York and Scarborough Teaching Hospitals NHS Foundation Trust

Reference: LM-POL-LABELLING

Laboratory Medicine: Completing Request Forms and Labelling Samples Policy

Version: 09

Summary	This policy describes the requirements for completing request forms and labelling samples to facilitate correct identification of patients and maximise the useful information available in the report.	
Keywords	Pathology, Request Forms, Labelling Samples	
Target audience	All York & Scarborough Teaching Hospitals NHS Foundation Trust staff who fill in request forms and label samples for work to be undertaken within Laboratory Medicine	
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Version Control

Change Record

Date	Author	Version	Page	Reason for Change
14/03/05	G. Claxton	01		First publication
08/03/07	G. Claxton	02		Amendments to appendix1 regarding the use of Nuffield's unique patient numbers and the use by Capio of NHS numbers for transfusion samples.
28/04/09	G. Claxton	03		Change to Trust Policy Format
09/09/11	G. Claxton	04		3.1.6 Handwritten additions to Ordercomms requests not acceptable
19/05/14	E. Fox	05		Updated to new Trust format. Reference to ISO 15189; 2012 in Introduction scope and practice. Removal of 3.2.4 Microbiology special conditions no longer apply.
17/06/16	E. Fox	06		Rewrite for clarity – location deemed as essential.
15/05/18	E. Fox	07		Requirement for signature of the individual who has drawn the sample to comply with ISO 15189;2012 - 5.4.2.2 Instructions for Pre-collection Activities For samples requested in order comms, requestors must ensure all samples are labelled with the correct barcodes and the barcodes are of good quality and placed in the correct orientation and the sample has been recorded as ticked as taken.
28/01/20	E. Fox	08		Removal of cervical Cytology detail following loss of service.
10/08/22	E. Fox	09		Change to Trust Policy Format and realigned to provide easier reading.

Reviewers/contributors

Name	Position	Version Reviewed & Date
Elizabeth Fox	SHYPS Quality Manager	Version 09 10/08/22

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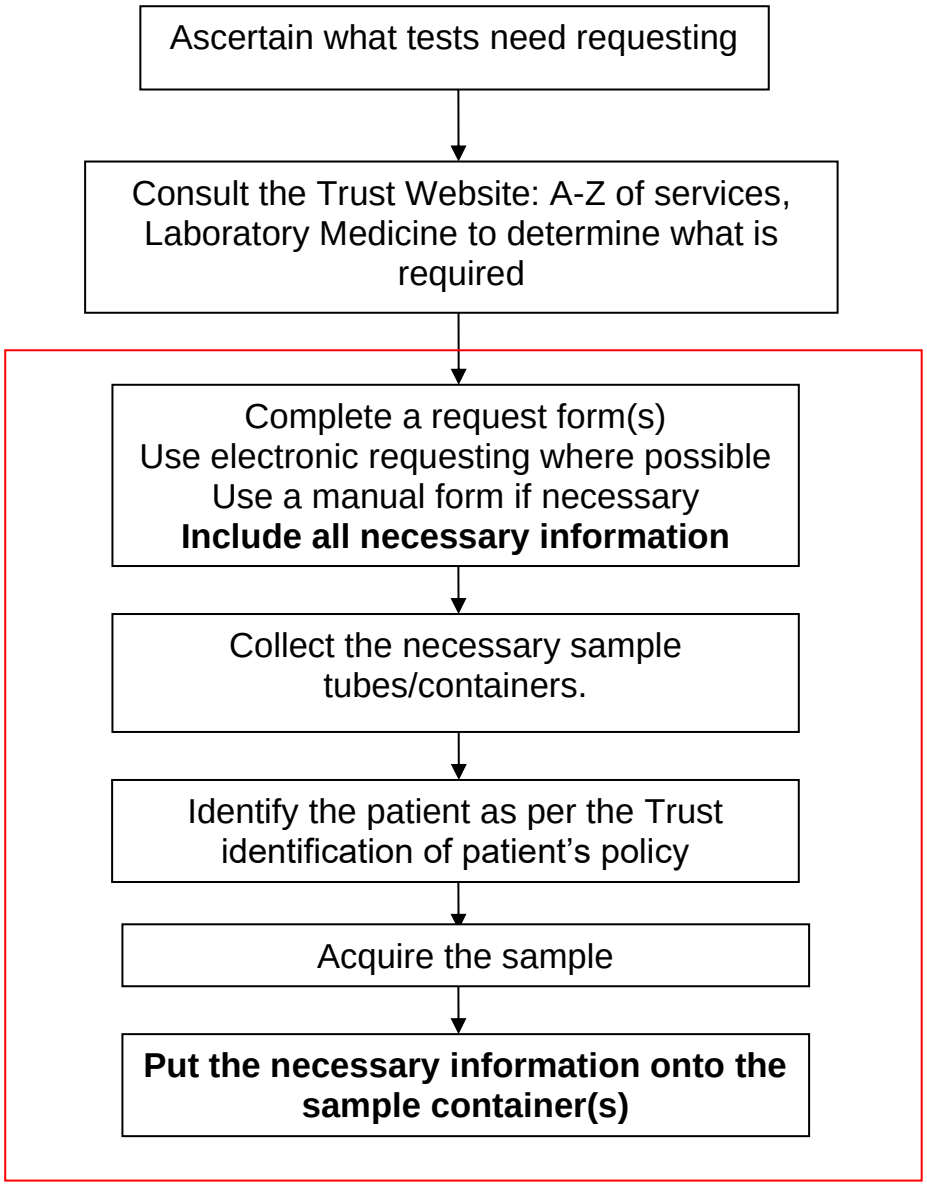
Process flowchart



