Australian Government
Department of Health

NPAAC TIER 3A DOCUMENT

REQUIREMENTS FOR THE COMMUNICATION OF HIGH RISK PATHOLOGY RESULTS

(First Edition 2020)

National PATHOLOGY ACCREDITATION Advisory Council

Print ISBN: 978-1-76007-422-7

Online ISBN: 978-1-76007-423-4

Publications approval number: DT0001906

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First edition 2020

Australian Government Department of Health

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The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to advise the Australian, state and territory governments on matters relating to the accreditation of pathology laboratories. A key role of NPAAC is to develop and maintain pathology quality standards for accreditation. NPAAC also advises on pathology accreditation policy initiatives and initiates and promotes education programs about quality in the provision of pathology services.

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

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

Scope

The *Requirements for the Communication of High Risk Pathology Results (First Edition 2020)* is a Tier 3A NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services.* The latter 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. The principles align with those espoused in the *National Consensus Statement: Essential elements for recognising and responding to acute physiological deterioration*[*], and the *Medical Board's Good Medical Practice: a code of conduct for doctors in Australia*. [†]

Whilst there must be adherence to all the Requirements in the Tier 2 document, reference to specific Standards in that document are provided for assistance under the headings in this document.

The purpose of this document is to provide guidance and the minimum best practice standards for the management and communication of high risk pathology results by the pathology service. This is with the aim of minimising potential risks to patients and maximising the contribution of pathology testing to the management of patients. The pathology service is required to provide medical and scientific consultation on these results when sought but decisions about the management of the patient are made by the managing clinician.

The effective communication of these results is a shared responsibility between the laboratory staff and the attending medical team. It is recognised that communication by laboratory staff may be hampered because adequate contact information has not been provided or that delays may occur after receipt of the information by a member of the medical team if this is not escalated to the attending medical officer. Standards of care to address these situations are outside of the scope of this document.

It is not the intention of the document to provide alert thresholds and alert lists.

It is noted, also, that the protocol for the communication of high risk results may differ from the treatment of results nominated by the referring clinician as urgent.

This document refers to partially complete and final pathology results, including supplementary and amended pathology reports.

[*] https://www.safetyandquality.gov.au/our-work/recognising-and-responding-deterioration/recognising-and-responding-physiological-deterioration/national-consensus-statement-essential-elements-recognising-and-responding-acute-physiological-deterioration

[†] https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx

Abbreviations

Abbreviation	Description
ACSQHC	Australian Commission on Safety and Quality in Health Care
AS	Australian Standard
ISO	International Organization for Standardization
NPAAC	National Pathology Accreditation Advisory Council
PoCT	Point of Care Testing
RMPS	Requirements for Medical Pathology Services

Definitions

Term	Definition
Alert threshold	means the upper and/or lower threshold of a test result or the magnitude of change (delta) in a test result within a clinically relevant time period, beyond which the finding is considered to be a medical priority warranting timely action.
Alert list	means a list of critical tests and tests with alert thresholds for high risk results which ideally reflect an agreed policy between the laboratory and its users for rapid communication within a pre-specified time frame and according to a procedure.
High risk results	means results that require communication in a timely manner because they indicate a potential risk to the patient and require the immediate attention of the referring practitioner. High risk results may be subcategorised using a risk assessment as critical or significant, but both categories require communication to the referring practitioner in a clinically appropriate time frame.

Introduction

The *Requirements for the Communication of High Risk Pathology Results (First Edition 2020*) addresses the need for pathology services to recognise and respond in the event that testing yields results which indicate that a patient is at high risk of an adverse clinical outcome. These results must be effectively communicated within a clinically acceptable timeframe to enable the attending medical officer to make timely management decisions.

Recognition and initiation of a response to these high risk results relies on the development by the laboratory staff, of policies and processes that prioritise the safety of the patient and the mitigation of risks to the patient. These processes will vary between laboratories in order to address the varying characteristics of local referrers, their patients, and the laboratory's operations. The effective communication of these results, is, however, a shared responsibility between the laboratory staff and the attending medical team. It is recognised that communication by laboratory staff may be hampered because adequate contact information has not been provided or that delays may occur after receipt of the information by a member of the medical team if this is not escalated to the attending medical officer. Standards of care to address these situations are outside of the scope of this document.

These Requirements are intended to serve as minimum Standards in the accreditation process and have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardization including:

AS ISO 15189 *Medical laboratories – Requirements for quality and competence*

These Requirements should be read within the national pathology accreditation framework including the current versions of the following NPAAC documents:

All Tier 2 and 3 Documents

In addition to these Standards, laboratories must also comply with all relevant jurisdictional legislation (including reporting requirements).

