<table>
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<th>Title</th>
<th>Directorate of Laboratory Medicine Specimen Acceptance Policy</th>
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<tbody>
<tr>
<td>Version</td>
<td>009</td>
</tr>
<tr>
<td>Reference Number</td>
<td>OPS PROC-067</td>
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**Supersedes:**
- Version 008
- Significant Changes: Harmonisation of adult & paediatric Specimen Acceptance Policies

**Originator or modifier**
- Originated By: M Hynes,
- Designation: CSR Manager, DLM Quality Manager, DLM Operations Manager
- Modified by: J Nelson, A Cartmill
- Designation: DLM Quality Manager, DLM Operations Manager

**Ratification**
- Ratified by: DLM Board
- Date of Ratification: 7th December 2011

**Application**
- All staff

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- Circulated by: M Hynes
- Dissemination and Implementation: Refer to section 11.

**Review**
- Review Date: February 2014
- Responsibility of: Central Specimen Reception Manager

**Date placed on the Intranet:** 20th Feb 2012

**Please enter your EqIA Registration Number here:** 263/11
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1. Introduction

1.1. This policy sets out Central Manchester Foundation NHS Trust’s policy for the acceptance process for specimens requiring analysis by Directorate of Laboratory Medicine. It provides a robust framework to ensure that all specimens are correctly & unambiguously identified.

1.2. A separate policy document describes procedures for Blood Transfusion specimens

1.3. This policy aims to provide an overarching process to specimen rejection to help balance the ‘requirement to process’ against the ‘risk to patient safety’.

2. Purpose

2.1. The purpose of this document is to ensure that the Trust meets best practice to ensure Patient Safety and the effective reporting of Laboratory Medicine results and reports, ensuring compliance with Clinical Pathology Accreditation (UK) Ltd (CPA) standards and the British Committee for Standards in Haematology Guidelines. This document also takes into account other appropriate national guidelines from such as the Royal College of Pathologists, the Association of Clinical Biochemists and the Institute of Biomedical Science.

2.2. The policy applies to all Trust staff and to external organisations that use the Trust’s Laboratory Medicine Services.

2.3. Implementation of this policy will ensure that:
   - Laboratory Medicine specimens are unequivocally identified to a patient
   - Results are reported to the requester at the correct location
A separate policy document describes procedures for Blood Transfusion specimens.

2.4. Non compliance with this policy will result in requests being delayed or rejected

3. Roles and Responsibilities

3.1. The responsibility for requesting a laboratory service/test lies with an authorised and trained practitioner.

3.2. Where the requesting practitioner is not directly able to label specimens and request forms and package them for transportation themselves, these tasks will be considered to have been delegated to a person within the requesting practitioner’s team. However the requesting practitioner has overall responsibility for:-
   - Ensuring that specimens have been labelled according to this policy
   - Ensuring that the request form is completed correctly, in full, according to this policy
   - Ensuring that the specimens are packaged and transported to the laboratory according to the guidance given and relevant legislation in force.
   - Ensuring that where specimens have been rejected, repeat specimens are collected
3.3. It is the responsibility of the person taking the specimen to identify the patient, label the specimen and ensure that the information supplied on the request form and specimen are accurate and match in each case. Trust staff shall adhere to the Trust Patient Identification Policy v4 (RM011)

3.4. Laboratory staff have the responsibility for conducting analyses only on specimens that have been correctly identified.

3.5. Getting it right first time will ensure that there is minimum waste of resources and improved patient safety

4. Labelling of Specimens

4.1. All specimens MUST be clearly and unequivocally identified with a minimum of three key identifiers (see section 7) which must be correct and match the information given on the request form. It is best practice to use more than the minimum.

4.2. Specimen containers must be labelled at the time of collection, with cross-checking to positively identify the patient and ensure patient safety. Pre-labelling of blood collection tubes is poor practice, increases risks of misidentification and is not acceptable.

4.3. Neonatal Specimens

4.3.1. When requesting investigations on new born babies, to prevent specimen rejection the baby’s NHS or hospital number, date of birth, name must be used, not the mother’s details

4.3.2. Request forms and samples must be labelled with the baby’s current details (as on PAS) at the time of sampling. Pre-printed forms with earlier details which have been superseded will not be accepted.

