DOCUMENT CONTROL PAGE	
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Author	Originated / Modified By: Aatar Hashmi/Andrew Sayce Designation: Central Specimen Reception Manager/DLM Quality Manager
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Table 1: Sample acceptance criteria for MFT (Oxford Road Campus, Trafford and Wythenshawe)

Mandatory Labelling Requirement
Samples MUST be labelled with four unique identifiers which are as follows: • District Number / NHS number • Surname • Forename • Date of birth Transfusion only – handwritten, signed and dated If this information is not provided, no analysis will be performed. The event will be reported as an incident on Ulysses if appropriate.
Date and time of sample collection **Must** be provided to support sample validity
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.
See section 6 for additional department specific requirements
Electronic ordering must be used were available unless there is downtime, to reduce manual forms and associated transcription risks
The **request form (if required)** information **MUST** match the information on the **sample.** **Request forms MUST** also contain: • the patient's location/destination for the report (or a location code) • Tests required • Name of Consultant or GP • Patient sex • Date and time of sample collection • Anatomical site and type of sample (where relevant) • **All relevant clinical information** • For Blood Transfusion – Form and sample **MUST** be signed by person collecting sample If the information is not provided where the sample is repeatable/ reproducible, no analysis will be performed, and the sample will be discarded. Where the sample is unrepeatable/ unreproducible, the risk to the patient of rejection of the sample must be weighed against the risk of acceptance of a wrongly labelled sample, local procedures will be followed. Laboratory Medicine will accept no responsibility for samples analysed which initially failed to meet the acceptance criteria and will issue a disclaimer on such reports.

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 Trust 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 and the British Committee for Standards in Haematology Guidelines for administration of blood products and Guidelines on Pre Transfusion Compatibility Procedures in Blood Transfusion Laboratories.

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 blood Safety and Quality regulations 2005 and Safer Practice Notice 14, Right Patient, Right Blood.

The policy applies to all Trust staff and departments that use the Trusts Division of Laboratory Medicine Services.

Implementation of this policy will ensure that:

- Laboratory Medicine 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.

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 taking the sample has 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 samples are packaged and transported to the laboratory according to the guidance given and relevant legislation in force

  Trust staff must adhere to the Trust Patient Identification Policy, RM011.

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

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. Transfusion have additional specific requirements which can be seen in Section 6.2.

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 number of key identifiers.

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 tubes/sample tubes and pots increases risks of misidentification and is not acceptable. If a sample requires labelling by hand for any reason, the district number (MFT) or NHS number (GP) must be used. The field on the sample container label may refer to this as either ‘district no.’ or ‘ref. no.’ depending on the container type.

To ensure all samples are processed, printed sample ID labels must be fully readable i.e. no information missing or unreadable due to printer alignment 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 possible and will not delay turnaround time. Examples can be found in section 8.

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 should be provided.

Neonatal Sample Requirements

When requesting investigations on new-born babies, to prevent sample rejection the baby’s district number, 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 on ICE / EPR will not be accepted.

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

For multiple births, the mandatory requirements are surname, DOB, District number PLUS twin/triplet number.

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

4.2 Completing Request Forms

Laboratory Medicine requires the use of the electronic order communication systems wherever possible. The system interfaces with the Trust patient administration system and therefore the request form and sample label will print with full demographic and request details. Transfusion have additional specific requirements which can be seen in Section 6.2.

Electronic barcoded labels must be printed at the time of sampling and generated the patient's wristband where possible. This ensures that the time on the sample is the time of collection and not the time the request was made and importantly that it is the correct patient who has the correct sample taken, preventing 'wrong blood in tube (WBIT) incidents.

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 Clinical Information

Adequate and relevant clinical information must be provided by the requestor. 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.

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.

Table 2. Sample/Form requirements for Oxford Road Campus and Trafford ICE

Service	ICE Labels	ICE Paper Request Form	Handwritten Bottles	Handwritten Forms
Blood Sciences **Biochemistry** **Haematology** **Immunology**	Yes	No	No	**Downtime only** 1. Form on intranet 2. Attached to specimen bag
Microbiology **Virology**	Yes	No	No	**Downtime only** 1. Form on intranet 2. Attached to specimen bag
Cellular Pathology **Cytology** **Histopathology**	Yes	Yes	No	**Where specified** Ophthalmic, bronchoscopy, unisoft from endoscopy, EBUS, FNA request, Trafford General requests, muscle biopsy RMCH, placenta
Transplant	Yes	Yes	No	**Downtime only** Form on intranet
Transfusion	No	Yes	Yes	**Downtime only** Form on intranet
Genetics	No	No	Yes	**Yes** Form on intranet

