MANAGEMENT PROCESS DESCRIPTION MPD637/6

Requirements for Sample Labelling and Request Form Completion

This Management Process Description replaces MPD637/5	**Copy Number**
	Effective **24/01/19**

Summary of Significant Changes

Change of author to David Ward

CR32636 – Requirement to notify hospital clinician when a sample is unsuitable and may delay patient care

CR34682 – Include expired sample tubes in authorised concession section.

CR36175 – For neonatal sample tubes, allow an attached label that has been completed at the time of phlebotomy, which meet the sample acceptance criteria.

CR36512 - Allow omission of year from date taken on sample

CR 36640 - Exceptions statement for IgA samples previously removed in error, has been restored.

Policy

To specify minimum requirements for the labelling of samples and

for the completion of request forms for all referrals to RCI laboratories.

Purpose

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.

Responsibilities

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

Definitions

A&E - Accident and Emergency

HTR -Haemolytic Transfusion Reaction

FMH - Feto-maternal haemorrhage

ICCBBA - International Council for Commonality in Blood Bank Automation

CHI – (Community Health) The is the unique patient identifier used in Scotland

HCS – (Health and Care) The is the unique patient identifier used in Northern Ireland

PDS - Personal Demographics Service

DTS - Diagnostics and Therapeutic Services

ODT – Organ donation and transplantation

Applicable Documents

ESD121 BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories 2012

MPD71 – Management of Sample Labelling Deviations

MPD13 - Concessions and Planned Deviations for Processing Inadequately Labelled Diagnostic Services 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

ESD156 Infectious Diseases in Pregnancy

Screening Programme Laboratory Handbook

FRM11 SpS Concession request

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. 2012 (ESD121)

'3.2.2 It is essential that the request form and sample conform to the requirements as described in the guidelines on the administration of blood components (BSH, 2009).

As a minimum,

*The sample tube **must** be completed with the patient core identifiers*

(Last name, first name, date of birth, NHS number (if the NHS number is not immediately available, a temporary unique identification number should be used until it is)).

*These core identifiers **must** exactly match the request form and patient identification band (or equivalent).*

- *Date and time of sampling and the identity of the person taking the sample (e.g. initials or signature, according to local policy) should be recorded on every sample tube and request form to provide a full audit trail.*
- *These minimum labelling requirements apply to both adult and paediatric/neonatal blood samples.*
- *Sample tubes should never be pre-labelled.*

- *Pre-printed labels (pre-printed away from the patient or taken from the patient's notes e.g. 'addressograph' labels) should not be used to label pre-transfusion blood sample tubes for compatibility testing. Only labels that are printed 'on demand' and attached to the sample tube next to the patient at the time of phlebotomy are acceptable. All hand-written sample labels should be completed legibly and accurately (in ball point pen to avoid washing out or smudging).*
- *Organisations should have a clear policy on the rejection of pre-transfusion blood samples which do not meet minimum labelling requirements. There should be no changes or amendment of patient core identifiers once samples have been sent to the laboratory. It is suggested that organisations should adopt a 'zero tolerance' policy.*

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 guidelines and standards 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/CHI/HCS number if available; the identifiers supplied on the sample and request form must match.

Omission of year from date taken on a sample is 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/CHI/HCS 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.	Optional must be used if NHS number is not available	Desirable - must be used if NHS number is not available
Address	Optional	Optional for reference samples but essential for antenatal screening samples see ESD156)
Date	**Essential**	**Essential**
Signature of person taking sample	**Essential**	Not required
Requesting institution	Not required	**Essential**
Requesting Clinician	Not required	**Essential**
Signature of requester	Not required	**Essential**
Clinical information/test required	Not required	**Essential**
Sample source e.g. blood, spleen	**Essential if not peripheral blood**	**Essential if not peripheral blood**

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/CHI/HCS 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 MPD13]. 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: *D100 – 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 will organise a documented authorised deviation [see MPD71 & MPD13] to allow samples to be tested with the understanding that the RCI cannot be fully responsible for errors made as a result of unacceptable labelling in the referring organisation.

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

Extract from BSH Guidelines on the administration of blood components 2009 (ESD117):

'Pre-printed labels (pre-printed away from the patient or taken from the patient's notes e.g. 'addressograph' labels) should not be used to label pre-transfusion blood sample tubes for compatibility testing. Only labels that are printed 'on demand' and attached to the sample tube next to the patient at the time of phlebotomy are acceptable'

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.

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. A read-only copy of this list can be viewed at G:\001 National Share\001 Everyone\Sample labelling.

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.

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. 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.
- Archived samples for IgA deficiency/Anti-IgA investigation referred from hospital Immunology Departments
- 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.