4.3.3. For neonates, three patient identifiers must be used; the surname, DOB & Unique identification number (ie hospital number or NHS number)

4.3.4. For multiple births, the mandatory requirements are surname, DOB, unique identification number (Hospital number) PLUS twin/triplet number

5. Completing Request Forms

5.1. Laboratory Medicine requires the use of the electronic order communication systems wherever possible (eg Trust ward order or Sunquest ICE communications systems), as the system interfaces with PAS and the request form will print with full demographic details.

5.2. Adequate and relevant clinical information must be provided by the requestor. This can be fully electronic. It is a valuable aid in ensuring Patient Safety as Biomedical and Clinical Scientists in the laboratory are trained to be aware of the importance of
relevant clinical information when validating and authorising results, especially when
cumulative records are available. An unexpected test result can highlight the need
for immediate further testing, the need for a result to be communicated urgently or
may indicate the possibility of an incorrectly labelled specimen or request form.

5.3. Adequate clinical detail is essential for laboratories to identify any samples which
require additional Biosafety measures for safe handling and processing of
specimens(Refer to “High Risk Document”)

5.4. Request forms should be signed by the person collecting the specimen. Electronic
signatures are acceptable when using order communication systems.

5.5. Request forms should include the contact details (e.g. bleep number) of a
responsible clinician if this is not the person collecting the specimen.
GP specimens should include the patient address.

6. General requirements

6.1. Patient details on specimen and accompanying request form, including bar codes
where used, must match.

6.2. It is good practice to include the date & time of collection on all specimens and in
some cases it is essential. Multiple specimens taken at different times on a single
patient MUST be labelled on the tube with the time (24 hour clock) when the
specimen is taken e.g. oral glucose tolerance test. The request form should indicate
that there are multiple specimens with the times recorded (24 hour clock) and the
times should match the times written on the tubes in order to preserve the sampling
sequence.

6.3. The procedure for correct identification of specimens requires that each specimen
and the request form are kept together in a single bag for inspection, with the
request form in the side pocket and specimen in the sealed section. In the event of
leakage only the single patient’s specimen(s) will be affected. Do not place
specimens from more than one patient in the same bag.

6.4. Sequential specimens on the same patient, e.g. glucose tolerance test, may be
transported in one bag with the request form. Samples which are unstable e.g.
insulin, free fatty acids should be sent immediately to the laboratory. Each
specimen should be identified with a time in addition to the other items.

6.5. Referring laboratory specimens
Sub-samples (aliquots) of a primary specimen that are sent to or received from
referring/al laboritories should be labelled with the forename, surname and date of
birth in addition to a tube number.
7. Mandatory Labelling Criteria for Specimens and Request Forms

The mandatory key identifiers are three of the following:
- Unique identification number (e.g., hospital number)
- Forename (First Name)
- Surname (Family Name)
- Date of birth

A single identifier may be used in exceptional circumstances for instance during a major incident, or unknown A&E patient. This must be a **unique** identification number.

The key points are summarised in the table on page 8.

7.1. Blood Transfusion requirements:

The Hospital transfusion team recommends best practice outlined by the BCSH guidelines. Blood transfusion specimens require additional information; CMFT staff, please see the Trust Transfusion Policy. GPs, please contact Blood Transfusion for guidance. Addressograph labels are NOT acceptable, specimens MUST be handwritten.

7.2. Histopathology requirements

Specimens for diagnostic histopathology **always** require a hospital number. Due to the difficulty in repeating a tissue specimen different criteria are used in Histopathology, additional information is available on the laboratory website. Specimens from High Risk patients **MUST** be identified (Refer to the Paediatric Histopathology User Guide or the Adult Histopathology User Guide as appropriate).

7.3. Cytopathology Requirements

Cervical Cytology
The department applies a Zero Tolerance Policy for cervical specimens as detailed in the British Society for Clinical Cytology (BSCC) Recommended Code of Practice for Laboratories Participating in the UK Cervical Screening Programme (2010). Details of specimen acceptance may be found on the laboratory website in the document ‘Information pack for Sample Takers’

Non-gynaecological Cytology
The department has additional requirements detailed in the policy ‘Manchester Cytology Centre Non gynaecological cytology service User Manual – January 2011’, available on the laboratory website

