

AUSTRALIAN COMMISSION  
ON SAFETY AND QUALITY IN HEALTH CARE



TRIM: D22-40572

# Requirements for cervical screening

First Edition 2023

Published by the Australian Commission on Safety and Quality in Health Care  
Level 5, 255 Elizabeth Street, Sydney NSW 2000

Phone: (02) 9126 3600

Email: [mail@safetyandquality.gov.au](mailto:mail@safetyandquality.gov.au)  
Website: [www.safetyandquality.gov.au](http://www.safetyandquality.gov.au)

ISBN: 978-1-922880-72-7

© Australian Commission on Safety and Quality in Health Care 2023

All material and work produced by the Australian Commission on Safety and Quality in Health Care (the Commission) is protected by copyright. The Commission reserves the right to set out the terms and conditions for the use of such material.

As far as practicable, material for which the copyright is owned by a third party will be clearly labelled. The Commission has made all reasonable efforts to ensure that this material has been reproduced in this publication with the full consent of the copyright owners.

With the exception of any material protected by a trademark, any content provided by third parties and where otherwise noted, all material presented in this publication is licensed under a [Creative Commons Attribution–NonCommercial–NoDerivatives 4.0 International licence](https://creativecommons.org/licenses/by-nc-nd/4.0/).



Enquiries about the licence and any use of this publication are welcome and can be sent to [communications@safetyandquality.gov.au](mailto:communications@safetyandquality.gov.au).

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

Australian Commission on Safety and Quality in Health Care. Requirements for cervical screening.  
1st ed. Sydney: ACSQHC; 2023

## Disclaimer

The content of this document is published in good faith by the Commission for information purposes. The document is not intended to provide guidance on particular healthcare choices. You should contact your health care provider for information or advice on particular healthcare choices.

The Commission does not accept any legal liability for any injury, loss or damage incurred by the use of, or reliance on, this document.

2023 First edition supersedes *Requirements for laboratories reporting tests for the National Cervical Screening Program (Second Edition 2019)*, *Requirements for validation of self-collected vaginal swabs for use in the National Cervical Screening Program (First Edition 2019)*, *Performance measures for Australian laboratories reporting cervical cytology (Third Edition 2015)*

## Contents

Scope .....	5
Definitions .....	6
Introduction .....	7
1 Clinical Governance .....	8
2 Risk management .....	9
3 Quality Management .....	10
4 Personnel .....	12
5 Specimens .....	13
6 Equipment .....	15
7 Reporting .....	17
Appendix 1: Program Indicators .....	18
References .....	21

### **National Pathology Accreditation Advisory Council**

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to the accreditation of pathology laboratories and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. A function of NPAAC is to formulate standards and initiate and promote education programs about pathology tests.

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

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

### **Australian Commission on Safety and Quality in Health Care**

The Australian Commission on Safety and Quality in Health Care (the Commission) leads and coordinates national improvements in health care safety and quality. The Commission works in partnership with patients, carers, clinicians, the Australian state and territory health systems, the private sector, managers, healthcare organisations, colleges and professional organisations to achieve a safe, high-quality and sustainable health system.

The Commission's statutory functions include formulating model national schemes that provide for the accreditation of organisations that provide health care services and relate to healthcare safety and quality matters.

The Commission is responsible for the administration of the National Pathology Accreditation Scheme on behalf of the Australian Government Department of Health and Aged Care (the Department). The Department retains responsibility for the regulation and funding of pathology in Australia.

# Scope

The *Requirements for cervical screening (First Edition 2023)* is a Tier 4 NPAAC document and must be read in conjunction with Tier 2 and Tier 3 documents. This document sets out the standards for using Human Papillomavirus nucleic acid testing as the primary screening method for cervical cancer screening.

Tier 2, *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. Tier 3 documents include specific governance actions relating to retention, packaging and transport and development and use of in-house in vitro diagnostic medical devices.

Testing of self-collected vaginal swabs has been included in this document. In many contexts, the self-collection of cervical screening specimens for Human Papillomavirus analysis is more acceptable to the National Cervical Screening Program participants than is the collection of specimens by a clinician.

