Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Specimen and Request Form Labelling Policy

This procedural document supersedes: PAT/T 8 v.7 - Specimen and Request Form Labelling Policy.

Did you print this document yourself?

The Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version. **If, for exceptional reasons, you need to print a policy off, it is only valid for 24 hours.**

Executive Sponsor(s):	Abigail Trainer Deputy Chief Nurse
Author/reviewer: (this version)	Richard Stott
Date written/revised:	16/04/2020
Approved by:	Patient Safety Review Group 4/12/2020 Policy Approval and Compliance Group
Date of approval:	13 January 2021
Date issued:	21 January 2021
Next review date:	September 2023
Target audience:	Clinical staff, Trust-wide

Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 8	21 January 2021	• New style format included. • Removal of references to Cytology as these samples are sent directly to the external laboratory. • Section 4.4.1 Includes phonetic patient names for unknown patients. • Section 4.5 Telephone contact re certain rejected samples in ED.	Dr Richard Stott
Version 7	24 October 2017	• New style format included. • Clarification of what constitutes a point of reference. • Revised monitoring section to reflect cessation of SQLAs and Clinical Governance Committee performance target for care groups. • Addition of learning from significant adverse events.	Dr Richard Stott
Version 6	17 October 2013	• New style format included. • Removal of reference to general numbers for neonates. • Addition of criteria for ICE order comms labels. • Link to HSE notice	Dr Richard Stott
Version 5	February 2011	• Use of district number for all Trust requests in place of other patient identification numbers. • Added sample labels consistent with the order communications software due to be introduced from April 2011.	Dr Richard Stott
Version 4	December 2009	• Amendment form and contents page added • Paragraphs numbered • Introduction - addition of - "and patient wrist band (if applicable)." • P7, addition of – "or 'Sharps' included"	Dr Richard Stott
Version 3	June 2009	Reviewed, no change – Short review time given to coincide with the introduction of new wristbands	Dr Richard Stott
Version 3	February 2007	• Alteration to minimum data sets for identification of specimen details (no change to minimum data sets for request form) • Histopathology sample containers should be handwritten • Pre-printed addressograph labels are NOT acceptable on sample containers • Labels printed contemporaneously, will be accepted on sample containers if they include the minimum sample data set and are initialed by the person taking the sample to confirm that they have verified identification with the patient. • Clarification that samples will not be analysed if additional essential information is incomplete	Dr Wardell

Contents

Page No.

1. INTRODUCTION

Correct sample identification and handling is a mark of good medical practice. Samples that cannot be properly identified because they fail to meet the criteria laid out in this policy are a risk to the patient.

In conjunction with the current version of the Trust's "Patient Identification Policy" (PAT/PS 7), this policy establishes the minimum identification criteria for Pathology specimens and request forms to be accepted for analysis.

Inadequately or inaccurately labelled specimens or forms will not be accepted unless they are considered to be 'unrepeatable'. A classification of 'unrepeatable' will be on an individual specimen basis following discussion with senior members of Pathology staff and in these cases the requestor may be required to come to the laboratory to amend the request information and document that they have done so. Any labelling discrepancy will be included on the pathology report.

All medical laboratories are required to have appropriate and effective policies and procedures in place to address the requirements of ISO/IEC 17025 and/or ISO 15189 such that that the integrity of samples is adequate for analysis, and results are reported accurately, clearly, unambiguously and objectively and, where necessary, include comments upon the quality or adequacy of the sample which may have compromised the result.

2. PURPOSE

This policy outlines the required information to provide patient identification criteria for Pathology specimens and request forms in order for them to be accepted by the laboratory for analysis.

3. DUTIES AND RESPONSIBILITIES

Pathology will make every effort to ensure requests are processed in a safe and timely manner but it is essential that request forms and samples are labelled appropriately and legibly in compliance with this policy. It is also important to clearly identify the investigations required with relevant supporting information.

- It is the responsibility of managers to ensure that –
    - Staff in their area of responsibility are aware of the content of this policy and the current version of the Trust's Patient Identification Policy (PAT/PS 7) and follow the required elements for all pathology requests.
    - All patients have been formally identified according to the appropriate sections of the Trust's Patient Identification Policy. In particular an ID band may be required.

- It is the requestor's responsibility to ensure that –
    - All requestor, location and patient details on the request form or computer screen are correct, clearly legible and that the request form is signed if required for the requested tests (eg blood transfusion related requests).
    - The investigations required are clearly identified with relevant supporting information.
    - Any required timings are clearly indicated (eg sample time relative to treatment).
    - All appropriate Health & Safety requirements are complied with as detailed in the Health and Safety Policy (CORP/HSFS 1).

