REQUEST FORM AND SPECIMEN LABELLING POLICY

CG45

Specific staff groups to whom this policy directly applies	Likely frequency of use	Other staff who may need to be familiar with the policy
Those involved in the collection and labelling of pathology samples and for requesting testing. Those involved in the receipt and preparation of samples for testing	Daily	Divisional Managers

Main Author:	Andrew Heryet, Laboratory Manager, Pathology Sciences
Consultation Route:	Heads of Departments, Laboratory Managers, Senior Pathology Staff in Pathology and Neuropathology, Clinical Risk Managers, Heads of Nursing, Clinical Matrons, Clinical Directors, General Managers, Assistant GMs
Ratifying Committee:	**Clinical Effectiveness Committee**
Date Ratified:	**May 2019**
Review date:	**April 2021**
Version :	**V07**
KEY WORDS;	Request Form and Specimen Labelling

POLICY FOR REQUEST FORM AND SPECIMEN LABELLING		
Document Status: **Draft**		
Version	**Date**	**Comments / Summary of Change**
5	August 2010	
6	2013	Changes to labelling criteria. Added: roles & responsibilities. Alignment to Transfusion policy
7	May 2019	

Policy for Request Form and Specimen Labelling

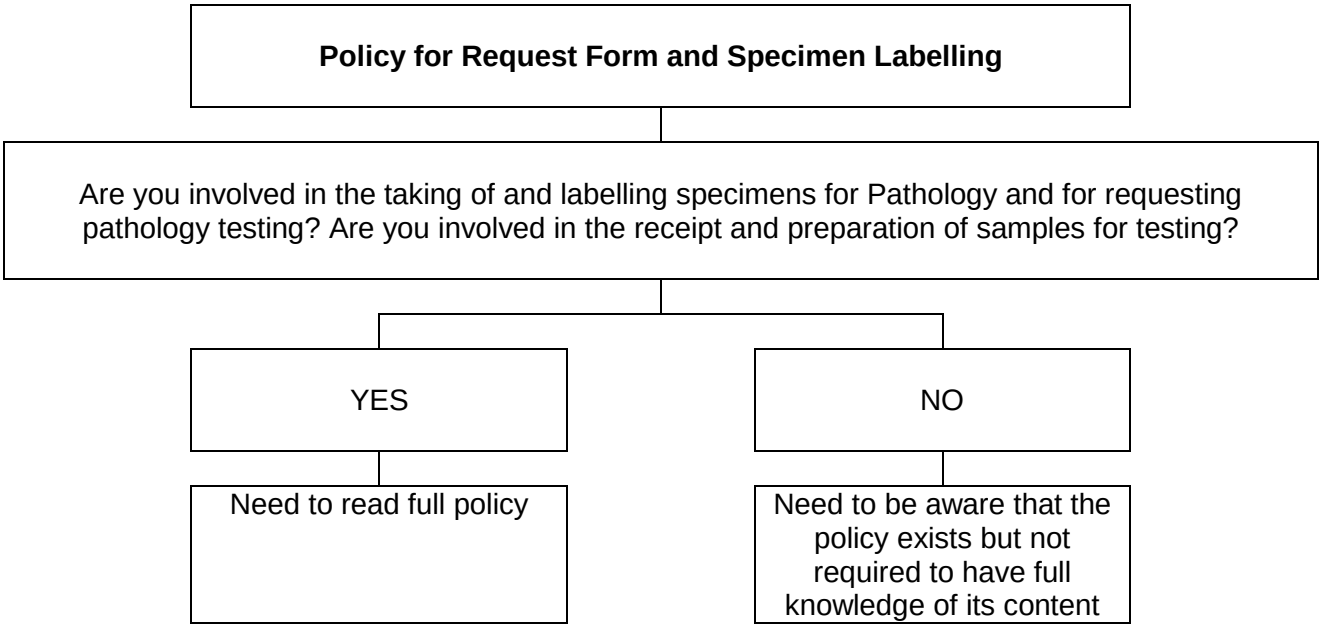
Index

0 Executive Summary

This policy sets out the requirements in the Trust for the labelling of samples and the accompanying pathology request forms. Key features are:

- Defining the minimum requirements for labelling of samples and request forms and which must be adhered to by all Trust staff
- Describing any Pathology discipline-specific requirements
- Actions which will taken in the event of non-conformance which includes a requirement to undertake formal investigation and root-cause analysis

Flowchart Guide for the use of this Policy



1 Policy Statement

1.1 It is the policy of North Bristol NHS Trust that all samples taken for laboratory investigation and accompanying request forms will be labelled to a minimum standard that minimises the risk of harm to patients.