The *Requirements for cervical screening (First Edition 2023)* include the minimum standards that a laboratory must meet in order to offer testing of self-collected vaginal swabs for Human Papillomavirus as part of the National Cervical Screening Program as an in-house in vitro diagnostic medical device. The Therapeutic Goods Administration (TGA) is responsible for ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose. Australian laboratories that develop and use in-house in vitro diagnostic medical devices are considered to be the manufacturer. These laboratories are required to meet regulatory requirements set out in the [Therapeutic Goods \(Medical Devices\) Regulations](#).

This document replaces three previous Tier 4 NPAAC documents, namely:

- Requirements for laboratories reporting tests for the National Cervical Screening Program (Second Edition 2019)
- Requirements for validation of self-collected vaginal swabs for use in the National Cervical Screening Program (First Edition 2019)
- Performance measures for Australian laboratories reporting cervical cytology (Third Edition 2015)

# Definitions

Term	Description
National Cervical Screening Program	a joint program of the Australian Government and the state and territory governments. It is implemented by a range of health professionals, including general practitioners, women's health nurses, gynaecologists, gynaecological oncologists, cytologists and pathologists. <sup>1</sup>
National Cancer Screening Register	a single electronic record for each person in Australia participating in cervical and bowel screening. <sup>2</sup>
Quality assurance	relates to participation in relevant Quality Assurance Programs, performance reviews and corrective actions where performance is unsatisfactory.
Quality control	relates to processes to monitor assay performance and record corrective actions; and internal audits with a focus on the modified analytical processes.
Sample adequacy	assessed using internal cellularity control.
Self-collection/self-collected specimen	a lower vaginal specimen that can be used to perform a Human Papillomavirus test. The lower vaginal specimen could be collected by the patient, or the healthcare professional (if the patient has difficulty collecting the specimen by themselves or prefers the clinician to collect the specimen using a self-collection swab without using a speculum). Liquid based cytology cannot be performed on a self-collected specimen. <sup>3</sup>
Specimen analysis	the process of examination that produces a result.
Specimen integrity	quality and suitability of the specimen for analysis or examination.
Specimen traceability	the ability to track all specimens back to a patient or to its origin.
Underscreened	women and people with a cervix who are over 30 years of age and are two or more years overdue for their routine five-yearly cervical screening test. <sup>3</sup>
Validation	confirmation of plausibility for a specific intended use or application through the provision of objective evidence that specified requirements have been fulfilled. <sup>4</sup>
Verification	confirmation of truthfulness, through the provision of objective evidence that specified requirements have been fulfilled. <sup>4</sup>
Workforce	all people working in a laboratory, including pathologists, clinical scientists, cytology scientists and any other employed or contracted, locum, agency, student, volunteer or peer workers. The workforce can be members of the laboratory or medical company representatives providing technical support who have assigned roles and responsibilities in the laboratory. <sup>5</sup>

# Introduction

The primary aims of the *Requirements for cervical screening* are to protect women and people with a cervix from harm occurring as a result of poor-quality screening processes, from collection, including self-collections, to the communication of results. The *Requirements for cervical screening (First Edition 2023)* have been designed to be implemented in pathology laboratories along with Tier 2 and Tier 3 national pathology accreditation standards.

The National Cervical Screening Program aims to prevent cervical cancer through regular testing for Human Papillomavirus so that if present it can be monitored or investigated further if needed. The program targets women and people with a cervix from 25 to 74 years of age.

Despite the success of Human Papillomavirus vaccination in reducing cervical cancer overall, it is still one of the cancers where screening for early evidence of cancer enables the prevention of progression. Most invasive cervical cancers occur in underscreened or never screened people. Having regular screening tests offers the best protection against cervical cancer.

All cervical screening participants now have the choice to collect their own cervical screening test specimen. Self-collection improves participation in screening for all people eligible for screening by providing choice and overcoming barriers to participation associated with the requirement for a speculum examination.

