Manchester University
NHS Foundation Trust

DOCUMENT CONTROL PAGE

Title:	Laboratory Medicine Sample Acceptance Policy
Version:	13
Supersedes:	Division of Laboratory Medicine Sample Acceptance Policy Version 12
Application:	All MFT

Originated / Modified By:	Andrew Sayce
Designation:	DLM Quality Lead
Ratified by:	DLM Board & CSS Q&S Committee
Date of Ratification:	DLM Board: 01/05/2024 CSS Q&S Committee: 14/05/2024

Issue / Circulation Date:	01/07/2024
Circulated by:	Andrew Sayce
Dissemination and Implementation:	Refer to Section 11
Date placed on the Intranet:	01/07/2024

Planned Review Date:	14/05/2027
Responsibility of:	Andrew Sayce

Minor Amendment (If applicable) Notified To:	
Date notified:	

EqIA Registration Number:	2024-109

Table of Contents

1 Introduction

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

2 Purpose

The purpose of this document is to ensure that the Trust meets best practice to reduce risk to patient safety and the provide effective reporting of Laboratory Medicine results and reports.

This policy applies to all Trust staff and departments that use the Division of Laboratory Medicine services.

Implementation of this policy will ensure that:

- samples sent to laboratory medicine are unequivocally traceable/identified to the right patient.
- the right 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.

The requesting practitioner has overall responsibility for: -

- ensuring that the requesting of a service/test for this patient is correct.
- ensuring that where samples have been rejected, repeat samples are collected as appropriate.

The person collecting the sample has responsibility for: -

- adhering to the MFT Patient Identification Policy
- ensuring that the patient has given valid consent.
- 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 samples are packaged and transported to the laboratory according to the guidance given.

Laboratory staff have the responsibility for conducting analyses only on samples that have been correctly labelled and can be unequivocally traceable to the right patient. This procedure must only be performed by competent staff.

4 Sample Labelling Requirements

4.1 Mandatory Sample Labelling Requirements

Sample labelling requirements. Samples must be labelled with four patient identifiers: • MRN / NHS number • Surname • Forename • Date of birth Only one barcode label per sample. The label must be attached to the correct sample container type. Legal name must be used, not preferred name
Request form (digital or paper) requirements. The request form must contain: • the patient's location/destination for the report • name of Consultant / GP • sex • date and time of sample collection. • tests required. • anatomical site and type of sample (where relevant) • all relevant clinical information
Electronic ordering must be used were available
See section 7 for department specific specimen acceptance requirements

4.2 Transfusion Samples

This policy does not cover transfusion samples. For details on the minimum requirements for sample acceptance and ordering for MFT Hospital Transfusion Laboratories see document Hospital Transfusion Laboratory: Sample Acceptance and Ordering Policy on the MFT policy hub.

4.3 Sample labelling.

Section 4.1 describes the mandatory requirements for labelling samples, at a glance. Further requirements are detailed below.

All samples must be clearly and unequivocally identified with a minimum of four key patient identifiers. It is best practice to use more than the minimum number of key identifiers.

If a request form is required, the information on the sample must match the information given on the request form.

Sample containers must be labelled at the time of collection, with cross-checking to positively identify the patient and ensure patient safety. Pre-labelling of sample collection

containers increases the risk of misidentification and is not acceptable.

Once the sample has been collected the sample collection must be documented in Epic. This will prevent delays in reporting and ensure the report is directed to the correct clinical team. To ensure the order is sent electronically to the laboratory system, staff collecting a sample must document the specimen collection in Epic by scanning the container label once the sample has been successfully collected.

If a sample requires labelling by hand for any reason, the MRN (MFT) or NHS number (GP) must be used.

Printed sample ID labels must be fully readable i.e. no information missing or unreadable due to printer misalignment or label damage. It is the responsibility of the person collecting the sample to ensure all four key identifiers are legible before sending the sample to the laboratory.

Correct label orientation on the sample ensures automation of sample processing, where available, and will prevent delays in reporting. See section 8 on how to avoid common errors in sample labelling.