1. Introduction

Clinical Governance demands that at the time of request a sample must be uniquely labelled and uniquely associated with a test request. The information which appears on a specimen and on the accompanying request form MUST match and fulfil the minimum criteria set out by regulatory and accreditation bodies. The location of the patient and the identity of the requestor must be accurately stated, and relevant clinical details supplied as appropriate for interpretation and reporting of results.

This policy sets out the requirements for correct sample and request form labelling for all requests received by Laboratory Medicine in a manner that provides an unequivocal link with the patients from whom they are collected.

In the interests of patient safety and diagnostic management, both request form and samples, must contain an adequate amount of information. Any sample which does not contain the essential labelling requirements may be rejected, as this may put patients at risk. No patient should suffer an adverse outcome, or delay in treatment, due to the mislabelling of samples or request forms.

2. Scope

The policy has been written to give guidance to the users of pathology services in the collection and handling of pathological samples. It includes the criteria for labelling that the staff performing specimen reception functions will apply to either accept or reject a sample.

Individual departments provide specific information for tests on a test directory available on the York & Scarborough Teaching Hospital Foundation Trust (YSTHFT) website, A-Z of Services which includes Pathology/Laboratory Medicine:

York & Scarborough Hospitals Website

This policy is aimed at all staff involved in arranging/initiating requests and/or acquiring samples for sending to Pathology and must be used in conjunction with Trust identification of patient's policy.

3. Duties and responsibilities

SHYPS Pathology Group Director: Will communicate this policy to medical staff in the Trust and will have the ultimate decision to accept or reject a specimen.

SHYPS Clinical Staff: Will apply this policy in their work so that the best quality of result is achieved for the patient.

SHYPS Senior Management Team and Quality Representatives: Will communicate this policy to service users and staff of pathology, monitor its compliance and follow up users that persistently fail to comply.

Senior Staff : Will ensure that their staff follow this policy providing support to their staff where required in the interpretation of this procedure incorporating advice on handling of precious samples (samples that are non-repeatable), danger of infection samples, and sample integrity

for analyses that require attention within a set timeframe.

All Laboratory Staff: Before accepting a clinical specimen, Pathology staff must ensure the minimum criteria for sample identification are met as stated in this policy. Departmental Standard Operating Procedures (SOP's) are aligned to this policy. All laboratory staff are required to follow this policy, applying it fairly across all users of the service in the interest of the patient. Pathology staff will take and record appropriate action where required and refer problematic decisions to senior staff.

