Policy

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

Objective

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

N.B. This Policy is ONLY to be used for H&I test referrals and excludes other NHSBT Diagnostic Services

Changes in this version

Remove reference to MPD13 and replace with SOP5713

Roles

- **H&I Staff involved in the receipt and testing of samples**

1. Requirements for Acceptable Labelling

1.1 Applications

All samples received by H&I 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 the Diagnostics LIMS.

1.2 Sample identification

Samples and request forms must contain at least the minimum identification details as required by the guidelines and standards applicable to the type of test(s) requested. All samples for testing by NHSBT H&I laboratories must be labelled with sufficient details to ensure accurate patient / donor identity.

1.2.1 Relevant Guidelines

See appendix 1 **- Summary of requirements of relevant external standards and guidelines**

1.2.2 Minimum Sample Labelling

As a national organisation, the NHSBT 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 appended standards and guidelines we need to ensure there is sufficient labelling on each sample to minimise the risk of misidentifying a patient or donor.

It is important to limit the production of duplicate identities of patients / donors on the Diagnostics LIMS as this can pose an information governance risk, and as such we must endeavour to use unique identifiers such as NHS (or CHI/HCS) numbers with all samples.

Samples should 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. Pretransfusion samples (e.g. for

HLA/HPA selected platelets) must have three identifiers, the identity of the person taking the sample (signature or initials) and the sample collection date.

Note samples for pre-transfusion testing must be handwritten / demand printed labels.
Addressographs cannot be accepted for pretransfusion samples.

	Sample **Note** samples for pre-transfusion testing must be handwritten / demand printed labels	**Request Form**
NHS/CHI/HCS number Except for non-UK residents or unless patient/donor identity is confidential e.g. GUM or deceased organ donor	**Essential where available** Mandated by NHS England since April 2013	**Essential where available** Mandated by NHS England since April 2013
Name First (given) and last (family) name Unless patient/donor identity is confidential e.g. GUM or deceased organ donor	**Essential**	**Essential**
Date of Birth Unless patient/donor identity is confidential e.g. GUM or deceased organ donor	**Essential**	**Essential**
OTDT number for deceased donors only	**Desirable**	**Desirable**
Hospital number	Optional	Optional
Address	Optional	Optional
Sample collection date	**Essential**	**Essential**
Signature of sample collector	**Essential for pre transfusion samples**	Optional
Requesting institution	Not required	**Essential**
Name of requester	Not required	**Essential**
Signature of requester	Not required	**Essential**
Clinical information/test required	Not required	**Highly desirable /** **Essential in some cases**
Sample source e.g. blood, spleen	**Essential if not peripheral blood**	**Essential if not peripheral blood**

1.3 Exceptions

1.3.1 Exception where no further action is required

In the following circumstances no further actions are required as the patient/donor/research participant has been uniquely identified.

Bone marrow registry donors with a unique registry identifier.
Patients or donors whose identity is confidential [e.g. GUM, R&D, Bone Marrow Registry donors with a unique registry identifier or pre-transplant samples].
Samples with only two identifiers (i.e. name and date of birth) taken from potential stem cell donors who are not covered by anonymity are acceptable for testing if they are accompanied by a form that ▪ contains at least three person identifiers **and** ▪ clearly identifies the respective, potential recipient ▪ Identifiers on sample and form must match
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.
Research samples received with a sample specific identifier whose identity is confidential and where it is agreed as part of the study that the requester accepts responsibility for the results

1.3.2 Exceptions where a comment must be made in the report

Samples from the following groups may be accepted; however, a comment must be recorded in the Diagnostics LIMS and on the report to state that NHSBT may not fully accept responsibility for these results see DAT260. A concession need not be raised if **labelling is sufficient to ensure the patient/donor is uniquely identified**.

Minor differences in spelling between form and sample or previous LIMS records when the patient details can be confirmed by an enquiry to the requester or to the NHS Personal Demographic Service. N.B. The enquiry and the outcome must be recorded in the patient record.
Samples with only two identifiers (i.e. name and date of birth) are acceptable for testing if they are accompanied by a form that contains at least three person identifiers. Providing the request for testing is not for transfusion purposes.
Samples with three identifiers but with a test request form with only two of the same identifiers can be accepted if the testing is not for transfusion purposes.

