Table 1:
Mandatory labelling requirements for Laboratory Medicine Samples.

Quick Ref Guide for all samples excluding Blood Transfusion and Histopathology.

Each request accepted by the laboratory is considered an agreement.

Mandatory Labelling Requirement	Action by Laboratory if requirement not met
The specimen **MUST** be labelled with all the following: • Patient's full name • Hospital number or NHS Number. • Date of birth The following information shall also be provided. • Ward/Clinic • Correct date and time of sample collection	A lack of patient or sample information may result in the laboratory not conducting the analysis / examination introducing delays to patient diagnosis and treatment. Laboratory medicine will consider the patients best interest if a sample has been compromised. If a sample analysis is declined an EC code is added to Meditech with rationale. Where the sample is irreplaceable or deemed clinically critical, 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 by a HCPC registered member of staff. Laboratory Medicine will accept no responsibility for samples analysed which initially failed to meet the acceptance criteria. A comment is added to the report to suggest the results are reviewed with caution.
The request form data **MUST match** the above specimen information. The request form must contain **as a minimum:** • Patient's name • Hospital number or NHS Number. • Date of Birth For Haematology samples for Malaria and Microbiology specimens, foreign travel **MUST** be indicated for Health and Safety purposes to protect those handling the sample from risk of exposure to harmful pathogens. The following information shall be provided. • Identity and contact information of the requestor. • Investigations required; products requested. • Correct date and time of the specimen collection The following information should be provided. • Gender • Clinical details • Special product requirements • All relevant clinical information	
Remember: • Never send samples from more than one patient in one singular bag, the samples will be declined for analysis unless they are irreplaceable. • Multiple samples taken from one patient at different times **MUST** be labelled on the sample container with the time (24 hr. clock) when the sample is taken.	

For Blood transfusion and Histopathology please refer to the discipline specific Laboratory handbooks found on the Intranet or details can be found within this SOP.

1. Introduction

This policy sets out Alder Hey Children's NHS foundation Trust's policy for the acceptance process for samples requiring analysis by 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. Principle of the method

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 15189:2012/2022, the Blood Safety and Quality Regulations and the Human Tissue Authority regulations.

The policy applies to all Trust staff and departments that use Laboratory Medicine Services. There is a separate guidance procedure for external referral organisations.

Implementation of this policy will ensure that:

- Laboratory Medicine samples are unequivocally traceable/identified to a patient and when applicable anatomical site
- 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 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. Trust staff must adhere to the Trust policy for Patient Identification RM25, the most current version being available on the Trust Document management system (DMS).

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

4. Patient preparation

It is critical that the patient is correctly identified by the ward staff when collecting and labelling clinical specimens for investigation. In addition, several diagnostic tests will require specific patient preparation, such as a fasting sample or a timed specimen series. It is the responsibility of the requesting clinician to obtain consent for the collection of specimens. For certain tests (e.g., genetic testing) written consent may be required in addition to the request form.

For Histology samples patients that are prepared in theatres or clinic outpatient departments should be in accordance with Trust standard operating procedures and given consent.

Post-mortem samples need to be prepared in accordance with mortuary standard operating procedures and given consent where applicable prior to transfer to the laboratory.

Laboratory Handbooks are available on the Trust intranet for each discipline within Laboratory medicine. They provide specific detailed patient preparation information for each sample type. The Patient Consent Policy C7 is also available on the Trust DMS.

5. Specimen requirements and means of identification

For specific guidance on the Labelling and handling of laboratory specimens please refer to the Laboratory Handbooks available on the Trust Intranet site and Trust policy RM50 available on the DMS.

Mandatory Labelling Criteria for Samples and Request Forms (Blood transfusion and Histopathology excluded)

Samples and accompanying request form **MUST** be labelled with

- Patient's full name
- Hospital number or NHS Number.
- Date of birth

It is vital that the sample and request form are compatible i.e the information above is provided on the specimen and the request form and that they match.

They shall also provide the following.

