NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

REQUIREMENTS FOR LABORATORIES REPORTING TESTS FOR THE NATIONAL CERVICAL SCREENING PROGRAM

(First Edition 2017)

NPAAC Tier 4 Document

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First edition 2017 — First edition that supersedes the *Requirements for Gynaecological (Cervical) Cytology* and *Performance Measures for Australian Laboratories Reporting Cervical Cytology*.

Australian Government Department of Health

Contents

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to advise the Australian, state and territory governments on matters relating to the accreditation of pathology laboratories. A key role of NPAAC is to develop and maintain pathology quality standards for accreditation. NPAAC also advises on pathology accreditation policy initiatives and initiates and promotes education programs about quality in the provision of pathology services.

Publications produced by NPAAC are issued as accreditation materials to provide guidance to medical pathology laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a potential risk to public health and patient safety.

Scope

The *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (First Edition 2017)* is a Tier 4 NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services* and the Tier 4 document *Requirements for Medical Testing of Microbial Nucleic Acids.* The *Requirements for Medical Pathology Services* is the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.

Whilst there must be adherence to all the Requirements in the Tier 2 document, reference to specific Standards in that document are provided for assistance under the headings in this document.

This document sets out the standards for using HPV nucleic acid testing (NAT) as the primary screening method for cervical cancer screening with reflex liquid based cytology (LBC) in cases positive for oncogenic HPV types.

Testing of self-collected specimens, of symptomatic women and in the post-treatment setting has also been considered.

Abbreviations

AIMS	Australian Institute of Medical Scientists
AIS	Adenocarcinoma in situ
AS	Australian Standard
ASC	Australian Society of Cytology
CIN	Cervical intraepithelial neoplasia
CTASC	Certificate of Cytotechnology of the Australian Society of Cytology
HC2	Hybrid Capture 2
HPV	Human Papillomavirus
HPV NAT	HPV nucleic acid testing
HSIL	High grade squamous intraepithelial lesion
LBC	Liquid based cytology
LSIL	Low grade squamous intraepithelial lesion
NATA	National Association of Testing Authorities, Australia
NCSP	National Cervical Screening Program
NCSR	National Cancer Screening Register
NHMRC	National Health and Medical Research Council
QAP	Quality Assurance Program
PCR	Polymerase chain reaction
RCPA	Royal College of Pathologists of Australasia
RCPAQAP	Royal College of Pathologists of Australasia Quality Assurance Program
TGA	Therapeutic Goods Administration

Definitions

Term	Definition
Abnormal report	means those reports including all technically satisfactory reports which were not negative.
Acceptable range	means ± 2 standard deviations.
Assay	means HPV nucleic acid test.
Cytologist	means a cytotechnologist holding a CT(ASC) qualification which includes the gynaecological cytology component or an equivalent qualification as determined by the Australian Society of Cytology (ASC) or the Australian Institute of Medical Scientists (AIMS), which designates competence in gynaecological cytology.
Device	means instrument assay is processed on.
Follow-up specimen	means a specimen taken following an unsatisfactory result (recommended within 6 weeks) or following an "intermediate risk" screening result (recommended at 12 months). It may also mean a test taken when a woman is under surveillance following a discordant screening and histology result.
HPV NAT	means HPV nucleic acid testing.
HPV 16/18 positivity	means positivity rate for HPV 16 , HPV 18 or HPV 18/45 (as some assays give combined HPV 18/45 result).
LBC	means liquid based cytology.
HPV positivity rate	means detection rate of all oncogenic HPV types (as defined below).
Minimum sample size	means the minimum number of specimens needed to give a statistically valid comparison to nationally calculated HPV positivity rate, currently determined to be 2000 specimens.

Term	Definition
Non-screening (diagnostic)	means a test performed where there is an indication disease may be present e.g. clinical history, signs (visually abnormal cervix, etc.) or symptoms (abnormal bleeding, pain, etc.). This classification is also used for specific tests taken after treatment to ensure the effectiveness of that treatment.
Oncogenic HPV types	means HPV types 16 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, ±66, 68).*
Oncogenic HPV not detected.	means those specimens in which no HPV considered to have a significant risk of causing cervical cancer was detected in the specimen.
Oncogenic HPV positivity	means positivity rate of detection of oncogenic HPV types as defined above.
Other Oncogenic HPV positivity	means positivity rate of oncogenic HPV other than HPV 16/18 (or HPV 45 if detected in an assay which cannot distinguish 18 and 45).
Query batch	means a batch of specimens for which any oncogenic HPV positivity rates fall outside the acceptable range.
Reflex LBC	means a cytological examination performed on a liquid-based sample when oncogenic HPV is detected on a screening HPV NAT.
Requirements for Medical Pathology Services (RMPS)	means the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.
Scientist	means the same as the definition in the NPAAC *Requirements for the Supervision of Pathology Laboratories*.
Screening	means testing of apparently healthy people who are at risk of developing a certain disease. Screening tests can predict the likelihood of someone having or developing a particular disease.

* HPV types are classified as carcinogenic on the basis of extensive review of the evidence by the International Agency for Research on Cancer. Currently IARC has classified 12 HPV types as definitely carcinogenic on the basis of sufficient evidence relating to cervical cancer. These are types 16,18,31,33,35,39,45,51,52,56,58,59. IARC currently classifies type 68 as probably carcinogenic. A further group of HPV types are currently classified as possibly carcinogenic on the basis of limited evidence, which may change over time in future IARC reviews. These are types 26, 53, 66, 67, 70, 73, 82, 30, 34, 69, 85, 97.

Term	Definition
Senior Scientist	means the same as the definition in the NPAAC *Requirements for the Supervision of Pathology Laboratories.*
Specimen	means any tissue or fluid from a patient that is submitted to the laboratory for testing.

