NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

REQUIREMENTS FOR LABORATORIES REPORTING TESTS FOR THE NATIONAL CERVICAL SCREENING PROGRAM

(Second Edition 2019)

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*
Second edition 2019	Revised and reprinted

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 (Second Edition 2019)* 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

AIS	Adenocarcinoma in situ
AS	Australian Standard
ASC	Australian Society of Cytology
CIN	Cervical intraepithelial neoplasia
CT(ASC)	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
RCPA QAP	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.
Assay	means HPV nucleic acid test.
Co-test	means a procedure in which a human papillomavirus test and liquid based cytology are done at the same time to check for cervical cancer. The HPV test looks for DNA or RNA from certain high risk types of HPV in samples of cells taken from the cervix.
Cytologist	means a cytologist holding the Australian Society of Cytology CT(ASC) qualification which includes the gynaecological cytology component.
Device	means instrument assay is processed on.
Follow-up specimen	means a specimen taken following an "intermediate risk" screening result (recommended at 12 months). It may also mean a test taken when a woman is under surveillance or following a discordant screening and histology result.
HPV NAT	means HPV nucleic acid testing.
HPV 16/18 positivity	means that HPV 16 and/ or HPV 18 (+/- 45)* are detected.
LBC	means liquid based cytology.
HPV positivity rate	means the rate of any oncogenic HPV types (as defined below).
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.).
Oncogenic HPV types	means HPV types 16 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, ±66, 68).†

* As some assays give combined HPV 18/45 result

† 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 (types 26, 53, 66, 67, 70, 73, 82) or possibly carcinogenic on the basis of inadequate evidence (30, 34, 69, 85, 97), which may change over time in future IARC reviews.

Term	Definition
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).
Primary screening	means the detection and identification of the microorganism of interest in asymptomatic patients
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.
Clinical Scientist	means the same as the definition in the NPAAC *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories.*
Specimen	means any tissue or fluid from a patient that is submitted to the laboratory for testing.
Trainee scientist	means a person who holds a basic science degree with limited experience in cytology who is undertaking a documented formal training program which is intended to lead to the ASC CT(ASC) qualification.

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Introduction

The *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (Second Edition 2019)* 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) has changed 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 (previously) 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 and testing platforms will be limited, similar to the Bowel Cancer Screening Program in

[‡] 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.

Australia. The requirement for daily use of third party (non-manufacturer) controls is an additional level of quality assurance. The First Edition of this document included a requirement for each laboratory to monitor their HPV positivity rate per batch of 2000 samples, and to report variance from the national rate, as monitored by the NCSR, on at least a quarterly basis. This additional quality measure was intended to monitor broader assay performance issues, and was based on data from the Compass Trial which indicated that a sample cohort of 2000 was required to produce a robust sample size in which to examine HPV positivity rates. A commitment was made to review the utility of this quality measure when national testing data became available. Consideration of data available from the first 6 months of the NCSP has indicated that the rate per 2000 is not currently functioning as a useful quality indicator, the rates in individual laboratories being affected by factors including demographic differences in tested populations and differences in classification of screening episodes. While comparison between a laboratory's positivity rate and the national rate is still considered a necessary internal benchmarking exercise, reporting of rates outside the confidence limits to the NCSR is no longer mandated as a standard. All other quality measures, including the necessity to report 90% of results within a 10 day period, remain in place.

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 care practitioner has been introduced. The self-collection program is a pioneering initiative and at this stage evidence is limited on the optimal NAT method. The specimen may 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. An initial meta-analysis of 36 studies involving self-collection for HPV testing 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. This was confirmed in a subsequent meta-analysis[2] which also demonstrated a clear difference between PCR-based tests and other assays in terms of sensitivity in self-collect samples. For this reason the use of a PCR-based assay is required in the assessment of self-collect samples. Self-collection will be closely monitored by the NCSP and the collected data will inform later revisions 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.

A detailed review of issues relating to Performance Measures for HPV NAT and LBC in the renewed NCSP have not been addressed in the current version of the Requirements, and will be considered alongside the development of numeric standards when sufficient data has accrued. It is proposed to rename these measures Program Assurance Measures to reflect the intent to monitor the performance of the Screening Program as a whole, rather than the performance of individual cytology screeners, now that the primary screening tool is HPV testing rather than cytology. Appendix B which details strategies for investigating failure to meet Program Assurance Measures for LBC has been retained for completeness, but only becomes normative when and if numerical standards are set.

