

1. Purpose

- 1.1 To provide a consistent approach to managing and communicating critical risk laboratory results.

2. Background

- 2.1 Ineffective or unreliable communications of critical test results are major sources of harm for patients around the world.
- 2.2 On 2 December 2015, the NSW Coroner recommended the implementation of a state-wide critical result notification policy including the development of a state-wide guideline for notifiable thresholds for all critical results.
- 2.3 The International Standards Office requires that laboratories have a system for identifying and communicating critical and abnormal results ^{7a}.
- 2.4 The Royal College of Pathologists of Australasia - Australasian Association of Clinical Biochemists Working Party for High Risk Results has developed a consensus document to provide Australasian laboratories and clinicians with guidance on establishing policies and procedures for the management of high risk (critical) results ^{7b}.
- 2.5 Recommendations have also been developed for the management of high risk (critical) laboratory risk results by other bodies such as the Clinical Laboratory Standards Institute ^{7c}.
- 2.6 Implementation of the consensus statement recommendations will harmonise the management of high risk (critical) laboratory results notification in NSW and ensure that all laboratories are able to achieve best practice.

3. Scope

- 3.1 This policy is mandatory and applies to all staff working in NSW Health Pathology laboratories providing pathology services.

4. Definitions

- 4.1 **High Risk (Critical) Result:** Results requiring immediate medical attention and action because they indicate a high risk of imminent death or major patient harm ^{7b}.
- 4.2 **High Risk (Significant) Result:** Results that are not imminently life-threatening but signify significant risk to patient well-being and therefore require medical attention and follow-up action within a clinically justified time limit ^{7b}.
- 4.3 **High risk result:** A collective term used to denote results that require communication in a timely manner i.e. high risk (critical) results, High Risk (significant) results and results of critical tests ^{7b}.
- 4.4 **Alert threshold:** The upper and/or lower threshold of a test result or the magnitude of change (delta) in a test result within a clinically significant time period, beyond which the finding is considered to be a medical priority warranting timely action ^{7b}.
- 4.5 **Alert list:** A list of high risk (critical) laboratory tests and tests with alert thresholds for high risk results ideally reflecting an agreed policy between the laboratory and its users for rapid communication within a pre-specified time frame and according to a procedure ^{7b}.

5. Policy Statement

5.1 Alert List of High Risk (Critical) Tests

5.1.1 An alert list of high risk (critical) tests performed in NSW Health Pathology laboratories must be available in each laboratory.

5.1.2 The alert list should be created in consultation with its users and based on best practice or clinical outcome data.

5.1.3 As the methodology for high risk (critical) laboratory risk tests may vary between the laboratories, each laboratory must include method-specific alert thresholds.

5.2 Notification of High Risk (Critical) Results

5.2.1 A procedure for identifying high risk (critical) results must be available in each NSW Health Pathology laboratory.

5.2.2 The procedure should be created in consultation with its users and include:

- a) Acceptable mode(s) for the transmission of high risk (critical) results
- b) Clinical staff who are authorised to receive high risk (critical) results and an escalation procedure to be followed when the appropriate recipient(s) of a high risk (critical) result cannot be reached in a clinically appropriate timeframe and
- c) Acceptable mode(s) for the acknowledgement of the receipt of high risk (critical) results to confirm that results were accurately and effectively communicated.

5.2.3 Laboratories must ensure that the notification of high risk (critical) results is appropriately documented, and an audit process is developed to monitor compliance by staff in communicating high risk (critical) results and the success of communications.

5.2.4 Notification must be made in accordance with the NSW Health Pathology Policy - Release of Pathology Test Results NSWHP_PD_016.

5.3 High Risk (Critical) Results Alerts List

5.3.1 The following NSW Health Pathology High Risk (Critical) Alerts Lists support the implementation of this policy:

- [NSW Health Pathology High Risk \(Critical\) Results Alerts List – Chemical Pathology](#)
- [NSW Health Pathology High Risk \(Critical\) Results Alerts List – Haematology](#)
- [NSW Health Pathology High Risk \(Critical\) Results Alert List – Microbiology](#)

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5.4 High Risk (Significant) Results

5.4.1 The following NSW Health Pathology High Risk (Significant) Results support the implementation of this policy.

- [High Risk \(Significant\) Results - Anatomical Pathology - NSWHP_SD_069](#)
- [High Risk \(Significant\) Results - Immunology - NSWHP_SD_070](#)

6. Roles and Responsibilities

- 6.1 Managers are responsible for ensuring staff are aware of the requirements in this policy and the NSW Health Pathology High Risk (Critical) Results Alerts Lists and that records are retained according to NPAAC requirements ^{7e}.
- 6.2 Laboratory staff are responsible for notification of critical results and documenting communication of high risk laboratory results in accordance with this policy and the NSW Health Pathology High Risk (Critical) Results Alerts List.