Synovial Fluid Analysis Service
Requirements for specimen acceptance are available in the document ‘Manchester Cytology Centre Synovial fluid analysis service User Manual – April 2011’ which is viewable on the laboratory website.
<table>
<thead>
<tr>
<th>Mandatory Labelling Requirement</th>
<th>Action by Laboratory if requirement not met</th>
</tr>
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<tbody>
<tr>
<td><strong>Specimens MUST</strong> be labelled with 3 unique identifiers from</td>
<td>No analysis will be performed. The event will be reported as an incident on Ulysses</td>
</tr>
<tr>
<td>• unique identification number (eg hospital number)</td>
<td>Where the specimen is repeatable/reproducible, no analysis will be performed and the specimen will be discarded.</td>
</tr>
<tr>
<td>• Surname</td>
<td>Where the specimen is unrepeatable/unreproducible, the risk to the patient of rejection of the specimen must be weighed against the risk of acceptance of a wrongly labelled specimen, local procedures will be followed.</td>
</tr>
<tr>
<td>• Forename</td>
<td>Laboratory Medicine will accept no responsibility for specimens analysed which initially failed to meet the acceptance criteria and will issue a disclaimer on such reports.</td>
</tr>
<tr>
<td>• Date of birth</td>
<td></td>
</tr>
<tr>
<td>The <strong>request form</strong> data <strong>MUST</strong> match the above information on the <strong>specimen</strong> or be labelled with another suitable unique identifier.</td>
<td></td>
</tr>
<tr>
<td>Drug administered, dose, time of last dose, time of specimen in relation to dose for therapeutic drug monitoring</td>
<td></td>
</tr>
<tr>
<td><strong>Multiple specimens</strong> taken at different times on a patient <strong>MUST</strong> be labelled on the specimen container with the time (24 hr clock) when the specimen is taken. The <strong>request form</strong> should be labelled accordingly.</td>
<td></td>
</tr>
<tr>
<td>See section 8.1 – 8.3 for additional department specific requirements</td>
<td></td>
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</tbody>
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The **request form** data **MUST** match the above **specimen information**
- Surname
- Forename
- Date of birth/unique identification number

**Request forms SHALL** also contain:
- the patient’s location/destination for the report (or a location code)
- Tests required
- Name of Consultant or GP
- Name of the requester and contact number (bleep or extension)
- Patient gender
- Date and time of specimen collection
- Anatomical site and type of specimen
- (where relevant)
- All **relevant clinical information**
- Patient address for GP requests

| A lack of patient or specimen information may result in the laboratory not conducting the analysis/examination |
| Examples could include: |
|  • no swab site indicated |
|  • no dates and times of sampling |
|  • no clinical details given |
|  • location for report delivery not given |
| It may not be possible to issue a report or to interpret results. |
| Appropriate comments will be made on the report where this can be issued. |

**Good practice demands the provision of more than the minimum of information.**

The use of NHS number is becoming more prevalent and will be considered as an essential identifying criterion in future policy. The DLM is currently reviewing ways in which this can be implemented.

**Anonymous/Uniquely Identified Specimens and Requests**

In certain circumstances, patient identification details are intentionally hidden or substituted with particular ID numbers (eg. Sexual Health, Clinical trials, donor specimens) In such instances, a properly coded identifier must be used in place of the patient surname & forename.
8. **Rejection of Specimens**

Specimens will be rejected by Laboratory Medicine if they do not comply with the criteria detailed above. The final decision to accept or reject a specimen rests with Laboratory Medicine.

The process for rejection of specimens is as follows:

8.1. **Repeatable/reproducible specimens that do NOT meet the mandatory requirements (Not Blood Transfusion*)**

Laboratories will not process unlabelled or mislabelled specimens which are reproducible or repeatable.

Local laboratory procedures will be followed for issuing a report and notifying requesting clinician/ward that repeat specimen collection is necessary.

For regulations applying to Blood Transfusion specimens please refer to the Blood Transfusion Policy.

8.2. **Unrepeatable/unreproducible specimens that do NOT meet the mandatory requirements (Not Blood Transfusion*)**

In a number of circumstances, it would not be possible to repeat the collection of the specimen. The laboratory would classify these as ‘Unrepeatable/unreproducible specimens’ or unique specimens. Please note in general that specimens of Blood would not normally be classified as ‘Unrepeatable’.

For regulations applying to Blood Transfusion specimens please refer to the Trust Blood Transfusion Policy.