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Introduction

The *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (First Edition 2017)* together with the *Requirements for Medical Pathology Services* and *Requirements for Medical Testing of Microbial Nucleic Acids*, set out the minimum requirements for best practice in relation to the HPV NAT and operation of gynaecological cytology services by laboratories participating in cervical screening. This document provides guidance for the additional steps laboratories must take when using HPV NAT alone as a primary screening test in a population of both vaccinated and unvaccinated women. The Requirements also form the basis for laboratory accreditation in this area.

The National Cervical Screening Program (NCSP) will change from two yearly Pap smear screening to five yearly primary HPV testing (with partial genotyping and liquid-based cytology triage). This change has been driven in part by the success of Australia's early adoption of the National HPV Vaccination Program. It must be acknowledged that at the time of writing these Requirements there is limited published evidence on the performance of any screening test specifically in vaccinated women (including Pap smears, Liquid based cytology (LBC) or HPV NAT).[†] However, the available information, including extensive evidence on the performance of HPV NAT prior to vaccination, together with comprehensive modelling strongly suggests that we can expect HPV NAT to outperform conventional Pap smears or LBC in both vaccinated and unvaccinated women. Furthermore, HPV vaccination has been shown to reduce the prevalence of HPV 16 and 18 in young women, bringing it close to the prevalence seen in older women prior to HPV vaccination, a cohort where there is extensive empirical evidence about the performance of HPV NAT. The performance of the NCSP as a whole, as well as individual laboratories and HPV NAT methods, will be closely monitored.

Australia is one of the first countries to move to HPV NAT for cervical cancer screening. With information currently based only on pilot programs it is very important that this is adopted with as much protection of the welfare of women as is possible. HPV NAT in the more familiar symptomatic or post treatment setting is usually conducted on a number of occasions and in association with other investigations such as cytology and colposcopy which adds a layer of security if for some reason an individual test fails. In the screening setting there is now a 5 year testing interval meaning that failure to detect HPV positivity could expose a woman to a prolonged interval, up to 10 years without further observation. Secondly, while there are inevitably built in deficiencies in any form of testing, it is important that easily preventable pre-analytical issues such as unsatisfactory specimens are dealt with, for while these may be less than 1% of tests, this translates to large numbers of individual women once millions of tests are performed annually. Similarly test performance has to be closely monitored to detect partial or total reagent failure, testing platform failure, operator errors, or any other occurrence that results in a significant change in screening detection rates. The need for large scale re-collection of specimens would cause distress, a large cost and loss of confidence in the screening program. To this end the Requirements include additional quality measures for HPV NAT in the screening setting.

Cervical screening tests continue to be funded through Medicare permitting a diversity of laboratories to participate in the program and multiple HPV NAT platforms to be used. This is in contrast to the Netherlands and England where screening services are more centralised

[†] Palmer TJ, McFadden M, Pollock KG, Kavanagh K, Cuschieri K, Cruickshank M, et al., Bhatia R, Kavanagh K, Cubie HA, Serrano I, Wennington H, Hopkins M, et al.

and testing platforms will be limited, similar to the Bowel Cancer Screening Program in Australia. While third party (non-manufacturer) controls assure individual test platform and reagent performance, the use of different testing platforms in many different laboratories requires a means of overseeing overall test performance within a time frame which would allow for re-testing, if this is needed. To achieve this, periodic comparison of the laboratory's HPV detection rate against the national average rate has been included as a Standard. Despite suggestions to the contrary, it has previously been shown in an Australian study that there is no significant difference in oncogenic HPV infection rates based on where a woman lives (urban, rural or remote) or between indigenous and non-indigenous women.[‡]

In order to ascertain the minimum batch required to give a robust sampling, a cohort of over 20,000 HPV tests undertaken as part of the Compass Trial at VCS was utilised. Taking into account variation between sample groups, analysis indicates that a sample cohort of 2000 is required to be able to produce a robust sample size in which to examine HPV positivity rates, based on a power of 0.80 and a level of significance of 0.05. The 2000 cases must be accrued within a timeframe that is determined by the expiry time of the collection medium such that the specimen still remains suitable for HPV NAT and LBC, should this be required. This time is specified by the manufacturer and is noted to vary with the type of collection medium, conditions of storage and the HPV NAT platform in use.

In choosing equipment for screening, the suitability of the HPV NAT in conjunction with the selected collection medium must be checked against manufacturer's kit inserts and published literature to confirm that population based screening is an intended use for that combination of HPV NAT platform and collection medium.

To reach women, who for various personal or cultural reasons have never participated in the screening program, an option of self-collection under the supervision of a health practitioner has been introduced. The specimen is likely to be less representative than a specimen collected under direct vision requiring more sensitive testing using nucleic acid amplification and is not satisfactory for reflex LBC testing. Although there is limited evidence at this stage as to the optimal method of testing, PCR has been selected as it was the method used in the only large meta-analysis of self-collection for HPV testing to date. This is a pioneering initiative with limited but supportive data available at this stage.[1] Self-collection will be closely monitored by the NCSP and the collected data will be used in the later revision of these Requirements.

It is also intended that laboratories providing HPV NAT or LBC in the non-screening (diagnostic) setting should be able to continue to provide this service. There is a critical need to be able to correlate histological, cytological, colposcopic and clinical findings, often in the context of a multidisciplinary team meeting, in order to determine management of the patient.

The NCSP is a joint program of the Commonwealth and state and territory governments. The Standing Committee on Screening of the Australian Health Ministers' Advisory Council has national oversight of the NCSP and has developed a Quality Framework for the NCSP to provide guidance on delivering high quality and safe cervical screening services.

[‡] Garland et al BMC Medicine, 9:104, 2011

The *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (First Edition 2017)* supports the NCSP Quality Framework in achieving high quality pathology laboratory services. This standard supersedes the *Requirements for Gynaecological (Cervical) Screening and Performance Measures for Australian Laboratories Reporting Cervical Cytology*.