Users: The responsibility for requesting a laboratory test lies with the patient's medical team and lead named consultant or practitioner managing the person's care. It is the responsibility of the requestor to ensure samples are correctly labelled and that request forms are completed to the required standard and that samples are transported to the laboratory within a 4-hour period to maintain sample integrity. Exceptions to this transport time can be found within the Pathology/Laboratory Medicine area of the Trust Website (includes tests where sample degradation may occur if sample not received immediately or on ice); if in any doubt refer to the appropriate laboratory department.
At the point where the patient is identified prior to taking the sample, the York Trust patient identification policy must be used.
All samples must be accompanied with the appropriate request form relevant to the test request.

4. Policy Content

4.1 Guidance on Collection

The collection and handling of specimens is the first step in the examination process. Mistakes at this point may lead to the rejection of samples in the laboratory. The quality of results may be affected by a lack of, or wrong clinical information, equally the integrity of the result may be affected by wrong or inaccurate patient details. A delay may be incurred by the wrong location.

All procedures carried out on a patient need the informed consent of the patient. It is assumed that when a sample is sent to the laboratory, the clinician responsible for the care of the patient has obtained the appropriate and valid consent for the test, storage and sharing of the patient's information with the relevant Health Care Professionals to generate the result so that the laboratory is not required to confirm or document consent. The name of the requestor, who should normally be medical, must be provided to satisfy requirements for consent to test. This is particularly important for sensitive tests such as HIV, syphilis, chlamydia etc. In most cases samples will be collected whilst the patient is conscious.

Written consent is not required unless a future issue can be predicted. For most routine laboratory procedures, consent can be inferred when the patient presents himself or

herself with a request form and willingly submits to the usual collecting procedure, for example venepuncture.

At the point where the patient is identified prior to taking the sample, the YSTHFT Patient Identification Policy must be adhered to. If conscious, check the patients name and date of birth verbally. If unconscious use the wrist band, checking that if the patient has more than one wrist band, e.g. neonates, that they are the same.

Specimens should be labelled once phlebotomy is complete at the patient bedside and before approaching the next patient, ensuring that sample details match those of the patient.

Samples should NOT be pre-labelled as this leads to an increased chance of specimen interchange. Patient information should NOT be crossed through and changed as this may lead to sample rejection by the laboratory.

4.2 The NHS, CHI or health and care number

Use of the NHS number, CHI or Health and Care number on paper and electronic patient records is a mandatory requirement included within the NHS Operating Framework 2008/9. The Pathology computer system uses the NHS number as the primary patient identifier so that all data can be linked and patients identified.

1. Everyone registered with the NHS in England and Wales has their own unique NHS Number made up of 10 digits shown in a 3-3-4 format.

2. The Health and Care Number was introduced for the use and benefit of patients and clients resident within Northern Ireland. This number will be used, from birth, for life for receipt of Health and Social Services in Northern Ireland. The Health and Care Number is a 10 digit number randomly selected and allocated to everyone in Northern Ireland. The first two characters of the Health and Care Number must always lie within the range 32 - 39.

3. Everyone registered with a Scottish GP practice has their own unique ten-digit number Community Health Index (CHI) number.

4.3 The criteria for sample labelling & request form completion

The practitioner collecting samples is responsible for ensuring the identification of the correct patient and should confirm their details with those recorded on the sample and request form.
The identification of the patient by the laboratory is from two sources.

(1) Patient sample(s).
(2) Request form.

Samples may be received in two ways:

1) Manually written request form and handwritten or addressograph labelled sample labels (not for transfusion).
2) Via an ordercomms system directly transferring the request into the pathology LIMs with the sample label displaying a barcode distinct to this electronic request.

For samples requested in order comms, requestors must ensure all samples are labelled with the correct barcodes and the barcodes are of good quality and placed in the correct orientation and the sample has been recorded as ticked as taken.

