

## Pathology

## Section : Specimen Reception Areas

## Standards for the Labelling of Request Forms and Specimens for Pathology Investigation

Site/Area of application	Leeds Teaching Hospitals NHS Trust Clinical Commissioning Groups, Community-based Healthcare Providers & External Customers
Index code	PPATH-POL-33 v4.3
Superseded documents	PQME1011 v4.3
Implementation date of this version	<b>20th March 2023</b>
Approval	Approved via CSU QA Forum Meeting held 2/3/23
Author(s)	Conor O'Malley, Ian Cocking, Nicola Millican, Rachel Trafford, Mark Davy, Mark Dunn, Magda Burgess, Carys Lippiatt, Victor Gill, Dan Carless
Reason for change	No change to content. Document re-indexed (migration to Q-Pulse).
<b>Impact on training needs and requirements for competency assessment</b>	
The change/s in this version does not affect the manner in which the technique is performed, and includes only minor changes, so no further action is required other than to be aware of the change.	
<b>Keywords for search</b> Samples, request forms, specimens, Labelling Policy, acceptance criteria	
This document is controlled using the Pathology EQMS software. Controlled printed copies can be identified by the authorisation signature present in the space below. Upon request, further authorised copies can be obtained through the department's quality system. Uncontrolled copies may be printed for an individual's use but <b>should not be used after 1 week from the date of printing.</b>	

Signature

**CONTENTS**

**1 INTRODUCTION.....3**

**1.1 SCOPE AND PURPOSE .....3**

**1.2 AREA OF APPLICABILITY .....3**

**2 REQUIREMENTS.....3**

**2.1 REQUEST FORMS.....3**

**2.2 SPECIMEN COLLECTION .....4**

**2.3 LABELLING STANDARDS .....4**

**2.4 EXCEPTIONS TO THIS POLICY .....5**

**2.5 REJECTION OF SPECIMENS AND REQUESTOR NOTIFICATION .....7**

**2.6 MONITORING .....8**

# 1 INTRODUCTION

## 1.1 Scope and purpose

This document is based on a number of sources, including:

1. Blood Transfusion Samples National Guidelines (British Committee for Standards in Haematology, Blood Transfusion Taskforce (1999)), which were produced in collaboration with the Royal College of Nursing and the Royal College of Surgeons of England.

Individuals collecting biological specimens for analysis must also be aware of:

- [Guidelines on the positive identification of patients](#)  
Mandates that patients are positively identified prior to any clinical activity, including the collection of pathology [laboratory medicine] specimens.
- [Guidance on labelling samples that present a danger of infection to Healthcare Professionals, and/or are collected from patients suspected of being infected by Hazard Group 3 organisms/pathogens \(Leeds Health Pathways website\)](#)  
This is a requirement under health and safety (H&S) legislation.
- <http://www.hse.gov.uk/safetybulletins/clinicalinformation.htm>  
HSE Safety Alert on the provision of information on specimen request forms to staff in clinical diagnostic laboratories, to enable them to apply the correct safety measures to control any risk. Recent investigations have identified a lack of sufficient relevant clinical details being provided on specimen request forms. This has resulted in samples being handled at the wrong biological containment level, with a subsequent increase in risk of infection to laboratory staff.
- [Hospital Transfusion Team - Safer Transfusion Guidelines.](#)  
LTHT policy on safer transfusion procedures  
Include the LTHT Unknown Patient Policy

## 1.2 Area of Applicability

- All clinical areas within the Leeds Teaching Hospitals NHS Trust
- Clinical Commissioning Groups, Community Healthcare Providers and all other external customers.

# 2 REQUIREMENTS

## 2.1 Request forms

It is the responsibility of the requestor to ensure that request forms are completed correctly, even if these duties are delegated.

- The use of ICE-printed labels on request forms is strongly encouraged
- In exceptional cases where request forms are filled in by hand, they **must be clear, legible and completed in full.**

- If a patient is confirmed as positive for a Hazard Group/Category 3 pathogen, or where there is strong clinical suspicion, request forms must contain relevant travel history and occupational risk factors. **Forms and samples must be labelled with yellow Danger of Infection stickers**

## 2.2 Specimen Collection

It is the responsibility of the person collecting the sample from the patient to ensure that the patient is correctly identified, and that the specimen container is correctly labelled. Wherever possible, samples MUST be labelled with the patient present, with labelling taking place immediately after the sample has been collected

- Never pre-label sample tubes.** The practice of pre-labelling specimen containers, either by hand or with printed labels prior to the sample being taken is a well-established cause of error.
- The patient should have their identity confirmed against the information on the request form (electronic or paper) in accordance with the LTHT [positive patient identification policy](#). If the request form is incomplete, or does not match the information given by the patient, **specimens must not be taken**. Wherever possible, the request form details must be checked against the details provided verbally by the patient and against details on the patient's wristband.
- The specimens must be labelled **immediately** after being collected at the patient's side, with information taken from the request form (if ICE labels are not available) and at the point at which the specimens are taken.
- All specimen containers must be clearly labelled, ideally with ICE labels. The use of printed addressograph labels is not permitted and will result in the rejection of the sample, as these do not contain all the requisite information.
- When ICE-printed labels for specimens are used, they must:
  - Be generated before sample collection - taken to the patient prior to phlebotomy
  - Be checked against the request form for accuracy
  - Not be used to confirm the identity of the patient. Patient identification must be done from the [request form](#)
- If, for some reason the container does not have a label, write on a blank label and attach to the tube/container.