The *Requirements for cervical screening (First Edition 2023)* were developed by the National Pathology Accreditation Advisory Council (NPAAC) in collaboration with the Australian Government, states and territories, private and public laboratories, anatomical pathology experts and consumers.

These are minimum standards considered acceptable for good laboratory practice.

Importantly, the *Requirements for cervical screening* provide a nationally consistent statement about the standard of care consumers can expect from pathology laboratories.

NPAAC documents can be accessed at the Australian Commission on Safety and Quality in Health Care [website](#).

Comments on this document from users can be directed to:

## **Australian Commission on Safety and Quality in Health Care**

Level 5, 255 Elizabeth Street  
Sydney NSW 2001

Phone: 1800 304 056

Email: [pathology@safetyandquality.gov.au](mailto:pathology@safetyandquality.gov.au)

Website: <https://www.safetyandquality.gov.au/our-work/accreditation/pathology-accreditation-standards>

# 1 Clinical Governance

Item	Action
Clinical governance	<p>1.01 The laboratory uses the safety and quality systems from Tier 2 and Tier 3 Standards when:</p> <ol style="list-style-type: none"><li>Implementing policies and procedures for National Cervical Screening Program testing</li><li>Managing risks with the transport, testing and reporting of cervical screening specimens</li><li>Identifying training requirements for the cervical screening workforce</li><li>Designing and maintaining a safe testing environment</li><li>Partnering with consumers in the provision of services.</li></ol>

---

The *Requirements for Medical Pathology Services* sets out requirements in relation to:

- Clinical governance
- Risk management
- Quality management
- Ethical practice

These systems and processes form the foundation for safe and good practice in implementing the *Requirements for cervical screening*. Those systems and processes should be applied in relation to cervical screening. For example, policy and procedure requirements in the *Requirements for Medical Pathology Services* about timeliness and maintenance apply when drafting policies and procedures for cervical screening.

Key tasks for a laboratory may include:

- Setup of a comprehensive suite of policies, procedures and protocols that emphasise safety and quality
- Mechanisms to maintain currency of policies, procedures and protocols, and to communicate changes in them to the workforce.
- Review the use and effectiveness of policies, procedures and protocols through audits or performance reviews

Develop or adapt a legislative compliance system that incorporates a compliance register to ensure that policies, procedures and protocols are regularly and reliably updated, and respond to relevant regulatory changes, compliance issues and case law.

---



## 2 Risk management

Item	Action
Collection, testing and reporting on specimens	2.01 The laboratory uses a risk-based approach when testing specimens, including self-collected specimens, and has processes to assess: <ul style="list-style-type: none"><li>a. Specimen integrity</li><li>b. Specimen traceability</li><li>c. Specimen analysis</li><li>d. Quality Control</li><li>e. Quality Assurance</li></ul>

---

Key tasks for a laboratory may include:

- Review the laboratory's risk management system, and ensure that it is appropriately designed, resourced, maintained and monitored
  - Consider existing sources of information about safety, and whether more information is needed to reliably assess risk
  - Consider whether risk management orientation, education and training are adequately covered in the laboratory's education and training program
  - Ensure clear allocation of roles, responsibilities and accountabilities for maintaining the risk management systems and for performing the actions required
  - Regularly review risks and develop reports for the laboratory's governing body and workforce
  - Periodically review the effectiveness of the risk management system
-

