

Policy

Release of Pathology Test Results

NSWHP_PD_106

1. Purpose

1.1 To provide a consistent approach to managing the release of pathology test results to clinicians and patients or other authorised entities.

2. Background

- 2.1 Pathology results are critical to patient care and treatment.
- 2.2 The Royal College of Pathologists of Australasia Release of Pathology Results to Patients Guideline recognises that the patient is entitled to their pathology results for an examination performed for, or on, their behalf, in addition to a referring and/or treating clinician. This entitlement is also recognised in the NSW Health Privacy Manual for Health Information.
- 2.3 NSW Health Pathology test results are available in the eMR when approved and validated for release.
- 2.4 Access to the laboratory information management systems (LIMS) is restricted to NSW Health Pathology employees/health employees under specified rules, roles and obligations.
- NSW Health Pathology may only view, access, use and disclose personal health 2.5 information when it is necessary for them to do so to carry out their work duties.
- NSW Health Pathology has a duty of care to ensure that such results are provided in a way that minimises the risk of harm or distress to the patient.
- 2.7 NSW Health Pathology must ensure that only authorised results are released to persons approved to receive the result via approved modes of delivery.

3. Scope

- 3.1 This policy is mandatory and applies to all NSW Health Pathology staff.
- 3.2 This policy only applies to pathology results that have been validated and authorised for release from the LIMS. It does not apply to:
 - any other Health records held by NSW Health Pathology; or a)
 - the release of pathology results to anyone other than the requesting b) clinician (or their staff) or patient (or their authorised representative).

All other requests for pathology results (e.g. as part of a legal proceeding or for investigative or law enforcement purposes) should be directed to NSW Health Pathology's Privacy Contact Officer.

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3.3 This policy also does not apply to the release of pathology results to forensic pathologists (including forensic pathologists employed by NSW Health Pathology) conducting postmortems under the direction of the Coroner. Release of pathology results in these circumstances is addressed by section 9.3 of the NSW Health Coroners Cases and the Coroners Act 2009 PD2010_054 and section 11.3.5 of the NSW Health Privacy Manual for Health Information.

4. Definitions

Authorised result	A pathology test result that has been completed and authorised for release by an approved member of staff or by an approved algorithm through the LIMS.			
Consent	Permission for something to happen or agreement to do something.			
Critical risk result	Results requiring immediate medical attention and action because they indicate a high risk of imminent death or major patient harm.			
Critical test	A pathology test that requires immediate communication of the result irrespective of whether it is normal, significantly abnormal or critical to support patient clinical care.			
eMR	Electronic Medical Record			
Health record	A documented account, whether in hard copy or electronic form, of a patient's health, illness and treatment during each visit or stay at a health service. A health record holds the same meaning as a "health care record", "medical record", "clinical record", "clinical notes", "patient record", "patient notes", "patient file", "pathology results" and so on.			
High risk result	A collective term used to denote results that require communication in a timely manner i.e. critical risk results, significant risk results and results of critical tests.			
LIMS	Laboratory Information Management System			
Patient	Any person who receives a health service and to whom, as a result, a health practitioner owes a duty of care.			

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Privacy	The right of an individual to have their personal health information safeguarded from loss, misuse and unauthorised disclosure in order to protect the privacy of an individual's personal health information.			
Sensitive tests	Certain pathology test results that require a greater level of protection due to the sensitive nature of the health information. The HealtheNet Pathology Sensitive Test Reference Group has recommended the following results be deemed sensitive:			
	 a) Drug and alcohol tests b) All pregnancy related tests in children under 18 years of age c) HIV tests and HIV drug assays d) Sexually transmitted infection tests e) MCS tests (genital) f) Specific notifiable STIs for example Chlamydia, Gonococcus requests g) ABO Typing Paternity Group h) All NPAAC Level 2 genetic testing 			
Significant risk result	A pathology test result that is not imminently life-threatening but signifies significant risk to patient well-being and therefore requires medical attention and follow-up action within a clinically justified time limit.			
SMS	Short Message Service			

5. Policy Statement: Release of Results

5.1 To Clinicians

- 5.1.1 Authorised results may be given to requesting clinicians or their staff. Results must not be provided until they have been validated and authorised.
- NSW Health Pathology staff are required to confirm the identity of the person making the request and ensure that the person making the request is authorised to receive the result. For this purpose, the following information must be recorded:
 - a) Name of the person making the request
 - Position in the medical practice or facility
 - Phone number of the medical practice or facility (preferably the main landline number).