7. Legal and Policy Framework

- a) International Standards Office, 2012, ISO 15189:2012 Medical laboratories – Requirements for quality and competence
- b) Campbell A, Caldwell G, Coates P, Flatman R, Georgiou A, Horvath AR, Lam QT, Schneider HG. Consensus Statement for the Management and Communication of High Risk Laboratory Results Clin. Biochem. Rev 2015; 36:97-105
- c) CLSI. GP47-Ed1: Management of Critical- and Significant-Risk Results, 1st Edition, Young A.
- d) NSW Health Pathology High Risk (Critical) Results Alerts List – Chemical Pathology (NSWHP_SD_037)
- e) NSW Health Pathology High Risk (Critical) Results Alerts List – Haematology (NSWHP_SD_038)
- f) NSW Health Pathology High Risk (Critical) Results Alert List – Microbiology (NSWHP_SD_042)
- g) NSW Health Pathology High Risk (Significant) Results – Anatomical Pathology (NSWHP_SD_069)
- h) NSW Health Pathology High Risk (Significant) Results – Immunopathology (NSWHP_SD_070)
- i) Release of Pathology Test Results Policy - NSWHP_PD_016
- j) National Pathology Accreditation Advisory Council, Requirements for the Retention of Laboratory Records and Diagnostic Material, Australian Government Department of Health and Ageing, Canberra, 7th edition, 2018

8. Review

This policy will be reviewed by 01/04/2023.

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9. Risk

Risk Statement	If high risk test results are not communicated due to ineffective or unreliable communication and processes the consequences could result in harm to patients.
Risk Category	Clinical Care and Patient Safety

10. Further Information

For further information, please contact:

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11. 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	Policy Author	Sections Modified
1.0	31/05/2016	ELT	31/05/2016	High	Chemical Pathology Clinical Stream Lead	New Policy
2.0	05/10/2017	Policy Sponsor	05/10/2017	High	Chemical Pathology Clinical Stream Lead	Minor amendment - 1.1 Update hyperlink of Alerts List.
3.0	11/12/2017	SLT	11/12/2017	High	Chemical Pathology Clinical Stream Lead	Minor amendments - Document transferred onto current template; Update contact; Remove name reference at Section 7 and 10
4.0	5/01/2019	SLT	15/01/2019	High	Chemical Pathology Clinical Stream Lead	Minor amendment – Section 3 and 8 Remove “Chemical Pathology” from scope; Change review date.

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5.0	30/10/2019	Chair, Clinical Governance Quality and Risk Committee	18/10/2019	High	Chemical Pathology Clinical Stream Lead	Minor amendment to naming convention i.e. "high risk (critical) alert list, revised Haematology and Chemical Pathology Alerts, new templates, new contact), update review date.
5.1	06/11/2020	Executive Director Strategy & Transformation	05/11/2020	High	Chemical Pathology Clinical Stream Lead	Minor amendment to Section 5.3 - Addition of links to NSW Health Pathology High Risk (Critical) Results Alert List – Microbiology and Section 5.2.4 & 7e) - Release of Pathology Test Results (NSWHP_PD_016)
5.2	19/11/20	Executive Director Strategy & Transformation	18/11/2020	High	Chemical Pathology Clinical Stream Lead	Minor amendment – removal of links to NSW Health Pathology High Risk (Critical) Results Alert List – Microbiology whilst amendments are made to the Supporting Document (NSWHP_SD_042)
5.3	11/03/21	Executive Director Clinical Operations	22/02/21	High	Chemical Pathology Clinical Stream Lead	Policy Sponsor changed from Executive Director, Strategy and Transformation to Executive Director, Clinical Operations.

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6.0	06/05/22	Director Clinical Operations	02/05/2022	High	Clinical Stream Manager	Addition of Section 5.4 High Risk (Significant) Results to incorporate Anatomical Pathology and Immunopathology policy documents. Hyperlinks added for NSWHP_SD_069 and NSWHP_SD_070 and NSWHP_SD_042
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