



**Australian Government**

**Department of Health**

## **The National Cancer Screening Register Rules 2017 (the Rules) – Data requirements for pathology providers**

The Rules require certain cervical screening information to be notified by pathology to the Commonwealth Chief Medical Officer (CMO) through the National Cancer Screening Register (the Register) within 14 days, from 1 December 2017.

Below is guidance to assist with interpretation of what kind of data to report under each of the mandatory fields, to align with the AIHW NCSR program performance and monitoring reporting and with the NPAAC requirements as appropriate.

Data requirements that are not mandatory, must be reported if known by the colposcopist.

### **1. Demographic information as derived from the NPAAC standards and the AIHW National Cervical Screening Program Data Dictionary**

<b>Data attributes in the Rules</b>	<b>Mandatory</b>	<b>Specific information under NPAAC requirements and for AIHW reporting</b>
Patient information	<ul style="list-style-type: none"><li>• Yes</li></ul>	<ul style="list-style-type: none"><li>• full name</li><li>• date of birth</li><li>• gender</li><li>• address</li></ul>
Patient information	<ul style="list-style-type: none"><li>• No, report if known</li></ul>	<ul style="list-style-type: none"><li>• medicare number</li><li>• healthcare identifier</li><li>• indigenous status</li><li>• country of origin</li><li>• preferred language</li></ul>
Approved pathology practitioner information	<ul style="list-style-type: none"><li>• Yes</li></ul>	<ul style="list-style-type: none"><li>• full name</li><li>• provider number</li><li>• name of accredited pathology laboratory</li><li>• address of accredited pathology laboratory</li></ul>
Approved pathology practitioner information	<ul style="list-style-type: none"><li>• No, report if known</li></ul>	<ul style="list-style-type: none"><li>• healthcare identifier</li><li>• accredited pathology laboratory healthcare identifier</li></ul>
Sample collector information	<ul style="list-style-type: none"><li>• No, report if known</li></ul>	<ul style="list-style-type: none"><li>• provider number</li><li>• healthcare identifier of individual healthcare provider</li><li>• address of premises where sample was collected</li><li>• healthcare identifier of healthcare provider organisation where sample was collected</li></ul>
Screening test requestor	<ul style="list-style-type: none"><li>• No,</li></ul>	<ul style="list-style-type: none"><li>• provider number</li></ul>

<b>Data attributes in the Rules</b>	<b>Mandatory</b>	<b>Specific information under NPAAC requirements and for AIHW reporting</b>
information	report if known	<ul style="list-style-type: none"> <li>• healthcare identifier of individual healthcare provider</li> <li>• address of premises where request was made</li> <li>• healthcare identifier of healthcare provider organisation where the request was made</li> </ul>

### **1. Information about any test derived from the NPAAC standards and the AIHW National Cervical Screening Program Data Dictionary.**

<b>Mandatory data attributes in the Rules</b>	<b>Specific information under NPAAC requirements and for AIHW reporting</b>
Any test	<ul style="list-style-type: none"> <li>• test type (e.g. HPV, cytology or histopathology)</li> <li>• date of test</li> <li>• recommendation (see point 4)</li> </ul>

### **2. HPV information derived from the NPAAC standards- National HPV coding sheet**

<b>Mandatory data attributes in the Rules</b>	<b>Specific information under NPAAC requirements</b>
Collection method	<ul style="list-style-type: none"> <li>• Practitioner collected sample; or</li> <li>• Self-collected sample</li> </ul>
Specimen site	<ul style="list-style-type: none"> <li>• Not stated;</li> <li>• Cervical;</li> <li>• Vaginal; or</li> <li>• Other gynaecological site</li> </ul>
Reason for test	<ul style="list-style-type: none"> <li>• Primary screening HPV test; Follow-up HPV test (Repeat HPV test after intermediate risk result or unsatisfactory test)</li> <li>• Co-test <ul style="list-style-type: none"> <li>- Test of cure</li> <li>- Investigation of signs or symptoms</li> <li>- Other, as recommended in guidelines</li> </ul> </li> <li>• Other</li> </ul>
Test result (HPV test result – oncogenic HPV)	<ul style="list-style-type: none"> <li>• Unsatisfactory</li> <li>• Oncogenic HPV not detected</li> <li>• HPV 16/18 detected <ul style="list-style-type: none"> <li>- Type 16 detected</li> <li>- Type 18 detected</li> <li>- Type 18/45 detected</li> </ul> </li> <li>• Oncogenic HPV (not 16/18) detected <ul style="list-style-type: none"> <li>- One or more of the following types detected: 31, 33, 45, 52 or 58</li> <li>- One or more of the following types detected: 35, 39, 51, 56, 59, 66 or 68</li> </ul> </li> </ul>
Test type (name of test)	<ul style="list-style-type: none"> <li>• Qiagen</li> </ul>

