (HR HPV AMP Kit)	
Copan	106142	Self Vaginal FLOQSwabs	Collection Device	Cepheid GeneXpert Systems (Xpert HPV) Roche cobas 4800/5800/6800/8800 (cobas HPV) BD Viper LT (Onclarity HPV) Abbott m2000 (RealTime HR HPV) Alinity m (HR HPV AMP Kit)	
Hologic	105827	Aptima Cervical Specimen Collection and Transport Kit	Collection Device and Mediums	Hologic Panther (Aptima HPV)	
	107680	Nylon Flocculated Cervical Swabs, 5 pieces	Collection Device	True Lab Uno Dx True Lab Duo	
Miraclean Technology	107682	Nylon Flocculated Cervical Swabs, 20 pieces	Collection Device		
	107684	Nylon Flocculated Cervical Swabs, 25 pieces	Collection Device	TrueLab Quatro	
Qiagen	105242	careBrush	Collection Device	Qiagen careHPV test systems	
	105241	careHPV Collection Medium	Transport Mediums		
	106100	Roche Cervical Collection Brush (Bulk)	Collection Device	Roche cobas 4800/5800/6800/8800 (cobas HPV)	
Roche	106140	Roche Cervical Collection Brush (Sterile)	Collection Device		
	106094	Roche Cell Collection Medium	Transport Medium		
Rovers Medical Devices	106144	Evalyn Brush	Collection Device	BD Viper LT (Onclarity HPV)	
Rovers Medical Devices	106715	Cervex Brush-Combi	Collection Device	BD Viper LT (Onclarity HPV)	
Rovers Medical Devices	100949	Cervex Sampling Brush	Collection Device	Cepheid GeneXpert Systems (Xpert HPV)	
Becton Dickinson (BD)	106713	SurePath	Transport Mediums	Roche cobas 4800/5800/6800/8800 (cobas HPV) Abbott m2000 (RealTime HR HPV) Alinity m (HR HPV AMP Kit) BD Viper LT (Onclarity HPV) Hologic Panther (Aptima HPV)	
Hologic	100951	PreservCyt/ThinPrep	Transport Mediums	Roche cobas 4800/5800/6800/8800 (cobas HPV) Abbott m2000 (RealTime HR HPV) Alinity m (HR HPV AMP Kit) Cepheid GeneXpert Systems (Xpert HPV) BD Viper LT (Onclarity HPV) Hologic Panther (Aptima HPV)	



Reagent and consumable bundles for simplified procurement

PFSCM has organized some automated molecular platform reagents and consumables into "bundles" by platform to streamline the ordering process, reduce errors, and simplify delivery planning. PFSCM's reagent and consumable bundles are not a pre-packed physical kit, but rather a virtual grouping of all the individual stock-keeping units (SKUs) needed to perform a specific diagnostic test or operation on a particular platform.

These bundles are integrated into PFSCM's supply chain control tower, OneNetwork, and mapped to their corresponding SKUs. As a result, when a client selects a single bundle item, it automatically includes all the necessary kits, controls, system reagents, and consumables in the correct quantities for the specified number of tests. This approach simplifies ordering by allowing the user to choose one bundle item and indicate the number of tests required, rather than having to identify and order each SKU separately, thereby reducing confusion and the risk of missing components. The table below lists the available HPV bundles:

TABLE 2: HPV reagent and consumable bundles for automated molecular platforms

Product Bundle	Platform	Manufacturer	PFSCM SKU
cobas 4800 HPV Kit and Consumable Bundle - 960 Tests	cobas 4800	Roche -	B10205
cobas 4800 HPV Kit and Consumable Bundle -240 Tests	cobas 4800		B10206
cobas 5800 HPV Kit and Consumable Bundle - 480 Test	cobas 5800		B10174
cobas 6800/8800 HPV Kit and Consumable Bundle - 480 Tests	cobas 6800/8800		B10175
m2000 High-Risk HPV AMP Kit and Consumable Bundle - 96 Tests	m2000	Abbott	B10176
Alinity m HR HPV AMP Kit and Consumable Bundle - 384 Tests	Alinity m	Abbott	B10207
Truenat HPV-HR Reagent Bundle - 5 Tests	True Lab Uno Dx		B10208
Truenat HPV-HR Reagent Bundle - 20 Tests	True Lab Duo	Molbio	B10209
Truenat HPV-HR Reagent Bundle - 25 Tests	TrueLab Quatro		B10210

^{*}Individual reagents and consumables are available upon request.



