



National Cervical Screening Programme

**Operational Policy and Quality Standards for High-Risk
Human Papillomavirus (HrHPV) Testing
(interim)**

NCSP Operational Policy and Quality Standards for High Risk Human Papillomavirus (HrHPV) testing

This document brings together NCSP Operational Policy and Quality Standards relating to the provision of high-risk human papillomavirus (HrHPV) testing, as per the Guidelines for Cervical Screening in New Zealand (2008).

**Primary
objective of
high risk
human
papillomavirus
testing**

The primary objective of high risk human papillomavirus (HrHPV) testing is to provide ancillary testing to cytology to detect the presence of HrHPV subtypes which increase risk of developing high grade or worse lesions of the cervix.

All processing, evaluation and reporting of HrHPV testing must be performed on pathology laboratory premises.

HrHPV Testing Policy

Purpose To ensure that cytology LBC samples are accurately processed and tested for high risk human papillomavirus (HrHPV) using a validated test procedure.

Policy HrHPV testing of LBC samples must be carried out using approved and validated processes and used in accordance with manufacturer instructions. Laboratories must conduct adjunct HrHPV testing to cytology as defined in the Guidelines for Cervical Screening in New Zealand, incorporating guidelines for HrHPV testing.

Details Please note the following:

- the test procedure must be endorsed by an internationally recognised accreditation agency such as FDA or be CE marked and/or
- internally clinically validated to meet at least the performance of internationally validated tests¹
- sensitivity of the test for the detection of CIN2 or worse in women 30 years or over must be at least 90%
- appropriate controls must be included and the outcomes documented and stored
- the HrHPV test must test for a minimum of 13 most common HrHPV subtypes
- LBC samples only are recommended for HrHPV testing. The HrHPV test procedure must be validated (internationally or in-house) for each LBC product being tested
- sampling, collection, transport, volume, and storage of LBC samples for HrHPV testing must be in accordance with manufacturers' recommendations or with a suitably validated process
- all staff performing HrHPV testing must demonstrate competency in performing the test procedure and issuing results
- results must be reported to the NCSP-Register in approved format as either *HrHPV detected*, *not detected* or *invalid test*
- cytology with adjunctive HrHPV testing should be reported together or the cytology reported in consideration of the HrHPV test result
- turnaround times are defined under standards 513 and 518
- swabs are not recommended for NCSP funded HrHPV testing where LBC is available. If a laboratory does not provide LBC for HPV testing, advice as to the type of HPV swab to be used must be provided.

¹ Example of validation procedure:

Seabrook JM and Hubbard RA. Achieving Quality Reproducible Results and Maintaining Compliance in Molecular Diagnostic Testing of Human Papillomavirus. *Arch Pathol Lab Med.* 2003;127:978–983 (reference to Clinical Laboratory Improvement Amendments (CLIA)).

Staffing Policy

Staff reporting on HrHPV testing must be appropriately trained and qualified.

Accreditation Policy

Purpose To ensure that all laboratories providing services for the NCSP are accredited.

Policy All laboratories providing services for the NCSP must be accredited by International Accreditation New Zealand (IANZ) for provision of gynaecological cytology, and/or histology services.

Details Laboratories must inform the Ministry of Health of the results of the IANZ assessment (both the annual surveillance process and the four yearly reassessment) and any change to their accreditation status.

IANZ must also inform the Ministry of Health at the time of informing the laboratory if there is any change in accreditation status.

A laboratory considering introducing new tests or technologies into the cervical screening pathway must first:

- notify the NCSP that the test or technology is under consideration
- ensure that the test or technology has been appropriately validated. This includes approval of all sites partaking in multi-site processing (hub and spoke arrangements)
- ensure that the test or technology has been notified to IANZ in accordance with requirements of their contract
- communicate to smear takers any transition to new tests or technologies well in advance of implementation, to allow ample time for smear takers to clarify the implications of any changes.

Internal Quality Assurance Policy

Purpose Internal quality control for a laboratory is an essential component of quality assurance for the NCSP.

The purpose of internal quality control systems is to:

- identify potential sources of error in the laboratory's operation
 - implement controls to detect and minimise errors, particularly false negative and false positive results
 - implement improvements to operational processes, especially when the need for remedial action has been identified.
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Policy Laboratories must have policies and practices that ensure the quality of gynaecological cytology, HrHPV testing and histology. Policies must define staff responsibilities and laboratory procedures.

Laboratories must ensure that:

- staff appointed are appropriately qualified and experienced
- staff achieve and maintain competency in the tasks they perform
- high quality and accurate systems are in place for reporting, including mechanisms for ensuring data integrity throughout all key steps in the preparing, reading and reporting process
- NCSP approved Bethesda coding system for reporting cytology and the SNOMED system for classifying histology results are used
- control processes are in place to ensure that the reporting requirements of the Health (National Cervical Screening Programme) Amendment Act 2004 and the Cancer Registry Act 1993 are met
- satisfactory internal systems for quality control and quality improvement are in place, including monitoring of data entry.