### 3 Quality Management

Item	Action
Quality measures	<p>3.01 The laboratory has processes to routinely participate in an approved external quality assurance program by:</p> <ul style="list-style-type: none"> <li>a. Collecting and submitting data on Program Indicators (See Appendix 1) in the format required for Human Papillomavirus nucleic acid testing and liquid-based cytology</li> <li>b. Reviewing external quality assurance reports and other quality measures and acting to improve its performance</li> </ul>
<p>The Royal College of Pathologists of Australasia Quality Assurance Programs have approved external quality assurance programs for cytology and microbiology.</p>	
Detection rates	<p>3.02 The laboratory has processes to review its Human Papillomavirus 16, 18 and non 16 or 18 detection rates at least quarterly and:</p> <ul style="list-style-type: none"> <li>a. Monitor the positivity rate and the unsatisfactory rate for clinician-collected and self-collected specimens</li> <li>b. Benchmark its rates against current rates reported from the National Cancer Screening Register</li> </ul>
Internal audit	<p>3.03 The laboratory has a process for follow-up to correlate the results of Liquid Based Cytology with relevant histopathology</p>
<p>3.04 The laboratory undertaking Human Papillomavirus nucleic acid testing, as part of the National Cervical Screening Program, uses suitable controls for Human Papillomavirus 16,18, non 16 or 18 and other, each day the test is run</p>	
<p>Commercially supplied Human Papillomavirus assays may include controls. Where the manufacturer does not include controls, independent controls developed by the laboratory should be used.</p>	
<p>3.05 The laboratory has procedures to identify, investigate and act when a batch of reagent fails</p>	
<p>3.06 The laboratory notifies the Therapeutic Goods Administration and the National Cervical Screening Program within five business days when a batch of reagent fails, and this failure could impact the quality of testing of other providers</p>	

---

In-house  
validation

3.07 The laboratory validates new technologies, methodology and off label use of sampling equipment in accordance with the *Requirements for development and use of in-house in vitro diagnostic medical devices*

---

Specimen stability for self-collected vaginal swabs are validated and should not exceed the transport and handling conditions already validated by the comparator laboratory.

Analytical performance is verified by individual laboratories within a laboratory network prior to implementation in the laboratory.

It is best practice that any modifications to the self-collect device is re-validated. For example, variations made to an in-house in vitro device, such as a change in swab type or methodology must be re-validated.

A reasonable minimum number of positive self-collected screening specimens required for validation is 30. Based on a Human Papillomavirus positivity rate of 8.9%, laboratories may need to test up to 300 specimens to achieve at least 30 Human Papillomavirus positive self-collected specimens.

---

## 4 Personnel

Item	Action
Scope of clinical practice	<p data-bbox="459 414 991 450">4.01 The laboratory has processes to:</p> <ul style="list-style-type: none"><li data-bbox="571 481 1294 546">a. Define the scope of practice for pathologists, clinical scientists and cytology scientists</li><li data-bbox="571 548 1369 647">b. Monitor practices to ensure pathologists, clinical scientists and cytologists operate within their designated scope of practice</li><li data-bbox="571 649 1374 741">c. Review the scope of practice periodically and whenever a new procedure or technology is introduced or substantially altered</li></ul>

---

Pathologists involved in gynaecological cytology require competence in cytology and histology of gynaecological specimens to facilitate histological and cytological correlation.

Cytology staff examining gynaecological liquid-based cytology will hold the qualification Certificate of Technology of the Australian Society of Cytology that includes a gynaecological cytology component. Members of the workforce preparing for the examination of the Certificate of Technology of the Australian Society of Cytology may report on liquid-based cytology under supervision.

Review of scope of practice should be undertaken at least every three years or sooner if there is a change in position, technology, service provision by the laboratory or new procedures introduced.

---

## 5 Specimens

Item	Action
Clinician-collected and self-collected specimens	<p>5.01 The laboratory has processes to provide information to clinicians and patients on the collection and self-collection of cervical specimens. The information provided</p> <ol style="list-style-type: none"> <li>a. Is easily accessible</li> <li>b. Is clear, concise and tailored to their needs</li> <li>c. Informs clinicians which self-collection devices the laboratory processes</li> <li>d. Specifies the handling and transport of cervical specimens</li> </ol>

---

The information provided to clinicians and patients should include, but is not limited to:

- a. Information about how the collection medium used by the requesting clinician to collect the cervical specimen is:
  - i) used as intended by the manufacturer, or
  - ii) has been validated in house by the laboratory
- b. Identification of the specimen as one of the following:
  - screening specimen
  - follow-up specimen
  - specimen from a patient with symptoms or signs suspicious for cancer
  - post-treatment for high-grade squamous intra-epithelial lesion and adenocarcinoma-in-situ
- c. Identification of specimen collection type as one of the following:
  - clinician-collected
  - self-collected
- d. Specimens collected by clinicians from the cervix should be taken under direct vision so that the specimen is suitable for both for Human Papillomavirus testing and for reflex liquid-based cytology<sup>6,7</sup>
- e. Instructions for self-collection suitable for patients and clinicians
- f. Expiry dates, storage and transportation conditions as required by the relevant manufacturer or the conditions of in-house validation.