In each section of this document, points deemed important for practice are identified as either 'Standards' or 'Commentaries'.

- A Standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a Laboratory can attain accreditation – Standards are printed in bold type and prefaced with an 'S' (e.g. **S2.2)**. The use of the word '**must**' in each Standard within this document indicates a mandatory requirement for pathology practice.

- A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a 'C' (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a Standard or not. Where a Commentary contains the word '**must**' then that commentary is considered to be **normative**. Note that when comments are expanding on a Standard or referring to other legislation, they assume the same status and importance as the Standards to which they are attached. Where a Commentary contains the word '**must**' then that commentary is considered to be **normative**.

Please note that any Appendices attached to this document may be either normative or informative and should be considered to be an integral part of this document.

Please note that all NPAAC documents can be accessed at - www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm

While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

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1. Clinical Governance

(Refer to Standard 4 in *Requirements for Medical Pathology Services*)

The timely communication of high risk pathology results is a core expectation of medical practice. This section details requirements that have already been broadly enunciated in the NPAAC Standard *Requirements for Medical Pathology Services (Third Edition 2018)* and *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018).* It also reviews requirements from the Australian Commission on Safety and Quality in Health Care (ACSQHC) and the Medical Board of Australia.

The Medical Board of Australia[‡] defines a "referral" as sending a patient to obtain an opinion or treatment from another doctor or healthcare professional. This process usually involves the transfer (in part) of responsibility for the patient's care, usually for a defined time and for a particular purpose, such as care that is outside of the referring doctor's area of expertise. With this definition in mind, a request for a laboratory test is legitimately construed as a referral.

The requirement of a laboratory to notify a clinician of a patient's high risk results is captured by the ACSQHC's standard titled *Communication of Critical Information*.[§] In the view of the Australian Commission on Safety and Quality in Health Care (ACSQHC)[**], "clinical handover" traditionally refers to the transition of care that occurs at the end of one shift and the beginning of another when critical information about a patient's care emerges or changes. It has broadened the requirements for handover to include all key times throughout the delivery of health care including transitions of care when critical information about a patient's care emerges.

The shared responsibility of the pathology service and the medical service for the effective communication of high risk results is best delivered by clear governance structures that recognise this interface. This Standard addresses exclusively the governance requirements of the pathology service.

S1.1 The designated person, who is a medical practitioner, is responsible for the clinical governance of the laboratory.

S1.2 The designated person must specify the results which pose a high risk to the safety of a patient (high risk results) and ensure that these results are communicated to the requesting medical practitioner or their delegate in a timely and effective way to allow timely decision making.

C1.2 Laboratories should refer to NPAAC's *Requirements for Medical Pathology Services (Third Edition 2018)* (SC8.3, SC8.4) and *Appendix A - Risk Points*, the *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)* (SCG1.1, 1.2 and 1.3), Medical Board of Australia's *Good Medical Practice: a code of conduct for doctors in Australia, March 2014* (sections 2.1.3, 4.2.1, 4.3.3 and 4.4.3) and Australian Commission on Safety and Quality in Health Care, National Safety and

[‡] Good Medical Practice: a code of conduct for doctors in Australia, March 2014
[§] https://www.safetyandquality.gov.au/standards/nsqhs-standards/communicating-safety-standard/communication-critical-information
[**] National Safety and Quality Health Service Standards, Communicating for Safety Standard, 2019

Quality in Health Service Standards, *The Clinical Governance Standard and The Communicating for Safety Standard, 2019* (Action 6.9). ††

S1.3 The designated person must take a risk based approach to the development of the policies and procedures for the communication of high risk result. Refer to *Appendix A*.

2. Structured Communication Procedures

(Refer to Standard 8 in *Requirements for Medical Pathology Services*)

Laboratories must have documented procedures for the communication of high risk results. As much as possible, clinical users of the laboratory should be consulted in the development of these procedures and they should be available for clinical users to view and review in conjunction with the laboratory.

A worked example of a communication event is provided in ***Appendix A*.**

S2.1 The laboratory must use modes of transmission for the communication of high risk results that enable timely notification and acknowledgement of receipt.

C2.1(i) Verbal notification **must** be performed by a competent individual.

C2.1(ii) Verbal communication is the most time effective, initial mode of notification of high risk results, and should include an acknowledgement of receipt.

C2.1(iii) Other forms of communication may be used provided they **are** secure, reliable, timely and have been agreed upon by the users of the laboratory's services.

C2.1(iv) Where these channels of communication are used, there should be a system to acknowledge receipt of the high risk result.