1.2 The patient's primary identifier is the NHS number and must be used whenever possible. A correctly assigned MRN must be used where NHS number is not known

1.3 In normal circumstances, unlabelled or inadequately labelled specimens will not be processed. The laboratory will attempt to telephone or page the requestor or requestor's location and inform them that the sample is unlabelled or inadequately labelled and that this policy forbids the processing of the sample in that state or the labelling of the sample by the laboratory. The requestor will be clearly advised that another sample will be needed if the test results are still required.

1.4 There is recognition that there are certain circumstances where samples are unrepeatable, for example:

(a) Histology and Neuropathology where all relevant tissue has been removed or where further clinical intervention is inappropriate
(b) Cytology specimen where further clinical intervention is inappropriate
(c) Cerebrospinal Fluid
(d) Samples taken at a specific time e.g. for post-anaphylaxis mast cell tryptase investigations
(e) Samples where all relevant tissue has been removed or where further clinical intervention is inappropriate e.g. spleen, lymph nodes, bone marrow.

When Pathology departments receive incorrectly labelled samples which cannot be repeated,

- the requestor will be informed and clearly advised that the final results of this sample will be withheld until such time that the sample is adequately labelled and compliant with this policy
- the requestor must, where practicable arrange for the sample to be correctly re-labelled as soon as possible so that the sample can be processed
- the final report will include a statement detailing the shortcomings of the sample / form and alert the requesting practitioner to take responsibility for the results and any action taken as a result of the report.

1.5 All incidents of non-conformity with the policy identified by staff in Pathology Sciences will be documented using departmental systems and escalated using the Trust Datix incident reporting system when appropriate.

2 Purpose of the Policy

2.1 This policy sets out the **essential information** required for the adequate identification of pathology specimens and request forms. It is to be used in conjunction with the Packaging, Handling and Delivery of Laboratory Specimens Policy, the NBT Blood Transfusion Policy and the Pathology Sciences and Neuropathology User manuals.

2.2 In addition the policy will enable the Trust to demonstrate continued compliance with the standards set by appropriate regulatory and accreditation bodies.

3. Scope of the Policy

3.1 This policy applies to members of Trust staff who:
- are responsible for the collection and labelling of samples for laboratory investigation
- are responsible for the completion of Pathology and Neuropathology request forms

- receive samples for laboratory investigation.

3.2 This policy applies to users of the NBT Pathology service who take specimens for investigation.

3.3 This policy excludes the labelling of samples / sample aliquots sent between NBT laboratories or referred to and from other centres. Where there is derogation from the standard described in 6.1, this will need to be discussed between parties and any agreed change must ensure patient safety.

3.4 Samples which, for the purposes of confidentiality do not bear a patient name but have a unique clinic number, are excluded from the mandatory requirement to have a patient name. Arrangements are in place to cover those specific circumstances.

4 Definition of Terms

Request Form: Document bearing patient information, nature of sample collected and the details of testing required. This may be in either paper or in electronic (e.g. ICE) format.

Datix: North Bristol NHS Trust Incident Reporting and Risk Management System.

5 Roles and Responsibilities

5.1 All staff who take samples for Pathology are responsible for ensuring that,

- the specimen containers and request forms contain the necessary information to correctly identify the patient
- those samples are collected in manner that meets the requirements of the tests requested

5.2 Managers and senior staff in clinical areas are responsible for ensuring that staff who collect samples,

- are aware of this policy
- are competent in sample collection, requesting and labelling

Managers and senior staff in clinical areas must also ensure that appropriate action is taken where incidents arising from breaches of this policy occur. This will include responding to or reporting incidents on Datix, conducting root cause analysis and assessing any feedback provided to them.

5.3 Pathology staff who receive samples which cannot be processed due to breaches in this policy must ensure that departmental procedures for acceptance of samples are followed and that all non-conformances are reported in their departmental reporting systems and on Datix if appropriate.

5.4 Pathology and Divisional managers will ensure that,

- staff in their areas are familiar with and adhere to this policy and any local procedures
- reporting systems are in place to record non-conformances
- departments will monitor and audit compliance with this policy
- Pathology Sciences' Governance and Assurance Committee (PSGAC) has oversight of all aspects of compliance with this policy to be able to evaluate effectiveness and impact upon quality standards.
- outcomes from audit and monitoring are fed back to Divisions and through the Trust's clinical governance structure.