- The person responsible for taking the specimen (whether medical, nursing or phlebotomy staff) **MUST** ensure that -
    - All the necessary information is present on the request form. Staff should **NOT** proceed with the specimen collection procedure if this is not the case.
    - Containers are legibly labeled with the correct details of the patient. In particular that the specimen details match those on the form and patient wrist band (if applicable).
    - Containers are securely packaged so they do not leak and are unlikely to be broken on the way to the laboratory.
    - Specimens to be transported by road are packaged in compliance with the Carriage of Dangerous Goods by Road (ADR) Regulations. For details see section 4.5 of the policy on collection & handling of Pathology Specimens (PAT/IC 11).
- All Pathology laboratory staff involved in the receipt and testing of specimens are required to ensure that samples and forms are labelled to the standards set out in this document before testing can proceed.

4. PROCEDURE

4.1 Minimum Data Set for Identification on ICE Pathology Requesting Labels.

Each of the following constitutes a single contributor to patient identification, normally all of these will be present on the ICE request form labels:

- **District Number or NHS number (For primary care & other trusts patients)**
- **Patient Surname and Forename (in full, not initials)**
- **Date of birth (DOB)**
- **Gender**
- **Patient address**
- **Request number barcode**

All of this data will correspond to that on CaMIS at the time the label is printed and the patient demographics should always be checked with the patient prior to taking samples.

Printed labels for attaching to sample tubes contain the following data –

- **District Number or NHS number**
- **Patient Surname and Forename**
- **Date of birth (DOB)**
- **Request number barcode**

If the correct procedures are being followed, ICE sample labels will have had their content checked against an ID band or confirmed by the patient at the time they are printed. The patient ID is transmitted electronically to the lab system as well as printed on the labels, therefore this method of requesting is more secure than, and should be used in preference to, hand written forms.

If the patient has moved location since the request was created on ICE it is essential to hand write the correct location on the request form, failure to do so will result in reports being handled as if the original location still applied and may delay action on critical results.

4.2 Minimum Data Set for Identification on a Written Request:

Each of the following constitutes a single contributor to patient identification. A minimum of 3 complete, accurate and legible items must be present on the request form to achieve unique identification of the patient.

- **District Number and/or NHS number (For primary care & other trusts patients)**
- **Patient Surname and Forename (in full, not initials)**
- **Date of birth (DOB)**
- **Patient address if District Number /NHS number not supplied**

A minimum of 3 identical patient identifiers must be present on both the request form and on each individual specimen container to demonstrate that it corresponds with the associated request.

Please note - A district number / NHS number must be provided on any transfusion related request (including antenatal screening).

In addition to the minimum data set for patient identification please ensure all other relevant fields of the request form are completed:

- **Ward/ Practice, Consultant/GP**
- **Patient address**
- **Patient gender**
- **Date and time of collection**
- **Specimen type**
- **Investigation(s) required**
- **Name of requesting clinician and bleep number**
- **Relevant clinical details**

- **Current drug therapy**
- **Copy reports, if required**
- **Patient category (PP/ CAT 2 / NHS)**

Samples may not be analysed if other essential information is incomplete. Please see additional department specific details in section 4.3 for information.
Please Note:

- Pre-printed addressograph labels are NOT acceptable on sample containers (except for samples labeled according to a safe patient identification procedure which has been pre-approved by Pathology).
- Addressograph labels are acceptable on request forms.
- Labels printed contemporaneously (i.e. beside patient and at the time that the sample is being taken) will be accepted on sample tubes if they include the minimum data set **and are initialed by the person taking the sample to confirm that they have verified identification with the patient.** (It is important that the size and thickness of labels placed on samples does not cause difficulties with sample testing. Therefore please seek guidance from the relevant pathology departments before using labels produced by clinical systems).

4.3 Additional Department Specific Details:-

Blood Transfusion and Blood Grouping Requests (see Hospital Blood Transfusion policy PAT/T2). Requests will be rejected (and only emergency group O blood packs made available) if the following additional requirements are not followed:-

- **Person taking blood must sign specimen and request form to confirm patient identification has been checked.**
- **A unique patient identifier must be provided (NHS number / District number). This number must be referenced on trust systems ie we cannot accept another trust's locally assigned numbers.**
- Request form must be signed by requesting Doctor.
- Latest Hb result and reason for transfusion, number of units required, time and date required, special requirements e.g. CMV negative or irradiated products required should be indicated on the form.
- Except for emergency transfusions there must be two independent samples tested to provide the patient's blood group and subsequent cross match.

Clinical Biochemistry

- For glucose and lipids, state fasting or non-fasting.
- For drug analysis, time of last dose and time of sample collection are required.
- For antenatal screening for Down's Syndrome and NTD, gestational age and patient weight must be provided.
- For pregnancy tests and female hormones, state LMP or day of cycle.
- Patient gender **must** be included for reference ranges to be included on report.