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.

The *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (Second Edition 2019)* supports the NCSP Quality Framework in achieving high quality pathology laboratory services.

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)*[3] 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 during the transition phase.

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

All Tier 2 and Tier 3 Documents

Tier 4 Document

- *Requirements for Validation of Self-Collected Vaginal Swabs for Use in the National Cervical Screening Program*
- *Requirements for Medical Testing of Microbial Nucleic Acids*
- *Performance Measures for Australian Laboratories Reporting Cervical Cytology*

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

[§] Cancer Council Cervical Screening Guidelines

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**.

Please note that any Appendices attached to this document may be either **normative** or **informative** in nature and should be considered to be an integral part of this document. Please note that all NPAAC documents can be accessed at Department of Health.

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 6 in *Requirements for Medical Pathology Services*)

HPV NAT

S1.1 HPV NAT must be supervised by a Pathologist with relevant qualifications, competencies and scope of practice in NAT.

C1.1 The supervising pathologist may delegate operational supervision to a Clinical Scientist with relevant qualifications, competencies and scope of practice 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 Clinical Scientist trained and competent in liquid based cytology.**

S1.4 Cytology staff employed for examining gynaecological 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.

[**] *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories*

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

C1.5 If the number of abnormal cases reported by a Pathologist or Scientist is insufficient, the Pathologist or Scientist **must** take part in documented supplementary activities designed to meet this requirement and maintain expertise.

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 liquid based cytology and any imaging devices being employed within the laboratory to assist in the examination of LBC slides.

C1.10 Pathologists or Cytologists examining LBC must participate in a LBC module in an external quality assurance program.

2. Facilities

(Refer to Standard 7A 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 8A in *Requirements for Medical Pathology Services*)

Specimen requirements for practitioner collected tests

S3.1 **The laboratory must advise requesting health practitioners that the specimen must be identified as a screening specimen, follow-up specimen, specimen from a patient with symptoms or signs suspicious for cervical neoplasia, post-treatment for dysplasia specimen or a self-collected specimen (see below).**

S3.2 **The laboratory must provide advice for requesting health practitioners on the collection of satisfactory cervical specimens using suitable collection medium and device, 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 used by requesting health practitioners to collect the cervical specimen must be suitable and validated for use with both the HPV NAT offered and the LBC test, as intended by the manufacturer.**

Retention (Screening tests only)

S3.4 **Where LBC has not been performed, the original screening specimen must be retained for a period of at least two weeks after the report is validated.**

S3.5 **Where LBC has been performed, the residual specimen 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 Table 10.5 in the *Requirements for the Retention of Laboratory Records and Diagnostic Materials*.**

Retention (Non-screening (diagnostic) tests)

S3.6 **The specimens for HPV NAT and LBC must be retained in accordance with Table 10.5 in the *Requirements for the Retention of Laboratory Records and Diagnostic Materials*.**

Specimen requirements for self-collected tests

S3.7 **Self-collected specimens must be clearly identified as such.**

S3.8 **The laboratory must provide instructions for self-sampling for patients and health practitioners, including instructions for storage and transport of specimens.**

S3.9 **The collection device and collection medium if used, must be suitable and validated for use with the HPV NAT method.**

C3.9 If the use of self-collected vaginal swabs has not been validated by the manufacturer, the laboratory **must** validate the use of self-collected vaginal swabs either through direct comparison with health practitioner collected cervical samples, or using methodology as described in the *Requirements for Validation of Self-Collected Vaginal Swabs for Use in the National Cervical Screening Program.*[††]

Retention (Self-collected tests)

S3.10 **The self-collected HPV NAT material must be retained in accordance with Table 10.5 in the *Requirements for the Retention of Laboratory Records and Diagnostic Materials*.**

[††] http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm

Analytical

4. Equipment

(Refer to Standard 7B 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.

Assays are expected to meet what are commonly referred to as the *Meijer criteria.*[4] If the described sensitivity and specificity of the assay in the manufacturer's kit insert does not demonstrate compliance with these criteria, the laboratory is required to demonstrate that evidence of compliance is available in peer-reviewed published literature.

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.[4]

(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.

