NSW Health Pathology

Policy

Labelling Requirements for Pathology and Forensic Specimens

NSWHP_PD_023

1. Purpose

To:

a) Standardise the minimum labelling requirements for pathology specimens (including samples received from Forensic Medicine)
b) Define the criteria for the acceptance or rejection of specimens submitted to NSW Health Pathology (NSWHP) laboratories for testing and
c) Document the notification requirements for managing unsuitable specimens.

2. Background

2.1 Pathology is a critical part of the diagnostic and forensic process. Pathology specimens provide essential information that assists patient management including determining appropriate treatment, which influences clinical outcomes of patients.

2.2 Positive and unambiguous identification of patient specimens is integral to the accuracy and reliability of pathology and forensic analysis.

2.3 Unlabelled, mismatched or mislabelled specimens are the main source of pre-analytical errors in the laboratory and these errors can result in:

a) Adverse patient outcomes including misdiagnosis and delayed, omitted or incorrect treatment

b) Poor patient experience for patients who require a second sample to be recollected or the loss of irreplaceable specimen

c) Delays in finalisation of investigations done under direction of the coroner including delays in final reports provided to the coroner.

3. Scope

3.1 This policy applies to all clinical, laboratory, collection and Central Specimen Reception staff participating in the collection and labelling of pathology sent to, or received in, a NSWHP laboratory.

3.2 This policy does not apply to specimens provided for pre-transfusion testing. Please refer to the NSW Health Pathology Minimum Patient Identification Requirements for Pre-Transfusion Testing Policy NSWHP_PD_009.

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4. Definitions

AUID	Area Unique Identifier (AUID) – an identifier generated for a patient within a Local Health Distric
Autopsy Pathologist	A doctor performing an autopsy who requests pathology to be performed
FMCN	Forensic Medicine Case Number
ICN	Individual Case Number
IHI	Individual Healthcare Identifier
LIS	Laboratory Information System which records, manages, and stores data for clinical and forensic laboratories
MRN	Medical Record Number
Mismatched specimen	A specimen is labelled with one patient's details accompanied by a request that is labelled with another patient's details
Mislabelled specimen	A specimen that is identified with incorrect patient identifiers, for example, the specimen and request are labelled with patient A's details, but the specimen was taken from patient B also known as a Wrong Blood in Tube (WBIT) episode
Patient identifiers	Specific data items approved for use as patient identifiers, for example, patient name (family and given names), date of birth, MRN, gender, address including postcode, Healthcare record number, IHI, AUID, FMCN, or ICN
Patient identity in doubt specimen	A specimen where there is doubt about the integrity of the labelling, for example, evidence suggesting removal of a previous adhesive label or a label from one patient stuck over that of another patient
PMT	Post Mortem Technician
Precious specimens	A specimen that was collected using an invasive or surgical procedure including but not limited to: • Any surgical, or post-mortem (coronial and non-coronial) procedure for example tissue or biopsies • Amniotic fluid/ Chorionic villus sampling (CVS)/ fibroblasts

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- Body or aspirated fluids, for example, joint, pleural, peritoneal, ascitic, Cerebrospinal fluid intraoperative fluids/pus/swabs, FNA smears and Bone marrow aspiration
- Bronchial washing/lavage
- Corneal scrapings or vitreous fluids
- Endoscopic brushings
- Sexual assault specimens
- Supra -pubic bladder collection

Specimens not re-collectable due to a passage of time which is critical to patient care such as:

- Neonatal blood glucose
- Specimens from patients treated with antibiotics or other drugs including:
- B12/Folate (if a transfusion or B12 has been administered)
- Interfering drugs for example N-acetylcysteine (NAC) for paracetamol
- Procedural specimens for example Glucose Tolerance Test (GTT), Synacthen tests and Dynamic Function Tests
- Time dependent drug levels