---

Retention	<p>5.02 The laboratory has processes for the retention of the original screening specimen, consistent with the current edition of the <i>Requirements for the retention of laboratory records and diagnostic material</i></p>
-----------	---

---

The specimens for Human Papillomavirus nucleic acid testing (including self-collected specimens) and for liquid-based cytology, must be retained in accordance with *Requirements for the retention of laboratory records and diagnostic material*.

---

---

In addition, where liquid-based cytology has not been performed, the original screening specimen must be retained for a period of at least two weeks after the report is validated.

Where liquid-based cytology has been performed, the residual specimen must be retained for a period of at least one month after the report is validated.

---

## 6 Equipment

Item	Action
Screening specimens	<p>6.01 The laboratory has processes to ensure it uses commercially supplied Human Papillomavirus nucleic acid tests that are clinically validated for primary screening and listed on the Australian Register of Therapeutic Goods.</p> <hr/> <p>The Human Papillomavirus nucleic acid testing method will include tests for Human Papillomavirus genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68, and separately identify Human Papillomavirus 16 and Human Papillomavirus 18.</p> <p>Human Papillomavirus tests that give a result for Human Papillomavirus 18/45 will be managed as: Human Papillomavirus 18.</p> <hr/> <p>6.02 The laboratory has processes to ensure Human Papillomavirus nucleic acid testing assays used in primary screening are validated and meet best practice screening criteria</p> <hr/> <p>The Meijer Criteria<sup>8</sup> are the minimum standard laboratories use when assessing assays for use in the National Cervical Screening Program.</p> <p>Laboratories incorporate a control for cellularity to detect inadequate or empty cervical screening specimens.</p> <p><i>Diagnostic Human Papillomavirus Nucleic Testing</i></p> <p>The current usage of Human Papillomavirus as a diagnostic test for symptomatic women and people with a cervix and in the post treatment setting is covered by the <i>Requirements for medical testing of microbial nucleic acids</i></p> <p><i>Diagnostic Liquid Based Cytology</i></p> <p>Within the National Cervical Screening Program Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding (NCSP Guidelines) liquid-based cytology will be performed on women and people with a cervix in a number of clinical situations with or without concurrent Human Papillomavirus nucleic acid testing.</p> <hr/>
Self-collected specimens	<p>6.03 The laboratory has a process to ensure self-collected specimens are tested using a methodology that has been validated, that is either:</p> <ol style="list-style-type: none"> <li>a. Listed on the Australian Register of Therapeutic Goods</li> <li>b. Using an in-house validated Human Papillomavirus nucleic acid test assay</li> </ol> <hr/>

- 
- c. Referred to another laboratory where the self-collect device is validated for testing

---

Australian Register of Therapeutic Goods listed Human Papillomavirus assays must stipulate a claim for self-collected specimens.

- 
- 6.04 The laboratory has a process to ensure polymerase chain reaction-based assays are used for the assessment of self-collected cervical screening specimens
-