- Identity and contact information of the requestor
- Correct date and time of sample collection
- Haematology requests for Malaria and all Microbiology samples- Foreign travel indicated on request form.

Other requirements for all specimen types

- Sample source and test request information should be complete and match.
- The sample must be relevant to the test requested.
- Care must be taken when sending high risk specimens that the container and the specimen bag are fully sealed.

- The department reserves the right to decline leaking or externally contaminated specimens.
- Where multiple patient samples are received in one bag samples will be rejected, as we cannot ensure that the samples were collected correctly and are from the intended patient.
- Multiple samples from the same patient will be accepted in one bag attached to one request form except for Microbiology. it is necessary to keep each sample in a separate specimen bag to prevent cross contamination. This is particularly important for PCR samples as this is an extremely sensitive test.
- Multiple samples taken at different times on a single patient **MUST** be labelled on the tube/container with the time (24-hour clock) when the sample is taken.

Mandatory Labelling Criteria for Samples and Request Forms for Blood Transfusion

Samples and accompanying request form **MUST** be handwritten and labelled as follows:

- Patient's full name
- Hospital number or NHS Number.
- Date of birth
- Ward/Clinic
- Date and time of the sample
- Signature of person taking sample
- Investigations required.
- Products requested.
- Special product requirements e.g. CMV negative

Specimens that fail to fulfil this minimum criterion will be discarded and the requesting ward informed. A canned code is added to Meditech and an Incident raised on InPhase against the requesting department.

Timing of pre-Transfusion testing: To ensure that the specimen used for compatibility testing is representative of a patient’s current immune status, serological studies (Antibody Screen and Crossmatching) should be performed using blood collected no more than 3 days in advance of the actual transfusion when the patient has been transfused or pregnant within the preceding 3 months, or when such information is uncertain or unavailable. The 3 days includes the dereservation period, e.g., if the sample was 1-day old, the blood would have to be transfused within 2 days. Where there has been no transfusion or pregnancy within the preceding 3months, the sample is valid for up to 7 days.

2 samples are required to determine a patient's unknown blood group and need to be taken at least 30 minutes apart.

Mandatory Labelling Criteria for Samples and Request Forms for Histopathology

Samples and accompanying request form **MUST** be labelled as follows:

- Patient's full name
- Hospital number or NHS Number.
- Date of birth
- Specimen site e.g. Left Kidney

It is vital that the sample and request form are compatible i.e the information above is provided on the specimen and the request form and that they match.

They shall also provide the following.

- Identity and contact information of the requestor
- Correct date and time of sample collection

Desirable information on all request forms

- Patients Gender
- Sample type and investigation required
- Signature of person taking sample
- Histopathology -If the sample is 'Fresh' – i.e. not transported in 10% Neutral Buffered Formalin.
- Clinical details

For **Histopathology and cytology** specimens',

The samples must be brought in a specimen transport container directly to Laboratory Medicine specimen reception (**not via the pod system**).

All fresh samples must be pre-booked and arrive at the laboratory before 4pm. See repertoire within the Handbook for more information on relevant samples.

Tissue samples in Formalin must arrive at specimen reception between the hours of 9am and 5.15pm.

All internal requests must be generated via Meditech. There are Meditech user guides for staff available on the intranet. Problems with placing orders should be directed to the IT department. Training for all clinicians ordering Tests is available from the Meditech/IT team.

In the event of Meditech downtime a paper Histology Meditech downtime form must be used. Samples will not be accepted unless an order has been generated and the minimum identification criteria are placed on the container and request form. The specimens must be labelled correctly otherwise they will be returned.

Advice on completing or printing a request form can be obtained from the IT department.

Urgent samples should be clearly marked and in the case of fresh tissue brought immediately to the Histopathology Department.

6. Failure to meet acceptance criteria

For **Blood Transfusion** samples, in line with BSH guidelines, the trust has a Zero tolerance policy, therefore, if the information on the specimen, form and electronic record does not totally correspond, the sample must be rejected, and the requesting clinician informed. For regulations applying to Blood Transfusion samples please refer to the Trust Blood Transfusion Policy.