Haematology

- Patient gender must be included for reference ranges to be included on report.

Microbiology

- Include specimen type and site.
- **For antibiotic assay levels e.g. Gentamicin, the relevant questions must be answered on the ICE system or a 'Gentamicin sticker' must be applied to the written request form and the following information completed:**

  Mg of last dose given
  Date and Time of last dose
  Date and time that sample was taken (pre and post dose samples required for multiple dosing).

  Please refer to Gentamicin guidance document. Gentamicin labels are available from Pathology reception.

Histopathology / Non Gynae cytology

- Include specimen type and site on both request form and specimen container.
- Indicate patient consent / objection to use of surplus tissue for education / Quality Control.

4.4 Additional Information

4.4.1 Unidentified Patient Requirements

The request form and samples must contain a unique identifier number (i.e. District number) and patient gender. Preferably, unknown patients will also be identified using a randomly assigned phonetic name (eg Hotel Bravo) and an estimated DOB. Where possible, the unique identifiers used should be registered on CaMIS. This enables results to be accessed on ICE by the clinical staff.

Prior registration on systems may not be possible in all cases (e.g. during a Major incident or failure of computer systems) and, in these cases the request will be entered on to the pathology computer system using a temporary number (T- prefix), either using the patient demographics provided or the district number as the surname and 'Unknown' as the forename. These results will only be available by searching systems via patient details. Please refer to the Trust's Major Incident policy (CORP/RISK 1).

No other data is required and any other data provided must be regarded as provisional until the patient is formally identified.

All request forms must be signed.

4.4.2 Genito-Urinary Medicine (GUM) Patients Requirements

Where name is not appropriate, then GUM number, DOB and gender will be acceptable. The GU med number, gender and date of birth are required and MUST match exactly on the form and sample (odd numbers are male patients).

For use with ICE, existing patients are given a new number which comprises their original numerical identity with a GL prefix. These numbers are registered on the Lilly system and the details are then communicated to ICE and the lab system to permit requesting of tests.

4.4.3 Paediatric Samples/Gas syringe Requirements

Use labels provided and attach to each sample tube

4.4.4 Health and Safety Requirements

In 2011 the HSE issued a reminder regarding the legal requirement to notify certain infection risks on pathology request forms (http://www.hse.gov.uk/safetybulletins/clinicalinformation.htm).

Affix 'Danger of Infection' stickers on samples **and** request forms from patients with the following conditions:

- Hepatitis B, Hepatitis C and HIV
- Cases of infective or suspected infective diseases of the liver
- Known or suspected cases of Mycobacteria (TB)
  Salmonella typhi / paratyphi (Typhoid / Paratyphoid)
  E.coli 0157
  Dysentery with Shigella dysenteriae
  Brucellosis
- Patients in at-risk groups

4.5 Inadequate and Incorrectly Labelled Requests and Unsuitable Samples

The Directorate will make every effort to ensure requests are processed in a safe and timely manner but it is essential that request forms and samples are labeled appropriately and legibly in compliance with this policy.

It is also important to clearly identify the investigations required with relevant supporting information.

If you have any doubts regarding this policy please ring the relevant department for further information.

Specimens will **not** be accepted for analysis if: -

- There is no unique identification of the patient i.e. they do not meet the minimum data set for identification.
- Blood transfusion requests without handwritten identification details on samples and signed form and sample.
- There is an incorrect sample type or tube.
- Incorrectly filled coagulation specimens (pale blue citrate tubes). ED will be telephoned about rejection of these if we are informed the patient is receiving anticoagulants.
- Incorrect transportation conditions.
- Sample is received in a hazardous condition e.g. leaking or sharps attached.
- Sample or request form is un-labelled or incorrectly labeled with less than the minimum data sets for patient identification.
- Request form does not include all of the essential additional information e.g. fully completed gentamicin label.
- Pre-printed addressograph label used on sample container (with the exception of samples labeled according to safe patient identification procedures and pre-approved by Pathology).
- Mismatch of details between the form and sample(s).
- The information provided is illegible.

5. TRAINING/ SUPPORT

This policy and the Patient identification policy are no-longer referenced during the Trust's induction.

The training requirements of staff will be identified through a training needs analysis. Role specific education will be delivered by the service lead responsible for the specific clinical skill.

- The Trust provides training in phlebotomy techniques and the additional requirements associated with transfusion samples. This training includes all relevant aspects of this policy.
- The Trust provides training on aseptic collection of microbiology specimens (Swabs, blood cultures and urines). This training includes all relevant aspects of this policy.
- Training in the use of the ICE order communications system is available via the IT trainers.