Responsible collector	Any person collecting the pathology sample including NSWHP phlebotomists, clinicians, post-mortem technicians and/or forensic pathologists collecting pathology specimen as part of their role
Requesting doctor	A doctor responsible for requesting the testing and providing the request form
Specimen	Any tissue or fluid from a patient that is submitted to NSWHP or external agency for analysis or testing
Specimen reception	Staff who receipt and process specimens in NSWHP pathology and forensic laboratories
Unlabelled specimen	A specimen that is not identified with any patient identifiers or medical officers name in the case of Forensics
Inadequately labelled specimen	A specimen that does not comply with minimum labelling requirements, for example, specimens that are unlabelled, mislabelled, mismatched or has less than the minimum labelling requirement

Wrong Blood in Tube (WBIT)	Occurs when patient A is on the request and the label, but patient B's blood is in the sample also known as a mislabelled Specimen

5. Policy Statement

5.1. Acceptance and Rejection of Specimens Flowchart

5.1.1 The Acceptance and Rejection of Specimens Flowchart shows how NSWHP specimens will be managed on receipt by the NSWHP's laboratory specimen reception or by forensic medicine (Appendix A).

5.2. Accountabilities of the Responsible Collector

Pathology Specimens

5.2.1 The Responsible Collector must:

a) Ensure that the patient is positively identified prior to the collection of the sample

b) Label the specimen in the presence of the patient at the time of specimen collection

c) Ask the patient or witness to confirm the details on the pathology specimen container.

Specimens received from Forensic Medicine

5.2.2 The Forensic Pathologist may:

a) Collect a sample as part of the post-mortem examination (with a coronial direction received) or as part of the preliminary investigation in terms of Section 88A of the Coroners Act 2009

b) Make a written request for a sample to be taken and it is clear, what sample and from where on the deceased person.

5.2.3 The Forensic Pathologist or Responsible Collector must:

a) Label the specimen at the time of collection, prior to taking further specimens from another patient.

Note: Exceptions to this requirement are set out in 5.6.

5.3. Minimum Labelling Requirements – Request Form

5.3.1 When identifying a patient, three (3) patient identifiers must be used on the request form. The preferred identifiers include:

a) Patients full name (surname, first name and any middle names)

b) MRN or unique patient identifier such as an AUID or FMCN used in Forensic Medicine

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c) Date of birth.

5.3.2 The patient's address or gender may be used in place of a preferred identifier, if it is not known or available.

Note: Exceptions to this requirement are set out in 5.6.

5.4. Other Requirements – Request Form

5.4.1 The request form should also contain the following information:

a) Name or other unique identifier of the person legally authorised to request examinations or use medical information together with the destination for the report

b) Type of sample

c) Anatomic site of origin, where appropriate

d) Examinations/tests requested

e) Any relevant clinician information

f) Patient gender

g) Date of request

h) Date and time of specimen collection

i) Referring hospital or referrer (Forensic medicine) if required.

5.5. Minimum Labelling Requirements – Specimen

5.5.1 All specimens must be traceable to an identified individual.

5.5.2 When identifying a patient, three (3) patient identifiers should be used where practicable. The preferred identifiers include:

a) Patients full name (Surname, first name and any middle names)
b) MRN or unique patient identifier such as an AUID, FMCN or ICN
c) Date of birth.

5.5.3 Two (2) of the preferred identifiers must be used if three (3) cannot be accommodated.

5.5.4 All patient information on the request form must match the patient information on the specimen.

Note: Exceptions to this requirement are set out in 5.6.

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5.6. Exceptions

Unidentified or Unconscious Patients

5.6.1 For unidentifiable or unconscious patients, a minimum of two (2) patient identifiers must be used. This might include:

a) MRN or other patient identifier
b) A further descriptor, for example, patient gender, motorbike accident.

5.6.2 For forensic medicine, three (3) identifiers are required in all cases.

Forensic Medicine

5.6.3 Cases of unknown ID are managed by NSW Police in the first instance.

5.6.4 If a specimen is taken for the purposes of ID, the normal procedure for unknown or unidentified samples must be followed. In this case other identifiers are used such as gender or a unique identifier.

Minor Errors

5.6.5 Correction of incorrect details, relabelling of specimens or retrospective labelling of unlabelled specimens is not permitted except as specified in clauses 5.6.6 to 5.6.10.