S2.2 Laboratories must notify the requesting clinician or the managing clinician responsible for the patient's care of a high risk result.

C2.2(i) Where the responsibility for receiving pathology results has been delegated by the clinician or clinical organisation to another person, the laboratory staff **must** seek to speak to a person who is authorised to receive high risk results. They **must** then advise that this is a high risk result and ask for it to be communicated to the attending medical officer urgently.

C2.2(ii) Laboratories should have procedures which ensure that current patient contact details are captured and can be accessed.

S2.3 The laboratory must have an escalation procedure for when initial notification attempts of high risk results fail.

C2.3(i) Laboratories **must** have an escalation procedure to guide laboratory staff in the event that the requesting clinician or delegate cannot be contacted. For critical results in community based settings, this may include instructions to contact the patient or carer or relevant external agencies.

C2.3(ii) There **must** be a procedure to follow up abandoned notifications even when the time frame of clinical risk has passed.

C2.3(iii) All steps taken **must** be documented in accordance with **S2.5**.

S2.4 The laboratory must define what data needs to be communicated to the recipients of high risk results.

C2.4 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;
(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.

S2.5 The laboratory must document high risk result notification events.

C2.5(i) Laboratories **must** document notification events preferably in association with the record of the high risk result. Laboratory record systems or data source should contain:

(a) identity of the patient tested;

(b) test that was performed;

(c) test result with the units of measurement;

(d) identity of the recipient of the notification

(e) date and time that the notification was made (where there was verbal communication);

(f) date and time of the acknowledgement of receipt of the result (where there was non-verbal communication).

C2.5(ii) For verbally communicated high risk results, the laboratory record or data source **must** also contain the identity of the notifier.

C2.5(iii) Unsuccessful notification attempts or any difficulties in meeting the requirements for notification should also be documented.

Point of Care Tests (PoCT)

High risk results may be detected by PoCT medical services. The designated person who is a medical practitioner[‡‡] is responsible for the development of procedures for the management of high risk results in a PoCT service.

S2.6 Operators must have received training in the recognition of high risk results and the need to communicate them immediately to the attending medical officer.

[‡‡] S1.1 *Requirements for Point of Care Testing*

3. Identification of high risk results

(Refer to Standard 8 in *Requirements for Medical Pathology Services*)

The identification of high risk pathology results is fundamental to the management of risk to patients. While it is not the purpose of this Standard to prescribe lists of high risk results, some resources for laboratories who are developing or reviewing their criteria are included in ***Appendix B***.

S3.1 The laboratory must use a risk based approach to compile an alert list of high risk results.

C3.1(i) The alert criteria **must** be available for users of the laboratory service.

C3.1(ii) Laboratories should consult its clinical users in the compilation of the alert list.

C3.1(iii) The alert list criteria may be subject to customisation in consultation with clinical users.

S3.2 The laboratory must have procedures to ensure that high risk results are reliably identified.

C3.2(i) Laboratories **must** have procedures to inform laboratory staff when a high risk result has been generated. The system should distinguish high risk results from other results. Where there is a high volume of results, an electronic identification procedure is preferable to a manual one.

C3.2(ii) The laboratory **must** have a procedure for when and how to communicate high risk results that are preliminary. If an initial result is deemed high risk the laboratory may choose to communicate a preliminary or unvalidated result to allow for early clinical intervention. In such cases the recipient of the result should be informed that the result is preliminary and will be confirmed by repeat or further testing.

4. Specific risk points for the management of high risk results

(Refer to Standard 9 in *Requirements for Medical Pathology Services*)

Collection and transport of samples from patients in high acuity settings

It is recognised that arrangements for the collection and transport of specimens from high acuity settings may be subject to different governance structures.

S4.1 **There must be a clear understanding between parties as to their responsibility for collection and transport of pathology specimens.**

S4.2 **Where the pathology service is responsible for the collection and transport of specimens collected from patients in high acuity settings, these functions must be performed in accordance with best practice to allow testing within a clinically optimal timeframe.**

C4.1(i) **S4.2** enables referring clinicians to be able to make timely patient management decisions.

C4.1(ii) Referrers should have a clear understanding of the turnaround time for testing from high acuity settings and the processes of notification of high risk results to referrers in those settings. These arrangements should be readily available to referrers from those settings.

C4.1(iii) Where the referrer has a high suspicion of a high risk finding, they should notify the laboratory that a specimen has been dispatched so that its arrival can be recognised promptly, testing expedited, and results communicated back to the managing clinician.