## 2.3 Labelling standards

Completion of the following fields is mandatory, and where information is missing or illegible the **request will be rejected.**

The **REQUEST FORM** **must** contain the following:

Index Code: PPATH-POL-33 Version 4.3	Title: Pathology Sample/Request Form Labelling Policy	Page 4 of 9
---	---	-------------

**ALL Patients**

- i. Forename & Surname in full, initials are not permitted
- ii. Date of Birth (DoB)
- iii. Any one of the following: PAS Number\* / NHS Number / ED (A&E) number (identifier used must be on both request form and sample)
- iv. Consultant/ GP (or Requesting Officer within Pathology for referrals from other hospitals)
- v. Location: GP Surgery/ Ward/OPD/Unit (or hospital/department for referrals from other hospitals) **\*This is essential - a location is required to ensure that the report is issued to the correct location\***
- vi. Date of request
- vii. Time of sample collection (where relevant)
- viii. Clinical details e.g. presenting complaint, relevant medication, procedure etc.
- ix. Investigation/Tests required
- x. Infection status (where relevant)
- xi. **Handwritten requests only:** Signature, printed name and contact number of the person taking responsibility for completing the request card). N.B. This information is provided in digital format on all ICE requests based on the requestor's login.

\* see below transfusion service-specific requirement (section 2.4, 'x') relating to PAS number provision

**The details on the request form MUST match those on the specimen container**

Labelling of the **SPECIMEN:**

**ALL Samples**

- i. Forename & Surname in full, initials are not permitted
- ii. Date of Birth (DoB)
- iii. Date and time of collection
- iv. NHS number, and where applicable, the ED (A&E) number (same identifier must be used on request form). See below transfusion service-specific requirement (section 2.4, 'x') relating to PAS number provision
- v. **Blood Sciences & Microbiology ICE Requests only:** the ICE accession number on the sample must match that on the form

**The details on the specimen container MUST match that on the request form:  
The same identifiers must be used on both the form and sample**

**Reminder: In the interests of patient safety, where any of the information is missing or illegible, the request will be rejected.**

## 2.4 Exceptions to this policy

There are a number of exceptions to the labelling standards where, if carried out correctly, will result in the sample(s) being processed. These include:

- i. Samples collected for the Centre for Sexual Health and patients with anonymised Sexual Health Service numbers (all sites) will be accepted when labelled with Sexual Health Service-printed labels; this reflects national guidance.
- ii. **Occupational Health** - these requests do not always have an NHS number e.g. if the member of staff is not yet registered at a healthcare establishment in the Leeds/West Yorkshire area.

- iii. Samples collected from patients recruited into non-blinded (non-anonymised) clinical trials will be accepted if the patient's first name, surname, DOB, date and time of sample collection are provided on both the sample and the request form. Additionally, the study ID, tests required and visit number must be clearly identified on the request form.
- iv. Anonymised samples arriving as part of a clinical trial will only be accepted if the following 3 pieces of information are provided on both the form AND the sample: the patient's unique study ID number, the patient's date of birth and the date and time of sample collection. Additionally, tests required and visit number must be clearly identified on the request form.
- v. Date and time of collection on samples referred to LTHT from other hospitals - allowances will be made when the date and time of collection are not provided, with the caveat that the referring hospital accepts full responsibility for the results.
- vi. **Unknown patients**, where the surname and/or forename are not known e.g. unconscious patients brought into LTHT. In such instances the LTHT Accident and Emergency Department Unknown Patient Policy must be followed. The PAS or ED (A&E) number must be on the sample **and** request form. Details on the request form and sample must also match.
- vii. **Neonatal patients** – In the absence of an assigned forename, “Baby” or “Twin 1”/“Twin 2” etc. can be used in place of the forename, but must additionally include: **surname, date of birth** and one of the following identifiers: PAS/A&E/NHS number on both the sample and request form.

vii. **Microbiology service-specific exceptions:**

- Clinical details are essential for correct and safe processing. If not supplied on the request card from blood cultures collected in **ED only**, these can be obtained by telephone, and will not be rejected. It is not essential to provide clinical details on the request form for MRSA screens and NAAT requests, as the reason for requesting is implicit from the request.
- Requests from external hospitals are acceptable with the requestors lab number as an identifier, as long as this is present on both the request form and the sample. The requesting hospital laboratory takes responsibility for the labelling of the referred samples.
- Where a sample is rejected on the basis of no clinical details being provided, where this involves a critical sample, the case will be discussed with senior clinical staff, and **may** be processed if it is agreed that rejection will adversely affect patient care.

viii. **Genetics Laboratory service-specific exceptions:**

- Sample Labelling and acceptance.