5.6.6 Minor spelling or numerical errors resulting in an incorrectly labelled specimen causing mismatched specimen to the request form may occur, for example, Brown instead of Browne, Kalie instead of Kaylie. In this case the other forms of identification must be accurately reflected.

5.6.7 Where the error is minor and therefore recollection is not warranted, the Specimen Reception Manager may apply discretion to the enforcement of the minimum labelling requirements.

5.6.8 Reasons for exercising discretion should be recorded in the LIS by the Specimen Reception Manager.

5.6.9 Reported diagnostic results of specimens with minor errors must include a comment covered in Section 7. The most appropriate comment must be chosen.

5.6.10 In the case of forensic medicine specimens, the specimen reception staff must:

a) Contact the appropriate area of FASS to advise of minor identification error
b) Request an updated form be sent to the Laboratory to rectify the error

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c) Set aside the sample until correct forms have been received and the corrections noted in both paper and electronic formats in the case of a deceased patient.

5.7. Inadequately Labelled Specimens

5.7.1 Mismatched, mislabelled, unlabelled or patient identity in doubt specimens, that do not meet the minimum labelling requirements, will be treated as inadequately labelled specimens.

5.7.2 Inadequately labelled specimens must not be processed by the laboratory until measures are taken to identify the sample. This may be done using a unique identifier such as a barcode and a label indicating why the specimen is inadequately labelled, for example, "UNLABELLED" in the case of a completely unlabelled specimen.

5.7.3 If an inadequately labelled specimen is received by Central Specimen Reception or the laboratory, the specimen must be entered into the LIS as follows:

a) The specimen is inadequately labelled and has been cancelled for tracking purposes

b) The reason why the specimen is inadequately labelled, that is:

i. Mislabelled
ii. Mismatched and/or
iii. Unlabelled and

c) The date and time of receipt in the Laboratory.

5.7.4 The specimen must be physically identified as an inadequately labelled specimen by using a distinct and noticeable sticker or stamp which indicates the date and time of receipt in the Laboratory and the reason why the specimen is inadequately labelled.

5.7.5 Central Specimen Reception or the location in NSWHP where the non-conformance is identified, must contact the responsible collector, Medical Officer or ward to notify them that the specimen is unsuitable, has been cancelled and a recollection is required in the case of a specimen that is not a precious specimen.

5.7.6 The National Association of Testing Authorities (NATA) General Accreditation Criteria: ISO 15189 Standard Application Document, May 2019 states at Section 5.4.6 that:

... "Where inadequately labelled samples are received and accepted for testing, the facility must assure itself of the identity of each sample. If samples that do not meet minimum acceptability criteria are accepted and tested, a record must be kept of any subsequent action taken.

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Note: The facility retains responsibility for the testing and reporting of inadequately labelled samples even where the identity is confirmed by the collector.

Samples that are received unlabelled, mislabelled or insufficiently labelled must not be relabelled after receipt or sent back to the collector for relabelling. The exception is for irreplaceable specimens (e.g. histology specimens). In such cases the original specimen label must remain unaltered and visible. However, an additional label may be added to the container to aid traceability through the laboratory. The person applying the additional label must be identifiable in the records and the original labelling issue must be included as a comment in the final test report".

6. Precious Specimens

Inadequately labelled specimens that are also irreplaceable specimens must be dealt with as follows:

6.1 The Responsible Collector or Medical Officer must be contacted, advised of the error and agree to sign a waiver to accept full responsibility for the identification and labelling of the specimen before the specimen will be accepted by the Laboratory for processing.

6.2 Where a waiver has been completed and the specimen has been accepted for processing per Section 6.3 of this Policy:

a) The specimen(s) must be physically identified using a unique identifier such as a barcode and a label affixed indicating the error, for example, unlabelled or mismatched specimen prior to processing

b) Acceptance of the specimen for testing must be recorded in the LIS and the laboratory must be informed of error.

6.3 Where a waiver is not completed, the matter must be escalated to the Central Specimen Reception Manager for resolution.