6 The Policy

6.1 Minimum Information required for all Pathology Requests (except where noted by discipline specific requirements in 6.2 including Blood Transfusion Department)

	ESSENTIAL	DESIRABLE
Specimen	• NHS number **OR** other unique identity number • Patient surname • Patient first name • Date of birth • Initialled / Signed by specimen collector • Date of specimen collection	• Nature of sample including qualifying details • Time of specimen collection (Note 1)
Request Form	• NHS Number **OR** other unique identity number • Patient surname • Patient first name • Date of birth • Date and Time of specimen collection • Initialled / Signed by specimen collector (Note 2) • Name and location of Requesting Practitioner • Type of specimen and, if appropriate, anatomical site of origin • Investigations required	• Clinical Information, including relevant medication • Patient's Address (including Post code) and telephone Number • Practitioners contact Number (bleep or extensions)

Notes:

1) There are circumstances and certain tests where the Time of Collection becomes an essential requirement;

   (a) When dealing with a series of urgent samples from the same patient, the sample times become crucial for correct chronology of result availability. If the time is not provided this may cause confusion about the latest test result available and may therefore impact upon patient treatment.

   (b) Clinical Chemistry:

   - All dynamic function tests e.g.Glucose tolerance test, Water deprivation test, Short Synacthen test, Dexamethasone suppression test
   - Endocrine tests: ACTH, Cortisol
   - Chemistry/toxicology tests: Glucose, Troponin T, Ammonia, Salicylate, Paracetamol, Ethylene glycol, Ethanol
   - Specialist referred tests:Renin/aldosterone, Insulin, C-peptide, Chromogranin A, Gut hormones, Homocysteine, White cell enzymes

   (c) Immunology: Post Anaphylaxis Mast Cell Tryptase

   (d) Microbiology: Antibiotic assays, CSFs and tissue specimens.

2) When electronic requesting systems are used e.g. ICE, the clinician makes the request in ICE. However when the label is printed it is this that identifies the individual who has taken the sample, unless there are legible initials to identify otherwise. ICE labels must be securely affixed to all samples. The individual labelling the sample must ensure that

the label complies with the above criteria; if information is missing (due to printer error) the individual must write the information legibly on the sample(s) and initial the sample(s).

3) Any discipline-specific derogation from the above criteria is provided in section 6.3.
4) The request form must be completed by the clinician and needs to match the sample. Both the sample and form must be signed by the taker.
5) Blood Transfusion requests must not be made on ICE
6) Where samples are required to be taken from unknown / unconscious patients, the following data items must be used as patient identifiers:
   - Unique identifier number (e.g., Cerner or Major Incident number)
   - Gender
   - Approximate age of patient
   - Surname – Requestor to write "Unknown"
   - Forename – Requestor to identify and record gender

6.2 Neonatal Samples

It is recognised that labelling samples from neonates will require adaptation due to the potential lack of information available for a new born and the small label size on neonatal bottles:

- Specimens must be labelled with infant's surname, date of birth and hospital number – this will be generally in the form of a printed label attached to the bottle. Date of collection and initialling by the specimen collector will also be required.
- Request forms must be labelled as stated in 6.1 except that there may be no first name and the Hospital number may be used as the unique identity number.
- For multiple births, where there is no first name, specimens and request forms must clearly indicate the individual baby's status in addition to the surname, date of birth and Hospital number e.g. Twin 1, Twin 2

It is recognised that obtaining blood samples from neonates is very challenging and that as extreme pre-term infants have a very small circulating volume repeated sampling may be harmful. If there are concerns about the labelling of a sample the laboratory will contact the specimen collector to discuss the request as stated in 7.1.

6.3 Discipline Specific Requirements

(a) Blood Transfusion

Refer to NBT Blood Transfusion Policy CP 2a for further information.

<u>Request Form</u>

The request form must be completed by a Doctor or appropriately trained and competency assessed nurse who has received specific training in completing Transfusion requests.

The sample collection declaration on the request form must be completed by the person taking the blood, including signature, bleep/contact number. This individual must be trained and competency assessed {Obtaining a venous blood sample}

In addition to the information listed in section 6.1, the following details are also required for the safer administration of blood and blood products.

- Indication of special requirements e.g. Irradiated / CMV negative
- Consultant name
- Location of the patient undergoing transfusion

- Past obstetric and transfusion history
- Diagnosis, reason for request
- Quantity and type of blood components required
- Date and time blood component required

Specimen

Blood Transfusion samples must be hand written immediately at the bedside using the patient's wristband (where possible) with positive patient identification, e.g. ask the patient to state their date of birth.