The **MINIMUM** criteria for sample & request form labelling is defined below:
****PLEASE NOTE ADDITIONAL CRITERIA FOR BLOOD TRANSFUSION APPLY** See Section 4.4.**

Sample	**Request Form**
Patient SURNAME	Patient SURNAME
Patient FORENAME	Patient FORENAME
Date of Birth **OR** NHS / Hospital Number **(Both required for transfusion)**	Date of Birth **OR** NHS / Hospital Number **(Both required for transfusion)**
Date & time sample taken	Date & time sample taken (Order comms records time request generated)
	Patient's consultant, GP or name of requesting practitioner
	Patient location & destination of report (ward / GP)
	Investigation required
	High risk status
	ALL NON-BLOOD SPECIMENS
	Specimen Type
	Specimen Site

Note that SURNAME and FORENAME is considered as one identifier and the minimum identifiers on the sample **MUST** agree with the request form. Identifiers must be correctly spelt and complete, i.e. initials are insufficient, as is an age of a patient or just a year of birth. Details should be written legibly, preferably in CAPITALS and must include as minimum details in the ABOVE table.

It is strongly recommended that the specimen tube be labelled with **date and time of collection and the signature of the person** who collected the sample. Laboratories may accept samples that do not have date and time of collection on the request form / sample.

The following additional information is considered **desirable** but may be considered as essential for some tests.

Sample	**Request Form**
Location of patient	Clinical information including relevant medication (which is sometimes essential e.g. Drug History (dose & time of last dose for drug assays), antibiotic history (vital as part of microbiology request)
Source (ward / GP)	Patients sex
Time taken to ensure sample integrity and to relate to reference ranges for some tests	Practitioner bleep / contact number
Sample type (s) and anatomical site (s) (essential for Microbiology and Histology)	Time sample taken
Signature of the individual who has drawn the sample	Patients address

Pathology provides Service User Information on the Laboratory Medicine Website, accessible both through 'Staff Room' the YSTHFT intranet and the YSTHFT website A-Z of services; this contains the information that users may need to collect specimens, and contact numbers for specialist advice. Individual departments will state the additional requirements for those tests that require special measures. These special measures may include; storage conditions of specimens before delivery to the laboratory, if rapid delivery to the laboratory is required and information on any additional forms or patient details that may be needed, e.g. haemoglobinopathy patient questionnaires.

4.4 Blood Transfusion Requests

The minimum criteria for sample & request form labelling applies; however, in the case of Blood Transfusion requests, special conditions apply; please refer to the YSTHFT Blood and Blood Component Policy for full details.

The importance of correct patient identification, sample labelling, documentation and record keeping cannot be overstated since most deaths associated with blood transfusion are a result of clerical errors.

A request to the Blood Transfusion laboratory is represented by the provision of information sufficient to satisfy minimum requirements for identification and documentation.

The patient ID must be unique and there must be an auditable link between each stage of the procedure, from sample collection to final reporting/issuing of compatible blood.

Blood Transfusion sample labelling: Blood samples must be taken and labelled from one patient at a time.

The sample tube must be labelled immediately after the blood has been added by the person taking the sample. This should be done at the (bed)side of the patient. An addressograph or ICE/order comm label must not be used on the sample tube; if used the sample will not be processed by the transfusion department.

It is mandatory that the NHS number for all Blood Transfusion samples is included. Samples must be handwritten on to the specimen tube. If the NHS number is not available; the hospital reference number (or accident and emergency) number must be used. N.B: If both hospital number AND NHS number are provided, they MUST match on both form and sample.

Blood Transfusion request form completion: The request form must contain the same patient identifiers as the specimen together with further essential information; Location, gender of the patient, consultant and/or GP, clinical details, number or volume and type of components required, and any other specific requirements relating to the request or patient e.g. irradiated products required.

Antenatal Requests: In addition to the minimum criteria, please include the following essential information; patient address, location, GP and/or consultant and E.D.D.

The Hospital Transfusion Laboratory will reject samples or request forms for the following reasons: -

- Those that do not show the minimum dataset, (last name and first name spelt correctly, date of birth, unique numeric identifier), date, time and the signature of the individual who has drawn the sample.
- Samples that are completely unlabelled or show evidence of being previously labelled with details of another patient, even if those details have been almost completely obliterated.
- Samples labelled with addressograph or other pre-printed labels.
- Samples for the same patient which the Transfusion Laboratory staff believe to be taken at the same time by the same person (other than as requested by the Laboratory for further testing).