In addition, the *NCSP*: *Guidelines for the Management of Screen Detected Abnormalities, Screening in Specific Populations and Investigation of Abnormal Vaginal Bleeding (the NSCP 2016 Guidelines)* have been developed by the Cancer Council Australia on behalf of the Commonwealth to provide guidance to health professionals and women as to best practice in the clinical management of women with positive HPV test results and abnormalities detected on subsequent liquid based cytology.[§]

It should be noted that all references to the National Cancer Screening Register in the document can mean both NCSR and or state/territory based cervical registers.

This document must be read within the national pathology accreditation framework including the current versions of the following NPAAC documents:

Tier 2 Document

- *Requirements for Medical Pathology Services*

All Tier 3 Documents

Tier 4 Document

- *Requirements for Medical Testing of Microbial Nucleic Acids.*

In addition to these Standards, laboratories must comply with all relevant state and territory legislation (including any reporting requirements).

In each section of this document, points deemed important for practice are identified as either 'Standards' or 'Commentaries'.

- A Standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a laboratory can attain accreditation — Standards are printed in bold type and prefaced with an 'S' (e.g. **S2.2**). The use of the word '**must**' in each Standard within this document indicates a mandatory requirement.

- A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a 'C' (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a Standard or not. Note that when Comments are expanding on a Standard or referring to other legislation, they assume the same status and importance as the Standards to which they are attached. Where a Commentary contains the word '**must**' then that Commentary is considered to be **normative**.

[§] wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Prevention

Please note that any Appendices attached to this document may be either **normative** or **informative** and should be considered to be an integral part of this document.

All NPAAC documents can be accessed at - www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm

While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

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1. Personnel

(Refer to Standard 4 in *Requirements for Medical Pathology Services*)

HPV NAT

S1.1 HPV NAT must be supervised either by a Pathologist or Senior Scientist with training and experience in NAT.[**]

LBC

S1.2 A Pathologist involved in gynaecological cytology must be competent in cytology and histology of gynaecological specimens to facilitate histological and cytological correlation.

C1.2(i) Where pathologists perform primary examination of cervical specimens, these **must** only be performed by pathologists who have appropriate training. Competency in primary examination **must** be demonstrated.

C1.2(ii) Competency may be demonstrated in a number of ways, including:

(a) participation in multi-disciplinary team meetings

(b) QAP participation

(c) conference attendance; and

(d) documented ongoing education.

S1.3 Cytology staff employed for examining LBC must be supervised by at least one (1) Pathologist or Senior Scientist trained and competent in cytology. [**]

S1.4 Cytology staff employed for examining LBC must hold a CTASC which includes a gynaecological cytology component.

C1.4(i) The change in the role of LBC from screening to a triage test requires a formal qualification for this enhanced role.

C1.4(ii) Trainees progressing towards a CTASC within 4 years may report LBC under supervision.

S1.5 To maintain competence, the Pathologist(s) and Cytologist(s) must examine, as a minimum, 60 abnormal LBC specimens per quarter.

[**] Requirements for the Supervision of Pathology Laboratories

Staff establishment for LBC

S1.6 The maximum workload for any person involved in primary examination of LBC is 70 slides per day. Where an individual undertakes duties in addition to primary examination, or is employed part time, the maximum rate should not exceed 10 slides per hour.

C1.6(i) Persons examining LBC specimens **must** not exceed this Standard regardless of the number of sites at which they are employed.

C1.6(ii) These limits are not a recommended optimal or average workload and **must not** be employed as a performance target for each Cytologist.

S1.7 The maximum workload for any person reporting using semi-automated imaging techniques must not exceed 150 slides per day.

C1.7(i) Persons examining LBC specimens **must not** exceed this Standard regardless of the number of sites at which they are employed.

C1.7(ii) These limits are not a recommended optimal or average workload and **must not** be employed as a performance target for each Scientist.

S1.8 A Pathologist who is competent in LBC must be available to consult with on site and to advise scientific staff and consult with clinicians.

C1.8 There **must** be ready access to an adequate conference microscope facility enabling simultaneous viewing, discussion and diagnosis by more than one observer.

Education

S1.9 Pathologists, Scientists or any staff performing HPV NAT must retain documentation confirming they have undertaken training specific to the HPV NAT performed in the laboratory.

S1.10 Pathologists or Cytologists examining LBC must retain documentation confirming they have undertaken continuing education specific to the use of liquid based collection systems and semi-automated devices being employed within the laboratory for the preparation and examination of gynaecological slides and participate in an external quality assurance program.

2. Facilities

(Refer to Standard 5A in *Requirements for Medical Pathology Services*)

For HPV NAT, specific requirements for facilities are set out in Standard 3 of *Requirements for Medical Testing of Microbial Nucleic Acids.*

S2.1 Any processing, evaluation and reporting of HPV NAT or LBC specimens must be in accredited pathology laboratories.

Pre-Analytical

3. Specimens

(Refer to Standard 6A in *Requirements for Medical Pathology Services*)

Specimen requirements for practitioner collected tests

S3.1 The laboratory must advise requesting practitioners that the specimen must be identified as a screening specimen, follow-up specimen, specimen from a symptomatic woman, post-treatment specimen or a self-collected specimen (see below).

S3.2 The laboratory must provide advice for practitioners on the collection of satisfactory cervical specimens, such that:

a) The collection of the specimen from the cervix should be under direct vision so that the specimen for HPV NAT is suitable for reflex LBC.[2, 3]

b) Expiry dates, storage and transportation requirements as recommended by the suppliers of the collection medium are adhered to.

S3.3 The collection medium/ device used by practitioners to collect the cervical sample must be suitable and validated for use with both the HPV NAT offered and the LBC test, as intended by the manufacturer.