Other HPV test kits and reagents

Not all HPV tests available through PFSCM are offered as bundled reagent and consumable packages. Some tests must be ordered as individual components, requiring users to select and procure each necessary item, such as the test kit, and reagents, separately.

TABLE 3: Other HPV test kits and reagents

Item	Platform	Manufacturer	PFSCM SKU
Hologic Kit Calibrators Aptima HPV, Kit of 5 Vials			105833
Aptima HPV DNA Assay, Kit of 100 Tests	Panther System	Hologic	105825
Hologic Kit Box 1 HPV 100T, Kit of 100 Tests			105831
Hologic Kit Box 2 HPV, Kit of 100 Tests			105835
Xpert HPV Assay, Kit of 10 Tests	GeneXpert Systems	Cepheid	101270
careHPV Test, Kit of 96 Tests		Qiagen	102095

PFSCM continuously updates its list of reagents and consumables to reflect the latest product availability and improvements. We encourage clients to regularly contact PFSCM to confirm the most current catalog information and ensure they have access to the newest and most suitable products for their needs.

Treatment solutions for cervical lesions

In addition to diagnostic tools for early detection of cervical cancer risk factors via HPV testing platforms, PFSCM provides treatment solutions for cervical precancer management. These treatment options align with WHO recommendations for ablative therapy and excision of precancerous lesions in low-resource settings. They are portable, easy to use, suitable for primary healthcare and mobile outreach, and enable immediate treatment of women who test positive for high-risk HPV, strengthening the efficacy and reach of "screen-and-treat" strategies.

TABLE 4: Thermal ablation and LEEP devices for cervical precancer treatment

Product Name	Device Type	Manufacturer	Use	PFSCM SKU
Liger HTU110	Thermal Ablation	Liger		100952
Wisap C3 ECO4	Thermal Ablation	Wisap	Cervical Precancer Treatment	106558
Liger ESU110 (LEEP)	LEEP Device	Liger		107023



Surgical accessories and visual assessment tools for cancer screening and treatment

PFSCM supports a range of essential medical supplies and facilitates the provision of surgical accessories and visual assessment tools critical for cancer screening and treatment.

Here's a summary of those tools and their importance:

- Cervical biopsy kit: contains instruments for collecting cervical tissue samples to detect precancerous or cancerous conditions.
- Electrosurgery system: cuts or coagulates tissue with high-frequency electrical current, minimizing blood loss during cancer surgeries.
- LOOP electrodes: used with electrosurgery for precise tissue excision in procedures like LEEP for cervical issues.

- Forceps (various types): grasps, manipulates, and removes tissue samples during biopsies and surgeries.
- Speculum vaginal graves: widens the vaginal opening for clear cervix visualization during examinations and procedures.
- **Examination lamp:** provides bright, focused light during examinations and procedures for accurate visualization.
- Kidney tray: holds surgical instruments during medical procedures.

TABLE 5: Surgical accessories and visual assessment tools

PFSCM SKU	Product	
102746	Electrosurgery System	
106983	Tishler Biopsy Punch, 10" (254mm)	
102757	Forceps Tissue for electrosurgery, 203mm	
104334	Loop Electrode 25x10mm, Disposable, Pack of 5 Pieces	
104335	Loop Electrode 10x5 mm, Disposable, Pack of 5 Pieces	
104333	Loop Electrode 20x12mm, Disposable, Pack of 5 Pieces	
104324	Forceps Lletz Pederson for electrosurgery, 22x102mm	
104330	Forceps Lletz Graves for electrosurgery, 35x 102mm	
104331	Lletz Lateral Vaginal Wall Retractor, Closed 254mm, Large Blades	
104322	Speculum Vaginal Graves for electrosurgery, 35x121mm	
106981	Foerster Dressing Forceps, 9.5" (241mm), Straight with S	
102765	Examination Lamp	
104327	Forceps Tishler Biopsy Punch Titanium for electrosurgery, 254mm	
104326	Kidney Tray, 203mm	
102770	Cervical Biopsy Kit, Pack of 1 Kit	



PROCUREMENT PATHWAY: How to Order



requisition or product

technical-related support.



Prequalified clients can log in to the HealthSupply Portal to view the full product catalog and place orders directly.

Contact PFSCM for more information on pfscm@pfscm.org

Additional resources

through your PR channel.

UNITAID, Clinton Health Access Initiative (CHAI), and UNICEF provide details on ablation device global pricing agreements TA-Fact-Sheet Draft-29022024.pdf

products

for efficiency.

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NEED HELP?

PFSCM's technical team is available to validate product compatibility with your program and recommend the correct bundles and other products.