If any of the above occurs, you will be asked to send a repeat sample and request form and is likely to cause delay in blood component release.

4.5 High risk samples

Any request on a patient who comes under the category of 'high risk' must include indication of this on the request form. The HSE advise the provision of sufficient information on specimen request forms to staff in clinical diagnostic laboratories to enable them to apply the correct safety measures to control the risk. The lack of sufficient relevant clinical details provided on specimen request forms can result in samples being handled at the wrong biological containment level resulting in increased risk of infection to laboratory staff.

4.6 The unidentified patient

Samples received from trauma or unconscious A&E patients must have at least one unique identifier number –a hospital generated case note number. An unidentified patient is to be entered onto CPD using the randomly generated phonetic lists available in the Emergency Department. The list comprises of 2 x Phonetic words which have been randomly generated from the phonetic alphabet with real names (i.e. Mike and India) removed.

Name: In the event of more than one "unidentified patient" arriving in the department a record must be kept of which names have been allocated to prevent duplication. The word Unknown is then to be entered as the 1st Forename i.e. Unknown Foxtrot Bravo would become Forename: Unknown Foxtrot Surname: Bravo. The allocation of the 2 x phonetic word groups is to be controlled at ED level.

Date of birth: The Trusts A&E department will allocate a day and month of birth of 01 Jan and then estimating the year of birth e.g. 01 Jan 1950 or 01 Jan 2017. When estimating DOBs, staff must remain cognisant of the significance to downstream diagnostic tests of those patients who are: under 1 year of age, under 12 years of age, were born after 1996 and are over 50years of age.

In such cases the patient should be registered on the Telepath computer system using the details written on the transfusion form:

Type the Unique identifier as the main registration case number.

In the Surname field, type eg Bravo

In the Forename field, type eg Unknown Foxtrot

In the DOB/AGE field type what is estimated by A&E. If it is not known, type NK. At the prompt press 'RETURN' to accept new patient.

Type the gender of the patient in the gender field.

Continue with registration in the usual way.

The requesting Medical Officer must accept the responsibility for correct and complete labelling. When a request is made by telephone, an auditable log must be kept. Assurance of patient details is vital and must be compared with historic computer records and the original request form, if available.

4.7 Sample Rejection

Pathology will make every effort to ensure that every specimen is processed correctly and that no vital specimen is lost but, in the event of doubt as to the integrity of the information provided or the source of a specimen, the laboratory reserves the right to refuse to process that request.

Specimens will be accepted for analysis provided:

- Samples are correctly labelled and request forms are completed to the agreed standard and fulfil the minimum criteria set out by accreditation bodies for Pathology as stated in this policy to provide an unequivocal link with the patients from whom they have been collected.
- The specimen is appropriate (i.e. correct blood tube, expiry date etc.)
- The investigation required is clearly indicated on the request form.
- The patient details have not been changed on the specimen container.
- The specimen is of acceptable integrity.

If samples or request forms are not labelled with the minimum criteria they may be rejected or the request may be returned to the sender (In these circumstances it will be even more difficult to activate the request if the identity of the sender is not provided).

Pathology staff **MUST NOT** amend details on the sample.

Any sample that is rejected will have a report issued with an appropriate standard comment indicating any deficiencies.

Exceptions may be made in the case of unrepeatable samples listed by department below in section 4.8.

4.8 Precious samples (non-repeatable samples)

Biochemistry: Un-named samples of CSF may be retained, and the requesting clinician asked to attend the laboratory to label the specimen.

Haematology: For bone marrow aspirates and slides the requesting clinician will be asked to come to the laboratory to complete the details.

Microbiology: Blood cultures, CSF, operative samples and other precious specimens that, in the opinion of the Consultant Microbiologist, would be difficult to replace: the requesting clinician may be asked to attend the laboratory to complete the details. The decision to reject samples in Microbiology rests with the Consultant Microbiologist as many samples are unrepeatable after patients have started antibiotic therapy. The Consultant Microbiologist will liaise with clinical colleagues and satisfy themselves as to the degree of doubt concerning identification of a patient and their sample.