S3.4 To avoid re-collection there must be sufficient residual specimen present for reflex LBC before additional samples are removed for other microbiological tests, such as Chlamydia, that may be performed subsequently on the screening sample.

Retention (Screening tests only)

S3.5 The HPV NAT material must be retained in accordance with S5.5.[††]

S3.6 The residual sample, where LBC has been performed, must be retained in accordance with the manufacturer's instructions, for a period of at least one month after the report is validated in accordance with S5.5 and with the *Requirements for the Retention of Laboratory Records and Diagnostic Materials.*

Retention (Non-screening (diagnostic) tests)

S3.7 The specimens for HPV NAT and LBC must be retained in accordance with the *Requirements for the Retention of Laboratory Records and Diagnostic Materials.*

[††] Requirements for the Retention of Laboratory Records and Diagnostic Materials

Specimen requirements for self-collected tests

S3.8 Self-collected specimens must be clearly identified as such.

S3.9 The laboratory must provide instructions for self-sampling.

S3.10 The collection device and collection medium if used, must be suitable and validated for use with the HPV NAT method.

Retention (Self-collected tests)

S3.11 The self-collected HPV NAT material must be retained in accordance with the *Requirements for the Retention of Laboratory Records and Diagnostic Materials.*

Analytical

4. Equipment

(Refer to Standard 5 in *Requirements for Medical Pathology Services*)

To be fit for purpose, in the Australian population with a mix of vaccinated and unvaccinated women, the test method must be suitable for use as per criteria below. This section outlines the requirements to be considered in selecting the equipment for HPV NAT within the NCSP.

This standard **must** be read in conjunction with Standards 5, 6 and 7 of the *Requirements for Medical Testing of Microbial Nucleic Acids.*

Screening specimens

S4.1 Laboratories must only use commercially supplied HPV NAT that are validated for primary population based screening.

C4.1 In selecting HPV NAT for use in the screening setting, in combination with the chosen collection medium, the laboratory **must** confirm that the manufacturer's kit insert lists population based screening as an intended use.

S4.2 The HPV NAT method must test for HPV genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68, and separately identify HPV 16 and HPV18.[‡‡]

S4.3 The test must be included on the Australian Register of Therapeutic Goods.

S4.4 HPV NAT assays used in primary screening as part of the National Cervical Screening Program must be demonstrated by the manufacturer, or in published studies to fulfil the following criteria:

a) For HPV detection in a satisfactory sample, show proven non-inferiority to validated reference assays (e.g. Hybrid Capture 2 (HC2) in cross-sectional equivalence studies using guidelines for test requirements which were developed by an international consortium[3].

b) Have demonstrated clinical sensitivity for HSIL of not less than 90% of HC2 or an equivalent test which has been demonstrated to achieve this level of sensitivity in women of at least 25 years of age.

c) Have a clinical specificity for HSIL not less than 98% of that of HC2 or an equivalent test which has been demonstrated to achieve this level of specificity in women of at least 25 years of age.

d) Display intra-laboratory reproducibility and inter-laboratory agreement with a lower confidence bound of 87% to be tested on at least 500 samples of which 30% were HPV positive.

e) Contain a control to monitor inhibition and/or assay failure.[§§]

[‡‡] HPV tests that give a result for HPV18/45 will be managed as HPV 18
[§§] There is no requirement that S4.4 (e) and (f) are independent of each other

f) Contain a control for cellularity to detect inadequate or empty cervical samples.

C4.4 Unsuitable specimens (eg. invalid specimens such as empty LBC containers or those contaminated with inhibitors such as lubricant) **must** be identified and reported as 'unsatisfactory' rather than 'HPV not detected'.

Non-screening (Diagnostic) HPV NAT

The current usage of HPV as a diagnostic test for symptomatic women and in the post treatment setting is covered by the *Requirements for Medical Testing of Microbial Nucleic Acids.*

Non-screening (Diagnostic) LBC

Within the NCSP 2016 guidelines LBC will be performed on women in a number of clinical situations with or without concurrent HPV NAT.

Self-collected specimens

S4.5 Self-collected specimens must be tested using a PCR test.

C4.5 Self-collected program is a pioneering initiative and at this stage evidence is limited on the optimal NAT method. A meta-analysis of 36 studies involving self-collection for HPV testing was published by Arbyn and colleagues[1] found that PCR-based assays showed similar levels of sensitivity and specificity between self-collected and practitioner-collected samples. Evidence for use of other HPV NAT or nucleic acid amplification methods is limited at this stage and will be subject to review in the future.

5. Quality assessment

(Refer to Standard 7 in *Requirements for Medical Pathology Services*)

This standard **must** be read in conjunction with Standards 5 and 7 *in Requirements for Medical Testing of Microbial Nucleic Acids.*

Quality Measures for HPV NAT (applies to all testing settings, including screening, test of cure and self-collected specimens)

S5.1 Laboratories must participate in an external quality assurance program.[***]

S5.2 Laboratories must investigate all discordances in external quality assurance for HPV and document corrective actions have been taken.

S5.3 Laboratories must have a documented method for monitoring rates of oncogenic HPV not detected, detected, and unsatisfactory specimens.

C5.3(i) HPV results **must** be stratified for HPV16/18, and other oncogenic HPV.

C5.3(ii) The rate of unsatisfactory specimens (as defined in the *NCSP 2016 Guidelines*) **must** be stratified based on "Routine screening", "Self-collection" or "Other (includes symptomatic women, test of cure etc.)".

S5.4 For HPV NAT within the NCSP, externally sourced non-manufacturer supplied control material must be used at least daily when tests are being performed.

Quality Measures for HPV NAT, Screening specimens only

S5.5 Laboratories must compare their rates of HPV detection in screening tests with the rates most recently reported by the NCSR.

C5.5(i) The purpose of this measure is to detect partial or total reagent failure, testing platform failure, operator errors, changes in collection media or other factors associated with specimen collection or any other occurrence that results in a significant change in screening detection rates.