6. MONITORING COMPLIANCE WITH PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Accuracy of request form and specimen container labelling. Suitability of samples for analysis.	Pathology reception staff.	Every request checked.	As detailed in section 4.5, breaches which prevent analysis will be recorded on outgoing reports in place of the results. Clinical staff may have to re-label unrepeatable specimens before they can be analysed.
Significant breaches are reported as incidents via DATIX.	Reported by Pathology reception staff	In real time via the DATIX process.	To Matrons, ward managers and relevant DATIX investigators.
Performance of individual divisions is monitored by pathology.	Logged by Pathology reception staff and analysed by senior staff.	All requests monitored.	Divisions are informed of breaches via the quarterly reports formerly sent as part of the Clinical Governance & Quality meeting's Pathology labelling improvement target. This report is received by Divisional Directors and Clinical Governance leads.

7. DEFINITIONS

ABBREVIATIONS LIST:

- Hb Haemoglobin
- CMV Cytomegalovirus
- NTD Neural Tube Defect
- LMP Last Menstrual Period
- ICE Integrated Clinical Environment

8. EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (see Appendix 1).

9. ASSOCIATED TRUST PROCEDURAL DOCUMENTS & REFERENCES

- Blood Transfusion Policy - PAT/T 2
- Patient Identification Policy - PAT/PS 7
- Health and Safety Policy - CORP/HSFS 1
- Pathology Specimens – Collection and Handling of Pathology Specimens PAT/IC 11
- Major Incident Plan - CORP/RISK 1
- Fair Treatment for All Policy - CORP/EMP 4
- Equality Analysis Policy - CORP/EMP 27

NB - According to the Patient Identification Policy, any patients who are unable or unwilling to identify themselves to the required level must be handled by the requesting staff as an "unidentified patient". Therefore the Trust's Mental Capacity Act 2005 Policy and Guidance, including Deprivation of Liberty Safeguards (DoLS)- PAT/PA 19 and the Privacy and Dignity Policy - PAT/PA 28 do not apply to application of this policy.

10 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) 2016).

For further information on data processing carried out by the Trust, please refer to our Privacy Notices and other information which you can find on the trust website:
https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

11 REFERENCES

HSE safety notice HID 5-2011 Provision of key clinical information on laboratory specimen request forms http://www.hse.gov.uk/safetybulletins/clinicalinformation.htm

European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) Regulations, 2021

ISO/IEC 17025

ISO 15189

APPENDIX 1 – EQUALITY IMPACT ASSESSMENT - PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Division	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Pathology labelling & requesting.	Clinical support services	Dr R Stott Pathology CG lead	Existing policy	16/4/2020

1) Who is responsible for this policy? Name of Division: Clinical support services

2) Describe the purpose of the service / function / policy / project/ strategy? Who is it intended to benefit? What are the intended outcomes? Policy is intended to ensure sufficient accurate patient information is provided on request forms and specimen containers to permit pathology staff to uniquely identify the patient and specimen, provide the required tests and report the results.

3) Are there any associated objectives? Legislation, targets national expectation, standards Identification as per Patient identification policy PAT/PS 7 v.5

4) What factors contribute or detract from achieving intended outcomes?

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? None of these are directly relevant to application of the policy however there are potential issues with handling of gender reassignment patients.

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] The issue of data mismatches affecting gender reassignment patients has been an ongoing problem but has recently become much more difficult with staff being reluctant to assist in resolving issues due to increasing awareness of the gender reassignment legislation. This has been raised via trust governance processes as we are often the middle man between primary and secondary care WRT patients undergoing or following reassignment.

6) Is there any scope for new measures which would promote equality? [any actions to be taken

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	no	
b) Disability	no	
c) Gender	no	
d) Gender Reassignment	Patients are affected as a consequence of their treatment but no	• Many reference ranges will not apply to individual patients according to the "preferred gender" stated on requests and recorded on CaMIS. Results for some tests will always reflect the genetic / developmental characteristics of a patient (eg muscle mass). Others may reflect treatment but not necessarily achieve normal levels for the reassigned gender. Tests from prior to any change will be flagged inappropriately. Results for these individuals need to be reviewed with care by clinicians who are aware of any hormonal treatments being received and the issues involved with each test. • Similarly the gender provided on the request may alter certain aspects of patient care - eg blood group of products transfused and availability of gender specific tests eg PSA, CA125 Mismatches between patient data on request forms and the CAMIS system may delay reporting and/or prevent clinical teams from referring to results due to the need for reports to reflect details on request forms and specimens.

	impact of the policy.	
e) Marriage/Civil Partnership	no	
f) Maternity/Pregnancy	no	
g) Race	no	
h) Religion/Belief	no	
i) Sexual Orientation	no	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	**Outcome 2**	**Outcome 3**	**Outcome 4**

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form in CORP/EMP 27

Date for next review: September 2023

Checked by: R Stott **Date: 16/4/2020**