Diagnostic Cytology: For easily repeated non-gynae samples a covering letter will be sent requesting a repeat sample. Where non-gynae samples are not easily repeated, samples will only be accepted at the discretion of the Histopathologist on duty at the time.

Histopathology: Due to the nature of specimens sent to Histopathology, it is not possible to request 'repeat' samples. It is therefore imperative that all patient identification information is present on both request form and sample. However, should specimens arrive unlabelled, the requesting clinician, or a delegated representative, will be asked to come to the laboratory to complete the details. If a sample has been sent from an off-site source, (e.g. General Practice), the requesting doctor must send written, signed, verification of patient ID.

In extreme cases where there constitutes a greater risk to the patient for clinical reasons a Consultant Level Clinician of the relevant department may authorise variation to this policy. In these circumstances, **the requesting clinician** must give written agreement to accept full responsibility for all potential outcomes and liability claims prior to the release of any results or interpretive comments. The report will show a clear disclaimer detailing the shortcomings of the sample and/or request and alerting the requesting practitioner to take responsibility for the results, and for any action taken because of the report.

No deviations will be permitted in relation to blood transfusion requests.

In all cases of the exceptions, a DATIX form will be completed and submitted to record

the incident.

5. Training Requirements

Healthcare Professionals, for example, nurses are able to sign a request form subject to the training and competency that they have received and achieved in support of the test or request that they are making to the laboratory. Training on, and the practice of, accurate labelling of specimens and samples is delivered and supported organisationally through a range of methods/processes linked to clinical interventions, both medical and non-medical dependant on your clinical area, for example; Blood Transfusion Competency – Sampling.

6. Monitoring Compliance

Compliance will be monitored in the reception areas of Pathology, but only obvious anomalies can be identified in this way. Correctly filled in request forms and labelled samples where the wrong patient has been bled could cause an adverse outcome for either of the two patients involved and could lead to a claim or other action questioning fitness to practice.

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Samples are unequivocally traceable, by request and labelling to an identified patient or site.	Network Quality Manager	All samples entering specimen reception are checked by reception staff. A DATIX is submitted for any errors found.	Monthly review by Network Quality Manager	SHYPS Clinical Governance Committee reports to CG4 Quality & Safety
Laboratory developed and documented criteria for acceptance or rejection of samples are applied	Network Quality Manager	Missing or erroneous information on the request can be picked up at any stage in the analytical process. An DATIX is submitted for any instances found	Monthly review by Network Quality Manager	SHYPS Clinical Governance Committee reports to CG4 Quality & Safety

7. Document Review

The document will be reviewed every two years

8. Associated Trust Documents

- Identification of Patients Policy
- Blood and Blood Component Policy

9. References

BS EN ISO 15189: 2012: Medical laboratories – Requirements for quality and competence which defines the requirements for the completion of request forms and sample labelling in the secondary sub-clause 5.4.4 Primary sample collection and handling.

Rules and guidance for pharmaceutical manufacturers and distributors 2007 or later (Orange Book)

MHRA standards for GMP/GLP to meet the EU Directive/Blood Safety Quality Regulations (2005): European Directorate for the Quality of Medicines & Healthcare (EDQM) Good Practice Guidelines for Blood Establishment Required to Comply with Directive 2005/62/EC
https://www.edqm.eu/en/good-practice-guidelines-blood-establishments

10. Definitions

Term	Definition
YSTHFT	York & Scarborough Teaching Hospitals NHS Foundation Trust
SHYPS	Scarborough, Hull, York Pathology Service
Laboratory Medicine	Also known as Pathology – A generic term for the departments in which the testing/analysis of the samples takes place
Users:	These are either the requester of a test or the clinician in charge of the patient care
Sample:	This is any fluid, tissue, organ or body part removed from a patient that requires analysis by a department of pathology to provide clinical information.
Request Form:	This is a record of the request, paper or electronic, that contains additional information regarding the patient, the sample(s) and/or testing required.
Unique Identifier:	An identifier that must be unique to each patient, normally their NHS number.