The sample must contain all of the information listed in section 6.1 in addition to which, the sample must be signed by the person taking the blood as confirmation that patient details are correct.

A Doctor, Registered Nurse or Midwife, a phlebotomist, Assistant Practitioner or Healthcare Assistant can take Blood Transfusion samples but must have been trained and assessed as competent in phlebotomy and Blood Transfusion practice.

(b) Histopathology / Diagnostic Cytopathology

- All request forms must contain a clear description of each specimen and relevant clinical details
- All specimens including electronic requests must be uniquely identified and carry the specimen type and site on the container (not the lid).
- If slides are prepared for Cytopathology, these must be labelled on the same side of the slide as the material **(in pencil)** with:
  - Patient Surname and Forename
  - DoB or NHS Number
  - 'Air-dried' or 'Fixed'

(c) Cervical Cytology

An Open Exeter printed HMR101 Cervical Screening Programme Request Form or ICE request form must be used and all parts completed.

(d) Microbiology

- All specimens other than blood must identify the specimen type and site on the container (not the lid).
- Clinical Information including details of any foreign travel and relevant medication is required for interpretation of results

(e) Genetics

- The mother's name, date of birth and hospital or NHS Number must be provided on all prenatal and neonatal requests
- Gestation must be provided for all foetal samples
- All request forms must indicate a specific disorder or locus to be investigated or a request to extract and store DNA (with consent).
- All request forms must contain a detailed clinical summary/reason for referral to allow for laboratory to decide upon the most appropriate testing strategy (specifically for cytogenetic and molecular cytogenetic requests)

- All request forms must carry the full name and address of the requesting clinician (not initials)
- The postcode is a requirement for the UK Genetics Testing Network and must be provided for all patients where possible.
- All request forms must specify the patient's postcode.
- For genetic studies, family history must always be provided including details of any members of the family who have been tested; i.e. name, DOB and laboratory number if available
- Individual sample slides must be identified with at least the patient surname and referring laboratory number. Please also leave room for genetics laboratory number.

(f) Neuropathology

- Generally, as for Histopathology.
- Hard copy request forms must be used.
- Clinical details, including previous and relevant history must be provided.
- For muscle and peripheral nerve biopsies performed in Neurosciences theatres by a neuropathologist or neurosurgeon as part of this Department's biopsy service, the request form may be sent to the laboratory in advance of the specimen but the specimen must be delivered appropriately labelled, as specified in 6.1.

6.4 Biohazards

When the specimen is from a known or suspected high risk patient then both the sample and request form MUST be labelled with a yellow biohazard sticker.

Clinical staff treating patients suspected of particular infections described by the Disease Specific Precautions A-Z Policy (IC04) must comply with all additional precautions relating to bagging and labelling of samples described within the policy. As directed in the policy, clinical staff are to contact Infection Prevention & Control Team or Medical Microbiologist prior to taking any specimens, if they have any concerns.

The air-tube must not be used to transport samples from any of the following biohazards.

- Risk of VHF (Viral haemorrhagic fever)
- High likelihood of MTB (Mycobacterium tuberculosis)
- Risk of CJD/BSE/prion (Creutzfeldt-Jakob disease, Bovine spongiform encephalopathy)

In addition the air-tube must not be used for the samples in the following circumstances;

- Individual sample liquid volume of greater than 50ml
- Combined sample volume of greater 100ml
- Contain formaldehyde – with the exception of specialist neuropathology samples.

It is it is important that samples are contained within a sealed bag and that samples from different patients are not placed into the same bag.

6.5 Confidential Samples with Unique Clinic Number

Samples which, for the purposes of confidentiality do not bear a patient name but have a unique clinic number, e.g. Genito-urinary medicine (GUM) clinics, are excluded from the mandatory requirement to carry a patient name. Where this is necessary, agreed procedures with departments are in place. This derogation cannot be applied to other situations without formal agreement.

6.6 Patient contact details

The responsibility is with the requestor to supply up to date contact details for the patient. This is vital especially when result transmission becomes urgent and there is a likelihood that results will need to be transmitted to the Out of Hours team.

7 Samples received that fail to comply with policy

All specimens being received into any of the constituent departments of Pathology Sciences, or the Neuropathology Department, will be checked for adequacy of labelling. In the event of a non-compliance with the policy the following actions will be taken,

7.1 Blood Transfusion: Unlabelled or inadequately labelled specimens or forms will not be accepted. A repeat sample will always be requested.