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- 5.1.3 In the case of phone requests, the recipient must be asked to repeat the result to ensure the accuracy of the transfer of information immediately after the result is provided.
- 5.1.4 Details of the mode of delivery when providing the result to the clinician or the clinician's staff on their behalf must be recorded, preferably in the LIMS or phone system where this functionality is available and include:
 - Time and date that the result was provided
 - b) Name and position of the recipient of the result and
 - c) Result given.
- 5.1.5 Staff releasing a result must undertake an authentication process and confirm who they are releasing the results. This ensures that the results are kept secure and confidential.
- 5.1.6 Transmission of results to clinicians by email must comply with NSWHP_PG_023 NSW Health Pathology Guideline – Distribution and Transmission of Sensitive Information as well as the requirements specified in section 9.2.5 of the NSW Health Privacy Manual for Health Information, including that the subject title of the email includes the word 'confidential' and that emails sent to destinations external to NSW Health are password-protected or encrypted prior to transmission.
- Test results or other personal health information must not be delivered to clinicians via Short Message Service (SMS) or left on answering machines or voicemail.
- Manual facsimile transmitted result delivery is not favoured and cloud-based facsimile is a preferred solution. If a manual facsimile is utilised, then a fax cover sheet must accompany these results.

5.2 High-Risk Results

High risk results must be managed in accordance with the High Risk (Critical) Laboratory Results NSWHP_PD_010.

A procedure for identifying high risk (critical) results must be available in each NSW Health Pathology laboratory. This procedure must include acceptable transmission modes, staff authorised to receive these results and an escalation procedure when the appropriate recipient cannot be contacted.

The information communicated to the recipient of a high-risk result must include the following:

- a) identity of the notifier
- b) identity of the patient tested

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- c) date and time that the sample was collected, where given
- d) test that was performed
- e) test result (with the units of measurement where relevant)
- f) reported applicable reference interval for the patient or clinical decision limit(s) for the test, and the offer of pathologist or scientist consultation.

5.3 To Patients

- Patients are entitled to their pathology test results.
- 5.3.2 NSW Health Pathology has a duty of care to ensure that a pathology test result is provided in a way that minimises the risk of harm or distress to the patient.
- Results of Sensitive tests, as defined in section 4 of this policy, must not be released directly to a patient without the prior approval of the supervising pathologist (or their authorised representative in the relevant department) or the clinical (medical) director.
- 5.3.4 Results may be released via different modes outlined in the following sections.

5.4 To My Health Record

- Non-Sensitive results may be released to a patient electronically through My Health Record as follows:
 - a) Authorised non-Sensitive test results held within the respective NSW Health Pathology LIMS will, where possible, be uploaded to HealtheNet.
 - b) Patients who have registered with My Health Record will be able to access their test results that have been sent from HealtheNet to My Health Record.

5.5 Releasing Results

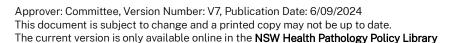
- Results may be released directly to the patient, or their authorised representative (see 5.8 of this policy), or a parent or guardian of a minor patient (see 5.9 of this policy). In all instances the person must meet the following conditions:
 - a) Results must only be released to patients whose identity has been verified in person or on-line.
 - b) The patient or delegate must complete and sign Section A and B of the NSW Health Pathology Patient Declaration and Consent Form.
 - The patient demographic information provided must be supported by a further source of identity.

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- d) At a minimum, proof of identity is required by sighting an original identity verification document in person or via the production of a copy of an identity verification document. Identity verification documents can include the following:
 - Current Australian driver's licence or
 - ii. Current Australian passport or
 - iii. Current Australian Medicare card
 - iv. Other documents which can provide proof of identification
- e) NSW Health Pathology may require further proof of identity at its discretion.
- Once the proof of identification is sighted, the type of identity verification document sighted must be indicated on the NSW Health Pathology Patient Declaration and Consent Form by the NSW Health Pathology staff member processing the request.
- In accordance with disposal code 2.6.8 of the General Retention and Disposal Authority: Patient Records (GDA17) and Administrative Records (GDA21) (GA-28) any copies of a patient's identity verification documents must be immediately destroyed/deleted after the transaction has been completed. No copies of identity verification documents may be kept, nor should there be any identification numbers relating to this identity verification kept as part of the process.