S4.3 **The laboratory must have a procedure to identify, track, and monitor progress of the sample through the laboratory system.**

Referred Tests and Send away tests

Tests may be referred from one laboratory to another laboratory for specialised testing not performed at the referring laboratory. There is an increase in risk of communication failure when multiple laboratories are involved in the testing of samples. This risk must be assessed and managed with the primary responsibility for this resting with the referring laboratory.

S4.4 **Where two or more laboratories are involved in the handling and testing of the specimen the referring laboratory must have a policy in place which clearly identifies the laboratory which is responsible for the notification to the referrer of a high risk result.**

S4.5 **The laboratory performing the test must always notify the referring laboratory of a high risk result**.

C4.5 In some circumstances the risk to the patient is reduced if the testing laboratory, in addition to notifying the referring laboratory, notifies the referrer directly as this may reduce the time to notification and allow the direct provision of an expert consultation, should it be required.

S4.6 **The referring laboratory must have a policy and procedure in place which documents its expectations of the laboratory performing the test with respect to its management of the notification of high risk results.**

C4.6(i) The performance of the laboratory performing the test against this function **must** be measured, reviewed and actions taken to identify and reduce any risks to patient safety.

C4.6(ii) Where the performance of the laboratory performing these tests is considered unsatisfactory that laboratory must be advised of this and remedial action requested.

Testing of samples collected by a radiologist or other proceduralist on behalf of the patient's clinical care team

Where specimens are collected by a Radiologist or other proceduralist on behalf of the clinical team who is managing the patient, there is a risk that the results are notified to the proceduralist only and not communicated to the clinical team. This risk must be addressed.

S4.7 **Where the requesting practitioner is a Radiologist or other proceduralist who is acting on behalf of a patient's clinical care team, then the request must include the details of the clinical team to ensure the high risk results are returned in a timely manner to enable decision making.**

C4.7 For combined reports of pathology and radiology, it is strongly recommended that the entire of both reports are provided and not edited by persons who are not the reporting medical practitioner because of the risk that the meaning or significant information may be lost from the report.

5. Resilience of Online Systems

(Refer to Standard 3, Standard 4 and Standard 8C in *Requirements for Medical Pathology Services*)

Refer to Standard 2 and the *Requirements for Information Communication and Reporting.*

S5.1 The laboratory must have documented procedures to ensure that high risk results can be identified and communicated to the referring medical practitioner in the event of a failure of the usual communication channel.

S5.2 The laboratory must ensure that the communication via the back-up communication channel conveys the necessary information to enable the referring medical practitioner to interpret the result. This includes reference ranges and an indication of criticality.

S5.3 The laboratory's business continuity plan must include provisions to back up electronic systems, to recover and restore patient data files.

C5.3 The laboratory's business continuity plan should include:

(a) patient files
(b) referrer contact details.

6. Procedures to Maintain and Monitor High Risk Result Notification Systems (Audit Process)

(Refer to Standard 3 in Requirements for Medical Pathology Services)

S6.1 The laboratory must regularly review and monitor the outcomes of their high risk result management practices.

C6.1(i) The laboratory's alert criteria and management procedures **must** be reviewed and updated where feasible in consultation with representative users of the service in accordance with risk evaluation.

C6.1(ii) Laboratories **must** establish quality indicators to monitor laboratory performance in the high risk protocols. Parameters monitored may include the percentage of high risk results that were successfully communicated and the times taken to communicate results (from the time such results became available).

S6.2 In accordance with the laboratory's risk management plan, the laboratory must undertake a risk assessment, and audit and undertake relevant remedial actions in relation these Requirements.

7. Consumer engagement

(Refer to Standard 2, Standard 3, Standard 5, Standard 7, Standard 8 and Standard 9 in *Requirements for Medical Pathology Services*)

The rights of patients to safe and high quality healthcare, including pathology testing, are outlined in the Australian Charter of Healthcare Rights,[§§] The Medical Board of Australia's Good medical practice. A code of conduct for Australia's doctors and expanded upon in Requirements for Medical Pathology Services for the purpose of accreditation of laboratories.

Consumers must be able to expect the timely and effective communication of high risk pathology results to their attending medical officer.

S7.1 The wellbeing of patients and their rights must be primary consideration in the provision of pathology services.

[§§] https://www.safetyandquality.gov.au/australian-charter-healthcare-rights

Appendix A Communication protocol (Informative)

A blood culture is recognised as positive in a diagnostic laboratory on a Sunday evening at 11pm. The laboratory technician calls the requesting institution and is transferred through to the ward where s/he asks to speak to the on-call doctor

(i) Verbal communication between person-to-person in real time should be considered the optimal mode of transmission of high-risk results.

