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Table 1: MFT Sample Acceptance Criteria for referred samples

Mandatory Labelling Requirement
Samples **MUST** be labelled with a minimum of four of the five identifiers below: • Unique ID e.g. NHS/district/hospital number • Surname • Forename • Date of birth • External lab number
For any sample received with a request form, if there is a discrepancy between the forename, surname, date of birth or external lab number provided, the sample will be rejected irrespective of the number of identifiers provided.
Multiple samples taken at different times on a patient **MUST** be labelled on the sample container with the time (24 hr. clock) when the sample is taken.
If a request form is required, then the request form data MUST match the above sample information • Unique ID e.g. NHS/district/hospital number • Surname • Forename • Date of birth • External lab number **Request forms MUST** also contain: • the patient's location/destination for the report • Tests required • Patient gender • Date and time of sample collection • Anatomical site and type of sample (where relevant) • **All relevant clinical information e.g. foreign travel** A lack of patient or sample information may result in the laboratory not conducting the analysis / examination. Appropriate comments will be made on the report where this can be issued.
In certain circumstances, patient identification details are intentionally hidden or substituted with particular ID numbers (e.g. Sexual Health, Clinical trials, donor specimens), in such instances, a properly coded identifier must be used in place of the patient's last name & first name.

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

1. Introduction

This policy sets out Manchester University NHS Foundation Trust's policy for the acceptance process for samples requiring analysis by Division of Laboratory Medicine. It provides a robust framework to ensure that all samples are correctly and unambiguously identified.

This policy aims to provide an overarching process to sample rejection to help balance the 'requirement to process' against the 'risk to patient safety'.

2. Purpose

The purpose of this document is to ensure that the service user meets best practice to ensure patient safety and the effective reporting of Laboratory Medicine results and reports, ensuring compliance with ISO 15189 standard clause 5.4.6.

This document also considers other appropriate national guidelines such as the Royal College of Pathologists, the Association of Clinical Biochemists and the Institute of Biomedical Science.

The policy applies to all users of the Trusts Division of Laboratory Medicine Services.

Implementation of this policy will ensure that:

- Samples are unequivocally traceable/identified to a patient
- Results are reported to the requester at the correct location

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

3. Roles and Responsibilities

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

Where the requesting practitioner is not directly able to label samples 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 samples have been labelled according to this policy
- Ensuring that the request form where used is completed correctly, in full, according to this policy
- Ensuring that the electronic requesting of a service/test for this patient is correct
- Ensuring that the samples are packaged according to the P650 packing instructions for diagnostic samples and transported to the laboratory according to the guidance given and relevant legislation in force
- Ensuring that where samples have been rejected, repeat samples are collected as appropriate

It is the responsibility of the person taking the sample to identify the patient, label the sample and ensure that the information supplied on the request form/electronic request and sample are accurate and match in each case.

Laboratory staff have the responsibility for conducting analyses only on samples that have been correctly identified and can be unequivocally traceable to a patient.

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

4. Procedure

4.1 Labelling of Samples

All samples **MUST** be clearly and unequivocally identified with a minimum of four key identifiers (see table 1) which must be correct and if a request form is required, the information on the sample MUST match the information given on the request form. It is best practice to use more than the minimum key identifiers.

All printed sample ID labels must be fully readable i.e. no information is missing/unreadable due to printer alignment or label damage. It is the responsibility of the service user to ensure all four key identifier all fully readable before sending the sample to MFT.

4.2 Completing Request Forms

Adequate and relevant clinical information must be provided by the requestor. This can be written on a request form or fully electronic. It is a valuable aid in ensuring patient safety as Consultants, 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. Adequate and relevant clinical details such as foreign travel is also a requirement for Microbiology samples to aid in the identification of High risk samples which require additional biosafety measures for safe handling and processing.

Correct location of the patient is essential as 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 sample or request form.

4.3 General requirements

Patient details on sample and accompanying request form (if required), **MUST** match.

Multiple samples taken at different times on a single patient **MUST** be labelled on the tube with the time (24 hour clock) when the sample is taken e.g. oral glucose tolerance test.
Drug administered, dose, time of last dose, time of sample relation to dose for therapeutic drug monitoring must be provided.

The procedure for correct identification of samples requires that each sample and the request form (if required) for each patient are kept together in a single bag for inspection.

Sequential samples on the same patient, e.g. glucose tolerance test, may be transported in one bag.

5. Specific Departmental requirements

5.1. Histopathology requirements

Samples from High Risk patients **MUST** be identified (Refer to the Paediatric Histopathology User Guide or the Adult Histopathology User Guide as appropriate)

Specimens must be rejected if only the lid and not the side of the specimen bucket/pot is labelled.

Specimen site and specimen type are required for all samples.

Histopathology require patient identification on sexual health and donor specimens. The following information should be flagged if relevant.

- Any danger of infection
- If patient on HSC 205 pathway
- If patient is NHS or Private

Unless there is prior agreement in place, users should confirm with clinical lead that MFT will accept a referral before sending it.

5.2. Cytopathology Requirements

Cervical Cytology
The department applies a Zero Tolerance Policy for cervical screening samples as detailed in the British Association for Cytopathology (BAC) Recommended Code of Practice for Laboratories Participating in the UK Cervical Screening Programme (2017).

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 sample acceptance are available in the document ‘Manchester Cytology Centre Synovial fluid analysis service User Manual – April 2011’ which is viewable on the laboratory website.

5.3. Haematology

Coagulation
Samples for coagulation must arrive in original sample vial within 4hours of venepuncture or separated and frozen. Frozen samples arriving defrosted will be rejected.

6. Rejection of Samples

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

For repeatable/reproducible samples that do NOT meet the mandatory requirements:

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

Local laboratory procedures will be followed for issuing a report and notifying requesting laboratory that repeat sample collection is necessary.

For unrepeatable/unreproducible samples that do **NOT** meet the mandatory requirements:

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

Examples of unrepeatable/ unreproducible samples would include:

- All histology and non-gynae cytology samples.
- Bone marrow, CSF samples, tissues and other fluids obtained by invasive procedures (NOT blood samples).
- Dynamic function test samples.
- Post-mortem samples where recollection is not possible
- Samples 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.
- Samples 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 samples:

- The sample may only be processed once the risk of accepting an incorrectly labelled sample 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.

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

7. Package and transportation of samples

Specimens must be packaged according to P650 instructions with a UN3373 diamond point label – Biological Substance, Category B.

Please note instructions P650 requires three layers of packaging:

- Primary container (e.g. universal tube, vial)
- Secondary container (e.g. specimen bag)
- Outer packaging (e.g. rigid transport box).

The primary sample must be individually bagged in a secondary bag and sealed. If the sample is liquid, enough absorbent material must be added to the secondary bag to absorb a potential spillage of the sample. The request form must be placed in the specimen bag's separate pouch.

Specimens must then be placed in a rigid box and closed. The box must comply with Transport Regulations. The outside must be clearly labelled Biological Substance Category B, with a UN3373 diamond label. The laboratory address should be clearly written.

If a sample is sent by post, please note that Royal Mail will only carry UN3373 Diagnostic Specimens if they are packed following Packaging Instruction P650 and:

- Are sent by first class post or Special Delivery
- The packet is marked with the sender's name, telephone number and address

8. References and Bibliography

Institute of Biomedical Sciences: (2016) 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)

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

IATA Guidance document – Infectious substances. 53rd Edition (2012) of the IATA Dangerous Goods Regulations (DGR).