## 7 Reporting

Item	Action
Report layout	<p>7.01 The laboratory has processes for documenting reports that meet the requirements of the current National Cervical Screening Program Guidelines<sup>9</sup> as stipulated, and updated from time to time on the Cancer Council Australia <a href="#">website</a> and:</p> <ol style="list-style-type: none"><li>consider available previous screening history provided by the National Cervical Screening Program</li><li>are combined when more than one result is being issued</li><li>include an overall cervical screening risk classification (for cervical screening tests, where relevant)</li><li>include specimen type</li><li>include test results</li><li>include management recommendation consistent with National Cervical Screening Program policy.</li></ol> <hr/> <p>Cervical screening risk classification is only required for screening specimens, including primary screening, follow-up, and tests of cure.</p>
Abnormality reporting	<p>7.02 The laboratory has processes to ensure a pathologist confirms all liquid-based cytology reports indicating a cellular abnormality</p>
Reporting to National Cancer Screening Register	<p>7.03 The laboratory has processes to submit data on Human Papillomavirus tests, liquid-based cytology and cervical histopathology to the National Cancer Screening Register in line with its requirements that:</p> <ol style="list-style-type: none"><li>Are complete and timely</li><li>Comply with the <a href="#">National Cancer Screening Register</a> data format and structure</li><li>Include all relevant identifying information and demographic information</li><li>Incorporates Aboriginal and Torres Strait Islander status, where this is supplied by the referrer</li><li>Includes relevant cervical screening test outcomes data for Human Papillomavirus, liquid-based cytology and histopathology</li></ol>

# Appendix 1: Program Indicators

**IMPORTANT NOTE:** The following program indicators are to be used as a guide and are not mandatory requirements for accreditation.

The program indicators have been included to support pathology laboratories involved in the National Cervical Screening Program to monitor how well they implement the safety and quality practices described in the *Requirements for cervical screening*. These program indicators are a tool to support quality improvement activities. No benchmarks are set for any program indicator.

The Royal College of Pathologists of Australasia Quality Assurance Programs is one organisation collecting program indicator data and providing this to the National Cervical Screening Program for review. They provide an approved external quality assurance program. The de-identified data is provided back to pathology laboratories involved in the National Cervical Screening Program to monitor performance.

Laboratories may choose to use other approved quality assurance programs.

Oversight of the program indicators for cervical screening rest with the National Cervical Screening Program and its National Cervical Screening Program Clinical Advisory Committee. They have responsibility for developing and maintaining numerical indicators that set national performance targets and benchmarks.

The indicators below set out the calculations to measure numerical performance.

## Indicator 1:

### The number and percentage of episodes reported as “unsatisfactory”.

1. Laboratories must report to their external quality assurance program by March for the previous calendar year unless a different date is specified.
2. The data to be submitted includes the total cervical screening specimens broken down by satisfactory and unsatisfactory Human Papillomavirus nucleic acid tests and unsatisfactory reflex liquid-based cytology.
3. Unsatisfactory tests are to be broken down by collection type; that is clinician-collected versus self-collected specimens.
4. The definition of “unsatisfactory” for Human Papillomavirus nucleic acid testing and liquid-based cytology is defined in the [National Cervical Screening Program Guidelines](#).

## **Indicator 2:**

**The proportion of all technically satisfactory cervical screening tests in which Human Papillomavirus is not detected or Human Papillomavirus (16/18) or (not 16/18) are detected.**

1. Laboratories must report to their external quality assurance program by March for the previous calendar year unless a different date is specified.
2. For both clinician-collected and self-collected specimen groups, calculate the risk rating, low, intermediate, and high-risk results in five-year age cohorts standardised by the National Cervical Screening Program.
3. Calculate the proportion of technically satisfactory cervical screening tests for each of the subgroups identified above using National Cervical Screening Program definitions.

## **Indicator 3:**

**The proportion of all liquid-based cytology specimens reported as high-grade squamous intraepithelial lesion or adenocarcinoma-in-situ where cervical histopathology, taken within six months, confirms the abnormality as high-grade squamous intraepithelial lesion, adenocarcinoma-in-situ or cervical malignancy.**

1. Laboratories must report to their external quality assurance program by October in the following year unless a different date is specified.
2. The proportion of all liquid-based cytology specimens reported as high-grade squamous intraepithelial lesion with confirmed abnormality is to be submitted.
3. The proportion of all liquid-based cytology specimens reported as adenocarcinoma-in-situ with confirmed abnormality is to be submitted.
4. When calculating the proportions for 2 and 3, where there is more than one histopathology report for a liquid-based cytology specimen, only the one with the highest grade of abnormality is included.