Mandatory data attributes in the Rules	Specific information under NPAAC requirements
	<ul style="list-style-type: none"> <li>- Hybrid Capture III</li> <li>• Roche <ul style="list-style-type: none"> <li>- cobas 4800</li> <li>- cobas 6800</li> <li>- cobas 8800</li> </ul> </li> <li>• Abbott <ul style="list-style-type: none"> <li>- m2000</li> <li>- Alinity m</li> </ul> </li> <li>• Becton Dickinson <ul style="list-style-type: none"> <li>- Onclarity</li> </ul> </li> <li>• Cepheid <ul style="list-style-type: none"> <li>- Xpert</li> </ul> </li> <li>• Hologic <ul style="list-style-type: none"> <li>- Cervista</li> <li>- Aptima</li> </ul> </li> <li>• Seegene <ul style="list-style-type: none"> <li>- Anyplex</li> </ul> </li> <li>• Genera <ul style="list-style-type: none"> <li>- PapType</li> </ul> </li> <li>• Euroimmun <ul style="list-style-type: none"> <li>- Euroarray</li> </ul> </li> <li>• Other</li> </ul>
Test sample (collection media)	<ul style="list-style-type: none"> <li>• Not stated</li> <li>• PreservCyt Solution</li> <li>• SurePath medium</li> <li>• Other commercial self-collection device</li> <li>• Specimen transport medium</li> <li>• Flocked or cotton swab</li> </ul>
Test batch information unless the test is a diagnostic HPV test for: (i) a symptomatic person; or (ii) a person in the post treatment setting	<ul style="list-style-type: none"> <li>• Control kit – lot number and expiry date</li> <li>• Cellular (LBC) extraction kit – lot number and expiry date</li> <li>• Nucleic acid extraction kit – lot number and expiry date</li> <li>• Amplification kit – lot number and expiry date</li> <li>• Detection kit – lot number and expiry date</li> <li>• Wash buffer – lot number and expiry date</li> </ul>

### 3. Cytology test information derived from NPAAC Standards- National Cytology Coding sheet

Mandatory data attributes in the Rules	Specific information under NPAAC requirements
a) Specimen type	<ul style="list-style-type: none"> <li>• Not stated</li> <li>• Conventional smear</li> <li>• Liquid based specimen</li> <li>• Conventional and liquid-based</li> </ul>
b) Specimen site	<ul style="list-style-type: none"> <li>• Not stated</li> <li>• Cervical</li> </ul>