7. Report Comments

7.1 Reported diagnostic results of inadequately labelled specimens that have been tested and reported, must include one of the following comments which reflects the level of labelling non-conformance and the associated risk:

"Specimen was received unlabelled and the requestor or a delegate has been contacted, with testing authorised to proceed by the clinical team. Please consider this information when interpreting results."

or

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"Specimen was received mislabelled / incompletely labelled and corrective action has been performed by the requestor or a delegate with testing authorised to proceed. Please consider this information when interpreting results."

7.2 The comment must be entered as soon as possible to ensure correct interpretation of the results in all situations.

a) Where the specimens are determined to be incompletely labelled the comment should be entered at the point of detection and by the staff/area who has reported the non-conformance
b) If the specimen is received unlabelled and deemed clinically appropriate to test, this must be discussed with the scientist in charge of testing, and they must ensure the appropriate comment is added before reporting.

Forensic Medicine

7.3 Specimens need to be stored in appropriate storage conditions clearly labelled "Forensic Specimen in follow up". The forensic medicine site from which the specimen originated must then be contacted via email:

Newcastle	NSWPATH-FASSNewcForensicCaseCoord@health.nsw.gov.au
Sydney	NSWPATH-FASS-FMSYD-Staffstation@health.nsw.gov.au
Wollongong	NSWPATH-FASSFM-MortuaryW@health.nsw.gov.au

7.4 Where indicated by Forensic Medicine that the specimen cannot be guaranteed in accordance with Section 5.6.8 of this Policy, acceptance or rejection must be escalated to the Chief Forensic Pathologist for clinical decision on whether the specimen is to be tested and/or tested against DNA for confirmation of deceased persons.

7.5 In the case of urgent NSW Police investigations, local procedures must be applied to prevent any delay in testing.

8. Roles and Responsibilities

8.1 All NSWHP staff involved in the collection of pathology specimens must comply with this policy.
8.2 Each NSWHP site involved in specimen testing must have an effective process in place to ensure a standardised approach to the receipt, acceptance and rejection of specimens that complies with this policy.

8.3 Operations Directors or Managers of the service must ensure that:

a) The requirements of this policy are applied, achieved and sustained

b) All staff are made aware of their obligations in relation to this policy and

c) All staff receive appropriate training to enable them to carry out their obligations in relation to this policy.

9. Legal and Policy Framework

NSW Health Pathology Minimum Patient Identification Requirements for Pre-Transfusion Testing Policy NSWHP_PD_009

Medical Testing ISO 15189:2012

NPAAC Requirements for Medical Pathology Services (Second Edition 2018)

Australian Commissioning on Safety and Quality in Health Care, National Safety and Quality Health Service Standards, 2012

NSW Health Blood Management Policy Directive PD2018_042

ANZSBT Guidelines for Transfusion and Immunohaematology Laboratory Practice 1st Edition, November 2016

Blood Safe e-Learning Australia

The National Association of Testing Authorities (NATA) General Accreditation Criteria: ISO 15189 Standard Application Document, May 2019 Review

10. Review

This policy will be reviewed by 30 October 2025.

11. Risk

Risk Statement	Potential misidentification of a patient's pathology specimens could lead to adverse outcomes including clinical mismanagement, morbidity or mortality. Ensuring that samples are correctly identified allows for audit tracking of pathology collections in case of investigation of adverse events.
Risk Category	Clinical Care & Patient Safety ☒

Policy

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12. Further Information

For further information, please contact:

Policy Sponsor	Position: Director of Clinical Operations
	Name: Robert Lindeman
	Telephone: 0420 770 701
	Email: robert.lindeman@health.nsw.gov.au
Policy Contact Officer	Position: Director, Pre and Post Analytics
	Name: Judy Kempton-Webb
	Telephone: 0422 415 933
	Email: Judith.Kempton-Webb@health.nsw.gov.au

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	Policy Author	Risk Rating	Sections Modified
1.0	05/12/2019	Clinical Governance, Quality and Risk Committee	04/12/2019	Pre and Post Analytical Clinical Stream Lead	Medium	New policy.
2.0	12/09/2022	Director of Clinical Operations	12/09/2022	Director, Pre and Post Analytics	Medium	Sections relating to related comments when a specimen is accepted with minor or major labelling deficiencies.
3.0	21/10/2024	Chief Pathologist	15/10/2024	Director, Pre and Post Analytics	Medium	Comments when a specimen is accepted with minor or major labelling deficiencies. Changes to section 5.2.2 requested by Forensic Medicine.

