

WESTERN CAPE CERVICAL CANCER SCREENING GUIDELINES

1. Background and rationale

Cervical cancer remains a significant health challenge in South Africa, where it is the leading cause of cancer-related deaths among women. Despite advances in global cancer prevention and screening, South Africa continues to face a disproportionately high cervical cancer incidence and mortality rate. In 2023, an estimated 10 702 women were diagnosed with cervical cancer in South Africa, with 5 870 women dying from the disease. This is particularly concerning given that cervical cancer is largely preventable through vaccination and effective screening. These statistics highlight the ongoing struggle to achieve a significant reduction in the incidence of cervical cancer through cytology-based screening alone. The World Health Organization (WHO) also recognized cervical cancer as a serious health problem and through its Global Call to Action, urges countries to eliminate cervical cancer as a public health problem by 2030 through effective vaccination, screening, and treatment strategies.

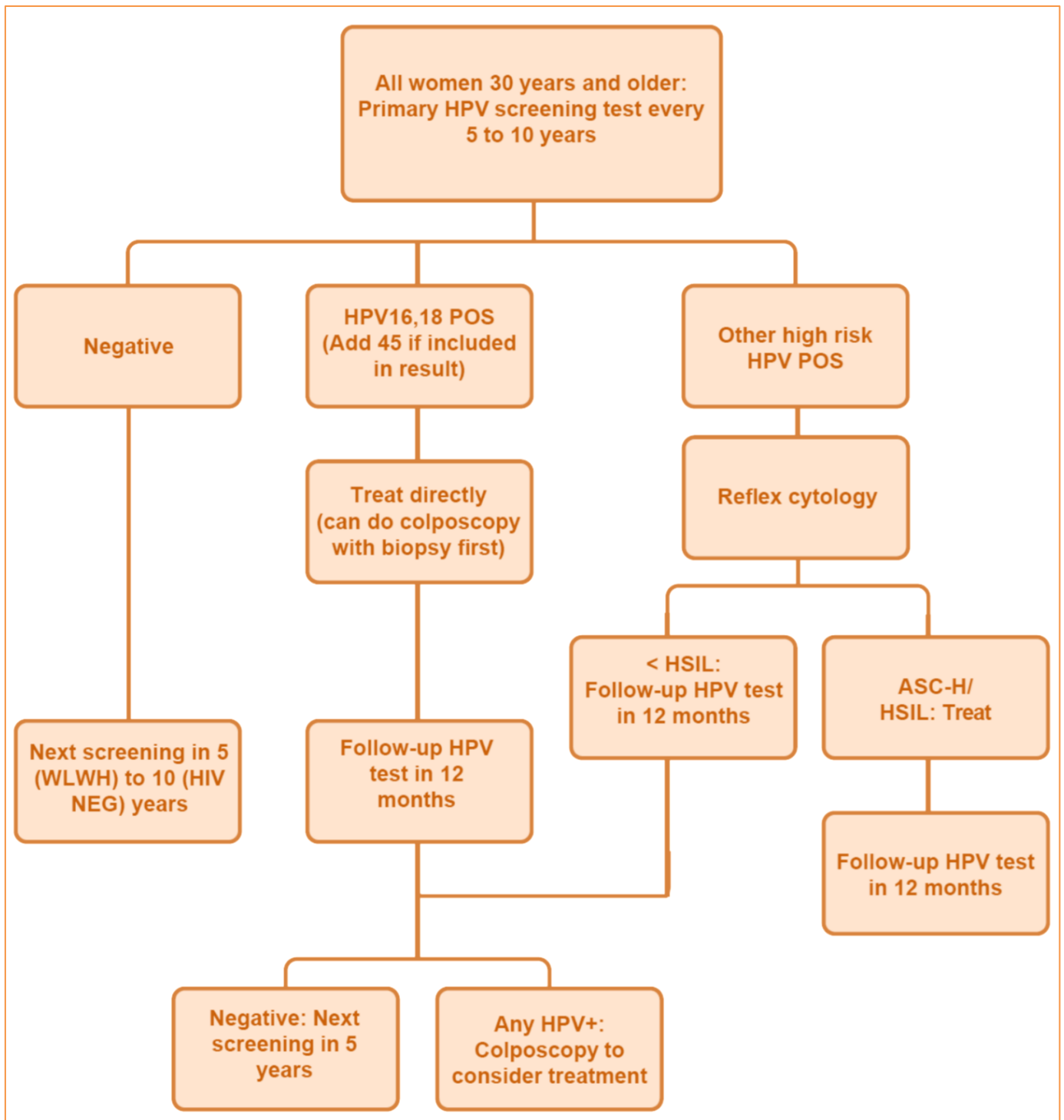
The primary cause of cervical precancer and cancer is persistent infection with high-risk (hr) human papillomavirus (HPV), particularly types 16, 18, and 45. HPV is one of the most common sexually transmitted infections globally, affecting approximately 70-80% of sexually active women at some point in their lives with at least one strain of the virus.

