

1. Purpose

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

2. Background

- 2.1 Pathology results are critical to patient care and treatment.
- 2.2 The Royal College of Pathologist 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.
- 2.3 NSW Health Pathology may only view, access, use and disclose personal health information when it is necessary for them to do so to carry out their work duties.
- 2.4 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.
- 2.5 NSW Health Pathology must ensure that only authorised results are released to only 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 LIS. It does not apply to:
 - a) any other Health records held by NSW Health Pathology; or
 - b) the release of pathology results to anyone other than the requesting 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.

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 post mortems 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.



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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 LIS.

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.

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.

Patient Any person who receives a health service and to whom, as a result, a

health practitioner owes a duty of care.

Patient Portal An online portal developed by NSW Health Pathology to provide patients

with verified and secure online access to their results as approved for

release using this mode of delivery.

The right of an individual to have their personal health information **Privacy**

safeguarded from loss, misuse and unauthorised disclosure in order to

protect the privacy of an individual's personal health information.

RSV Respiratory Syncytial Virus

PCR Test

Respiratory Triplex A multi-panel test that detects the following respiratory pathogens:

COVID-19, Influenza A, Influenza B and/or RSV



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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

5.1 Release of Results to Clinicians

- 5.1.1 Authorised results may be given over the phone, by fax or by email to requesting clinicians or their staff. Results must not be provided if the results have not been validated and authorised.
- 5.1.2 NSW Health Pathology staff are required to confirm the identity of the person making the phone, fax or email 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
 - b) Position in the medical practice or facility
 - c) Phone number of the medical practice or facility (preferably the main landline number).
- 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 phone call, fax or email providing the result to the clinician or the clinician's staff on their behalf must be recorded, preferably in the LIS or phone system where this functionality is available and include:
 - a) 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 Particular attention must be given to recipient authentication before releasing results by phone, fax or email to ensure that the results are kept secure and confidential.
- 5.1.6 Transmission of results to clinicians by email must comply with the requirements specified in <u>section 9.2.5 of the NSW Health Privacy Manual for Health Information</u>, 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.
- 5.1.7 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.
- 5.1.8 A <u>fax cover sheet</u> must accompany faxed results.

5.2 Authorised High-Risk Results

5.2.1 High risk results must be managed in accordance with the <u>High Risk Laboratory</u> Results Policy NSWHP PD 010.

5.3 Release of Pathology Results to Patients

- 5.3.1 Patients are entitled to a copy of their pathology test results for an examination performed on their behalf by NSW Health Pathology.
- 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.
- 5.3.3 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 must not be released until they have been validated and authorised.
- 5.3.5 Results may be released as follows:

5.4 Release of Results Electronically through My Health Record

- 5.4.1 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 LIS will, where possible, be uploaded to HealtheNet.
 - b) Non-Sensitive test results will be sent from HealtheNet to My Health Record after 7 days has elapsed since the result is validated and authorised.
 - c) Patients who have registered with My Health Record will be able to access their non- Sensitive test results that have been sent from HealtheNet to My Health Record.





5.5 Release of Results via mail, email or in person

- 5.5.1 Results may be released directly to the patient, or their authorised representative (see 5.9 of this policy), or a parent or guardian of a minor patient (see 5.10 of this policy), via email, mail and in rare situations in person. In all instances the person must meet the following conditions:
 - a) The patient must sign the <u>NSW Health Pathology Patient Declaration and Consent Form.</u>
 - b) Results must only be released to patients whose identity has been verified.
 - c) At a minimum, proof of identity is required by producing an original or certified copy of the following:
 - Current Australian driver's license or
 - ii. Current Australian passport or
 - iii. Two other forms of identification that include signature and current address details.
 - d) NSW Health Pathology may require further proof of identity at their discretion.
- 5.5.2 Release of results in person at NSW Health Pathology's premises is discouraged and should be used only as a last resort.
- 5.5.3 Hard copy results transmitted by email must comply with 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', steps are taken to ensure that the email address is correct and that the email is password-protected or encrypted prior to transmission.
- 5.5.4 Results transmitted by mail should use envelopes marked 'confidential', and care should be taken to ensure that addresses are complete and correct.
- 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
 - The person is the patient's authorised representative (see 5.9 of this policy) or parent or legal guardian (where the patient is a minor – see 5.10 of this policy) or
 - c) 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.



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- 5.5.7 Results of Sensitive tests 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.
- 5.5.8 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 retain copies of the identity verification process and record when and by what mode the result was provided to the patient as per current processes.

