Ref No: 695

POLICY FOR PATHOLOGY SAMPLE ACCEPTANCE

SECTION 1
PROCEDURAL INFORMATION

Version:	1
Ratified by:	Trust Document Ratification Group
Date ratified:	10/06/2021
Title of originator/author:	BRILS Integrated Quality Manager, Laboratory Medicine
Title of responsible committee/individual:	Division of Clinical Support Services Patient Safety Group
Date issued:	10/06/2021
Review date:	10/06/2024
Target audience:	The Policy applies to all Trust staff and departments, in addition to GP and Community users involved in the requesting, collection and taking of patient samples processed and analysed by the Laboratory Medicine Service.

Document History Summary

Version	Date	Author	Status	Comment
1a	10/08/2020	Quality Manager, Laboratory Medicine	Draft	First Draft of Policy
1b	16/09/2020	Quality Manager, Laboratory Medicine	Draft	Policy updated following comments within Lab Medicine. Approved at Lab Medicine Business and Governance Meeting 16/09/2020.
1c	01/10/2020	Quality Manager, Laboratory Medicine	Draft	Policy updated with comments from Barnsley CBU3 Clinical Director. Updates made to align both Barnsley and Rotherham Policies.
1d	13/01/2021	Quality Manager, Laboratory Medicine	Draft	Policy updated following presentation and discussion at Division of Clinical Support Services Governance Committee 27/10/2020 and Patient Safety Group 12/11/2020. Version updated to state Requesting Practitioner/Consultant/GP and location must be provided, but samples will not be rejected if not provided.
1e	09/02/2021	Quality Manager, Laboratory Medicine	Draft	Approved at Laboratory Medicine CMT 20/01/2021. Approved by Division of Clinical Support Services Governance Committee 09/02/2021.
1f	26/05/2021	Quality Manager, Laboratory Medicine	Draft	Minor amendments made following comments from Patient Safety Group. Approved at Patient Safety Group 08/04/2021.
1	18/06/2021	Quality Manager, Laboratory Medicine	Final	Ratified at Document Ratification Group 10/06/2021.

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1. INTRODUCTION

Correct identification of the patient is vital for diagnosis, treatment and monitoring of disease. Therefore, it follows that unequivocal identification of patient samples submitted for laboratory investigations and their compatibility with the correct request form, is essential.

Most common errors involving laboratory tests are as a result of problems in the pre-analytical phase (before analysis by the laboratory), including:

- Patient identification on request form and/or sample.
- Sample collection e.g. wrong sample, wrong tube type, failure to mix sample in tube where required.
- Using a syringe to collect blood samples intended for vacuum containers.
- Inadequate preparation of the patient for the test e.g. patient did not fast, took medication prior to sample.
- Errors in transcription into laboratory computer system due to illegible or incorrect data supplied.

To ensure patient safety and compliance with data protection legislation, laboratory tests must be assigned to the correct patient and the results must be received in the correct location. The requesting practitioner has responsibility for providing the required information on the electronic request or handwritten form. The practitioner collecting the sample has responsibility for collecting the correct volume of the right sample, from the identified and adequately prepared patient, into the right container and labelling it fully before leaving the patient.

This document sets out The Rotherham NHS Foundation Trust's Policy for the acceptance process for samples requiring analysis by the Laboratory Medicine Service. It provides a robust framework to ensure that all samples are correctly and unambiguously identified.

2. PURPOSE & SCOPE

2.1 Purpose

The purpose of this Policy is to ensure that the Trust meets best practice to ensure patient safety and the effective reporting of Pathology results and reports, ensuring compliance with ISO 15189:2012 standard clause 5.4.6 and the British Society for Haematology (BSH) Guidelines for Administration of Blood Products (2009) and Guidelines on Pre Transfusion Compatibility Procedures in Blood Transfusion Laboratories (2004). This document also takes into account other appropriate national guidelines from the Royal College of Pathologists (RCPath), the Association of Clinical Biochemists and Laboratory Medicine (ACB), the Institute of Biomedical Science (IBMS) and the Blood Safety and Quality Regulations (BSQR) (2005).

Implementation of this Policy will ensure that:

- Pathology samples are unequivocally traceable/identified to a patient

- The number of repeat samples required due to mislabeling or inadequate information is minimised
- The laboratory and clinical personnel have accurate clinical and sampling information for result interpretation
- Patient results are reported to the requester within the defined turnaround time
- Patient results are received at the correct location
- The Trust complies with the Data Protection Act (2018) with respect to accuracy of patient data and confidentiality
- Activity data is credited to the right Consultant and clinical area
- Laboratory staff are supported when the decision to reject samples has to be made

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

The use of the MEDITECH or CliniSys ICE electronic order communication system for requesting Pathology tests ensures compliance with the sample and request labelling requirements of this Policy.

The use of the MEDITECH or ClinSys ICE electronic order communication system is <u>not permitted</u> for the requesting of <u>Blood Transfusion</u> tests.

2.2 <u>Scope</u>

This Policy defines the minimum criteria that must be in place for the receipt and identification of all patient samples for analysis by the Laboratory Medicine Service. The Policy applies to all Trust staff and departments, GP and Community users that use the Trust's Laboratory Medicine Service.