## **Indicator 4:**

**The proportion of all liquid-based cytology specimens reported as possible high-grade squamous intraepithelial lesion or possible high-grade endocervical glandular lesion where cervical histopathology, taken within six months, confirms the abnormality as high-grade squamous intraepithelial lesion, adenocarcinoma-in-situ or cervical malignancy.**

1. Laboratories must report to their external quality assurance program by October in the following year unless a different date is specified.
2. The proportion of all liquid-based cytology specimens reported as possible high-grade squamous intraepithelial with confirmed abnormality is to be submitted.
3. The proportion of all liquid-based cytology specimens reported as possible high-grade endocervical glandular lesion with confirmed abnormality is to be submitted.
4. When calculating the proportions for 2 and 3, where there is more than one histopathology report for a liquid-based cytology specimen, only the one with the highest grade of abnormality is included.

## **Indicator 5:**

**The proportion of women or people with a cervix with histological diagnosis of high-grade squamous intraepithelial lesion, adenocarcinoma-in-situ or cervical malignancy who's cervical screening specimens were originally reported as low risk with a primary screening Human Papillomavirus nucleic acid test within the last 63 months must be reported to the laboratory's external quality assurance program.**

1. Laboratories must report to their external quality assurance program by October in the following year unless a different date is specified.
2. The proportion of low-risk screens in the 63 months preceding a histologically confirmed diagnosis of high-grade squamous intraepithelial lesion, adenocarcinoma-in-situ, cervical malignancy, is to be submitted.

# References

1. Cancer Council Australia. Clinical Guidelines. 1 Cervical cancer in Australia. Sydney: Cancer Council Australia, 2022. <https://www.cancer.org.au/clinical-guidelines/cervical-cancer/cervical-cancer-screening/cervical-cancer-in-australia> (accessed Jan 2023).
2. Australian Government Department of Health and Aged Care. About the National Cervical Screening Program. Canberra: Australian Government Department of Health and Aged Care, May 2023. <https://www.health.gov.au/our-work/national-cervical-screening-program> (accessed 15 May 2023).
3. Cancer Council Australia. Clinical Guidelines. Glossary of terms and abbreviations. Sydney: Cancer Council Australia, 2022. <https://www.cancer.org.au/clinical-guidelines/cervical-cancer/cervical-cancer-screening/appendices/glossary-of-terms-and-abbreviations> (accessed Jan 2023)
4. International Organization for Standardization. ISO 15189 Medical laboratories - Requirements for quality and competence. Fourth Edition. Geneva: International Organization for Standardization; 2022
5. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. 2nd ed. – version 2. Sydney: ACSQHC; 2021.
6. Arbyn M, Smith SB, Temin S, Sultana F, Castle P et al. Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated metaanalyses. *BMJ* 2018;363:k4823 | doi: 10.1136/bmj.k4823.
7. Cancer Council Australia. Clinical Guidelines. Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. Sydney: Cancer Council Australia, 2022. <https://www.cancer.org.au/clinical-guidelines/cervical-cancer/cervical-cancer-screening> (accessed Jan 2023).
8. Meijer CJ, Berkhof J, Castle PE, Hesselink AT, Franco EL, Ronco G, Arbyn M, Bosch FX, Cuzick J, Dillner J, Heideman DA. Guidelines for human papillomavirus DNA test requirements for primary cervical cancer screening in women 30 years and older, *International Journal of Cancer*, 2009 Feb 1;124(3):516-20.
9. Cancer Council Australia. Clinical Guidelines. Preparation of cervical screening reports. Sydney: Cancer Council Australia, 2022. <https://www.cancer.org.au/clinical-guidelines/cervical-cancer/cervical-cancer-screening/terminology/preparation-of-cervical-screening-reports> (accessed Jan 2023).

**AUSTRALIAN COMMISSION  
ON SAFETY AND QUALITY IN HEALTH CARE**

Level 5, 255 Elizabeth Street, Sydney NSW 2000  
GPO Box 5480, Sydney NSW 2001

Phone: (02) 9126 3600

Email: [mail@safetyandquality.gov.au](mailto:mail@safetyandquality.gov.au)

Website: [www.safetyandquality.gov.au](http://www.safetyandquality.gov.au)