Full name and at least one of the following identifiers should be indicated on both the sample and referral card:

Date of birth  
 NHS number  
 Patient number

Poorly labelled or unlabelled samples and request cards must be referred to the relevant Head of Section or Duty Scientist immediately. The table in appendix 1 of the document LGSR002 provides examples relating to the acceptance of poorly labelled samples for use by laboratory personnel.

- Blood samples from anonymous sperm donors

In rare circumstances where a women receiving sperm has an inheritable condition (autosomal dominant or x-linked) that is licensed by the HFEA for pre-implantation genetic diagnosis (PGD) and is undergoing such treatment, the DNA of the sperm donor would be required. The agreement with Leeds reproductive medicine unit is that they will send 3x 3ml EDTA blood tubes labelled with the patient's date of birth and unit number (F number).

#### ix. Research study samples

- Requests will **only** be rejected by R&D personnel; **all** requests will be processed/analysed irrespective of the patient identifiers provided, and rejection will be instigated by R&D staff where processing has been determined to compromise the validity of the study.

#### x. Transfusion service- use of PAS number

- Whilst not mandated, it is important to include the LTHT PAS number on the blood transfusion request form. PAS numbers are Trust specific.
- Including the PAS number on the request form is the only way to identify instances where a patient has transferred from another Trust and the wristband has not been changed on their admission to LTHT
- Wristbands from other Trusts must be removed and a LTHT wristband generated and applied on admission
- This is important as the BloodTrackTx electronic labelling system for blood transfusion samples will generate a label from the QR code on the patient wristband.
- The label includes the following details:- Full name, DOB, NHS no, PAS No, Date and time label was produced, name of staff member who produced the label and the location the PDA is allocated to.
- Any mismatches in the patient identification details on the request form/label/Telepath system will result in the transfusion sample being rejected
- The rejection of blood transfusion samples due to mismatched patient details is wholly preventable but is dependent on staff obtaining and labelling transfusion samples in accordance with LTHT Safer Transfusion Policy and LTHT Positive Patient ID Policy.

## 2.5 Rejection of specimens and requestor notification

Where specimens are from Acute Medicine, or are defined as critical by the requesting healthcare provider, laboratory staff will, so far as is reasonably practicable, contact the sender by telephone to inform them that a request has been rejected, giving the reason(s) why.

Index Code: PPATH-POL-33 Version 4.3	Title: Pathology Sample/Request Form Labelling Policy	Page 7 of 9
---	--	-------------

A report will be issued, stating the reason for rejection, on all samples.

If, in **exceptional circumstances** a specimen is unrepeatable e.g. CSF, bone marrow aspirate & trephine, ascitic, pleural and peritoneal dialysis fluids, the requestor may make provision for the sample to be processed. In such cases, the requestor will be asked to sign a declaration form [PQME5001] accepting personal responsibility for the results issued.

**To prevent this from occurring, all staff are reminded to take due care to ensure all samples are collected and labelled correctly.**

The use of declaration forms varies between disciplines in Pathology, due to the geographical location of some laboratories.

- Declaration forms from Trust locations are to be completed by the **REQUESTOR**, in the laboratory. Forms will **NOT** be sent out to other locations, unless attendance is geographically impossible.
- Declaration forms for GPs or external hospitals can be found on the Pathology website and sent to the department via transport or post, **ONLY** if the sample is deemed to be unrepeatable.

**Microbiology only:** Declaration forms can be to the department (microbiologydept@nhs.net) from sites other than the LGI, completed in person (LGI site only) or sent via air tube.

**Blood Transfusion:** Declaration forms are never accepted. Where the requirements of this policy are not met, a repeat specimen is always required.

Where results are issued following the completion of the declaration form, a qualifying comment will appear on the printed report. The report may be used by clinical staff only in full recognition of this qualifying comment.

**Genetics Laboratory only:** The table in appendix 1 of document LGSR002 provides examples relating to the acceptance of poorly labelled samples for use by laboratory personnel. Head of Sections and Duty Scientists will contact the referring clinician, and if they insist the specimen is unrepeatable a decision will be made about processing the sample.

Examples of unrepeatable samples include:

- Prenatal samples
- Tumour samples
- Bone marrow
- Post-mortem samples

If the sample is to be processed the clinician must complete a standard letter to accept responsibility for its identity (Declaration form, inadequately labelled specimen; [LGSR001](#)) before processing begins. If the sample is from outside St James's the letter must be emailed to the department, with the original sent by post.

## 2.6 Monitoring

Each specialty within Pathology has its own local approach to monitoring the incidence of incorrectly labelled samples and request forms. In instances where incorrect results have been

<b>Index Code: PPATH-POL-33 Version 4.3</b>	<b>Title: Pathology Sample/Request Form Labelling Policy</b>	<b>Page 8 of 9</b>
---	--	--------------------



issued in relation to a sample/request form labelling error, or a 'near miss' has resulted, a Datix record is created and assigned to the appropriate manager to investigate further.