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. for oral glucose tolerance test.

4.3.1 Neonatal Sample Requirements

When requesting investigations on new-born babies, the baby's MRN, date of birth and name must be used, not the mother's details. Request forms (if required) and samples must be labelled with the baby's current details at the time of sampling. Handwritten forms with earlier details which have been superseded in Epic will not be accepted.

For neonates who have not yet been given a forename, Baby is acceptable as the forename identifier. As soon as the baby has a forename, this must be used.

For multiple births, the mandatory requirements are surname, DOB, MRN, plus twin/triplet number.

For some national testing schemes for neonates, the NHS number is also often required.

4.4 Request forms.

Section 4.1 describes the mandatory requirements for request forms, at a glance. Further requirements are detailed below.

Epic must be used for requesting laboratory tests within MFT. Using paper request forms is a risk to patient safety as it delays processing, is open to transcription error and can prevent results being directed to the correct clinician.

Electronic barcoded labels must be printed at the time of sampling and generated from the patient's wristband where possible. This ensures it is the correct patient who has the correct sample taken, preventing wrong blood in tube (WBIT) incidents.

It is important that the ward/clinic location is correct as critical results may need to be

communicated to the patient's clinical team.

For therapeutic drug monitoring, drug administered, dose, time of last dose and time of sample in relation to dose must be provided.

4.5 Clinical Information

Adequate and relevant clinical information must be provided by the requestor. It is a valuable aid in ensuring patient safety as laboratory staff rely on this information when checking and authorising results.

Details of recent foreign travel is an essential requirement for Microbiology samples, to aid in the identification of high risk samples which require additional biosafety measures for safe handling and processing.

4.6 Requesting Tests During IT Downtime

During Epic downtime, the downtime request forms must be used. There is no change in specimen acceptance criteria during downtime. Master copy downtime forms can be found in the red downtime folders which should be available in all wards and clinics. Multiple copies of these forms should be kept in the red folder in preparation for a downtime.

4.7 Packaging and Sending Samples

If samples from different patients are received in one bag, the samples will be rejected due to the risk that the samples were incorrectly labelled.

Samples from the same patient for Biochemistry, Haematology and Immunology can be sent in the same bag but must not be mixed with any other discipline samples. Failure to follow this can result in a significant delay in the sample reaching the correct department and could lead to the samples being rejected.

If a request form is required, it must be securely attached to the appropriate sample bag.

Samples which are unstable e.g. insulin, free fatty acids etc, should be sent immediately to the laboratory.

5 Rejection of Samples

To ensure that samples are accepted and processed within the required timeframe, sample containers must be labelled as described in this policy. Samples that do not meet the requirements will not be processed. When a sample is rejected this is recorded in the patients record in Epic. It is then the responsibility of the patient's medical team to contact the laboratory if they wish to pursue the sample further. If they do not pursue the sample, it is assumed that they have repeated the request or decided not to repeat it.

5.1 Sample Acceptance Exceptions

There may be exceptional circumstances where the risk of harm to a patient from rejecting a clinically critical or irreplaceable sample is greater than the risk of harm from accepting a sample that does not comply with the requirements of this policy. Such a sample would only be processed once the risk of accepting it has been evaluated and considered to be

less than the risk of harm if the sample was rejected. This assessment must be performed by a senior member of the laboratory staff in conjunction with the patient's clinician (or responsible deputy).

If the sample is accepted, then the result report will indicate the nature of the labelling problem and advise caution when interpreting the results. The patient's clinical team will assume responsibility for accepting the results on the incorrectly labelled sample.

It is not possible to provide a list of clinically critical samples. The following are some examples of irreplaceable samples.

- 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.
- all histology and non-gynae cytology samples
- bone marrow, CSF samples, tissues and other fluids obtained by invasive procedures.
- samples for culture from normally sterile sites where antibiotic therapy has been subsequently started.