(ii) Laboratories must notify the requesting clinician or the clinician responsible for the patient's care of a high risk result. In some situations, the responsibility of receiving high risk results may be delegated by the clinician or clinical organisation to another person e.g. nurse unit manager or practice manager, who is then responsible for ensuring appropriate actions are taken. This delegation should be pre-determined and documented.

The on-call doctor is not available and the nurse on duty is notified but does not wish to take responsibility for the result.

The laboratory must have an escalation procedure for when initial notification attempts of high risk results fail.

(i) Laboratories must have an escalation procedure to guide laboratory staff in the event that the requesting clinician or delegate cannot be contacted. For critical results in community based patients, this may include instructions to contact the patient or carer.

(ii) The escalation procedure should suggest reasonable steps to follow before unsuccessful notification attempts are abandoned in the acute setting. There must be a procedure to follow up abandoned notifications even when the time frame of clinical risk has passed.

The laboratory staff member is returned to the switchboard and waits for the on-call doctor for ten minutes. S/he is transferred to an off-site doctor, and the result is notified. The laboratory staff member records the time of the call and the person notified in the LIMS.

(i) The information communicated to the recipient of a high risk result must include the following, where possible:

(a) identity of the notifier;
(b) identity of the patient tested;
(c) date and time that the sample was collected;
(d) test that was performed;
(e) test result (with the units of measurement where relevant).

(ii) Laboratories must document notification events preferably in association with the record of the high risk result. Laboratory record systems or data source should contain:

(a) identity of the patient tested;
(b) test that was performed;
(c) test result with the units of measurement;
(d) identity of the recipient of the notification and their clinical role;
(e) date and time that the notification was made (where there was verbal communication);

(f) date and time of the acknowledgement of receipt of the result (where there was non-verbal communication).

(iii) For verbally communicated high risk results, the laboratory record or data source should also contain the identity of the notifier.

(iv) Unsuccessful notification attempts or any difficulties in meeting the requirements for notification should also be documented.

Appendix B Resources for use by laboratories in the development of their procedures for the identification of high risk results (Informative)

1. Common High Risk Situations in which laboratory test results are commonly time-critical

Clinical Finding	Laboratory tests (serum/plasma unless otherwise stated)	Abnormality (High / Low/ Presence/ Non-Therapeutic or All results)
Altered level of consciousness including seizures	Blood glucose	H or L
	Electrolytes (Na ,K, Cl , HCO3)	H or L
	Urine drug screen	P
	Urinalysis	Glucose
	Carboxyhaemoglobin	H
	Urine ketones	P
	Calcium	H
	Anticonvulsant level	N-T
	INR on anticoagulant	N-T
	TSH	H or L
	CRP	
	CSF microorganisms/ antigens	P
	CSF cell count	White cells H
	HIV Abs	P
Poisoning or overdose	Suspected agents level or metabolites	All
Sudden visual loss	FBC/ ESR / CRP	
Stroke	FBC/ INR/ APTT	
	Blood culture	
Paralysis of one or more limbs	Electrolytes; FBC/ ESR/CRP	
	CPK	
	CSF protein / cells	
Headache / meningism	CSF	Xanthochromia / cells
	CSF infection screen	

Clinical Finding	Laboratory tests (serum/plasma unless otherwise stated)	Abnormality (High / Low/ Presence/ Non-Therapeutic or All results)
Cardiac dysfunction including arrhythmia	Electrolytes K / Na	L
	Digoxin level	N-T
	Troponin	H / rising
	TSH	H or L
	Blood culture / valve infection	
Clinical Hypoxia / desaturation	Arterial or venous blood gases	Low oxygen, high C)2; acidosis; alkalosis
	D-dimer	H
	Microbe detection by molecular techniques	P
	AFB by microscopy	P
	AFB by gene expert	P
	HIV Abs	P
Haemoptysis	GBM Abs	P
	ANCA	P
	AFB	P
Clinical Shock /hypotension	FBC including Hb/ WCC	Major variation from normal
		Abnormal cell morphology
	Coagulation tests	INR high; APTT long
	CRP	H
	Blood culture	Infection Present
	Tryptase	H
	Lactate (art/ venous)	H
	Osmolality	H
	Urinalysis	Blood/ white cells/ glucose
	Urine culture organisms	P
	Cortisol	L
	D-Dimer	H
	Amylase / lipase	H
Acute or subacute renal failure	Creatinine / urea	H
	ABG/ VBG	acidosis
	Nephrotoxic drugs	H
	electrolytes	Variably abnormal
	Uric acid	H
	Urine light chains	H
	ANCA	P
	GBM Ab	P
	Urgent Renal biopsy (Frozen +/- IF) on native or transplant	All