Mandatory data attributes in the Rules	Specific information under NPAAC requirements
	<ul style="list-style-type: none"> <li>• Vaginal</li> <li>• Other gynaecological site</li> </ul>
c) Reason for test	<ul style="list-style-type: none"> <li>• Reflex LBC cytology after detection of oncogenic HPV in primary screening HPV test</li> <li>• Cytology after detection of oncogenic HPV in self-collected sample</li> <li>• Reflex LBC after detection of oncogenic HPV in Follow-up HPV test</li> <li>• Cytology at colposcopy</li> <li>• Co-test               <ul style="list-style-type: none"> <li>i. Test of cure</li> <li>ii. Investigation of signs or symptoms</li> <li>iii. Other, as recommended in guidelines</li> </ul> </li> <li>• Other</li> <li>• Conventional Pap test to screen for cervical cancer precursors</li> </ul>
d) test result	<ul style="list-style-type: none"> <li>• Squamous</li> <li>• Endocervical</li> <li>• Other/non-cervical</li> </ul> <p><u>Unsatisfactory</u></p> <ul style="list-style-type: none"> <li>• Unsatisfactory for evaluation</li> <li>• Due to unsatisfactory nature of the specimen, no assessment has been made</li> <li>• Due to the unsatisfactory nature of the specimen, no assessment has been made</li> </ul> <p><u>Negative</u></p> <ul style="list-style-type: none"> <li>• Cell numbers and preservation satisfactory. No abnormality or only reactive changes</li> <li>• Not applicable: vault smear/previous hysterectomy</li> <li>• No endocervical component</li> <li>• Endocervical component present. No abnormality or only reactive changes No other abnormal cells</li> </ul> <p><u>Low-grade</u></p> <ul style="list-style-type: none"> <li>• Possible low-grade squamous intraepithelial lesion (LSIL)</li> <li>• Low-grade squamous intraepithelial lesion (LSIL) (HPV and/or CIN I)</li> <li>• Atypical endocervical cells of uncertain significance</li> <li>• Atypical endometrial cells of uncertain significance</li> <li>Atypical glandular cells of uncertain significance - site unknown</li> </ul> <p><u>Possible high-grade</u></p> <ul style="list-style-type: none"> <li>• Possible high-grade squamous intraepithelial lesion (HSIL)</li> <li>• Possible high-grade endocervical glandular lesion</li> <li>• Possible endometrial adenocarcinoma</li> <li>• Possible high-grade lesion – no-cervical</li> </ul>

Mandatory data attributes in the Rules	Specific information under NPAAC requirements
	<p><u>High-grade</u></p> <ul style="list-style-type: none"> <li>• High-grade squamous intraepithelial lesion (HSIL) (CIN 2/CIN 3)</li> <li>• HSIL with possible microinvasion/ invasion</li> <li>• Adenocarcinoma-in-situ</li> <li>• Adenocarcinoma-in-situ with possible microinvasion/invasion</li> </ul> <p><u>Carcinoma</u></p> <ul style="list-style-type: none"> <li>• Squamous carcinoma</li> <li>• Adenocarcinoma</li> <li>• Malignant cells – uterine body</li> <li>• Malignant cells – vagina</li> <li>• Malignant cells – ovary</li> <li>• Malignant cells – other</li> </ul>

**4. Recommendation information derived from NPAAC standards- National Screening Recommendation coding sheet.**

Mandatory data attributes in the Rules	Specific information under NPAAC requirements
Recommendation	<ul style="list-style-type: none"> <li>• No recommendation</li> <li>• Rescreen in 5 years</li> <li>• Rescreen in 3 years</li> <li>• Repeat HPV test in 12 months</li> <li>• Co-test in 12 months</li> <li>• Retest in 6 weeks</li> <li>• Refer for colposcopic assessment</li> </ul>

**5. Histopathology test information derived from AIHW National Cervical Screening Program Data Dictionary.**

Mandatory data attributes in the Rules	Specific information for AIHW reporting
Specimen site	<ul style="list-style-type: none"> <li>• Not stated</li> <li>• Cervical</li> <li>• Vaginal</li> <li>• Other gynaecological site</li> </ul>
Procedure used for obtaining specimen	<ul style="list-style-type: none"> <li>• Punch biopsy</li> <li>• Endocervical curettage</li> <li>• LLETZ/LEEP loop biopsy</li> <li>• Cone biopsy</li> <li>• Polypectomy</li> <li>• Subtotal hysterectomy</li> <li>• Hysterectomy</li> </ul>

Mandatory data attributes in the Rules	Specific information for AIHW reporting
	<ul style="list-style-type: none"> <li>• Amputated cervix</li> <li>• Other gynaecological sites</li> </ul>
Test result	<ul style="list-style-type: none"> <li>• Unsatisfactory</li> <li>• Not applicable</li> <li>• Negative</li> <li>• Low-grade</li> <li>• High-grade</li> <li>• Carcinoma</li> </ul>