Cervical cytology, through the Papanicolaou (Pap) smear test, has been a cornerstone in the prevention and early detection of cervical cancer. Despite its proven efficacy in reducing cervical cancer incidence and mortality in high-income countries, the same success, however, has not been uniformly replicated in low- and middle-income countries (LMICs), such as South Africa. Cervical cytology as a screening test suffers from relatively low sensitivity, resulting in false negatives. This limitation means that many precancerous lesions might not be detected in time for effective intervention. HPV DNA testing represents a significant advancement over traditional cytology for screening due to its superior sensitivity, making it a more effective tool for the detection of high-grade intra-epithelial lesions of the cervix. This method has a high negative predictive value (NPV) nearing 100%, which allows for safe longer intervals between screening tests for those with negative results. As a result, HPV testing reduces the need for frequent follow-up visits, ultimately proving to be more cost-effective compared to cytological screening.

This guideline provides a brief overview of the HPV DNA screening algorithm proposed for the Western Cape. A more detailed, comprehensive guideline will be made available in the coming months to further support its integration into the provincial cervical cancer screening programme.

2. HPV screening algorithm

The proposed HPV screening algorithm is as follows:



Abbreviations: ASC-H, atypical squamous cells - cannot exclude high-grade squamous intraepithelial lesion; HPV, human papillomavirus; hrHPV, high-risk human papillomavirus; HSIL, high-grade squamous intraepithelial lesion; NEG, negative; POS, positive; WLWH, women living with human immunodeficiency virus (HIV)

In summary:

All women aged **30 years and older**: Primary HPV screening test every 5 to 10 years.

Screening results can be categorized into three risk levels:

- Low risk: Negative for hrHPV types.
- Intermediate risk: Positive for hrHPV types but not HPV 16, 18, or 45.
- High-risk: Positive for HPV types 16, 18, or 45.



Management recommendations:

- If negative (low risk):
 - Next screen in 5 years for WLWH.
 - Next screen in 10 years for HIV-negative women.
- If other hrHPV positive (non-16/18/45) (intermediate risk):
 - Perform reflex cytology:
 - If result is less than HSIL (e.g., ASCUS, LSIL): Follow-up HPV test in 12 months.
 - If result is ASC-H or HSIL: Proceed to treatment.
 - Follow-up HPV test in 12 months after treatment:
 - If negative: Next screen in 5 years.
 - If any hrHPV positive: Refer for colposcopy to consider treatment.
- If HPV 16, 18, or 45 positive (high risk):
 - Patient should be referred for immediate treatment.
 - Colposcopy with biopsy may be performed before treatment but is not mandatory.
 - Follow-up HPV test in 12 months after treatment.
 - If negative: Next screen in 5 years.
 - If positive for any HPV: Refer for colposcopy to consider further treatment.

3. National Health Laboratory Services

3.1 Screening results turnaround time:

HPV Test Results: Typically, available within 72 hours after the specimen is received in the laboratory. However, it may take up to 7 days for the healthcare worker to receive the results.

Liquid-Based Cytology: Results are usually available within approximately 14 days.

3.2 Laboratory request form:

The healthcare worker should select the **HPV PCR screen/reflex cytology** option. Reflex cytology will **only** be performed if the patient tests negative for HPV 16, 18, and 45 but positive for other hrHPV types, in which case the laboratory technician will flag the sample for further analysis.

SPECIMEN TYPE / TEST	
<input type="checkbox"/>	Conventional Smear
<input type="checkbox"/>	Liquid Based Cytology
<input type="checkbox"/>	HPV PCR Screen
<input type="checkbox"/>	HPV PCR Screen / Reflex Cytology
<input type="checkbox"/>	Self Collected Sample
<input type="checkbox"/>	Other (please specify) _____



3.3 Results interpretation

If the screening result is negative, follow-up testing should occur in 5 years for WLWH and 10 years for HIV-negative women.