C5.5(ii) If a reagent batch failure is detected by a laboratory, the NCSP **must** be informed immediately so that other users can be notified.

C5.5(iii) In determining the laboratory's HPV detection rate in screening specimens, at least 2000 specimens tested in the same laboratory **must** be reviewed.[†††]

C5.5(iv) The test volume required for the calculation of this measure is dependent on the expiry time of the collection medium beginning from the time of collection. This period is determined by the storage times, as indicated by the manufacturer of the medium, and the type of HPV NAT testing platform. The specimens **must** be stored until a suitable test batch size has

[***] S7.2 Requirements for Medical Pathology Services

[†††] In order to ascertain the minimum batch required to give a robust sampling, a cohort of over 20,000 HPV tests undertaken as part of the Compass Trial at VCS was utilised. Taking into account variation between sample groups, analysis indicates that a sample cohort of 2,000 is required to be able to produce a robust sample size in which to examine HPC positivity rates, based on a power of 0.80 and a level of significance of 0.05.

been reached, but this **must** occur within such a timeframe that both HPV (re)testing and potential reflex LBC testing remain possible. If refrigerated storage is used the specimen **must** be kept at the refrigerated temperature from collection and during transport and handling.

C5.5(v) The NCSR will use the routinely submitted data to produce a quarterly age stratified data set (including mean ± two standard deviations) compiled from data from all HPV testing throughout Australia.

C5.5(vi) If the HPV positivity rate in screening tests is not within the two standard deviations, the laboratory **must** follow the procedures in ***Appendix A.***

C5.5(vii) If the laboratory's HPV detection rate in screening tests is within two standard deviations of the National Cancer Screening Register rate in each batch of at least 2000, then samples may be discarded in line with *Requirements for the Retention of Laboratory Records and Diagnostic Materials*.

C5.5(viii) To allow timely retesting, comparison of detection rates with the NCSR should occur at least quarterly.

Quality Measures for LBC (applies to Screening derived and Non-screening (Diagnostic) LBC).

S5.6 Each laboratory must document its procedures for internal audit which cover all its activities including:

a) a system of follow-up for correlating the results of LBC with relevant histopathology

b) a system within the laboratory for monitoring the performance of the laboratory as a whole and also the performance of individual Pathologists and Scientists.

C5.6 Each of these activities **must** be monitored at least annually and the results or outcomes recorded.

Post-Analytical

6. Reporting

(Refer to Standard 6C in *Requirements for Medical Pathology Services*)

S6.1 Where reflex cytology is performed, the HPV NAT and LBC results must be issued as a combined report.

C6.1 The laboratory issuing the combined report is responsible for transmission of the report to the referring health practitioner and the NCSR.

S6.2 The content of the report must include an overall cervical screening risk classification, specimen type, test results and management recommendation.

S6.3 The report format and management recommendation must be in accordance with the NCSP *2016 Guidelines*[2] and must take into account the previous screening history from the NCSR.

S6.4 The laboratory must have a documented procedure for the notification to National Cancer Screening Register.

C6.4 Laboratories **must** provide results, demographic data and test kit batch numbers and expiry dates to the NCSR for all patients. Refer to ***Appendix C***.

S6.5 Laboratories must report 90% of all cervical screening specimens within 10 working days of receipt.

S6.6 All LBC reports indicating a cellular abnormality must be confirmed by a Pathologist.

C6.6 In the context of Non-Screening (Diagnostic) LBC the comparison with biopsy findings, colposcopy and clinical findings is critical to patient care and may dictate the location of provision of these services.

7. Performance Measures for HPV NAT and LBC in the renewed NCSP

(Refer to Standard 6 in *Requirements for Medical Pathology Services*)

Currently there is insufficient data available to set numeric performance standards within the renewed NSCP. For samples through to the commencement date of the NCSP, the former performance measures for gynaecological cytology will still have to be calculated as specified in the NPAAC *Performance Measures for Australian Laboratories Reporting Cervical Cytology*. The new performance measures have been developed without set values at this stage. Numeric standards will be developed when sufficient data has been accrued.

Performance Measures for HPV NAT and LBC in the renewed NCSP will apply to collected samples taken by health care professionals after the implementation of the NCSP and does not include self-collected specimens. Most of the information required to calculate these measures will be provided to laboratories by the NCSR.

Performance Measure 1

S7.1 The number and percentage of screening episodes reported as 'unsatisfactory' must be reported to the RCPAQAP.

C7.1(i) This **must** be reported to the RCPAQAP by March in the following year.

C7.1(ii) This **must** include a breakdown distinguishing between those episodes in which the specimen was unsatisfactory for HPV NAT or for reflex LBC.

C7.1(iii) The definition of "Unsatisfactory" for HPV NAT and LBC is defined in *the NSCP 2016 Guidelines.*

C7.1(iv) No numerical standards have yet been set.

Performance Measure 2a

S7.2 Laboratories must provide the proportion of all technically satisfactory screening episodes[‡‡‡] reported in the categories low risk, intermediate risk and higher risk.[§§§]

C7.2(i) This **must** be reported to the RCPAQAP by March in the following year.

C7.2(ii) Laboratories **must** breakdown the risk categories for screening episodes to show underlying HPV NAT and LBC results.

C7.2(iii) Laboratories **must** further provide a breakdown by birth cohorts of women born before and after 30th June 1980 to separate younger mostly vaccinated women from older unvaccinated women.

C7.2(iv) No numerical standards have been set as yet.

[‡‡‡] The routine screening test taken in a woman who has not had a previous abnormality or from a woman who has had an abnormality investigated, treated if required and has returned to routine screening.
[§§§] Refer to ***Appendix D***

Performance measure 2b

S7.3 Laboratories must provide a breakdown of the HPV NAT and LBC results of all other episodes.[****]

C7.3(i) This **must** be reported to the RCPAQAP by March in the following year.