6 Anonymous and Unknown Patients

6.1 Unknown Patients

The MFT policy - Temporary Identification Criteria for Unknown or Unidentified Patients details the requirements for temporary identification to ensure the patient is uniquely identifiable and fulfils the specimen acceptance policy minimal identification criteria.

6.2 Major Incident Patients

During a major incident, patients presenting through ED will be allocated a Major Incident casualty number. Refer to the MFT Major Incident Plan on the EPRR pages on the intranet.

6.3 Anonymous Patients

In certain circumstances, patient identification details are intentionally hidden or substituted with particular ID numbers (e.g. sexual health, clinical trials, donor samples). In place of full patient identification, a properly coded identifier must be used.

7 Specific Laboratory Requirements

7.1 Blood transfusion

This policy does not cover transfusion samples. For details on the minimum requirements for sample acceptance and ordering for MFT Hospital Transfusion Laboratories see document Hospital Transfusion Laboratory: Sample Acceptance and Ordering Policy on the MFT policy hub.

7.2 Blood Sciences Automation

With the introduction of auto-receipt within the blood sciences laboratories, a readable barcode may be sufficient for requests made in Epic. This is dependent on fully functional IT and laboratory systems and will not be applicable during IT downtime.

7.3 Histopathology

All histopathology specimens must be accompanied by a paper request form.

Histopathology pots should be labelled with Epic labels. Epic generates one histology label for each pot. Each label contains patient demographics and must be placed on the side of the pot and not the lid.

Coroner post-mortem cases do not allow the use of printed labels therefore all samples will be handwritten. If the patient does not have an MRN, the NHS number or post-mortem case 'X' number can be used as the unique identifier.

Samples from High-Risk patients must be identified. Refer to the Paediatric Histopathology User Guide or the Adult Histopathology User Guide on the DLM pages of the MFT intranet.

7.4 Cytopathology

7.4.1 Cervical Cytology

The British Association of Cytology (BAC) recommended code of practice for cytology laboratories participating in the UK cervical screening programmes states, 'There should be a cervical screening programme specific or local sample acceptance policy conforming to UKAS ISO 15189 standards which outlines minimum patient identifiers; it should provide guidance on dealing with rejected samples.'

A link to the programme specific guidance referred to above detailing Sample Acceptance for cervical cytology is detailed here.

7.4.2 Non-Gynaecological Cytology

The department has additional requirements detailed in the policy 'Manchester Cytology Centre Non gynaecological cytology service User Manual, available on the laboratory website.

7.4.3 Synovial Fluid Analysis Service

Requirements for sample acceptance are available in the document 'Manchester Cytology Centre Synovial fluid analysis service user manual' which is viewable on the laboratory website.

7.5 Microbiology

Requests must state recent history of foreign travel in the clinical details. This determines the way the laboratory processes the sample. Failure to follow this can result in a significant delay in the sample reaching the correct department section. This could lead to delay in results and may put laboratory staff safety at risk.

Requests must state whether the patient has history of intravenous drug use (IVDU). This impacts the way the laboratory processes the sample.

Please access the MMMP website which outlines the requirements and contact details for Microbiology.

7.6 Mycology

Requests must state recent history of foreign travel in the clinical details. This determines the way the laboratory processes the sample. Failure to follow this can result in a significant delay in the sample reaching the correct department section. This could lead to delay in results and may put laboratory staff safety at risk.

Please access the MRCM website which outlines the requirements and contact details for Mycology.

8 Avoiding common errors

Many patient samples are rejected every day because of sample collection or labelling errors. This can lead to delays in treatment and cause patient harm. The following sections highlight some of the most common errors.

