Policy

To specify minimum requirements for the labelling of samples and for the completion of request forms for all referrals to RCI laboratories.

Objective

To ensure sufficient information is received to give confidence in the identity of the patient.
To specify the actions required in circumstances in which information given is discrepant or incomplete.

Changes in this version

CR61292 Section 2.3 cross-reference to SOP6645 which has replaced MPD71. CR61770 Section 1.5 clarification regarding deviations. CR71103 section 2.4 exceptions for IgA investigations referred to Barnsley. CR72785 requirements aligned with MPD405 and INF66 as per UKAS finding.

Roles

- **Head of Laboratory/RLM/Senior BMS** Must ensure compliance with this MPD
- **NHSBT staff** involved in the receipt and testing of samples must ensure samples and forms are labelled to the standards set in this policy.
- **Senior RCI or Medical staff** are required to sign Concession documentation to enable inadequately labelled samples to be tested in exceptional circumstances
- **Customer Services** will communicate the policy to referring organisations (hospitals, antenatal clinics, GP surgeries) and inform them of their responsibilities for ensuring referred samples and request forms are labelled to an acceptable standard

Process Description

1. Requirements for Acceptable Labelling

1.1 Applications

All samples received by RCI laboratories (other than those collected from blood donors by NHSBT staff). Obtaining consent for the requested tests is the responsibility of the requester, where consent has not been given for material to be used for other purposes e.g. quality control this must be noted in Hematos.

1.2 Sample identification:

Samples and request forms must contain the minimum identification details as required by INF66 – Red Cell Immunohaematology User Guide. These requirements meet and/or exceed the BSH Guidelines to ensure secure sample/patient identification. All samples for testing by RCI laboratories must be labelled with sufficient details to ensure accurate patient/donor identity.

1.2.1 Relevant Guidelines

- Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories.

Due to the size of neonate sample tubes, these may be accepted with an attached label, that has been completed at the time of phlebotomy, which meet the sample acceptance criteria.

1.2.2 Minimum Sample Labelling

RCI receives samples from many sources, so there is an increased chance of shared identifiers such as name, date of birth and hospital number. In order to comply fully with the above guideline, it must be ensured there is sufficient labelling on each sample to minimise the risk of misidentifying a patient or donor.

Samples must be labelled with 3 identifiers, one of which is the NHS number if available (see table below); the identifiers supplied on the sample and request form must match.

Omission of year from date taken on a sample may be acceptable, if the request form has the full date taken details included i.e. day/month/year

	Sample **Note** all RCI samples must be hand written /demand printed labels	Request Form
NHS number	**Essential (if available)**	**Essential (if available)**
Name First and last name spelt correctly Unless patient/donor identity is confidential	**Essential**	**Essential**
Date of Birth	**Essential**	**Essential**
Hospital Number or temporary unique identification number.	Essential - if NHS number is not available	Essential - if NHS number is not available
Address	Will only be accepted for paternal samples or samples from private patients	Will only be accepted for paternal samples or samples from private patients
Date sample taken	**Essential**	**Essential**
Time sample taken	**Essential for pre-transfusion samples**	**Essential for pre-transfusion samples**
Signature of person taking sample	**Essential**	**Essential**
Requesting institution	Not required	**Essential**
Requesting Clinician	Not required	**Essential**
Signature of requester	Not required	**Essential**
Clinical information/test required	Not required	**Essential**

1.3 Exceptions

Samples from the following groups may be accepted; however, a comment is recorded, where necessary in Hematos and on the report to state that RCI may not fully accept responsibility for these results (DAT582).

Trauma or unconscious A&E patients where identity is not yet established that have **a least one unique identifier** e.g. A&E or trauma number, Bone marrow registry donors with a unique registry identifier Ideally the sex and approximate age of the patient should also be given.
Patients or donors whose identity is confidential [e.g. Bone Marrow Registry donors with a unique registry identifier or pre-transplant samples]
Donation samples where the donor details are recorded in a secure system and the samples are identified by ICCBBA (International Council for Commonality in Blood Bank Automation) registered ISBT128 barcode donation numbers
Labelling must be sufficient to ensure patient identity.
Pre/post-transplant monitoring which are time critical
Samples from the partners of pregnant women with red cell antibodies may be accepted if both sample and request form have 3 identifiers, not necessarily including NHS number/ hospital number, e.g. name, DOB and address
Samples referred from Immunology Departments for confirmation of IgA deficiency to support clinical diagnosis are acceptable on non-standard NHS referral forms provided all demographic information is complete Note: Date taken on the sample is not crucial for samples referred from Immunology Departments (Some of these samples are aliquots archived by the referring lab)

1.4 Authorised Concessions:

In exceptional circumstances samples with inadequate labelling may be accepted for testing but only with a documented authorised concession [see SOP5713]. The following comment from DAT582 is recorded in Hematos and on the report:

D101 – This sample was tested under concession because it was inadequately labelled. Please see attached copy of concession form for details. Caution is required when accepting these results.