TrakCare Lab Web Results Viewer

NATIONAL HEALTH LABORATORY SERVICE Boitumelo Regional Hospital, Small Deel Road, Kroonstad, FS, 9500
Tel: 056 212 2169/2160, Fax: 056 213 1300

KROONSTAD LABORATORY

Practice Number 5200296 pg 1 of 1

FULL FINAL LABORATORY REPORT

PATIENT: **REPORT TO:**

Collected: 06/01/2025 09:00 SR MOKOENA
Received: 07/01/2025 22:10 Ward not stated
1st Print: 10/01/2025 08:26 Phedisong Clinic
Reprint: 10/03/2025 13:33 PO Box 23
Villiers
Free State
9840

Patient Location: Phedisong Clinic, Ward not stated
Hospital Number:

DISCLAIMER: If the date or time of collection is not included on the request form or the sample does not meet our laboratory requirement for collection, transport and processing, caution should be exercised when interpreting results as their accuracy cannot be guaranteed. Absent clinical details may affect the laboratory's interpretation of results.

FOR ENQUIRIES AND FOLLOW-UP TESTS, PLEASE QUOTE PATIENT'S MRN NUMBER

VIROLOGY

Specimen received: Cervical smear (Cervix)
Tests requested: HPV PCR Cervical Screen @
@ Test referred to another NHLS laboratory

Human Papillomavirus Investigations:

Human Papillomavirus (HPV) PCR Cervical Screen:

HR HPV Result HR HPV NOT detected

HR HPV Types Tested:

HR HPV 16 NOT detected
HR HPV 18 NOT detected
HR HPV 45 NOT detected
HR HPV NOT detected: genotypes 31/33/52/58
HR HPV NOT detected: genotypes 35/39/51/56/59/66/68

Recommendation Rescreen after ten years if HIV negative. Rescreen after five years if living with HIV or if clinically indicated.

Method comment The Alinity m HR HPV AMP assay can detect 14 HR HPV genotypes: 16, 18, 45, 31/33/52/58 and 35/39/51/56/59/66/68.

@ HPV PCR Cervical Screen referred to Universitas Academic Laboratory (Tel 051 405 3162)

Authorised by: Dr JC Kotze (Pathologist) HPV PCR Cervical Screen

-- End of Laboratory Report --

If other hrHPV types (excluding 16, 18, and 45) are detected, reflex cytology will be performed. The cytology result will guide the next steps: if the result is less than HSIL, follow-up HPV testing should occur in 12 months, and if the result indicates ASC-H or HSIL, referral for colposcopy should be considered.

FULL FINAL LABORATORY REPORT

PATIENT:

REPORT TO:

Collected: 10/12/2024 ?
Received: 10/12/2024 16:35
1st Print: 07/01/2025 08:15
Reprint: 10/03/2025 13:45

Dr Y. VALDEZ CRESPO
Casualty
Phekolong Hospital
Private Bag X3
Bethlehem
Free State
9700

Patient Location: Phekolong Hospital, Casualty
Hospital Number:
HPRN:

DISCLAIMER: If the date or time of collection is not included on the request form or the sample does not meet our laboratory requirement for collection, transport and processing, caution should be exercised when interpreting results as their accuracy cannot be guaranteed. Absent clinical details may affect the laboratory's interpretation of results.

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@ Test referred to another NHLS laboratory

Human Papillomavirus Investigations:

Human Papillomavirus (HPV) PCR Cervical Screen:

HR HPV Result HR HPV detected

HR HPV Types Tested:

HR HPV 16 NOT detected
HR HPV 18 NOT detected
HR HPV 45 NOT detected
HR HPV NOT detected: genotypes 31/33/52/58
HR HPV detected, not differentiated: one or more of
genotypes 35/39/51/56/59/66/68

Recommendation This sample was sent to cytology for further testing. This HPV result will be interpreted in combination with the cytology result, and an integrated recommendation will be provided.

Method comment The Alinity m HR HPV AMP assay can detect 14 HR HPV genotypes: 16, 18, 45, 31/33/52/58 and 35/39/51/56/59/66/68.

@ HPV PCR Cervical Screen referred to Universitas Academic Laboratory (Tel 051 405 3162)

Authorised by: Dr S Maphumulo (Pathologist) HPV PCR Cervical Screen

For HPV 16, 18, or 45-positive results, these types are strongly associated with a risk to develop cervical cancer, and immediate referral to a colposcopy clinic for further evaluation is necessary. A follow-up HPV test should be conducted 12 months after initial treatment, with further action determined based on the result.