C7.3(ii) Laboratories **must** provide a breakdown by birth cohorts of women born on or before and after 30th June 1980 to separate younger, mostly vaccinated women from older, unvaccinated women.

C7.3(ii) No numerical standards have been set as yet.

Performance measure 3a

S7.4 The proportion of LBC specimens reported as HSIL where cervical histopathology, taken within six months, confirms the abnormality as HSIL, AIS or cervical malignancy must be reported to the RCPAQAP.

C7.4(i) This **must** be reported to the RCPAQAP by October in the following year.

C7.4(ii) Where multiple histopathology reports fall within the six month period after the cytology report, the case **must** be compared with the highest grade of abnormality in the histopathology reports.

C7.4(iii) No numerical standards have been set yet.

Performance measure 3b

S7.5 The proportion of LBC specimens reported as possible HSIL where cervical histopathology, taken within six months, confirms the abnormality as HSIL, AIS or cervical malignancy must be reported to the RCPAQAP.

C7.5(i) This **must** be reported to the RCPAQAP by October in the following year.

C7.5(ii) Where multiple histopathology reports fall within the six month period after the cytology report, the case **must** be compared with the highest grade of abnormality in the histopathology reports.

C7.5(iii) No numerical standards have been set yet.

Performance measure 4

S7.6 The proportion of women with histological diagnosis of HSIL or malignancy which were originally reported as low risk with a primary screening HPV NAT within the last 63 months must be reported.

[****] For this measure, all other episodes includes symptomatic women and post-treatment specimens but not self-collected specimens

Appendix A Protocol to be followed if a batch of results larger than the minimum sample size has any HPV positivity screening tests only that is outside the acceptable range (query batch) (Normative)

The purpose of this Appendix is to set out the steps that **must** be taken if the HPV positivity rate of a batch of at least 2000 tests falls outside 2 standard deviations from the mean of the current range reported by the NCSR. This occurrence would raise the possibility of a technical issue affecting test sensitivity.

The first step is to examine whether the rate is still outside range when pooled with the results of the previous batch, which increases the sample size and therefore produces a more robust sampling population. If the HPV positivity still remains outside of the acceptable range, then the effect of instrument variability should be checked by comparison with the range determined for all users of that instrument. If instrument variability is excluded, the possibility of a variation in HPV positivity due to a non-representative age distribution within the batch should be investigated. The rate should be broken up between the younger vaccinated group and older non-vaccinated groups and compared to the age rates from the NCSR. If these factors are eliminated then the possibility of operator error resulting in failure of the test needs to be examined by re-testing the batch. Once a HPV positivity rate falls within the acceptable range the investigation for that rate can be finalised.

Any test batch where the HPV positivity rate falls outside two standard deviations of the acceptable range as reported by the National Cancer Screening Register (NCSR) **must** be investigated.

1. Laboratories **must** inform the National Cervical Screening Program (NCSP) of the occurrence of a query batch through its Quality and Safety Monitoring Committee including the following information:
    a. assay
    b. device
    c. batch and lot numbers of reagents
    d. number of specimens
    e. all HPV Positivity rates and number of specimens.
2. Laboratories **must** pool data from query batch with the previous batch of an equal or lesser number of specimens to determine if HPV positivity is still outside the acceptable range.
    a. If HPV positivity of the combined batch is within the acceptable range the investigation does not need to proceed but **must** be reported to NCSP and the investigation can be concluded.
    b. If HPV positivity of the combined batch is not within the acceptable range the laboratory **must** continue its investigation.

3. The laboratory **must** compare the HPV positivity rates of the query batch with the device and assay specific ranges from the NCSR.

    a. If HPV positivity of the query batch is within the acceptable device and assay specific range the investigation does not need to proceed but **must** be reported to NCSP and the investigation can be concluded.

    b. If HPV positivity of the query batch is not within the acceptable device and assay specific range the laboratory **must** continue its investigation.

4. HPV positivity rates of the vaccinated (born post-June 30, 1980) and non-vaccinated age cohorts of the query batch **must** be examined.

    a. If HPV positivity of the query batch is within the acceptable range for the age cohorts the investigation, the investigation does not need to proceed but **must** be reported to NCSP and finish investigation.

    b. If HPV positivity of the query batch is not within the acceptable range for the age cohorts, the laboratory **must** continue its investigation. If only one of the age cohorts is outside range, re-testing can be limited to that cohort.

5. Retest the query batch.

    a. If HPV positivity of the retested query batch is within the acceptable range the investigation does not need to proceed but **must** be reported to NCSP and the investigation can be concluded.

    b. If the HPV positivity of the retested query batch is still outside the range then a report **must** be completed including the following information:

        i. All data produced as part of the investigation (including but not limited to HPV positivity rates from pooled data from query batch with the previous batch, the device and assay specific ranges from the NCSP, the vaccinated and non-vaccinated age cohorts of the query batch, results from the retested samples)

        ii. HPV positivity data from the past 10 batches or three months, whichever is greater

        iii. Previous 12 months of RCPAQAP results

        iv. Previous 12 months of non-manufacturer control testing.

Appendix B Achieving the Performance Measures and Standards for LBC (Informative)

(Refer to Standard 2, Standard 3 and Standard 7 in *Requirements for Medical Pathology Services)*

When numeric standards are established, the following standards indicate the steps to be undertaken in investigating non-conformance in LBC. Currently this section is informative only but will become normative when numerical Performance Measures are established.

Investigation of HPV NAT performance is addressed in ***Appendix A***.

1. If any of the LBC Performance Measures are not met, the laboratory should undertake an internal review of specimens and slides, directed towards investigating the outlying measure. This review should be documented and completed within two months.

2. If the internal review of specimens (slides) reveals the cause for the failure of compliance, corrective action should be undertaken and documented.