Clinical Finding	Laboratory tests (serum/plasma unless otherwise stated)	Abnormality (High / Low/ Presence/ Non-Therapeutic or All results)
Liver Failure	Transaminases	H
	INR	H
	Ammonia	H
	Paracetamol	H
	Bilirubin	H
	Urgent liver biospy	All
	Copper level	
Intra-abdominal infection / inflammation / painful crisis	CRP	H
	FBC and film	Variable include sickling
	BHCG (ectopic)	P
Pregnancy	Urine rapid test	P
	BHCG	H or Falling
Suspected or proven bleeding	FBC (Hb)	L
	Blood group and urgent X match	
Bruising	FBC (platelets)	L
	Coagulation (INR/ APTT)	Abnormal
Palpable purpuric rash - urgent	CSF microbiology/ cells	P
	Skin biopsy	All
Suspected haemolysis	FBC/ morphology	Abnormal
	Serum Copper level	H
Transfusion reaction	Cross match	Repeat also
Pyelonephritis / UTI	Urine microscopy	abnormality
	Urine culture	organisms
Peritonitis in Peritoneal dialysis	Fluid microscopy	Organisms/ cell count
Aspirates of sterile sites (pericardial/ pleural/ ascites/ joint) and abscesses	Cell count/ microscopy/culture/ crystals	All
Post cytotoxic therapy	Electrolytes/ calcium/ uric acid	variable
	FBC	All

Clinical Finding	Laboratory tests (serum/plasma unless otherwise stated)	Abnormality (High / Low/ Presence/ Non-Therapeutic or All results)
Cancer	Cytology of biopsy or fluids	Malignant cells seen
	Bone marrow aspirate	Malignant cells seen/ cytopaenias / organisms
STI	Culture/ microscopy/ PCR of pathogens	P
Neonatal	Sepsis studies	P
Viral systemic illness	EBV serology- acute IgM/ monospot	P
	HIV serology	P
	Respiratory virus detection	P
Urgent exploratory surgery	Tissue	All
	Microbiology	All
Rhabdomyolysis/ compartment syndrome/ massive trauma	CPK/ myoglobin	All
	Electrolytes	
	Haematology include blood group	
Outbreak/ contagion	Unexpected organisms	All
	Non-prevalent resistance pattern	All
	Public Health Notifiable diseases	All

2. Anatomical Pathology

The majority of anatomical pathology and cytopathology reports do not require urgent communication; however, there are occasions when prompt communication of high risk results is required.

High risk results in anatomical pathology and cytopathology involve predominantly qualitative information rather than quantitative results, and therefore reference ranges and electronic flagging of abnormally high or low numerical numbers cannot be utilised to help determine what constitutes a critical result. Additionally, there are no universally-accepted lists of which diagnoses should be considered critical or high risk.

Nevertheless, in anatomical pathology and cytopathology, most high risk results will belong to one or more of the following categories (a to e):

a) expectedly urgent results,
b) infectious conditions,
c) unexpected results (unexpected tissue and unexpected malignancy),
d) specimens where malignancy was expected and no malignancy is identified, and
e) where an initial report is amended with significant implications for patient care.

a) Expected urgent results include frozen sections, transplant-associated biopsies, and some renal biopsies. With frozen sections, the requesting surgeon is usually present which allows for direct verbal communication of initial results. Evidence of transplant rejection and a large number of crescents in renal biopsies are examples of significant urgent test results that should be communicated in a timely manner.

b) Infectious results (including Notifiable diseases like tuberculosis) should be communicated urgently as measures are often required to reduce the risk of further transmission - for the safety of health care workers, family members and the general public. Some infectious conditions also require urgent treatment for the benefit of the patient (e.g. necrotising fasciitis, bacteria in heart valve specimens and cytomegalovirus in an immunocompromised patient).

c) Unexpected results include an unexpected organ or unexpected tissue. For example, adipose tissue in uterine curettings, mesothelial cells in a heart biopsy, and ureter in association with a hysterectomy specimen. Unexpected results also include the unexpected finding of malignancy or an unexpectedly higher grade of malignancy. An example of this would be where there was a clinical suspicion of cutaneous basal cell carcinoma and the diagnosis is a Merkel cell carcinoma.

d) Timely communication with the requesting clinician should be considered where no malignancy is identified in a specimen where malignancy was expected. A similar situation is where no chorionic villi are seen in uterine curettings which were expected to show products of conception (thus raising the possibility of an ectopic pregnancy).

e) The final category that should be considered for urgent communication is where the initial report is amended and the new diagnosis or further information is likely to affect patient care and management. For example, where a preliminary frozen section diagnosis is changed after the permanent sections have been examined. Another example would be where a previous benign diagnosis is superseded by a malignant diagnosis, or vice versa. This can occur following examination of further tissue, ancillary testing or after obtaining a second opinion.