FULL FINAL LABORATORY REPORT

PATIENT:

REPORT TO:

Collected: 06/11/2024 16:00
Received: 07/11/2024 18:53
1st Print: 10/11/2024 18:00
Reprint: 10/03/2025 13:52

SR MOSEA MA
Ward not stated
Phuthaditjhaba PHC Clinic
Private Bag X824
Phuthaditjhaba
Free State
9866

Patient Location: Phuthaditjhaba PHC Clinic, Ward not stated
Hospital Number:
HPRN:

DISCLAIMER: If the date or time of collection is not included on the request form or the sample does not meet our laboratory requirement for collection, transport and processing, caution should be exercised when interpreting results as their accuracy cannot be guaranteed. Absent clinical details may affect the laboratory's interpretation of results.

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Tests requested: HPV PCR Cervical Screen @
@ Test referred to another NHLS laboratory

Human Papillomavirus Investigations:

Human Papillomavirus (HPV) PCR Cervical Screen:

HR HPV Result HR HPV detected

HR HPV Types Tested:

HR HPV 16 detected
HR HPV 18 NOT detected
HR HPV 45 NOT detected
HR HPV detected, not differentiated: one or more of
genotypes 31/33/52/58
HR HPV NOT detected: genotypes 35/39/51/56/59/66/68

Recommendation This sample is positive for one or more of the following HPV genotypes: 16, 18, or 45. Please refer the patient for colposcopy and further management according to the provincial guidelines.

Method comment The Alinity m HR HPV AMP assay can detect 14 HR HPV genotypes: 16, 18, 45, 31/33/52/58 and 35/39/51/56/59/66/68.

@ HPV PCR Cervical Screen referred to Universitas Academic Laboratory (Tel 051 405 3162)

Authorised by: Dr JC Kotze (Pathologist) HPV PCR Cervical Screen

DEPARTMENT OF ANATOMICAL PATHOLOGY

Specimen received: Cervical smear (Cervix)
Tests requested: Gynaecological screening @
@ Test referred to another NHLS laboratory

CYTOPATHOLOGY REPORT

Cytology Number: HUYG/24-24124477-A
National screening program: NOT Indicated
Specimen Type: LBC

Clinical history

Yellow discharge noted

Satisfactory for evaluation: Yes with endocervical component absent / insufficient.

Final diagnosis: Negative for intraepithelial lesion or malignancy (NILM).

Ancillary testing: HPV testing has been performed
HR HPV Screening result: HR HPV detected

Recommendation: Rescreen after 1 year.

@ Gynaecological screening referred to Universitas Academic Laboratory (Tel 051 405 2805)

Authorised by: H Van Wyk (Medical Technologist) Gynaecological screening

-- End of Laboratory Report --

NB: Treatment decisions will be made by the clinician, and detailed treatment guidelines will be issued in a separate document in the coming months.

Screening eligibility and clinical management

This guideline is **specifically designed for asymptomatic women aged 30 years and older** for the **purpose of cervical cancer prevention through HPV DNA screening**. It is important to note that if a younger woman or a woman presenting with symptoms (such as abnormal vaginal bleeding, pelvic pain, or unusual discharge) reports to a healthcare facility for medical care, the necessary clinical steps must be taken to ensure appropriate care. In such cases further diagnostic investigation should be conducted. This may include clinical evaluation, an HPV DNA test, cervical biopsy, colposcopy or other appropriate investigations.

This guideline is not intended to replace clinical management for symptomatic women, and those presenting with symptoms should follow appropriate clinical pathways to ensure timely diagnosis and treatment.

Conclusion

The implementation of HPV DNA-based screening represents an important step forward in the fight against cervical cancer in South Africa. By adopting a more sensitive and cost-effective screening method, we can enhance early detection, reduce the burden of cervical cancer, and ultimately save lives. This guideline provides a foundation for the integration of HPV DNA testing into the provincial screening programme, aligning with global efforts to eliminate cervical cancer as a public health problem. Continued commitment to improving screening accessibility, education, and follow-up care will be essential to achieve significant progress in reducing cervical cancer incidence and mortality. As more comprehensive guidelines are developed and implemented in the coming months, it is essential that healthcare providers, policymakers, and communities work together to ensure that all women, particularly those at higher risk, benefit from the advances in cervical cancer prevention.