8.1 Sample collection errors.

- **Incorrect sample container -** In some laboratories this is the number one reason for sample rejection. Refer to Epic or the Division of Laboratory Medicine pages on the intranet for guidance on the correct sample type for each test.
- **Clotted sample -** Blood samples must be gently mixed immediately after collection to ensure any anticoagulant or preservative in the tube mixes fully with the sample.
- **Insufficient sample –** Sufficient sample must be provided for the requested tests. Some tests require the sample container to be filled precisely to the fill line. Refer to Epic and the Division of Laboratory Medicine pages on the intranet for guidance.
- **Haemolysed sample –** Common causes include: prolonged tourniquet application, traumatic venepuncture, insufficient filling of the container, over-vigorous sample mixing, and delays in sending samples to the laboratory.
- **Old sample –** Samples must be processed by the laboratory within a defined timeframe to avoid sample degradation. This timeframe is dependent on the tests requested. To avoid samples being rejected they should be sent to the laboratory as soon as possible following collection.
- **Sample leaked –** if a sample leaks from its container into the sample bag during transport then it may not be possible to process the sample. Ensure container lids are securely fastened.

8.2 Sample labelling errors.

The Division of Laboratory Medicine has collated the main issues associated with labelling of sample tubes with barcodes that lead to a delay in result provision or rejection of samples by the laboratory. This can be found on the Trust intranet page under Laboratory Medicine.

Ensure you have complied with the following before sending your samples to the laboratory:

- Ensure the correct barcode is attached to the correct sample. Laboratory Medicine staff are unable to remove barcodes or reprint barcodes. Failure to do this will result in sample rejection.
- Attach the barcode vertically and not horizontally. The barcodes are read by the analysers in the laboratory, and they are unable to read anything other than a vertical barcode.
- Only attach one barcode per sample.
- Care should be taken not to smudge/damage the barcode label and ensure it has not been cut off and therefore missing important sample information as it may fail the sample acceptance policy and be rejected. Smudged labels cannot be read by the laboratory analysers.
- If the sample requires a request form, please ensure all sections are completed and the form is sent with the sample.
- If after printing the electronic sample barcode, a decision is made not to take a sample from the patient, then the barcode should be discarded so as to prevent it being accidently used for another patient.
- Avoid covering the sample viewing window. Place the electronic sample barcode over the container label as laboratory staff may need to visually inspect the sample.

9 Equality Impact Assessment

<table>
<tr><td colspan="4">Equality Impact Assessment
Please record the decision whether the policy, service change or other key decision was assessed as relevant to the equality duty to:
• Eliminate discrimination and eliminate harassment.
• Advance equality of opportunity
• Advance good relations and attitudes between people</td></tr>
<tr><td>Not relevant</td><td>X</td><td>Relevant</td><td></td></tr>
<tr><td colspan="2">Where the decision was NOT RELEVANT, please record the reason for the decision below.
• The policy has an existing Equal registration.
• Minimal changes to the policy, mostly updates to system names and improvement of the lay out. No change to sample labelling requirements.</td><td colspan="2">Where the decision was RELEVANT, please record details of the outcome of the full impact assessment and summarise the actions that will be taken to eliminate or mitigate adverse impact, advance equality, or justification for the impact.</td></tr>
<tr><td colspan="2">Please enter the EqIA registration Number:</td><td colspan="2">2024-109.</td></tr>
</table>

10 Consultation, Approval and Ratification Process

Division of Laboratory Medicine Board: ratified on 01/05/2024 CSS Quality and Safety Board:

11 Dissemination and Implementation

Dissemination

Updated policy replaces the previous revision on the MFT Policy Hub.

Implementation

Implementation of Trust approved procedural documents.

Minimal changes to the specimen acceptance requirements. No specific implementation required.

The following will be monitored for compliance:

The Division of Laboratory Medicine will monitor compliance with this policy. Any trends or problem areas will be identified and escalated.

12 References and Bibliography

Institute of Biomedical Sciences: (March 2016) Professional Guidance: Patient Sample and Request Form Identification Criteria

The Good Laboratory Practice Regulations 1999 (SI 1999 3106)

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

ISO 15189:2022 Medical laboratories - Requirements for quality and competence

13 Associated Trust Documents

Hospital Transfusion Laboratory: Sample Acceptance and Ordering Policy Trust Patient Identification Policy

Policy to Consent for Examination or Treatment

Policy for Requesting, Review and Actioning of Diagnostic Test Results