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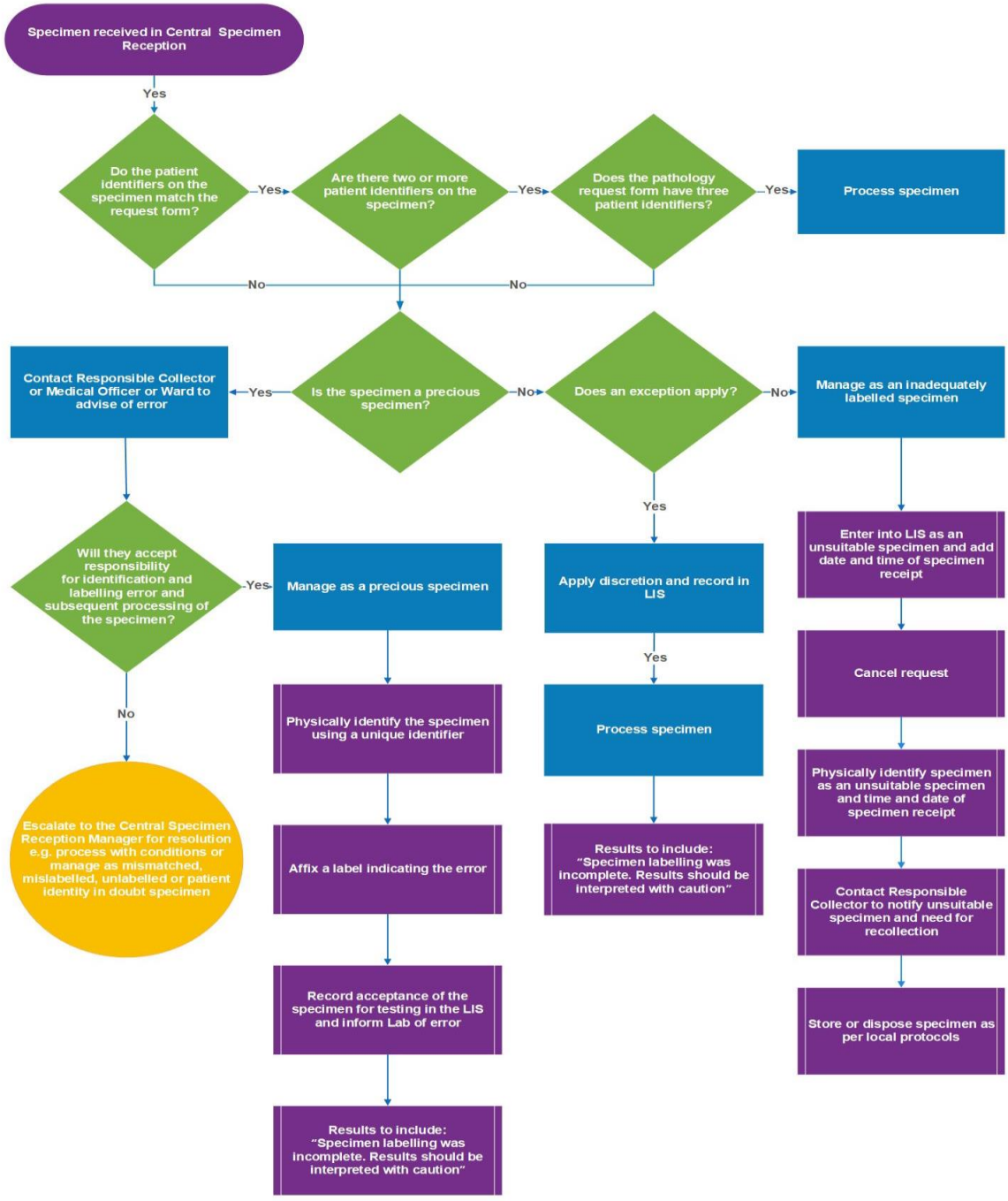
Appendix A - Acceptance and Rejection of Specimens Flowchart



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