Table 3. Sample/Form requirements for Wythenshawe EPR

Service	EPR Labels	EPR Paper Request Form	Handwritten Bottles	Handwritten Forms
Blood Sciences **Biochemistry** **Haematology** **Immunology**	Yes	Yes	No	**Downtime only** 1. Form on intranet 2. Attached to specimen bag
Microbiology **Virology**	Yes	Yes	No	**Downtime only** 1. Form on intranet 2. Attached to specimen bag
Cellular Pathology	Yes	Yes	No	**Where specified** Ophthalmic, bronchoscopy, unisoft from endoscopy, EBUS, FNA request, placenta
Transplant	Yes	Yes	No	**Downtime only** Form on intranet
Transfusion	No	No	Yes	**Downtime only** Pre-printed paper forms
Genetics	No	No	Yes	**Yes** Form on intranet

Downtime forms can be found on the Laboratory Medicine intranet page: -

https://intranet.mft.nhs.uk/content/hospitals-mcs/clinical-scientific-services/laboratory-medicine/using-our-services/requesting-tests-when-ice-is-not-available

4.4 Packaging and Sending Samples

Remember: One Bag One Patient. Where samples from different patients are received in one bag, samples will be rejected as we cannot ensure that the samples were collected correctly and are from the right patient.

Sequential samples on the same patient, e.g. glucose tolerance test, may be transported in one bag. Each sample should be identified with a time in addition to the other items. This is not applicable to Transfusion and the two sample rule (see section 6.2).

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

Samples from the same patient for Biochemistry, Haematology and Immunology can be sent in the same bag but must not 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 sample being rejected.

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

For Transfusion requests at ORC, a pouched bag must be used with the request form inserted so the printed text is visible.

Table 4. Bag colours for different locations

LOCATION	BAG COLOUR
Adult & Paediatric Emergency Department **(ORC/Trafford)**	Yellow Bags
RMCH **(ORC)**	Purple Bags
All other areas **(ORC/Trafford)**	Clear Bags
All areas **(Wythenshawe and Withington)**	Clear Bags

5. Anonymous and unknown patients

Emergency departments (EDs) often care for patients unable or unwilling to give their identity including people who are unconscious or who have a critical illness, people with a mental health condition or delirium, and people affected by drink or drugs. The MFT **Temporary Identification Criteria for Unknown or Unidentified patients Policy** (Reference ON8-5896) will be used to assign temporary identification to ensure the patient is uniquely identifiable and fulfils the Specimen acceptance policy minimal identification criteria.

During a major incident, patients presenting through ED will be allocated a MAJAX identification.

This will include the following identifiers;

- **MAJAX District Number** (8 digits, pre-blocked as MAJAX)

- **First name**: number in text format which may or may not also contain a site identifier (e.g. THIRTEEN, TWENTYSIXWYTH)
- **Surname**: surname from the phonetic alphabet with a MAJAX pre-fix (e.g. MAJAX HOTEL)
- **DOB**: Estimated D.O.B as outlined in the MFT **Temporary Identification Criteria for Unknown or Unidentified patients Policy** (Reference ON8-5896).

In certain circumstances, patient identification details are intentionally hidden or substituted with particular ID numbers (e.g. Sexual Health, Clinical trials, donor samples) in such instances, a properly coded identifier must be used.

In all cases, the patient identification information on the sample must match that on the request form.

6. Specific Departmental requirements

6.1 Auto sample receipting

With the introduction of auto-receipt within certain laboratories, an unblemished barcode may be sufficient for ICE/EPR requests for MFT. This is dependent on fully functional IT and laboratory systems and will not be applicable during IT downtime.

6.2 Blood Transfusion requirements

The Hospital transfusion team recommends and follows best practice outlined by the BCSH guidelines for administration of blood products (BCSH, 2009) and Guidelines on Pre Transfusion Compatibility Procedures in Blood Transfusion Laboratories, (BCSH, 2004). Blood transfusion samples require additional information;

MFT staff, please see the Trust Transfusion Policy.

GPs, please contact Blood Transfusion for guidance.

Printed labels on transfusion samples are **NOT** acceptable; transfusion sample labels **MUST** be handwritten. In addition to the four unique identifiers, samples must also have the date and time of collection written on the label and be signed by the person collecting the sample.

Transfusion samples **MUST** be accompanied by a request form. Transfusion Request forms **MUST** be signed by the requestor (and person collecting the sample if this is different). Date and time of collection **MUST** be written on the request form.

Failure to comply with these requirements will result in the rejection of the sample.

Pouched sample bags must be used for ICE requests, with the request forms inserted so the printed text is visible. Each new phlebotomy episode **MUST** be sent with a new request form and separate sample bag. Failure to use the correct sample bags or where two samples are sent in the same bag will result in sample rejection and can cause significant delay in treatment.

6.3 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).

Histopathology pots are labelled with ICE/EPR labels, ICE generates two histology labels for each pot. Both must be used; one label contains patient demographics; the other contains space for the user to add information regarding specimen type.

ICE labels must be attached to the specimen container and not to the lid of the container.

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 MFT district number, the NHS number or post-mortem case 'X' number can be used as the unique identifier.