When the transaction has been completed (i.e. test results have been provided as requested) the identity verification documents provided to NSW Health Pathology to facilitate the transaction must be securely destroyed/deleted.

The person responsible for the destruction of these records must sign and date Section C of the NSW Health Pathology Patient Declaration and Consent Form.

- 5.5.2 Release of results in person at NSW Health Pathology's premises is not encouraged and should be used only when other delivery modes cannot be met.
- Hard copy results transmitted by email must comply with the requirements specified in NSWHP_PG_023 NSW Health Pathology Guideline – Distribution and Transmission of Sensitive Information as well as section 9.2.5 of the NSW Health Privacy Manual for Health Information, including that the subject title of the email includes the word 'confidential', steps are taken to ensure that the email address is correct and that the email is password-protected or encrypted prior to transmission.
- Results transmitted by mail should use envelopes marked 'confidential', and care should be taken to ensure that addresses are complete and correct and that only the test results of that individual are included in the envelope.

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- 5.5.5 Test results should not be provided to a family member of a patient or a person who is, or asserts to be, the patient's "next of kin" or authorised representative unless the family member or other person is able to demonstrate that:
 - The patient lacks capacity to make decisions about the patient's health care; AND
 - b) The person is the patient's authorised representative (see 5.8 of this policy) or parent or legal guardian (where the patient is a minor – see 5.9 of this policy); OR
 - The patient has provided written consent (within no more than 3 months of the request being made) which expressly names the family member or other person as being authorised to access the information.
- 5.5.6 The patient is not entitled to access any materials that may have been used in preparing the report(s), for example, notes, printouts and worksheets.
- 5.5.7 Results of Sensitive tests must comply with 5.3.3.
- 5.5.8 Where a patient requests copies of historical pathology reports because they are changing doctors, and require the reports for their ongoing medical care, these copies should be provided in an envelope addressed to the nominated/attending medical practitioner.
- 5.5.9 NSW Health Pathology staff must record when and by what mode the result was provided to the patient on the NSW Health Pathology Patient Declaration and Consent Form.

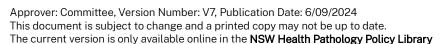
5.6 Release of Results Over the Telephone

- Results must not be released to a patient over the telephone until the patient's identity has been verified by confirming at least five of the following:
 - a) Full name*
 - b) Date of birth*
 - c) Gender
 - d) Address including residential postcode
 - e) Medicare number
 - f) Mobile phone
 - * Mandatory requirements
- Details of the phone call must be recorded in the LIMS or other medical record keeping system and include the details as specified in 5.1.4 of this policy.

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- 5.6.3 Test results or other personal health information must not be left on answering machines or voicemail.
- 5.6.4 Results of Sensitive tests must comply with 5.3.3.
- 5.6.5 The release of test results or other personal health information to a patient's authorised representative or a parent or guardian of a minor patient must also comply with sections 5.8 and 5.9 (respectively) of this policy.

5.7 Release of Results by SMS

- 5.7.1 Release of results directly to patients via SMS is currently not supported by NSW Health Pathology.
- 5.8 Release of Pathology Results Relating to Patients Who Lack Capacity or Otherwise with Patient's Consent
 - 5.8.1 A patient's authorised representative can access test results on the patient's behalf where the patient lacks capacity to provide consent (i.e. is incapable, despite the provision of reasonable assistance by another person, of understanding the general nature and effect of providing consent or communicating their intentions in that regard) due to age, injury, illness, physical impairment, mental impairment or developmental disability.
 - The NSW Health Records and Information Privacy Act 2002 sets out the list of people who can be an authorised representative on behalf of a patient. They are:
 - a) Someone who has an 'enduring power of attorney' for the individual or
 - b) A guardian, including someone with 'enduring guardianship', as defined in the *Guardianship Act 1987* or
 - c) If the individual is a child under 18, a person who has parental responsibility for them or
 - d) A "person responsible" under Section 33A of the Guardianship Act 1987 or
 - e) Any other person who is authorised by law to act for, or represent, the person.
 - 5.8.2 Where a patient can provide consent, an authorised representative may not obtain access to the patient's test results unless the patient expressly authorises the representative to do so (within no more than 3 months of the request for access being made).
 - 5.8.3 Where results are requested by a patient's authorised representative on behalf of the patient, extra care should be taken to establish whether the representative is legally authorised to receive the patient's results. The representative must provide documentation that confirms the legal authority of

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the person to receive the results on behalf of the patient (for example, current enduring power of attorney or guardianship documents where the patient lacks capacity, or written authorisation from the patient signed less than 3 months before the request is made which names the representative) prior to disclosure of results, and copies of that documentation must be retained in the secure NSW Health Pathology SharePoint site.

