

PATHOLOGY SPECIMEN ACCEPTANCE AND REJECTION PROCEDURE[®]

DOCUMENT SUMMARY/KEY POINTS

- “The highest risk in the pathology process is when a person presents to have their sample collected. If the person is not identified correctly, or the pathology sample and/or request form do not have the correct information about the correct person, the results may be attributed to another person or treatment may be delayed or missed.”
<https://www.rcpa.edu.au/>
- Submission of a request form (or electronic equivalent) and specimen(s) to the Children's Hospital at Westmead (CHW) Pathology constitutes a contract between the service user (on behalf of the patient) and the service provider (CHW Pathology) to provide medical laboratory services. Both parties are required to fulfil their obligations under this procedure to ensure that the quality of the diagnostic testing remains focused on the patient.
- This document details the CHW Pathology Department specimen acceptance and rejection procedure for all pathology specimens.

CHANGE SUMMARY

3 December 2019 minor amendments:

- Informative details added to *Labelling Criteria (Essential Criteria)*
- Clarification of the requirement for the CHW Pathology Department to have traceability of the identity of the person collecting the primary sample in the Medical Pathology Service records included in *Labelling Criteria (Request labelling (not blood transfusion))*

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1 st November 2019	Review Period: 3 years
Team Leader:	Pathology Quality Manager CHW	Area/Dept: Pathology

- Clarification of the re-labelling requirements to ensure the original label remains unadulterated for irreplaceable or precious samples in *Management of inadequately labelled specimens and incomplete requests*
- Addition of two further related document links

READ ACKNOWLEDGEMENT

- This document should be read and acknowledged by pathology, medical, nursing, phlebotomy and allied health staff, and must be used in conjunction with the following policies:

NSW Health Policy Directive Patient Identification Bands, Document no: PD2014_024
https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2014_024.pdf

SCHN Transfusion of Blood and Blood Components - Paediatrics Policy, Document no: 2007-8092
<https://www.schn.health.nsw.gov.au/policies/pdf/2007-8092.pdf>

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Purpose and Scope

This document aims to ensure the safety of the patient, and to ensure the right investigation is performed on the right specimen. It sets out the requirements for correct specimen and request labelling for all test requests received by the CHW Pathology laboratory service.

This document must be used in conjunction with the NSW Health Policy Directive Patient Identification Bands and SCHN Transfusion of Blood and Blood Components - Paediatrics Policy, as specimen labelling will only be accurate if the patient has been correctly identified.

Authorities

The Laboratory Director or their delegate is responsible for ensuring that this procedure is established, implemented and maintained.

All staff collecting specimens for analysis hold a duty of care to patients and should comply with this procedure. The ward/department manager must ensure that this procedure is fully implemented within their areas of responsibility.

Background

Proper collection and identification of pathology specimens is a significant factor in patient safety. Specimens must be collected in a manner that protects the integrity of the specimen. Improperly collected, contaminated, delayed, or altered specimens may result in incorrect interpretations of the patient's clinical condition. Accuracy of patient identification and specimen labelling is essential to maintain patient safety.

Clinical governance demands that a specimen must be uniquely labelled and accompanied by a test request. The information which appears on the specimen label and the accompanying request MUST match and fulfil a set of minimum criteria as defined by the National Pathology Accreditation Advisory Council (NPAAC).

The [NPAAC Requirements for Medical Pathology Services \(Second Edition 2018\)](#) states:

SA8.5 Specimen collection must be performed with accurate identification of the patient and labelling of specimens in accordance with written protocols.

SA8.7 The Medical Pathology Service must have a written policy for the management of inadequately labelled specimens and incomplete request forms.

Prior to accepting a clinical specimen, laboratory personnel must ensure certain minimum criteria for specimen identification are met. Criteria for specimen identification are given in this document.

The responsibility for requesting a laboratory test lies with the patient's clinical team. Thus, it is the responsibility of the requestor to ensure that specimens are correctly labelled and that requests are completed to the agreed standard. If specimens or requests are not labelled with the essential requirements, they may be rejected.

Procedure

Labelling criteria

Essential Criteria

Specimens must NEVER be pre-labelled. Labelling should be on the body of the container, and never on the lid.

All specimens must be clearly labelled at the time of the collection, in the presence of the patient/parent/carer, and if possible, the patient identifiers should be confirmed by the patient/parent/carer. If this is not practicable then the specimen labels MUST be confirmed against details on the patient identification band.

If a pre-printed specimen barcode label is not available at the point of specimen collection, the specimen container MUST be labelled in legible handwriting with the patient's full name (or coded identifier) and at least their date of birth or Medical Record Number (MRN), and preferably all three identifiers as well as the time and date of collection. Once the pre-printed specimen barcode label is available it may be affixed to the specimen container but it must not obscure the original handwritten label.

Specimen labelling (not blood transfusion)

At a minimum, specimens **must** be labelled with the following:

- Patient's full name, or coded identifier may be used when patient is to remain anonymous; and at least one of either:
- Patient's date of birth; or
- Medical Record Number (MRN); or
- Laboratory Accession Number

Additional identifiers may include the patient address or ward location.