Investigations when the delay in acquiring a new sample might **seriously** prejudice a successful clinical outcome for a patient.

Investigations where the sample cannot be replaced. Examples include: ▪ Samples taken pre-transfusion or transplant ▪ Samples taken at specific time periods [e.g. investigation of FMH or monitoring acute transplant rejection] ▪ Samples for specialist referral from abroad ▪ Stored samples [e.g. cryovials] ▪ Samples from a foetus
Samples from neonates or small children that may be difficult to replace, a decision should be made on an individual basis and not on the grounds of age alone
If the investigation, or supply of products is urgent and repeat samples cannot be supplied in time
Expired tubes It is RCI policy not to accept samples which have been taken into expired tubes as this is against manufacturers recommendations. However, if there is a clinical need to process the sample it can be tested under concession and the following coded comment is added to the report from DAT582: *DK49 – This sample was tested under concession because it was taken into an expired tube. This is against manufacturers recommendations and caution is required when accepting these results.*

1.5 Deviations:

In exceptional circumstances, referring organisations may be unable to comply with all sample labelling regulations. Customer Services and RCI will work with the referrer to perform a risk assessment and work to implementing a workable solution where possible.

2. Unsuitable Labelling

2.1 Unacceptable

Some samples, e.g. those that are completely unlabelled or totally discrepant, are unsuitable for testing in any circumstances.

2.1.1 If urgent and/or if blood products are required

The requester must be contacted to discuss the provision of a replacement sample. If there are serious difficulties in replacing the sample, or it is stated that the patient's clinical outcome may be seriously prejudiced, the case should be discussed with BMS in Blood Bank/Clinician at referring hospital.

2.2 Discrepancies between request form and sample

Samples where the patient details can be confirmed by an enquiry to the requester or to the NHS Personal Demographic Service. e.g. minor differences in spelling between form and sample may be tested

- If discrepancy is on the request form - a corrected request form is supplied by requestor.
- If discrepancy is on the sample it is not to be used for transfusion or transplantation purposes, and

The enquiry and the outcome are documented in the patient record, either hard copy or electronic. Details of the discrepancy are included in the report of the investigation.

2.3 Printed Labels

Addressograph labels are acceptable on request forms providing they don't obscure other vital details.

Labels which have been generated and attached at the bedside from scanning bar-coded wristbands at the time of phlebotomy from an automated system are acceptable for samples. Since it is not possible to distinguish reliably between these and *addressograph* labels they can be accepted only from referring organisations which have informed RCI in writing, that their sample labels are generated in an audited system and are demand printed at the time of phlebotomy. SOP6645

Bedside generated labels need to have positive, traceable identification of the sample taker, but do not require a signature.

Customer Services will maintain a list of referrers accepted by NHSBT as using secure demand printed labelling systems - DAT3727

2.4 Separated samples and serum or plasma only samples

Samples from which the serum/plasma or DNA has been separated by the referring organisation will not be accepted routinely unless referred for IgA investigation.

Exceptions: -

- Particular tests where separation at the time of sampling may be advantageous. The RCI laboratory will be responsible for discussing the need for separated samples in such circumstances and must explain the exceptional conditions to the referring organisation. For pre-transfusion testing, samples must be clearly labelled and signed by the person separating the samples. Accompanying documents should clearly state the nature of the samples, details of the person separating the samples and the time and date of sample separation. The original sample

container should be included if available and the details transposed onto the secondary container must be complete and identical to those on the original sample.

- A separated sample may be accepted if it is the only sample available for referral and the sample cannot be repeated e.g. HTR investigation, pre- transplant.
- Separated/archived samples for IgA deficiency/Anti-IgA investigation referred from hospital Immunology Departments. Samples may be lacking a signature and referred with pre-printed labels (not demand printed labels). This testing is performed at Barnsley only and senior staff are responsible for reviewing referred samples for acceptability prior to testing.
- Separated samples may be transferred between RCI laboratories. This is acceptable as the separation and labelling procedures are covered by internal operational procedures, including this MPD.

Separated samples are not acceptable for crossmatching red cells unless there are exceptional circumstances. In these circumstances, every effort is made to confirm the ABO group of the plasma/serum sample(s) and ensure it matches previous records, including those held by the referring hospital. The sample is only to be accepted for crossmatch if all these agree and there is a documented authorised concession.

3. Reporting:

Where appropriate, standard comments are used in preference to free text. (DAT582)

3.1 Samples tested under a concession/exception

If a concession has been approved, only those tests for which the concession was raised are reported. Any further investigation is carried out on a fully labelled sample. Reference to the concession documentation is included in the report. Details of the labelling deficiency/ discrepancy is included in the report together with a request for repeat sample(s) as soon as possible, if appropriate. A copy of the concession form is sent to the requester with the final report. (FRM11)

3.2 Samples which have not been tested:

Non-tested/rejected samples are reported using standard comments in preference to free text (DAT582).

A request for repeat sample(s) as soon as possible is included, if appropriate.

