# Request Form and Specimen Labelling Policy

# **Division:** Trust-Wide

# **Document No: CG-163**

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

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| Date of Approval:  | 28/01/2025  |  |  |  |
| Next Review Due:   | 28/01/2027  |  |  |  |
| Version:   | V9.0 (GP/PPP/0032 Pathology internal document number)   |  |  |  |
| KEYWORDS:  | Specimen Labelling  |  |  |  |
| Summary of changes<br>since the previous<br>version          | Updated to include Radar.<br>Included Policy CG-39.   |  |  |  |

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# 1. Executive summary

- 1.1 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 be taken in the event of non-conformance which includes a requirement to undertake formal investigation and root-cause analysis.
- 1.2 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.
- 1.3 The patient's primary identifier is the NHS number and must be used whenever possible. A correctly assigned medical record number (MRN) must be used where the NHS number is not known. Please note, an ICE number is not a unique identifier and MUST NOT be used.
- 1.4 Unless in circumstances described in section 7, unlabelled or inadequately labelled specimens will not be processed. The requestor will be clearly advised that another sample will be needed if the test results are still required.
- 1.5 There is recognition that there are certain circumstances where samples are unrepeatable, for example:
  - (a) Where further sample collection is inappropriate or impossible
  - (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.
- 1.6 When Pathology departments receive incorrectly labelled samples which cannot be repeated,
  - (a) the requestor will be contacted to either (1) re-label the specimen prior to processing or (2) await results until specimen traceability can be confirmed.
  - (b) the requestor must, when practicable, arrange for the sample to be correctly re-labelled as soon as possible so that the sample can be processed
  - (c) 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.

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1.7 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 Incident and Risk Reporting Systems (such as DATIX or RADAR) when appropriate.

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# 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 NBT Pathology Sciences' NBT Specimen Transport Policy, the NBT Blood Transfusion Policy (CG-109) and the <u>Pathology Sciences</u> 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 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 7.1, 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<br>collected, and the details of testing required or if Blood<br>Components are required. This may be in either paper or in<br>electronic (e.g.<br>ICE) format, noting that the latter must not be used for Blood<br>Transfusion. |  |  |  |
|--------------|--|--|--|--|
| RADAR        | North Bristol NHS Trust Incident Reporting<br>Management System.   |  |  |  |
| DATIX        | North Bristol NHS Trust Risk Management System.  |  |  |  |

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# 5. Roles and responsibilities

- 5.1 All staff who take samples for Pathology are responsible for ensuring that,
  - samples are collected in a manner to ensure the correct patient has been identified – please refer to <u>Venepuncture Policy CG-155</u>
  - Consent is obtained in accordance with NBT Consent Policy (CG-178)
  - the correct sample container has been used for the investigation requested
  - an appropriate amount of sample has been collected e.g. fill line for coagulation tests.
  - the patient has been suitably prepared for the test e.g. fasting or time delay between samplings.
  - the specimen containers and request forms contain the necessary information to correctly identify the patient
  - samples are collected in a manner that meets the requirements of the tests requested e.g. cryoglobulin samples need to be kept at body temperature
  - samples are sent to the laboratory in a timely manner for testing.
- 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.
- 5.3 Managers and senior staff in clinical areas must also ensure that appropriate action is taken where incidents arise from breaches of this policy. This will include responding to or reporting incidents on NBT's Incident Management System.
- 5.4 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 through Trust-wide Incident Management System if appropriate.
- 5.5 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' Management Group has oversight of all aspects of compliance with this policy to be able to evaluate effectiveness and impact upon quality standards. N.B. Blood Transfusion compliance is monitored by the Blood Transfusion Committee.
  - outcomes from audit and monitoring are fed back to Divisions and through the Trust's clinical governance structure.