5.8.4 The requirements in this section are in addition to those in 5.5.

5.9 Release of Pathology Results Relating to Minors

- For children under 14 years of age, the parent(s) or legal guardian(s) may request results on behalf of their child. The results must be released to the parent(s) or guardian(s) (subject to the considerations in 5.10.6 of this policy) but should not be released to the child in person unless the child is in the company of the parent(s) or guardian(s) and with the consent of the attending parent(s) or guardian(s).
- Children aged 14 or 15 years of age can request and receive their own test 5.9.2 results. In such cases, effort should be made to also seek the consent of a parent(s) or legal guardian(s) (subject to the considerations in 5.9.6 of this policy) unless the child objects and the objection is reasonable in the circumstances.
- Sensitive tests may be released to patients aged 14 or 15 years in accordance 5.9.3 with 5.3.3 and if the patient has been assessed as capable of understanding the nature and consequences of the particular test results. Such an assessment must be made by the supervising pathologist or clinical (medical) director. If there has been no opportunity to make such an assessment, Sensitive test results should not be released to the child.
- A young person aged 16 or 17 years of age has the right to access their own test 5.9.4 results including Sensitive test results in accordance with 5.3.3. Test results must not be provided to the young person's parent(s) or legal guardian(s) without the young person's consent unless:
 - a) Exceptional circumstances exist in which it is impracticable to obtain the young person's consent and
 - Release of the result to the parent(s) or guardian(s) is assessed to be in the best interests of the young person (subject to considerations in 5.9.6 of this policy).
- Persons under 18 years of age may gain access to pathology test results through My Health Record. Children aged 14 and over can register for My Health Record and decide whether to allow a parent and/or legal guardian to access My Health Records as a nominated representative.

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- 5.9.6 When considering whether to release test results to the parent(s) or guardian(s), it is important to consider:
 - Whether the release of information to the parent or guardian would prejudice the physical or mental health of the child/young person or other family member
 - The views of the child/young person b)
 - The purpose for which the disclosure is required c)
 - Whether the test result is Sensitive d)
 - Knowledge of the child's/young person's day-to-day living arrangements e)
 - f) Whether the relationship between the parents is amicable and how any disclosure may impact on the child's/young person's future care. Disclosure may not be in the child's/young person's best interest if there is a family dispute in which the child's/young person's health is being used as leverage by a parent.
- 5.9.7 The requirements in this section are in addition to those in 5.5.
- 5.10 Requests for Release of Toxicology or other Pathology Results to Child Protection Units (and other NSW Agencies)
- 5.10.1 Pathology test results (including toxicology results i.e. from urine drug screening performed for clinical management of the patient) may only be released by NSW Health Pathology in limited circumstances. In the absence of patient consent or another lawful basis for disclosure of pathology results (such as a request from NSW Police) then a subpoena or warrant would be required in accordance with NSWHP_PR_074 (Responding to Subpoenas and other lawful requests for Materials).

5.11 Chapter 16A Requests

- 5.11.1 Chapter 16A of the Children and Young Persons (Care and Protection) Act 1998 (NSW) authorises the exchange of information relating to the safety, welfare or wellbeing of children and young persons between "prescribed bodies." NSW Health Pathology is a prescribed body and therefore can share information with other prescribed bodies including public health organisations, public authorities, certain government agencies and non-government organisations.
- 5.11.2 Information may be shared where the releaser believes it will assist in:
 - a) making a decision, assessment or plan
 - b) the initiation or conduct of any investigation; or

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c) providing any services relating to the safety, welfare or wellbeing of the child.

Consent is not necessary for the exchange of information under Chapter 16A but it should be sought where possible.

- 5.11.3 Under Chapter 16A, provided it is done in a secure way, information may be exchanged:
 - a) in writing by letter, fax or email
 - b) orally over the phone or
 - c) in person.