1.3.3 Authorised Concessions

In **exceptional** circumstances samples with inadequate and/or discrepant labelling may be accepted for testing but only with a documented authorised concession [see SOP5713]. A comment must be recorded in the Diagnostics LIMS and on the report stating NHSBT does not accept responsibility for these results [See DAT260].

Investigations where the sample cannot be replaced, or a fresh sample obtained. Examples include but are not limited to: ▪ Samples taken pre transfusion or transplant ▪ Samples taken at specific time periods ○ [e.g. monitoring acute transplant rejection, monitoring antibody removal] ▪ 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 blood components is urgent and repeat samples cannot be supplied in time. 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 referred to a senior member of H&I staff for discussion with the patient's clinician. It may be agreed with the requester that the investigation will begin, but a report will not be issued until the work has been repeated on a new fully labelled sample. If the investigation is too urgent to wait for a repeat sample the original sample may be tested only as an authorised concession and with all necessary documentation. Blood components cannot be labelled as 'compatible' or 'suitable for' but should be issued for transfusion at the discretion of the patient's clinician.

1.4 Deviations

It should be noted that BSCH guidelines restrict the use of pre-printed labels for samples used for pre transfusion 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. Since it is not possible to distinguish reliably between these and *addressograph* labels, they can be accepted only from referring organisations which have informed the NHSBT, 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.

In **exceptional** circumstances, referring organisations may be unable to comply with all sample labelling regulations. Customer Services will organise a documented authorised deviation [see SOP5713] to allow samples to be tested with the understanding that NHSBT cannot be fully responsible for errors made as a result of unacceptable labelling in the referring organisation.
Hospitals and GPs with systems that have been checked and accepted by NHSBT are listed in DAT3727

1.5 Unacceptable for Testing

Samples that are completely unlabelled or with significant discrepancy between sample and request form, are unsuitable for testing in any circumstances.

2. 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: -

- A separated sample may be accepted if it is the only sample available for referral and the sample cannot be repeated e.g. pre- transplant
    - These samples must be subject to a documented authorised concession (see SOP5713)
- Separated samples may be transferred between laboratories within the NHSBT. These would be acceptable as the separation and labelling procedures would be covered by internal operational procedures, including this MPD.

3. Reporting of samples with labelling discrepancies or issues

Where appropriate, standard comments from the Diagnostics LIMS should be used in preference to free text.

3.1 Samples tested under a concession/exception

If a concession has been approved, only those tests for which the concession was raised should be reported. Any further investigation should be carried out on a fully labelled sample. Reference to the concession documentation should be included in the report. Details of the labelling deficiency / discrepancy should be included. Requests for repeat sample(s) should be sent as soon as possible, if appropriate.

3.2 Samples which have not been tested:

Non-tested samples must be recorded in the Diagnostics LIMS and should be reported using standard comments from the Diagnostics LIMS in preference to free text [See DAT260]. Include a request for repeat sample(s) as soon as possible, if appropriate.

Definitions

- **HCS** – (Health and Care) This is the unique patient identifier used in Northern Ireland
- **NHS Number** – The unique identification number assigned to English and Welsh citizens.
- **GUM -** Genito-Urinary Medicine
- **CHI Number** – Community Health Index - The unique identification number assigned to Scottish citizens.
- **OTDT** – Organ and Tissue Donation and Transplantation
- **H&I** – Histocompatibility and Immunogenetics
- **LIMS** – Laboratory Information Management System

Related Documents / References

- **ESD138 -** European Federation for Immunogenetics Standards For Histocompatibility & Immunogenetics Testing, current version
- The Quality and Safety of Organs Intended for Transplantation Regulations, current version
- National Patient Safety Agency Safer Practice Notice /2008/SPN001 Issued: 18 September 2008.
- **ESD121 -** British Committee for Standards in Haematology (BCSH), Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, current version
- **ESD175 -** Management system requirements of laboratories (ISO/IEC 17025 and ISO 15189) and inspection bodies (ISO/IEC 17020), current version
- **NOP 003 -** Packaging, Labelling and Transport of Organs in Deceased and Living Donation and Transplantation
- **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.
- **DAT260 -** H&I Autotext Comments
- **DAT3727 -** Demand Printed Labels - Hospital Acceptance List