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## 6. Procedures

6.1 Minimum Information required for all Pathology Requests (except where noted by discipline specific requirements in 7.4 including Blood Transfusion Department)

|              | ESSENTIAL  | DESIRABLE   |  |
|--------------|--|---|--|
| Specimen     | <ul> <li>NHS number <b>OR</b> other MRN</li> <li>Patient surname</li> <li>Patient first name</li> <li>Date of birth</li> <li>Date of specimen collection</li> </ul>  | <ul> <li>Nature of sample including<br/>qualifying details</li> <li>Number of pots when<br/>there are multiple<br/>specimens being sent with<br/>'1 of 2, 2 of 2' etc.</li> <li>Time of specimen collection (Note<br/>1)</li> <li>Date of specimen collection (if<br/>different from date on ICE label)</li> <li>Initialled / Signed by specimen<br/>collector</li> </ul> |  |
| Request Form | <ul> <li>NHS Number OR other unique identity number</li> <li>Patient surname</li> <li>Patient first name</li> <li>Date of birth</li> <li>Date and Time of specimen collection</li> <li>Initialled / Signed by specimen collector (Note 2)</li> <li>Name and location of Requesting Practitioner</li> <li>Type of specimen and, if appropriate, anatomical site of origin</li> <li>Investigations required</li> </ul> | <ul> <li>Clinical Information, including<br/>relevant medication</li> <li>Patient's Address including Post<br/>code and telephone Number (ideally<br/>mobile phone)</li> <li>Practitioners contact Number<br/>(mobile phone, bleep or extensions)</li> </ul>  |  |

#### 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 the default is midnight, which then 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

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test, Short Synacthen test, Dexamethasone suppression test

- Endocrine tests: ACTH, Cortisol
- Chemistry/toxicology tests: Glucose, Troponin T, Ammonia, Salicylate, Paracetamol, Ethylene glycol, Ethanol, Potassium
- 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.
- (e) Haematology: Pre- and post-Factor assays unless specified in the details of the request
- 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 7.4.
- 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

#### 6.2 Unknown Patient

6.2.1 Where samples are required to be taken from unknown / unconscious patients, the convention for assigning patient identifiers is as per that described in <u>Trust's Patient Identification Policy (CG-39).</u>

#### 6.3 Neonatal Samples

- 6.3.1 It is recognised that labelling samples from neonates will require adaptation due to the potential lack of information available for a newborn 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 7.1 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

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surname, date of birth and Hospital number e.g. Twin 1, Twin 2

## 6.4 Discipline Specific Requirements

## (a) Blood Transfusion - Requesting Blood Investigations and Components

Refer to NBT Blood Transfusion Policy CP-109 for further information.

Note, the laboratory has the option to accept certain samples under concession, when they meet certain criteria outlined in section 7.

#### (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:
  - o Patient Surname and Forename
  - o DoB or NHS Number
  - o 'Air-dried' or 'Fixed'

## (c) Cervical Cytology

A CSMS (Cervical Screening Management System) 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 fetal 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)
- All request forms must specify the patient's postcode. The postcode is a

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requirement to confirm the patient resides within the NHS England region and is therefore eligible for centrally funded genetic testing.

- For tumour specimens please ensure the correct referral form is used and all sample details completed.
- For genetic studies, relevant family history must always be provided including details of any members of the family who have previously 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.
- Include the number of pots when there are multiple specimens being sent with '1 of 2, 2 of 2' etc.

#### 6.5 Biohazards

- 6.5.1 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.
- 6.5.2 Clinical staff treating patients suspected of particular infections described by the IC07 A-Z and Isolation Policy 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.
- 6.5.3 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)

6.5.4 In addition, the air-tube must not be used for samples in the following  $P a g e \mid \mathbf{9}$  This document can only be guaranteed to be the current adopted version if opened directly from the NBT intranet.

circumstances:

- individual sample liquid volume of greater than 50ml
- Combined sample volume of greater 100ml
- Transfusion blood products and components
- Specimens for Histopathology
- Containers with formalin formaldehyde except for specialist neuropathology samples.
- Samples which need to remain frozen (e.g., via ice/dry ice)
- Samples which need to be kept warm (e.g., cryoglobulins)

# 6.5.5 It is important that samples are contained within a sealed bag of the correct colour and that samples from different patients are not placed into the same bag

#### 6.6 Confidential Samples with Unique Clinic Number

6.6.1 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.