Refer to <u>NSW Health PD2013_007</u> at 6.26 for details about what should be documented in the client health record. Where possible, information exchange forms should be used.

6. Training

6.1 Results may only be provided by staff who have been trained in the requirements of this policy, the <u>NSW Health Privacy Manual for Health Information</u> and the <u>NSW Health Privacy Information Leaflet for Staff.</u>

7. Records Management

7.1 Records must be retained according to current disposal authorities relevant to NSW Health Pathology including NPAAC Requirements for the Retention of Laboratory Records and Diagnostic Material.

8. Roles and Responsibilities

- 8.1 Managers are responsible for ensuring that staff are aware of the requirements in this policy, the <u>NSW Health Pathology High Risk Results Policy</u> and the <u>NSW Health Pathology High Risk Results Alerts List.</u>
- 8.2 Laboratory staff are responsible for notification of high risk results and documenting communication of high risk results in accordance with this policy and the NSW Health Pathology High Risk Results Alerts List.

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9. Legal and Policy Framework

- AS ISO 15189 Medical Laboratories Requirements for Quality and Competence
- Children and Young Persons (Care and Protections) Act 1998 (NSW)
- Guardianship Act 1987
- Health Services Act 1997(NSW)
- NATA Medical Testing Field Application Document Requirements for accreditation (2013)
- NPAAC Requirements for Medical Pathology Services (2018)
- NPAAC Requirements for the Retention of Laboratory Records and Diagnostic Material
- NSW Health Pathology High Risk Results Policy PD_010 and Alerts List
- NSW Health Pathology Patient Declaration and Consent Form
- NSW Health Pathology PR_074 (Responding to Subpoenas and other lawful request for Materials)
- NSW Health Policy PD2010_054 Coroners Cases and the Coroners Act 2009
- NSW Health Policy PD2013_007 Child Wellbeing and Child Protection Policies and Procedures for NSW Health
- NSW Health Privacy Manual for Health Information
- NSW Health Privacy Information Leaflet for Staff
- NSW Health Records and Information Privacy Act 2002
- NSW Privacy and Personal Information Protection Act 1988
- RCPA Guideline 2/2001; Release of Pathology Results and Tissue to Patients, 2014
- RCPA Policy 1/2209; Return of Tissue to Patients RCPA Guideline 2/2014; Managing Privacy Information in Laboratories

10. Review

This policy will be reviewed by 05/04/2027.

11. Risk

Risk Statement	Non-compliance with this policy may have serious consequences for the safe provision of a service, affect patient care, result in a privacy breach and/or significant damage to NSW Health Pathology's reputation.
Risk Category	Clinical Care and Patient Safety

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12. Further Information

For further information, please contact:

Policy Contact Officer	Position:	Director, Pre and Post Analytics		
	Name:	Judith Kempton-Webb		
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Policy Sponsor	Position:	CMIO and Director, Statewide Clinical		
		Services		
	Name:	Stephen Braye		
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13. Version History

The approval and amendment history for this document must be listed in the following table.

Version No	Effective Date	Approved By	Approval Date	Risk Ratin g	Sections Modified
1.0	15/01/19	Clinical Governance and Quality Committee	28/11/18	High	New Policy.
2.0	22/03/20	SLT	22/03/20	High	Amendments to requirements for release of results by mail, email, phone and SMS.
3.0	25/08/20	SLT	10/09/20	High	Amendments to requirements for release of negative COVID-19 report by mail, email or patient pick up.

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4.0	20/09/21	Chief Executive	19/09/21	High	Amendments to address release of positive COVID- 19 results direct to patients and clarify the mechanisms for releasing COVID-19 results to patients
5.0	03/08/22	Director, Clinical Services & CMIO	29/07/22	High	Amendments to address the release of Respiratory Triplex results and to streamline processes for the release of Respiratory Triplex results to patients. Also updated the background and removed replication of the High-Risk Results Policy.
6.0	08/04/24	Director, Clinical Services & CMIO	04/04/24	High	Amendments include removal of special requirements for Covid-19 results. Additional requirements on confidentiality and lab responsibilities for release of high-risk results.
7.0	05/09/24	Director, Clinical Services & CMIO	05/09/24	High	Changes to 5.11.2 Chapter 16A requests. Updated requirements for ID confirmation and updates to Patient declaration and Consent form.