6.4 Cytopathology Requirements

Cervical Cytology

The British Association for Cytopathology (BSCC) recommended code of practice for cytology laboratories participating in the UK cervical screening programmes 2015, updated 2017 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 below.

https://www.gov.uk/government/publications/cervical-screening-accepting-samples-in-laboratories/guidance-for-acceptance-of-cervical-screening-samples-in-laboratories-and-pathways-roles-and-responsibilities

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.

6.5 Microbiology Requirement

Must state history of foreign travel in clinical detail. This determines the way the laboratory process the sample.

- Must state whether patient has history of IVDU. This impacts the way the laboratory processes the sample.
- Microbiology expect requests to be received via electronic ordering (except for during periods of downtime). Please ensure your department team have relevant access.
- Please access the MMMP Website for further information / the User manual which outline the requirements and contact details for Microbiology.

https://mft.nhs.uk/the-trust/other-departments/laboratory-medicine/manchester-medical-microbiology-partnership/

7. 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.

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

Laboratories will not process unlabelled or mislabelled samples which are reproducible or repeatable. When a sample is rejected this is recorded in the LIMS under the details on the request form. It is then the responsibility of the requestor 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.

7.2. For unrepeatable / unreproducible samples that do **NOT** meet the mandatory requirements (with the exception of Blood Transfusion):

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)

Please note in general that samples of blood would not normally be classified as ‘Unrepeatable’.

7.3 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 less 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.

8. Common errors / troubleshooting

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

https://intranet.mft.nhs.uk/content/hospitals-mcs/clinical-scientific-services/laboratory-medicine/using-our-services/forms-information-and-resources

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

- Electronically request sample barcodes are test/tube specific. Please ensure the Haematology barcode is attached to the Haematology sample and the Biochemistry barcode is attached to the Biochemistry sample. We are unable to remove barcodes or reprint barcodes, failure to do this will result in sample rejection.

- Please 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.

- Please only attach one barcode per sample. If you need to add on a test, please phone the laboratory.

- Please be careful 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. Also, smudged labels cannot be read by the laboratory analysers.

- If the sample requires a request form, please ensure it is sent with the sample, it is completed correctly and that the form is signed.

- If after printing the electronic sample barcode, a decision is made not to take a sample off the patient, then the barcode should be discarded so as to prevent them being accidently used for another patient.

- Avoid covering the sample viewing window. Place the electronic sample barcode over the existing label as laboratory staff may need to visually inspect the sample.

9. IT Downtime

During ICE/EPR downtime, paper request forms must be used. There is no change in specimen acceptance criteria during downtime.

Template downtime forms can be found on the Laboratory Medicine intranet page: -

https://intranet.mft.nhs.uk/content/hospitals-mcs/clinical-scientific-services/laboratory-medicine/using-our-services/requesting-tests-when-ice-is-not-available

As part of the contingency process, all areas should store printed copies of the forms which can be photocopied as required. The laboratories will also hold a supply of printed forms for distribution if necessary.

10. Equality Impact Assessment

The Trust is committed to promoting Equality, Diversity and Human Rights in all areas of its activities.

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.

To enable the Trust to meet its legislative duties and regulatory guidance, all new and revised procedural documents, services and functions are to undertake an equalities impact assessment to ensure that everyone has equality of access, opportunity and outcomes regarding the activities. Contact the Service Equality Team (SET) on **Ext 66897** for support to complete an initial assessment. Upon completion of the assessment, SET will assign a unique EqIA Registration Number.

The Trust undertakes Equality Impact Assessments to ensure that its activities do not discriminate on the grounds of:

Religion or belief	Age
Disability	Race or ethnicity
Sex or gender	Sexual orientation
Human Rights	Socio economic

Before any committee, group or forum validate a policy or procedural document an EqIA Registration Number will be required. The EqIA number for this document is 263/11.

11. Consultation, Approval and Ratification Process

The document was ratified by the DLM Board.

12. Dissemination and Implementation

12.1. Dissemination

The information will be disseminated by the Lead Nurses/Ward Managers and Directorate Managers via the Divisional Manager for Clinical and Scientific Services.

12.2. Implementation of Procedural Documents

The guideline will be placed on the Laboratory Medicine website and appear on the latest Trust news and Team brief.

13. Monitoring Compliance of the Sample acceptance procedure

Any shortfalls identified will have an action plan put in place to address which will have timescales included for re-audit / monitoring.

Sample 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: tours around the laboratory or 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.

14. Standards and Key Performance Indicators 'KPIs'

The standard is ISO 15189:2012 clause 5.4.6

Specimen rejection information will be relayed to users were possible through various forums such as audit reports and clinical liaison meetings.

15. 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)
• BCSH Guidelines on Pre Transfusion Compatibility Procedures in Blood Transfusion Laboratories (2004)

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

MFT Trust Blood Transfusion Policy

16. Associated Trust Documents

CL 007 Blood Transfusion Policy
RM011Trust Patient Identification Policy