3. This documentation should be provided to the accreditation assessment body within three months.

4. If the internal review fails to reveal the cause for the failure to comply with the Performance Measures, independent external expert advice should be obtained.

5. The laboratory should:
   a. seek this advice immediately
   b. obtain advice relating to technical and quality issues which will enable them to comply with the Performance Measures
   c. be obtained and implemented within three months.

6. During the following twelve months, the Performance Measures should be monitored every three months.

7. If any subsequent LBC Performance Measures are not met at the end of twelve months, an independent external review of the specimens (slides) should be undertaken and documented.
   a. The purpose of the external review is to ensure patient safety.
   b. The external review will be conducted at the expense of the laboratory.
   c. The nature and extent of the external review will be determined and coordinated by the accreditation assessment body.

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Appendix C Information required to be provided to the NCSR (Informative)

This schedule outlines the recommended format for reporting to the NCSR.

Demographic and test data required to be sent to the Register

Group	Data element	
Client Identifiers	Medicare card number	Report if available
	Individual healthcare identifier	Report if available
Client data items	Name title	Report if available
	Family name	
	Given names	
	Other family name	Report if available
	Date of birth	
	Sex and gender identity	
	Indigenous status	Report if available
	Country of birth	Report if available
	Main language other than English spoken at home	Report if available
	Special circumstances e.g. HIV positive, Immunocompromised, DES-exposed, Daughter of DES-exposed, Granddaughter of DES-exposed	Report if available
Contact data items	Residential address	
	Residential suburb/town/locality name	
	Residential Australian state/territory name	
	Residential Australian postcode	
	Mailing address	Report if available
	Mailing suburb/town/locality name	Report if available
	Mailing Australian state/territory name	Report if available
	Mailing Australian postcode	Report if available
	Telephone number – home	Report if available
	Telephone number – work	Report if available

Group	Data element	
	Telephone number – mobile	Report if available
	Email address	Report if available
Provider data items	Medicare provider number	
	Healthcare provider identifier – organisation (HPI-O)	Report if available
	Healthcare provider identifier – individual (HPI-I)	Report if available
	Provider family name	
	Provider given names	
	Provider name of practice or medical centre	
	Provider practice address	
	Provider practice suburb/town/locality name	
	Provider Australian state/territory name	
	Provider Australian postcode	

HPV test collection method	1 Practitioner-collected sample		2 Self-collected sample		
HPV test specimen site	0 Not stated	1 Cervical	2 Vaginal	3 Other gynaecological site	
Reason for HPV test	1 Primary screening HPV test	2 Follow-up HPV test (Repeat HPV test after intermediate risk result or unsatisfactory test)	3 Co-test i. Test of cure ii. Investigation of signs or symptoms iii. Other, as recommended in guidelines		4 Other
HPV test result—oncogenic HPV ††††	U Unsatisfactory	0 Oncogenic HPV not detected	1 HPV 16/ 18 detected ‡‡‡‡ i. Type 16 detected ii. Type 18 detected iii. Type 18/45 detected	2 Oncogenic HPV (not 16/18) detected§§§§ i. One or more of the following types detected: 31, 33, 45, 52, or 58 ii. One or more of the following types detected: 35, 39, 51, 56, 59, 66, or 68	
HPV test type *****	1 Qiagen i. Hybrid Capture II	2 Roche i. cobas 4800 ii. cobas 6800 iii. cobas 8800	3 Abbott i. m2000 ii. Alinity m	4 Becton Dickinson i. Onclarity	5 Cepheid i. Xpert
	6 Hologic i. Cervista ii. Aptima	7 Seegene i. Anyplex	8 Genera i. PapType	9. Euroimmun i Euroarray	999 other

†††† All oncogenic HPV types detected are required to be reported, if more than one type is detected, the codes for each detected type must be reported, comma separated. Reporting at the level of "Not detected",
"HPV type 16/18 detected" and "Oncogenic HPV (not 16/18) detected" is mandatory. Laboratories should report more detailed information if their test outputs allow, using the more detailed codes as suffixes.

‡‡‡‡ One or more oncogenic HPV types 16 or 18 detected

§§§§ One or more oncogenic HPV types other than 16 and 18 - HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68

***** The HPV test types listed here will be tests that are registered on the ARTG for HPV testing of cervical samples. It is not an indication of which tests are suitable for use in the National Cervical Screening Program. Only those HPV tests that meet the requirements set out in the NPAAC Standards and Performance Measures for cervical screening should be used in the National Cervical Screening Program. Tests that do not meet the requirements now may meet them in future and therefore all tests listed on the ARTG will be coded. The HPV tests currently listed are tests which were known to be registered on the ARTG at the time of developing the coding sheet. There may be others that are on the ARTG and were not identified at the time of development or will be added in future. Any tests that are listed on the ARTG will be added to the coding sheet if the National Cervical Screening Program is informed.

HPV test sample	0 Not stated		1 PreservCyt Solution		2 SurePath medium
	97 Other commercial self-collection device		98 Specimen transport medium		99 Flocked or cotton swab †††††
HPV test batch information ‡‡‡‡					
Control kit	Lot number	Expiry date	Amplification kit	Lot number	Expiry date
Cellular (LBC) extraction kit	Lot number	Expiry date	Detection kit	Lot number	Expiry date
Nucleic acid extraction kit	Lot number	Expiry date	Wash buffer	Lot number	Expiry date

††††† If a swab is received by the laboratory in sampling media such as PreservCyt or SurePath, then it must be coded as "99 Flocked or cotton swab".
‡‡‡‡ For each of these codes one or more Lot numbers and associated expiry dates need to be reported. The fields need to be able to accept both letters and numbers as well as N/A (in the case of LBC extraction on a self-collected sample). Where a 'kit' includes reagents for multiple testing steps the Lot numbers and expiry dates should be repeated for each of the codes.