‡‡ HPV tests that give a result for HPV18/45 will be managed as HPV 18

(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.

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

b) Incorporate a control for cellularity to detect inadequate or empty cervical samples.

C4.4 Unsuitable specimens (e.g. 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

Self-collected program is a pioneering initiative and at this stage evidence indicates that only PCR-based assays show similar levels of sensitivity and specificity between self-collected and health practitioner-collected samples.[1,2] Evidence for utility of other HPV NAT or nucleic acid amplification methods will be subject to review in the future.

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

[§§] There is no requirement that S4.4 (e) and (f) are independent of each other

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 the *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 a relevant 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 (+/- 45) 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 **When HPV NAT is performed within the NCSP externally sourced non-manufacturer supplied control material for at least HPV types 16/18 must be used daily.** [†††]

C5.4 Use of registered control materials for other oncogenic HPV types should be incorporated as they become available.

S5.5 **If a reagent batch failure is detected by a laboratory, the laboratory must investigate the cause and take appropriate remedial action..**[‡‡‡]

C5.5 If the batch failure relates to a reagent failure with the potential to impact on the quality of testing of other providers, the laboratory **must** notify the TGA and NCSP immediately so that other users can be notified.

[***] S7.2 *Requirements for Medical Pathology Services*
[†††] ISO 15189 *Medical laboratories – Requirements for quality and competence – S5.6.2.2*
[‡‡‡] ISO 15189 *Medical laboratories – Requirements for quality and competence*

Quality Measures for HPV NAT, Screening specimens only

S5.6 Laboratories must compare their rates of HPV detection in screening tests with the rates most recently reported by the NCSR for internal benchmarking purposes.

C5.6(i) The NCSR will use the routinely submitted data to produce a periodic age stratified data set (including mean and 95% confidence interval) compiled from data from all screening HPV testing throughout Australia.

C5.6(ii) If the laboratory's overall HPV positivity rate in screening tests is not within the 95% confidence interval, the laboratory **must** investigate the cause (refer to ***Appendix A)***.

C5.6(iii) Monitoring of HPV positivity and investigation if required **must** occur at least quarterly and the results or outcomes recorded.

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

S5.7 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.

C5.7 Each of these activities **must** be monitored on an ongoing basis and the results or outcomes recorded.

Post-Analytical

6. Reporting

(Refer to Standard 8C 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 (for cervical screening tests, where relevant), specimen type, test results and management recommendation.

C6.2 Cervical screening risk classification is only required for screening specimens, including primary screening, follow-up and tests of cure.

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

S6.4 The laboratory must have a documented procedure for the notification to the NCSR.

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.

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

(Refer to Standard 8 in *Requirements for Medical Pathology Services*)

Currently there is insufficient data available to set numeric program assurance 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 program assurance measures have been developed without set values at this stage. Numeric standards will be considered when sufficient data has been accrued.

Program Assurance Measures for HPV NAT and LBC in the renewed NCSP will apply to specimens taken by health care practitioners after the implementation of the NCSP and do not include self-collected specimens at this stage.

Most of the information required to calculate these measures will be provided to laboratories by the NCSR.

All program assurance measures **must** be tabulated in accordance with ***Appendix D.***

Program Assurance Measure 1

S7.1 **The number and percentage of episodes reported as 'unsatisfactory' must be reported to the RCPA QAP.**

C7.1(i) This **must** be reported to the RCPA QAP by March in the following year unless a different date is specified by the RCPA QAP.

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

C7.1(iii) The definition of "Unsatisfactory" for HPV NAT and LBC is defined in the *NSCP 2016 Guidelines.* [3]

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

Program Assurance 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 RCPA QAP by March in the following year unless a different date is specified by the RCPA QAP.

[§§§] 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***

C7.2(ii) Laboratories **must** break down 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 30 June 1980 to separate younger mostly vaccinated women from older unvaccinated women.

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

Program Assurance 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 RCPA QAP by March in the following year unless a different date is specified by the RCPA QAP.

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

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

Program Assurance Measure 3a

S7.4 The proportion of all 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 RCPA QAP. This must include breakdown of results according to whether HPV 16/18, non-16/18 or no oncogenic HPV was initially detected.

C7.4(i) This **must** be reported to the RCPA QAP by October in the following year unless a different date is specified by the RCPA QAP.

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.