5.6 Release of Results over the telephone

- 5.6.1 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
 - g) Where and when the collection episode took place and/or requesting doctor if available.
 - * Mandatory requirements
- 5.6.2 Details of the phone call must be recorded in the LIS or other medical record keeping system and include the details as specified in 5.1.4 of this policy.
- 5.6.3 Test results or other personal health information must not be left on answering machines or voicemail.
- 5.6.4 In the case of Sensitive tests, results 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.
- 5.6.5 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 5.19 and 5.10 (respectively) of this policy.

5.7 Release of Results by SMS

5.7.1 Release of results (except for COVID-19 or Respiratory Triplex PCR results) directly to patients via SMS should only be considered in exceptional circumstances and is subject to approval by the Chief Executive and Chief Medical Information Officer. The following conditions must also be met:





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- a) Patient consent to receiving test results via SMS must be obtained and documented, for each specific test episode. When seeking consent, patients must be given a clear explanation of the nature of the results they would be provided. It is acknowledged in this policy that the patient's registration for an SMS must be by specific consent for this and that the provision to NSW Health Pathology of a mobile number does not constitute consent.
- b) Patients should be given options other than SMS by which to receive their results.
- c) The patient's identity and contact details must be verified (consistent with the requirements specified in 5.6) as soon as reasonably practicable before any information is sent via SMS.
- d) SMS messages must be clearly marked as being sent by NSW Health Pathology.
- e) An SMS message to a patient forms part of, and therefore needs to be included in, the patient's medical record (including recipient phone number, date sent, content of message and delivery success/failure).
- f) 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 5.9 and 5.10 (respectively) of this policy.

5.8 Specific provisions for the Release of COVID-19 and Respiratory Triplex PCR Results to Patients

5.8.1 This section 5.8 has been added to provide additional mechanisms for a patient to obtain their Respiratory Triplex PCR results. The procedure outlined in this section 5.8 does not apply in relation to the release of any other test results.

Release of COVID-19 and Respiratory Triplex PCR Results via SMS and Result Portal

- 5.8.2 In order to ensure the timely, efficient and secure release of COVID-19 and Respiratory Triplex PCR results to patients, use of SMS and the Result Portal is preferred and should be encouraged over other mechanisms specified in this policy (including mail, email, in person or via phone).
- 5.8.3 COVID-19 and Respiratory Triplex PCR results must not be released to a patient via SMS or the Result Portal unless and until the patient has registered or consented to receiving their COVID-19 or Respiratory Triplex PCR results in that way and their identity has been verified. Identity is verified by confirming at least three of the following patient identifiers:

For SMS:

- a) Surname*
- b) Date of birth*
- c) Residential postcode
- d) Gender
- e) Mobile phone number or date of collection*

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^{*} Mandatory requirements



For the Result Portal

- a) Full name (first name and last name and/or middle name) *
- b) Date of Birth*
- c) Residential address (including postcode)
- d) Gender
- e) Mobile phone number or Medicare Number or Date of Collection*
- * Mandatory requirements
- 5.8.4 When seeking a patient's consent to receiving their COVID-19 or Respiratory Triplex PCR results via SMS or the Result Portal, the patient must be given a clear explanation of the nature of the results that will be provided (including whether positive results will be provided). Consent must be specific and recorded for each specific test episode.
- 5.8.5 Subject to the patient's consent being obtained and the patient's identity being verified, the patient's COVID-19 or Respiratory Triplex PCR result may be released via SMS or the Result Portal.
- 5.8.6 SMS messages must be clearly marked as being sent by NSW Health Pathology.
- 5.8.7 NSW Health Pathology staff must retain records of the identity verification process, patient's consent, and the transmission of the result to the patient in an authorised NSW Health Pathology record-keeping system.

Release of COVID-19 or Respiratory Triplex PCR Results via Email

- 5.8.8 Section 5.5.1 does not apply to the release of a COVID-19 or Respiratory Triplex PCR result via email. Where a patient requests the release of their COVID-19 or Respiratory Triplex PCR result via email, the following process must be followed:
 - a) NSW Health Pathology staff must first verify the patient's identity by confirming at least three of the following patient identifiers either over the phone or via email:
 - Full name (first name, last name and/or middle name) *
 - Date of birth*
 - Address
 - Gender
 - Mobile Phone Number or Medicare Number or Date of Collection*
 - * Mandatory requirements
 - b) Care must be taken to ensure that the patient's email address is correct (e.g. by requesting that the patient email you first).