Cytology specimen type	A0 Not stated		A1 Conventional smear		A2 Liquid based specimen	A3 Conventional and liquid-based
Cytology specimen site	B0 Not stated		B1 Cervical		B2 Vaginal	B3 Other gynaecological site
Reason for cytology test	1 Reflex LBC cytology after detection of oncogenic HPV in primary screening HPV test		2 Cytology after detection of oncogenic HPV in self-collected sample		3 Reflex LBC after detection of oncogenic HPV in Follow-up HPV test	
	4 Cytology at colposcopy		5 Co-test i. Test of cure ii. Investigation of signs or symptoms iii. Other, as recommended in guidelines		6 Other	P Conventional Pap test to screen for cervical cancer precursors

Result	**Squamous**		**Endocervical**		**Other/non-cervical**	
Unsatisfactory	SU	Unsatisfactory for evaluation	EU	Due to unsatisfactory nature of the specimen, no assessment has been made	OU	Due to the unsatisfactory nature of the specimen, no assessment has been made
Negative	S1	Cell numbers and preservation satisfactory. No abnormality or only reactive changes	E- E0 E1	Not applicable: vault smear/previous hysterectomy No endocervical component Endocervical component present. No abnormality or only reactive changes	O1	No other abnormal cells
Low-grade	S2 S3	Possible low-grade squamous intraepithelial lesion (LSIL) Low-grade squamous intraepithelial lesion (LSIL) (HPV and/or CIN I)	E2	Atypical endocervical cells of uncertain significance	O2 O3	Atypical endometrial cells of uncertain significance Atypical glandular cells of uncertain significance - site unknown
Possible high-grade	S4	Possible high-grade squamous intraepithelial lesion (HSIL)	E3	Possible high-grade endocervical glandular lesion	O4 O5	Possible endometrial adenocarcinoma Possible high-grade lesion – non-cervical
High-grade	S5 S6	High-grade squamous intraepithelial lesion (HSIL) (CIN 2/CIN 3) HSIL with possible microinvasion/ invasion	E4 E5	Adenocarcinoma-in-situ Adenocarcinoma-in-situ with possible microinvasion/invasion		
Carcinoma	S7	Squamous carcinoma	E6	Adenocarcinoma	O6 O7 O8 O9	Malignant cells – uterine body Malignant cells – vagina Malignant cells – ovary Malignant cells – other

Clinical Management Recommendation Group

National Cervical Screening Program

Recommendation
0 No recommendation
1 Rescreen in 5 years
2 Rescreen in 3 years
3 Repeat HPV test in 12 months
4 Co-test in 12 months
5 Retest in 6 weeks
6 Refer for colposcopic assessment
7 Test taken at time of colposcopy, no recommendation
8 Discharge from program
9 Other management recommendation
S Symptomatic—clinical management required
P Rescreen in 2 years

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Appendix D Performance Measures Worksheets (Normative)

These work sheets are provided to assist laboratories in the calculation of these measures.

Table 1: Performance measure 2a (i), Screening result rates Screening episodes, Young vaccinated cohort

	HPV negative§§§§§	Oncogenic HPV (not 16 or 18)	HPV 16 &/ or 18	Total
LBC Unsat	Lower risk	Unsat	Higher risk	
LBC Neg		Intermediate	Higher risk	
LBC (pLSIL)		Intermediate	Higher risk	
LBC (pHSIL)		Higher risk	Higher risk	
Total				

Table 2: Performance measures 2a(ii), Screening episodes, Older unvaccinated cohort

	HPV negative******	Oncogenic HPV (not 16 or 18)	HPV 16 &/ or 18	Total
LBC Unsat	Lower risk	Unsat	Higher risk	
LBC Neg		Intermediate	Higher risk	
LBC (p)LSIL		Intermediate	Higher risk	
LBC (p)HSIL		Higher risk	Higher risk	
Total				

Table 3: Performance measure 2b (i), Other episodes, Young vaccinated cohort

	HPV negative	Oncogenic HPV (not 16 or 18)	HPV 16 &/ or 18	Total
LBC Unsat				
LBC Neg				
LBC (p)LSIL				
LBC (p)HSIL				
Total				

§§§§§ LBC not performed
****** LBC not performed

Table 4: Performance measures 2b (ii), Other episodes, Older unvaccinated cohort

	HPV negative	Oncogenic HPV (not 16 or 18)	HPV 16 &/ or 18	Total
LBC Unsat				
LBC Neg				
LBC (pLSIL)				
LBC (pHSIL)				
Total				

Table 5: Performance measure 3a, The PPV of HSIL (Histologically confirmed HSIL/ AIS cases among those with histological reports of HSIL.)

	HPV 16 &/ or 18	Oncogenic HPV (not 16 or 18) with HSIL/AIS LBC or persistent HPV+ (any type)	Total
Young vaccinated cohort			
Older unvaccinated cohort			
Total			

Table 6: Performance measure 3b, The PPV of pHSIL (Histologically confirmed HSIL / AIS cases among those with histological reports of HSIL.)

	HPV 16 &/ or 18	Oncogenic HPV (not 16 or 18) with HSIL/AIS LBC or persistent HPV+ (any type)	Total
Young vaccinated cohort			
Older unvaccinated cohort			
Total			

Table 7: Performance Measure 4 – Accuracy of low risk cervical screening reports

Number of women with histologically confirmed HSIL or malignancy in the year being interrogated, with any cervical screening reported by your laboratory during the preceding 63 months.	**4.1**

Number of women with histologically confirmed HSIL or malignancy in the year being interrogated, with a "lower risk" cervical screening report in the preceding 63 months.	**4.2**

Percentage of women with a histological diagnosis of HSIL or malignancy with "lower risk" cervical screening reported in the preceding 63 months by your laboratory.	**4.3**

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