For **Newborn Screening** refer to NHS Newborn Blood Spot Screening Procedure available on the trust intranet

The laboratory always considers the best interest of the patient receiving care. Specimen reception staff will liaise with a HCPC registered member of staff if a sample fails to meet the minimum acceptance criteria or if a sample has been compromised before complete rejection of the sample.

A HCPC registered member of staff will consider the risk of potential harm to the patient in rejecting the sample over accepting the sample and performing the analysis.

In general, if a sample has been compromised due to incorrect patient or sample identification, laboratory staff cannot be certain that there is unequivocal traceability of the sample to the patient. This could result in misdiagnosis and an incorrect treatment pathway started for the patient which could inadvertently cause harm. For this reasoning all samples that fail to meet the minimum patient identifiers (except for Histopathology samples and other listed in the section below) will be declined for analysis and a repeat sample requested when necessary. A code will be added to Meditech with rationale for rejection (TNP- Test not performed)

For samples that are to be sent off site for analysis, failure to meet the specimen acceptance criteria as defined in the Send away handbook (SAS) will result in the sample being TNP'd unless a member of ward staff attend specimen reception and clarify/amend the details.

Sample acceptance exceptions (Clause 7.2.6.2)

Samples that are not transported in a timely fashion or under the wrong temperature conditions but meet all other mandatory requirements will be analysed. A comment will be appended to the report stating how test results may be affected or whether a repeat sample may be required. (Clause 7.2.6.2a-2)

Samples that are received into the laboratory with insufficient sample to complete all analyses requested, but meet all other mandatory requirements, will be reviewed by an HCPC registered scientist. A decision will be made based on the clinical details regarding which tests can be analysed. A comment will be entered into Meditech against all those tests that could not be analysed. (QNS- quantity not sufficient). (Clause 7.2.6.2a-5)

Samples that are received into the laboratory in an incorrect container, but meet all other mandatory requirements, will be reviewed by an HCPC registered scientist. A decision will be made based on the test requested and the container received. If the sample is rejected, TNP will be added to Meditech and an EC marker. An attempt to contact the requestor will be made, however repeat calls will not be attempted. All information will be available on Meditech.

Clinically critical and Irreplaceable samples (clause 7.2.6.2b)

In a few circumstances, it would not be possible to repeat the collection of the sample. The laboratory would classify these as irreplaceable samples.
Please note in general that samples of Blood would not normally be classified as 'irreplaceable.

Examples of irreplaceable samples would include:

- All histology and non-gynae cytology samples- ward staff/clinicians who were initially responsible for taking the specimen are asked to attend specimen reception to amend the specimen details/request form details before the sample can be processed.
- 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.

The following comment should be appended to the report

This is an irreplaceable or clinically critical sample which did not meet the specimen acceptance criteria because [*type here the reason it did not meet the acceptance criteria e.g. sample unlabelled or information on the request form did not match that on the sample*] The test has been performed after liaison with clinical staff but please exercise caution when interpreting results for this patient. The laboratory takes no responsibility for samples analysed that fail to meet the minimum or mandatory acceptance criteria

Equality Impact Assessment

The Alder Hey Children's NHS Foundation Trust is committed to creating an inclusive organisation, which seeks to recognise diversity, promote equal opportunities and supports Human Rights in the provision of health services for the communities it serves and in its practice as a leading employer.

Equality, Diversity and Human Rights are central to the vision, values and long-term business development at Alder Hey Children's NHS Foundation Trust and therefore it is important that all three are embedded throughout the organisation into everything we do for patients, parents/ carers and staff.
For further details please refer to the Trust policy E1 on the Intranet.

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 these Quality failures to find trends and possible solutions to other Quality failures.

Standards and Key Performance Indicators 'KPIs'

The standard is ISO 15189:2022 section 7 Process requirements.

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