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- c) When the confirmation email is received from the patient, print a copy of the COVID-19 or Respiratory Triplex PCR result from the LIS and/or Patient Portal and scan it to a non-editable PDF format.
- d) Attach the PDF of the result to an email, ensure that the patient's email address is correct and that the subject title of the email includes the word 'confidential'. The email must also be password protected or encrypted. Passwords should be communicated to the patient by separate email or over the phone. Contact local IT for guidance on how to encrypt emails.
- 5.8.9 NSW Health Pathology staff must create and retain records of the identity verification process and emails with the patient in an authorised NSW Health Pathology recordkeeping system.

Release of COVID-19 and Respiratory Triplex PCR Results for Minors and others who lack capacity

- 5.8.10 The release of COVID-19 and Respiratory Triplex PCR results in respect of a minor patient must also comply with the following:
 - a) For minors who are under 14 years of age, the results (whether negative or positive) may only be released to the minor's parent or legal guardian, or to the minor with the consent of the parent or guardian;
 - b) For minors who are 14 15 years of age, the results (whether negative or positive) may be released to the minor without the consent of the minor's parent or legal quardian, or to the minor's parent or guardian;
 - c) A young person aged 16 or 17 years of age, the results (whether negative or positive) may be released to the minor without the consent of the minor's parent or legal guardian.
 - d) A young person aged 16 or 17 years of age has the right to access their own test results (whether negative or positive). Test results must not be provided to the young person's parent(s) or legal guardian(s) without the young person's consent:
- 5.8.11 The release of COVID-19 and Respiratory Triplex PCR results to other patients who lack capacity must comply with section 5.9.

5.9 Release of Pathology Results Relating to Patients Who Lack Capacity or Otherwise with Patient's Consent

5.9.1 A patient's authorised representative is able to 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 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:

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- 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.
- 5.9.2 Where a patient is able to 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).
- 5.9.3 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 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 local record keeping system.
- 5.9.4 The requirements in this section are in addition to those in 5.5 5.7.

5.10 Release of Pathology Results (other than COVID-19 and Respiratory Triplex results) relating to Minors

- 5.10.1 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).
- 5.10.2 Children aged 14 or 15 years of age are able to request and receive their own test 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 5.10.6 of this policy) unless the child objects and the objection is reasonable in the circumstances.
- 5.10.3 Sensitive tests may be released to patients aged 14 or 15 years in accordance 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.
- 5.10.4 A young person aged 16 or 17 years of age has the right to access their own test 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:





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- Exceptional circumstances exist in which it is impracticable to obtain the young person's consent and
- b) 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 5.10.6 of this policy).
- 5.10.5 Persons under 18 years of age may gain access to pathology test results through My Health Record. Test results relating to children should be recorded by NSW Health Pathology in HealtheNet provided that a sufficient period of time has elapsed since the requesting clinician was notified of the result to enable the clinician to provide the results to the patient. 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.
- 5.10.6 When considering whether to release test results to the parent(s) or guardian(s), it is important to consider:
 - a) 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
 - b) The views of the child/young person
 - c) The purpose for which the disclosure is required
 - d) Whether the test result is Sensitive
 - e) Knowledge of the child's/young person's day-to-day living arrangements
 - 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.
- 5.10.7 The requirements in this section are in addition to those in 5.5 5.7.

6. Training

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

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.



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8. Roles and Responsibilities

- 8.1 Managers are responsible for ensuring that staff are aware of the requirements in this policy, the NSW Health Pathology High Risk Results Policy and the NSW Health Pathology High Risk Results Alerts List.
- 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.

9. Legal and Policy Framework

- AS ISO 15189 Medical Laboratories Requirements for Quality and Competence
- Guardianship Act 1987
- 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 and Alerts List
- NSW Health Pathology Patient Declaration and Consent Form
- 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

10.1 This policy will be reviewed by 28/07/2023.

11. Risk

Risk Statement	Non-compliance with this policy may have serious consequences for the safe provision of a service, affect patie 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:

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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 Rating	Sections Modified
1.0	15/01/19	Clinical Governance and Quality	28/11/18	High	New Policy.
Click		Committee			
here to					
see Rescinde					
<u>d -</u>					
Release					
of Results					
Policy -					
Version 1 ndf					
<u>1.pdf</u>	20/20/202	0. =	00/00/000		
2.0	22/03/2020	SLT	22/03/2020	High	Amendments to requirements for release of results by mail, email,
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d - Release of Results Policy - Version 2.pdf					
3.0 Click here to see Rescinde d - Release of Results Policy - Version 3.pdf	25/08/2020	SLT	10/09/2020	High	Amendments to requirements for release of negative COVID-19 report by mail, email or patient pick up.
4.0 Click here to see Rescinde d - Release of Results Policy - Version 4.pdf	20/09/2021	Chief Executive	19/09/2021	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	03/08/2022	Director, Clinical Services & CMIO	29/07/2022	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.

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