#### 6.7 Patient contact details

6.7.1 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

- 7.1 All specimens being received into any of the constituent departments of Pathology Sciences, will be checked for adequacy of labelling. In the event of a non-compliance with the policy the following actions will be taken.
- 7.2 **Blood Transfusion:** Unlabelled or inadequately labelled specimens or forms will not be accepted. A repeat sample will only be requested when blood transfusion may be indicated. Samples may be accepted under concession, if the clinical impact on the patient is of greater risk for e.g., minor labelling error on an irretrievable sample, for example a 28-week antenatal patient who is D negative patient and has been given prophylactic anti-D after the sample was taken.
- 7.3 **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.

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- 7.4 **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.
- 7.5 **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.
  - 7.5.1 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.
  - 7.5.2 If the sample is received in an inappropriate container, the sample will not be processed but will be reported as inadequate
- 7.6 **Microbiology:** A repeat sample may be requested if appropriate. In exceptional circumstances the specimen may be considered unrepeatable.
- 7.7 **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.
  - 7.7.1 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.
- 7.8 **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.
- 7.9 **Neuropathology:** As for Histopathology specimens.

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#### 8. Monitoring effectiveness

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 Incident reporting System (e.g. Radar). For errors relating to Transfusion samples Root Cause Analysis of the incident must be undertaken within the requestor's area.

| What will be<br>monitored   | Monitoring/<br>Audit<br>method                                     | Monitoring<br>responsibility<br>(individual/group/<br>committee) | Frequency<br>of<br>monitoring | Reporting<br>arrangements<br>(committee/group<br>the monitoring<br>results are<br>presented to) | How will actions be taken to<br>ensure improvements and<br>learning where the monitoring<br>has identified deficiencies   |
|---|--|--|-------------------------------|---|---|
| Non-<br>conformities<br>against the<br>policy of<br>samples<br>received to<br>Pathology | Departmental<br>systems and on<br>NBT incident<br>reporting system | Laboratory staff   | As they occur                 | Departments   | Clinical area / ward managers<br>are responsible for ensuring<br>action plans are in place to<br>support improvements in<br>practice and interventions take<br>place as planned |
| Wrong blood in<br>tube incidents  | NBT incident<br>reporting system                                   | Clinician or<br>management in the<br>relevant area               | As they occur                 | Divisional/department<br>governance meetings  | Clinical area / ward managers<br>are responsible for ensuring<br>action plans are in place to<br>support improvements in<br>practice and interventions take<br>place as planned |

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| Trends in<br>number of<br>reported<br>incidents. See<br>8.2. | Analysis of data<br>collected by<br>departments<br>summarised by<br>absolute<br>numbers,<br>percentages and<br>cost | Quality Managers | Quarterly | Departments<br>PSGA committee<br>CCS Governance<br>committee | Identified trends will be<br>communicated to relevant<br>requestors, Divisional managers<br>Clinical area / ward managers<br>are responsible for ensuring<br>action plans are in place to<br>support improvements in<br>practice and interventions take<br>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

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#### 9. Associated policies/documents

- NBT Pathology Sciences' NBT Specimen Transport Policy (GP/PPP/004)
- NBT Blood Transfusion Policy CG-109
- Pathology Sciences User Handbook / Severn Pathology Website
- NBT Disease Specific Precautions A-Z Policy IC07

#### 10. References

- IBMS Patient Sample and Request Form Identification Criteria
- Blood Safety Quality and Regulations, 2005
- SW Regional Cervical Screening QARC Send Back Policy
- ISO 15189:2022 Medical laboratories. Requirements for quality and competence