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

Program Assurance Measure 3b

S7.5 **The proportion of all 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 RCPA QAP. This must include breakdown of results according to whether HPV 16/18, non-16/18 or no oncogenic HPV was initially detected.**

C7.5(i) This **must** be reported to the RCPA QAP by October in the following year unless a different date is specified by the RCPA QAP.

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.

Program Assurance Measure 4

S7.6 **The proportion of women with histological diagnosis of HSIL, AIS or cervical malignancy which were originally reported as low risk with a primary screening HPV NAT within the last 63 months must be reported to the RCPA QAP when this data is requested.**

Appendix A Guidance on investigating HPV detection rates (Informative)

If a laboratory's HPV detection rate is found to be outside of the 95% confidence interval from the mean national positivity rate, this may be a result of differences in the age distribution, high risk population, classification of screening status or other unmeasured factors.

The laboratory should consider the implementation of internal benchmarks using control charts, such as P-charts, for ongoing monitoring of the laboratory-specific positivity rate. The *Requirements for Testing of Microbial Nucleic Acids*[‡‡‡‡] also provides additional advice on operational validation and ongoing monitoring of assays.

This Appendix sets out the steps to be taken if the overall HPV positivity rate as monitored by the laboratory falls outside of the 95% confidence interval from the current mean national positivity rate.

1. The laboratory should compare their HPV positivity rates for the younger vaccine-eligible age cohort (born post-June 30, 1980) and older age cohorts (born pre-June 30, 1980) with the most recently available NCSR age-specific rates.
2. If HPV positivity rate is within the 95% confidence interval for the age cohorts the investigation does not need to proceed.
3. If HPV positivity rate is not within the 95% confidence interval for one or more of the age cohorts, the laboratory should investigate the device-specific ranges (contact the NCSR for these values).
4. If HPV positivity rate is not within the device and assay-specific 95% confidence interval, the laboratory should continue its investigation to determine the likely cause of the variance and ensure there has been no failure in quality.
5. If after following the above steps laboratories are still concerned they should consult with the NCSR.

[‡‡‡‡] *Requirements for Medical Testing of Microbial Nucleic Acids (Second Edition 2013)*

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

(Refer to Standard 2, Standard 3 and Standard 8 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 Program Assurance Measures are established.

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

1. If any of the LBC Program Assurance 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 Program Assurance 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 Program Assurance Measures
   c. implement corrective actions within three months.

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

7. If any subsequent LBC Program Assurance 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.

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	
Provider data items	Telephone number – mobile	Report if available
	Email address	Report if available
	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)****	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	10. other

**** For the purpose of this coding sheet, a repeat test after prior unsatisfactory screening test should be coded according to the circumstances of the original (unsatisfactory test). While this will most commonly be a primary screening HPV test, it may also be a follow-up test or a test of cure.

†††† 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 are potential tests that may be 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 Program Assurance Measures for cervical screening should be used in the National Cervical Screening Program. It is the responsibility of the providers to check the registration of HPV tests. 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		

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 Program Assurance Measures Worksheets (Normative)

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

Table 1: Program Assurance measure 2a(i), Screening result rates Screening episodes, Young potentially 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 (p)LSIL		Intermediate	Higher risk	
LBC (p)HSIL		Higher risk	Higher risk	
Total				

Table 2: Program Assurance measure 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: Program Assurance measure 2b(i), Other episodes, Young potentially 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

Table 4: Program Assurance measure 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: Program Assurance 3a, The PPV of HSIL (histologically confirmed HSIL, AIS or cervical malignancy cases among those with available histological reports)

	HPV 16 &/ or 18	Oncogenic HPV (not 16 or 18)	Oncogenic HPV not detected	Total
Young vaccinated cohort				
Older unvaccinated cohort				
Total				

Table 6: Program Assurance measure 3b, The PPV of pHSIL (histologically confirmed HSIL,AIS or cervical malignancy cases among those with available histological reports)

	HPV 16 &/ or 18	Oncogenic HPV (not 16 or 18)	Oncogenic HPV not detected	Total
Young vaccinated cohort				
Older unvaccinated cohort				
Total				

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

Number of women with histologically confirmed HSIL, AIS or cervical 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, AIS or cervical 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, AIS or cervical malignancy with "lower risk" cervical screening reported in the preceding 63 months by your laboratory.	**4.3**

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