This Appendix is not intended to provide an exhaustive list of high risk and critical results. Each pathology lab should have a policy for high risk results, and as part of this consider each of the above categories to decide which anatomical pathology and cytopathology diagnoses should be treated as high risk and how urgently they should be communicated to the referring clinician.

Additionally, there will always be a need for clinical judgement by the reporting pathologist to determine which other results should be communicated urgently. However, the pathologist may need the full clinical scenario, patient history and findings of other tests/medical imaging to assist with determining the criticality of results. This is where the provision of relevant clinical information by the requesting clinician helps facilitate optimal patient care.

Example of risk management assessment for abnormal anatomical pathology result[***]

Stage of Risk Management		Abnormal Result
Risk Analysis	Hazard identification	Unexpected breast cancer in a breast implant capsule
	Potential harm associated with the pathology result	Progression of cancer without treatment
	Clinical intervention that can reduce the risk of harm	Consideration of further surgery and oncology referral
Risk Estimation	Probability: Is there reasonable likelihood of harm in absence of intervention?	Yes
	Severity: Is there reasonable likelihood of severe damage if harm occurs?	Yes
	Urgency: Is immediate intervention necessary to reduce risk of harm?	No
	Risk of Process Failure: Is there reasonable likelihood that routine reporting would not permit timely intervention?	Possible
Risk Evaluation	Is the risk of process failure greater than the clinically acceptable risk, given the estimation of potential harm?	Yes
Risk Control	Category of abnormal result	Significant risk result
Risk Monitoring	Are results communicated within intended time frame? Do outcomes support the alert threshold? Are alternative systems available for communicating results available?	Follow-up auditing communication of high risk results would be useful

[***] CLSI. Management of Critical- and Significant-Risk Results. 1st ed. CLSI guideline GP47

3. Genetics

Examples of High Risk Results

- Specific leukaemia subtype-defining variants may require urgent testing, reporting and initiation of therapy within 4-24 hours of sample collection (e.g. in 2019 this would include testing and reporting (15;17) for acute promyelocytic leukaemia).
- Genetic tests that lead to stratification of care options (e.g. chromosome aneuploidy testing for infants in neonatal intensive care units)
- Clarification of chromosomal sex for neonates with ambiguous genitalia
- Cancer-associated variants that define response/nonresponse of a malignant disorder to specific therapeutic agents
- Recurrent chromosome anomalies that define the WHO acute leukaemia and tumour subgroups
- Genetic tests that indicate relapse of a malignant disorder
- Prenatal test results.

Significant Risk Results

Are results that are not imminently life-threatening however signify a significant risk to patient wellbeing and therefore require medical attention and follow up action within a clinically-justified time frame.

- Positive genetic test results that may lead to prenatal diagnosis, termination of pregnancy or other reproductive management decisions
- Genetic test results that indicate that a patient is not eligible for a management or therapeutic intervention, or support from a government program

- Predictive test results.

4. Biochemistry

Laboratories which perform biochemical testing should consider alert thresholds for test results which may indicate conditions that are life-threatening or associated with significant morbidity, examples of which are listed below.

Note: This list is not exhaustive and other conditions may be identified by laboratories and their clinicians that are important for unique clinical settings and local treatment guidelines. It is important to consider conditions for which timely clinical action is required and available.

Examples of test result abnormalities which may indicate these conditions are listed below but ultimately should be agreed upon by individual laboratories with their clinicians.

All analytes listed below refer to blood concentrations unless otherwise specified.

Critical Risk Conditions:

Acute myocardial injury – e.g. elevated troponin

Acute ischaemic event – e.g. elevated lactate

Acute deterioration in conscious state – e.g. decreased sodium, elevated/decreased glucose, elevated calcium, elevated pCO2, decreased cortisol, elevated ammonia

Severe sepsis/infection- e.g. Elevated CRP

Cardiac arrhythmia or arrest – e.g. Elevated/Decreased potassium, Decreased magnesium

Acute drug toxicity – e.g. Elevated paracetamol, Elevated Digoxin

Acute neuromuscular injury/dysfunction – Elevated CK, Decreased calcium

Hypoxia – Decreased pO2

Acute Kidney Injury – High delta change in creatinine

Acute liver injury – Elevated transaminases (ALT, AST)

Pre-eclampsia – Elevated urine protein in pregnant woman

Kernicterus – Elevated Total Bilirubin in neonate.