**Examples of unrepeatable/unreproducible specimens would include:**
- All histology and non-gynae cytology specimens.
- Bone marrow, CSF specimens, tissues and other fluids obtained by invasive procedures (NOT blood specimens).
- Dynamic function test specimens.
- Post mortem specimens where recollection is not possible
- Specimens collected in an acute situation where the clinical status of the patient may have changed e.g. drug overdose, hypoglycaemic episode, commencing anti-coagulant therapy, mast cell tryptase.
- Specimens for culture from normally sterile sites where antibiotic therapy has been subsequently started e.g. blood cultures

(This list is not intended to be exhaustive)

**Laboratory procedure when acceptance criteria are not met in the case of unrepeatable/unreproducible specimens.**

The specimen may only be processed once the risk of accepting an incorrectly labelled specimen has been evaluated against and considered to be greater than
the risk of potential harm to the patient, by a senior member of the laboratory staff in conjunction with the Clinician (or responsible deputy) in charge of the patient.

The event will be reported as an incident on Ulysses

Patient reports will be identified clearly with the non-compliance and that correct patient identification cannot be guaranteed


9.1. The best way to promote equality is to make sure it is embedded into all procedural documents. All Trust procedural documents must be inclusive. It is important to address, through consultation, the diverse needs of our community, patients, their carers and our staff. This will be achieved by working to the values and principles set out in the Trust’s Equality, Diversity and Human Rights Strategic Framework. The Trust is committed to ensuring all new procedural documents and functions are impact assessed and monitored in accordance within the letter and the spirit of the law regarding equality. The Trust’s Equality, Diversity and Human Rights Strategic Framework can be found on the Trust’s Intranet or from the Service Equality Team.

9.2. The Trust is committed to ensuring that no person or group of persons will be treated less favourably than another person or group of persons and will carry out our duty with positive regard for the protective characteristics, as outlined, in the Equality Act 2010. However, we also recognised that some people experience disadvantage due to their socio economic circumstances, employment status, class, appearance, responsibility for dependants, unrelated criminal activities, being HIV positive or with AIDS, or any other matter which causes a person to be treated with injustice. The Trust will also ensure that all services and actions are delivered within the context of current Human Rights legislation. Staff and others with whom we work, will adhere to the central principles of the Human Rights Act (1998).

9.3. The Service Equality Team (SET) has carried out an assessment. On this policy to determine the impact across the following equality dimensions: age, disability, gender (including transsexual / transgender), race, religion and belief, sexual orientation socio economic and patient experience. Equality and Diversity assessment (263/11)

10. Consultation, Approval and Ratification Process

The document was sent to the following groups for review:
- DLM Board
- Lead Nurses/Ward Managers and Directorate Managers via the Divisional Manager for Clinical and Scientific Services

The Policy will be ratified by the DLM Board in December 2011

11. Dissemination and Implementation

The guideline will be placed on the Laboratory Medicine website and appear on the latest Trust news and Team brief.
The information will be disseminated by the Lead Nurses/Ward Managers and Directorate Managers via the Divisional Manager for Clinical and Scientific Services.

12. Monitoring Compliance of Specimen Acceptance and Rejection

Specimen acceptance failures can involve many factors from individual staff requiring further training to a communication problem with an area/clinic.

It is necessary to record the SAP failures to find trends and possible solutions to multiple SAP failures.

Recording the information needs to be done in a way which allows trend analysis. This can be done on paper or via an electronic system. See local procedures.

Trends showing a problem with a user can be reported to the user in a constructive way, with the laboratory liaising with the user to solve problems. For example: producing specific address labels for external users, or tours around the laboratory, at liaison and MDT meetings.

The laboratory should keep the user guide as up to date as possible showing specific details such as transport media, labelling guides and time sensitive tests.

13. References and Bibliography

Institute of Biomedical Sciences: (July 09) Professional Guidance: Patient Sample and Request Form Identification Criteria www.ibms.org/publications

The Good Laboratory Practice Regulations 1999 (SI 1999 3106)
The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 (SI 2004 No. 994)

BCSH Guidelines
• BCSH Guideline on Administration of Blood Components (2009)

Royal College of Pathologists (May 2005)
• May 2005 Code of Practice for Haematology departments
• May 2005 Code of Practice for Histopathology
• May 2005 Code of Practice for Clinical Biochemistry

CMFT Trust Blood Transfusion Policy v7 (July 2010)

CPA Standards for Medical Laboratories
• Version 2.02 (Nov 2010)

14. Associated Trust Documents

CL 007 Blood Transfusion Policy
RM011Trust Patient Identification Policy v4