External Quality Assurance Policy

Purpose The objectives of external quality assessment schemes are to promote uniformly high standards of diagnostic reporting including adjunct testing (eg HrHPV testing) at each laboratory.

Policy In accordance with accreditation requirements, laboratories providing gynaecological cytology, HrHPV testing and/or histology services for the NCSP must participate to a satisfactory standard in an appropriate external quality assurance programme.

Details The external quality assurance programme must include:

- assessment against quantitative performance standards accepted by the NCSP, such as the Royal College of Pathologists of Australasia (RCPA) Quality Assurance Program
- external quality assurance reports, outcome measures and action sheets, which must be retained and made available to audit bodies
- laboratories are expected to use external quality assurance reports as part of their own quality control processes
- where there is an individual external quality assurance programme approved by the NCSP, this will be compulsory for individual participants
- individual external quality assurance programmes must include an appropriate mix of conventional smears and LBC slides for the mix of workload of the staff member (e.g. staff reporting 60% of conventional slides should see a ratio of three conventional smears for every two LBC slides).

As there are several HrHPV tests either already commercially available or in the process of becoming available, laboratories are expected to participate in external quality assurance to ensure competency in HrHPV testing e.g. through the RCPA, WHO reference laboratory or other appropriate body.

Reporting to Smear Takers and Specialists Policy

Purpose That HrHPV test samples are reported in the correct format to the right recipients in a timely manner.

Policy Laboratories must have in place protocols and procedures to ensure that all: HrHPV test samples received by the laboratory are reported to the smear taker and the NCSP-Register for all women residing in New Zealand at the time the sample was taken.
Conjunct cytology and HrHPV tests should be reported to the smear taker at the same time.

513: Reporting Gynaecological Cytology and HrHPV Test Results Standard

Standard Laboratories are required to report **90% of final gynaecological cytology results to smear takers within seven working days of receiving the specimen.**

Laboratories are required to report 100% of final gynaecological cytology results and HrHPV test results to smear takers within 15 working days of receiving the specimen.

Results for cytology and conjunct HrHPV tests should be reported together to the smear taker.

Target That laboratories report:

- 90% of the final gynaecological cytology results to smear takers within seven working days of receiving the specimen
- 100% of the final gynaecological cytology results **and HrHPV test results** to smear takers within 15 working days of receiving the specimen.

Measurement The following methods of measurement are used:

- Monitoring Reports
- NCSP-Register data
- provider compliance audits.

Forwarding Results to the NCSP-Register Policy

Purpose To ensure that the NCSP-Register receives all HrHPV test results.

Policy Laboratories must have processes in place for ensuring that all HrHPV test results are forwarded in the correct format to the NCSP-Register.

Details Results must be forwarded in the agreed codes and electronic format. HrHPV tests are reported as detected, not detected, or invalid.

Results sent through HL7 messaging must be accompanied by the matching laboratory referral form.

All electronic data must be accompanied by the matching laboratory referral forms containing the following information:

- full name
- date of birth
- address
- stated ethnicity (if available)
- NHI number
- previous screening event history (if not already recorded on the NCSP-Register)
- the identity of the smear taker or specialist according to their correct smear taker/specialist and health centre code.

HL7 messaging and electronic data must be formatted in accordance with the 'NCSP – Register Implementation Guide' (cytology, histology and HrHPV file format) distributed to the laboratories by the National Screening Unit.

Notes:

- If the NCSP-Register rejects the result provided by the laboratory, the laboratory must review the result and amend where necessary. The laboratory must then resend the result to the NCSP-Register.
- It is the smear taker's responsibility to gain the consent of a woman who has previously opted off/withdrawn from the NCSP, to have her previous screening event history sent to the NCSP-Register.

518: Sending Cytology Results to the NCSP-Register Standard

Standard All cytology results and HrHPV test results must be forwarded to the NCSP-Register, in the approved format and Bethesda coding, within 16 working days of receipt of specimen.

Target That 100% of the cytology results and HrHPV test results are forwarded to the NCSP-Register, in the approved format and Bethesda coding, within 16 working days of receipt of specimen.

Measurement The following methods of measurement are used:

- Independent Monitoring reports
 - NCSP-Register data
 - provider compliance audits.
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Providing Advice to Smear Takers Policy

Purpose To promote the laboratory's role in providing advice to smear takers, with the aim of improving the quality of smear taking.

Policy The laboratory must provide advice to smear takers on ways to improve the quality of smear taking.

Details Pathologists and senior cytoscientists must be readily available to advise smear takers regarding:

- the suitability/adequacy of gynaecological cytology and HrHPV test samples
- terminology of gynaecological cytology reports
- terminology of HrHPV test reports
- the clinical significance of the laboratory results
- further procedures or investigations that may be helpful
- updates and changes.