Significant Risk Conditions:

Cancer Diagnosis – e.g. Elevated tumour markers, new paraprotein identified on protein electrophoresis

Drug Toxicity Risk – e.g. Decreased TPMT activity

Thyrotoxicosis – Combination of suppressed TSH and elevated thyroid hormones (fT4 and fT3)

Hypothyroidism – Combination of high TSH and low thyroid hormones (fT4 and fT3).

5. Microbiology/ sepsis

(a) Sepsis is a high-mortality condition. Outcomes depend primarily on the early recognition of the condition and immediate initiation of appropriate antimicrobials, but identification of the pathogen and its antimicrobial sensitivity is required to confirm or modify treatment. Delays in the initiation of appropriate treatment increase sepsis mortality sharply and this drives demand for point-of-care testing for serum lactate and arterial blood gases.

(b) Conditions required to be notified by laboratories by telephone under the *Public Health Act* (or equivalent) in each jurisdiction.

(c) Conditions to be notified to referring doctors. This list is not exhaustive or binding. It is intended to stimulate risk assessment and consultation with requestors. Specialty units may negotiate notification of particular findings that are not applicable outside their particular setting.

Gram stain results on positive blood cultures

Microscopy results (cell counts, Gram's stain results) on cerebrospinal fluid (CSF)

New Mycobacterium tuberculosis diagnosis (smear, NAAT, culture)

Legionella pneumophila type 1 urinary antigen

Streptococcus pneumophila urinary antigen

Cryptococcal antigen (serum, CSF)

Shiga toxin positivity

Susceptibility results for *Mycobacterium tuberculosis* if resistant

Mucormycete isolates

Cryptococcus species isolates

Dimorphic fungus isolated

Haemophilus influenzae typing if type b

CSF PCR positive for GBS, HSV, MTB, VZV, Syphilis, pneumococcus, meningococcus polyoma virus

CSF PCR positive for GBS, HSV, MTB, VZV, Syphilis, pneumococcus, meningococcus or polyoma virus

Hepatitis A virus and Hepatitis E virus IgM

Parvovirus B19 if pregnant

Measles virus IgM

HIV new diagnosis

Positive culture on normally sterile fluids

Eye cultures

CSF PCR Positive for enterovirus

MRO for infection control (MRSA, VRE, CPE, MRAB, *Candida auris*)

Clostridium difficile the type of test should be specified

Pertussis

Clostridium difficile

Pertussis
Atypical pneumonia PCR panel
Salmonella, *Shigella* isolates
Meningococcus isolate/ Ag/ PCR/ IgM
Positive norovirus Ag/ RNA
Influenza A virus and Influenza B virus RNA
Dengue NS1 or IgM.

6. Immunology

Unlike many disciplines within pathology most Immunopathology laboratories operate on a Monday-Friday office hours basis with minimal need to call back staff for urgent performance of immunopathology tests. Nonetheless there are circumstances where the clinical suspicion of a particular diagnosis will warrant out-of hours and urgent testing and in those circumstances results would be conveyed to the requestor irrespective of the findings.

Other abnormalities which may be detected which are time critical (usually due to the speed of progression that can occur in their presence) include:

1. Autoantibodies associated with systemic vasculitis
    a. ANCA
    b. Anti-PR3
    c. Anti-MPO
    d. ANA
    e. Anti-ds DNA
2. Autoantibodies associated with acute renal and pulmonary inflammation
    a. Anti-GBM
3. Autoantibodies associated with acute demyelination and/or other acute neurological dysfunction
    a. Anti-Aquaporin 4 (NMO Ab)
    b. Anti-MOG
    c. Anti-NMDA
4. Grossly disordered lymphocyte subsets
5. HIV serology
6. Detection of paraprotein
7. Abnormal serum free light chains
8. Urinary light chain leakage
9. Immunodeficiency as evidenced by profoundly low Ig isotype levels
10. Phospholipid antibodies (anti- B2GP1; anti-cardiolipin)

7. Haematology

Full blood count numerical indices: leucocytes, neutrophils, haemoglobin and platelets.

Morphology findings:

Acute leukemia and acute promyeocytic leukemia

Parasites including malaria

Blood film suggesting of thrombotic microangiopathic anaemia

Blood film with bacteria

Other tests - INR

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Acknowledgements

A/Professor Beverley Rowbotham AO **(Chair)**

Associate Professor Rob Baird

Professor Francis Bowling

A/Professor Richard Brightwell

Dr Raymond Chan

A/Professor Roger Garsia

Dr Trina Gregory

Professor Jonathan Iredell

Dr Que Lam

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(First Edition 2020)

DT0001906 July 2021

www.health.gov.au/npaac