7.2 Clinical Biochemistry, Haematology and Immunology: A repeat sample will always be requested. In exceptional circumstances specimens may be considered unrepeatable. These will be discussed with the requestor on an individual basis.

7.3 Histopathology, Diagnostic Cytopathology: If brought by porter, inadequately labelled specimens will not be accepted (not signed for) and will be returned to source. If not delivered by hand to the laboratory (e.g. GP specimen) the requestor will be contacted to attend the department or where this is not practical relevant details will be taken over the phone and a record made on the request form. Such circumstances will be recorded on an internal incident form. These will be discussed with the requestor on an individual basis. For Cytopathology, a repeat sample may be requested depending upon the nature of the specimen.

7.4 Cervical Cytology: In the event of a sample pot or a request form being received which is not adequately labelled to permit patient identification or if there is a mismatch between information received on the request form and on the sample pot the sample will be discarded and a letter will be sent to the sample taker.

If identification information is satisfactory but key elements of the Clinical Information are missing OR sample is received in out of date pot, the sample will be accepted but will be reported as inadequate unless abnormal cells are present in which case the sample will be reported according to the grade of abnormality.

If the sample is received in an inappropriate container, the sample will not be processed but will be reported as inadequate

7.5 Microbiology: A repeat sample may be requested if appropriate. In exceptional circumstances the specimen may be considered unrepeatable.

7.6 Genetics: Samples will be considered on a case by case basis. Where the sample is considered unrepeatable, these will be discussed with the requestor on an individual basis.

For all other samples, this will depend on the type of information missing. The sample may be rejected and a repeat requested, or the sample may be stored only and reported as needing more information before onward processing can be undertaken.

7.7 Immunogenetics: Unlabelled or inadequately labelled blood samples or forms will not be accepted. A repeat sample will always be requested. Unlabelled or inadequately labelled spleen samples or forms will be discussed with the requestor on an individual basis.

7.8 Neuropathology: As for Histopathology specimens.

8 Monitoring, Audit of Effectiveness and Reporting

8.1 Monitoring the compliance of users with the policy is a continuous process. All non-conformances will be reported and investigated using, where appropriate, departmental reporting systems or, for incidents having a negative impact upon patient care, the Trust's electronic Accident and Incident Monitoring System (e-AIMS). Root Cause Analysis of the incident must be undertaken within the requestor's area. The e-AIMs system will also be used to report multiple incidents of a lower severity from a single, specified location - an investigation must be carried out and corrective actions taken to reduce incidents.

What is monitored:	How?	When?	By who?	Where are the results reported and reviewed?	Where shortfalls are identified, how will improvement and learning take place?
Non-conformities against the policy of samples received to Pathology	Departmental systems and on Datix	As they occur	Laboratory staff	Departments	
Wrong blood in tube incident recognised by clinician	Datix incident reporting system	As they occur	Clinician or manager of relevant area	Divisional/department governance meetings	Clinical area / ward managers are responsible for ensuring action plans are in place to support improvements in practice and interventions take place as planned
Trends in number of reported incidents. See 8.2.	Analysis of data collected by departments summarised by absolute numbers, percentages and cost	Monthly	Quality Managers	Departments PSGA committee CCS Governance committee	Outcomes of trend analysis will be given to requestors, Divisional managers Clinical area / ward managers are responsible for ensuring action plans are in place to support improvements in practice and interventions take place as planned

8.2 Monitoring of effectiveness will be centred upon collection of information relating to each incident that includes,

- Date of sample collection
- Details of patient as and if supplied
- Requestor name, specialty and location
- Sample type
- Reason for rejection
- Incident score where impact is known

9 References

9.1 NBT Pathology Sciences' Packaging, Handling and Delivery of Laboratory Specimens Policy
9.2 NBT Blood Transfusion Policy CP 2a
9.3 Pathology Sciences User Handbook
9.4 Blood Safety Quality and Regulations, 2005
9.5 Standards for the Medical Laboratory (CPA UK Ltd)
9.6 SW Regional Cervical Screening QARC Send Back Policy
9.7 IBMS Patient Sample and Request Form Identification Criteria
9.8 NBT Disease Specific Precautions A-Z Policy IC04

10 Consultation

Laboratory Managers and Heads of Department in Pathology Sciences and Neuropathology, General Managers, Clinical Directors, Heads of Nursing, Clinical Risk Managers

11 Approval

Version	Author	Date

A signature of the person approving the policy and date should be provided. This provides formal acceptance of the policy.

12 Review date

This policy will be reviewed at three-yearly intervals.