Definitions

- **A&E** - Accident and Emergency
- **HTR** -Haemolytic Transfusion Reaction
- **FMH** - Feto-maternal haemorrhage
- **ICCBBA** - International Council for Commonality in Blood Bank Automation
- **DTS** - Diagnostics and Therapeutic Services
- **ODT** – Organ donation and transplantation
- **PDS** - Personal Demographics Service

Related Documents / References

- **SOP6645 -** Management of requests to use Demand Printed Labels
- **DAT3727 -Demand Printed Labels - Hospital Acceptance List**
- **SOP5713 -** Concessions & Planned Deviations for Processing Inadequately Labelled DTS Samples and Managing of Transfer of SpS requests for investigations and associated products to an alternative hospital
- **DAT582** – Reporting Phrases in Hematos
- **INF66** – Red Cell Immunohaematology User Guide
- **FRM11** SpS Concession request

Appendices

- N/A

Training Plan for Documents:

Document Title	Requirements for Sample Labelling and Request Form Completion	
Document Number & Revision Number	MPD637/8	
Type of Change	Clarification points to current process	
Stakeholders who require training	**Trainee new to the process**	**Trainee trained to the previous revision.**
	All RCI staff involved in sample acceptance/booking samples into RCI LIMS	All RCI staff involved in samples acceptance/booking samples into RCI LIMS
Knowledge required prior to training	none	Trained to previous version.
Critical aspects of process	Failure to identify demographic discrepancies and failure to create correct patient record in Hematos could have potential patient impact. Staff are trained to SOP4368 and there is a second independent check of samples and demographics as part of the RCI sample reception process.	

Training Plan:

	Trainee new to the process	**Trainee trained to the previous revision.**
Recommended Training Method	• Separate training is not required - training is managed in conjunction with SOP4368 and DAT4494.	• Read only
Assessment	Assessment of competency is evidenced using • FRM511 • Assessment is captured in conjunction with SOP4368and DAT4494	Assessment of competency is evidenced using • FRM511
Cascade Plan	To be determined locally.	Author authorises self-directed training>

Training Score – Training Plan Risk Matrix (Collapsible – Click ▶ icon to open/close)

Use the *Training Plan Risk Matrix* to identify the training method and assessment required.

The *Process Criticality Score* is determined by the potential impact on donor/patient safety and/or product quality using the table below for guidance.

	Impact on Donor, Patient safety or product quality
1. Negligible	A process whose failure, in full or in part, **cannot** impact product quality, patient/donor safety or the ability to supply products/services.
2. Minor	A process whose failure, in full or in part, **may**: (i) impact other processes thereby indirectly impacting product quality, patient/donor safety (e.g. harm only results where multiple failures in multiple processes align) (ii) result in the discard of a small number of replaceable products and/or (iii) result in an inconvenient delay to the supply of products/services (e.g. delay of 1-3hrs of non-urgent product/service).
3. Moderate	A process whose failure, in full or in part, **may**: (i) indirectly impact product quality, patient/donor safety (e.g. harm only results where failures in more than 1 process align) (ii) result in the discard of a medium number of replaceable products and/or (iii) result in a temporary delay to the supply of products/services (e.g. delay of 4-12hours of non-urgent products/services).
4. High	A process whose failure, in full or in part, is **likely** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
5. Very High	A process whose failure, in full or in part, is **certain** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
Process Criticality Score	2

The *Criticality of Change Score* is determined by assessing the nature of change(s) and complexity of the process using the table below for guidance.

	Change to Trainee(s)
1. Negligible	An existing process to which no material changes are made. E.g. format changes, minor clarifications of existing practice, fixing typos.
2. Minor	An existing process to which new information is added but where changes to existing knowledge and practices are minimal. E.g. clarifications that tighten existing practices
3. Moderate	An existing process of low complexity with material changes requiring different people to take action and/or people to change the tasks they perform. E.g. new roles/responsibilities, changes to the order of existing tasks, new tasks

4. High	A new process of moderate complexity, OR An existing process of moderate complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
5. Very High	A new process of high complexity, OR An existing process of high complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
Criticality of Change Score	1

Training Plan Risk Matrix:

Process Criticality →

Criticality of Change ↓

	1. Negligible	2. Minor	3. Moderate	4. High	5. Very High
1. Low	1	2	3	4	5
2. Moderately Low	2	4	6	8	10
3. Moderate	3	6	9	12	15
4. High	4	8	12	16	20
5. Very High	5	10	15	20	25

	Trainee new to the process	**Trainee trained to the previous revision.**
Process Criticality Score	3	
Criticality of Change Score	2	2
Training Score	6	2

Recommended Training Method:

Training Score	Level of Risk	Examples of Training Methods	Examples of Assessment
1 - 3	Low	Read only	Record on FRM511 only
4 - 8	Manageable	Email, team brief, word brief	Knowledge/Observation Check & FRM511
9 - 14	Medium/Significant	Formal training package	Knowledge/Observation Check & FRM511 or FRM5076
15 - 25	High	Practical	FRM5076 or equivalent