Specimens **should** also be labelled with:

- Date and time of specimen collection. This is essential for certain timed tests such as glucose tolerance testing;
- Specimen type(s) and anatomical site(s) for non-blood specimens such as tissues, fluids, and swabs;
- Source/location of the patient.

If the minimum specimen labelling requirements are not met, the specimen will be rejected.

If there is evidence of re-labelling (e.g.: two labels or crossing out of information on the specimen) or any doubt to the identity of the specimen, the specimen will be rejected.

Request labelling (not blood transfusion)

Request forms or electronic equivalents **must** include the following:

- Patient's full name, or coded identifier may be used when patient is to remain anonymous;
- Patient's date of birth;
- Medical Record Number (MRN); Laboratory Accession Number; Patient's Address and/or Medicare number;
- Patient's sex;
- Date and time of specimen collection. This is essential for certain timed tests such as glucose tolerance testing;
- Staff ID number or initials of person collecting the primary sample and signature of patient/parent/carer/staff confirming identity of patient
- Specimen type(s) and anatomical site(s) for non-blood specimens such as tissues, fluids, and swabs;
- Source/location of the patient, i.e.: ward if applicable
- Test(s) requested, and indication of urgency if applicable;
- Relevant clinical details including clinical status of patient (e.g.: fasting);
- Name, address, provider number and contact details (telephone/pager) of the requestor.

If the minimum request labelling requirements are not met, the request may be rejected.

Blood transfusion

Refer to SCHN Transfusion of Blood and Blood Components - Paediatrics Policy, document no: 2007-8092.

Irreplaceable or precious specimens

Exceptions may be considered for irreplaceable or precious specimen types due to improper labelling, collection, handling if the extractable information may be of value. Examples of irreplaceable or precious samples include, but are not limited to: bladder washings; bronchoalveolar lavage (BAL); bone marrow specimens; cerebrospinal fluid (CSF); gynaecological specimens; meconium; pericardial fluid; peritoneal fluid; pleural fluid; post-mortem specimens; surgical specimens including skin biopsies; synovial fluid; other specimens for which recollection will absolutely not reflect the original collection, or the sample cannot be collected without high risk to the patient or a delay due to recollection could compromise patient safety.

These irreplaceable or precious specimens **MUST** be verified by the collector/requestor prior to being reported.

Management of inadequately labelled specimens and incomplete requests

The pathology staff member responsible for identifying problems with the specimen labelling or request, completes the relevant sections of the **DOC-OP-886 Pathology specimen corrective action form** and contacts the ward/department/laboratory responsible for referring the specimen.

If the collector/requestor attends pathology and completes the **Accountability Declaration** of the **DOC-OP-886 Pathology specimen corrective action form** verifying the identity of the specimen(s) collected and corrects the problems, the collector/requestor relabels the specimen with a handwritten label and the original label remains unaltered and visible.

If a specimen is initially received unlabelled, the original (blank) label on the specimen container is left unlabelled and a new handwritten label is applied to the specimen container.

Once the specimens have had their identity verified by the collector/requestor, Pathology then proceeds to process the specimen(s) and a comment is added to the pathology report as appropriate, and an IIMS is recorded.

Rejected specimens

Any specimen(s) received within the CHW Pathology department which does not meet the minimum required labelling criteria and is unable to be verified by the collector/requestor will be rejected unless deemed to be an irreplaceable or precious specimen as outlined above. The test(s) is cancelled, and a report issued by pathology indicating the cancelled status of the test(s), and the specimen is discarded.

Monitoring pre-analytical incidents

The Pathology Quality Manager is responsible for monitoring pre-analytical incidents including compliance with minimum specimen and request labelling requirements. Key performance indicators are measured and reported quarterly to the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP) Key Incident Management and Monitoring System (KIMMS) External Quality Assurance Program (EQA).

Terms and definitions

NPAAC

The National Pathology Accreditation Advisory Council advises the Commonwealth, state and territory health ministers on matters relating to the accreditation of pathology laboratories. NPAAC plays a key role in ensuring the quality of Australian pathology services and is responsible for the development and maintenance of standards and guidelines for pathology practices. NPAAC is comprised of representatives from all states and territories, nominees from peak professional bodies and the Department of Health.

Related documents

AS ISO 15189:2013 Medical laboratories - Requirements for quality and competence

<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm>

SCHN Transfusion of Blood and Blood Components - Paediatrics Policy, Document no: 2007-8092 <https://www.schn.health.nsw.gov.au/policies/pdf/2007-8092.pdf>

NSW Health Policy Directive Patient Identification Bands, Document no: PD2014_024.

https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2014_024.pdf

Australian Commission on Safety and Quality in Health Care. The National Safety and Quality Health Service (NSQHS) Standards Second edition.

<https://www.safetyandquality.gov.au/standards/nsqhs-standards>; accessed 2-Sep-2019.

NATA General Accreditation Criteria ISO 15189 Standard Application Document Issued May 2019, Effective July 2019.

<https://www.nata.com.au/phocadownload/gen-accreditation-criteria/ISO-15189-Application-Document-Medical-Testing-Supplementary-Requirements-for-Accreditation.pdf> accessed 12-Nov-2019

<https://www.rcpa.edu.au/Library/Fact-Sheets/Pathology-The-Facts/Docs/Path-Fcts-Booklt> accessed 3-Dec-2019

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