3. ROLES & RESPONSIBILITIES

It is the responsibility of each member of staff involved in the requesting of Pathology tests:

- To comply with the standards set out in this Policy
- To work within their own competence
- To report all issues regarding the labelling of Pathology ''precious'' samples (including near miss events), and issues regarding the labelling of ''High risk'' samples using the Trust's Incident Reporting procedures

Any such issues should be discussed at relevant Divisional Governance Committees and Trust level Governance Groups and any identified actions that result from the incident should be implemented.

It is the responsibility of each staff member and individual clinical departments to ensure they adhere to the training and audit requirements.

Roles	Responsibilities
Chief Executive and Trust Board	The Board, via the Chief Executive, is ultimately responsible for ensuring that systems are in place that effectively manage risks associated with the request and labelling of Pathology samples.
Medical Director	Responsible for implementing patient management strategies throughout the Trust that include appropriate requesting of investigations, and timely review and action of Pathology results.
Divisional Directors	Responsible for implementing patient management strategies throughout the Trust that include appropriate and timely requesting, labelling and review of Pathology tests, and having appropriate handover arrangements in place to review and act on abnormal results when a particular clinician is not available/away.
Consultant Medical Staff	Responsible for ensuring that their team, including junior staff read and understand this Policy, and adhere to the principles contained in it at all times.
Ward and Department Leads	Responsible for ensuring implementation within their area and for ensuring all staff who work within the area adhere to the principles at all times.
Requesting Practitioner	The responsibility for requesting a Pathology 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 with appropriate authority. Where these tasks are delegated, the responsibility ensuring that Pathology results are reviewed, actioned and filed in line with Trust Policy lies with the requesting practitioner. The requesting practitioner has overall responsibility for: • Ensuring that Pathology tests are only requested where they affect the management of the patient and by those authorised to do so. To prevent unnecessary requests, the patient record must be checked for results of any previous tests prior to testing. • Obtaining valid consent for the test where required, e.g. HIV or genetic testing. • Being aware of requirements for specialist assays by consulting the Trust Pathology website, or by contacting the appropriate department. • Determining any specific requirements for the tests being performed, e.g. fasting, timed

	samples, and informing the patient where necessary.
	• 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 or manual 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 in line with relevant legislation
	  ○ Ensuring that where samples have been rejected, repeat samples are collected as appropriate
	• Informing patients collecting their own samples, such as urine, fertility and post-vasectomy semen samples, of sample collection, labelling and transportation requirements.
	• Providing sufficient relevant and legible clinical information to enable correct interpretation of results.
	• Providing the requesting practitioners name and location to ensure results are returned to the requestor.
	• Ensuring that Pathology results are reviewed, actioned and filed in line with Trust Policy.

Practitioner taking the sample	It is the responsibility of the practitioner taking the sample to: • Adhere to the Trust Patient Identification Policy and the Trust Venepuncture Procedure. • Check the correct identity of the patient and ensure correlation with patient demographic information documented on the request form. • Where possible, and prior to collection, confirm that the specific preparatory requirements for the test to be undertaken, e.g. fasting, have been complied with. • Obtain valid consent for the sample to be taken. • Take sufficient sample for the requested tests to be carried out. • Collect samples from the appropriate site, e.g. away from intravenous lines. • Collect samples in the correct order and into the appropriate container. Blood must not be transferred from one container to another.

	• Fill sample bottles with the correct volume if indicated. • Label sample containers with at least the minimum data required, at the time of collection. • Ensure that containers are not pre-labelled or taken away for labelling. • ALL transfusion samples are handwritten. • Record their details on the request form along with the date and time of sample collection and, when possible, record this on the sample. • Take steps to ensure that the requestor is informed where insufficient or no sample is obtained. • Seal the sample (or samples from the same patient with one form) in the bag attached to the request form or as supplied for order comms (exceptions for large samples). • Ensuring that samples are transported to the Pathology laboratory in accordance with specimen/sample requirements detailed on the Trust Pathology webpage.
Pathology Staff	Laboratory Medicine staff have the responsibility for conducting analysis only on samples that have been correctly identified and can be unequivocally traceable to a patient and the communication of critically abnormal results in a timely manner.
Patient Collection own Sample	Patients collecting their own sample are responsible for the labelling and transport of the sample to the laboratory in line with information provided by the Requesting Practitioner.

4. PROCEDURAL INFORMATION

4.1 General Information

All Pathology requests received and accepted by the Laboratory Medicine Service are considered to be an agreement between the requester and the laboratory.

Information relating to the sample requirements, collection of samples, test information and expected turnaround times for tests are provided on the Pathology webpage https://www.therotherhamft.nhs.uk/Pathology/Pathology/

CliniSys ICE Order Communications system will prompt the user regarding any specific considerations for patient preparation and sample collection based on the selected test.

4.2 Urgent Samples

Samples requiring urgent processing must be identified as such. Procedures for requesting urgent tests are located on the Pathology webpage https://www.therotherhamft.nhs.uk/Pathology/Pathology/.

4.3 Patient Preparation

Any special considerations for the preparation of a patient, e.g. fasting, or requirements for the sample (e.g. sample timing or site) are provided in the test repertoire on the Pathology webpage.

Certain tests require patient consent to be given due to the nature of the testing and the consequences of the results. Any genetics testing requested must have the patient's informed consent prior to taking the sample and these tests often require a specific request card to document this formally. When electronic requests are generated, it is assumed that the requesting Practitioner named on the request form has discussed the consequences of the results with the patient and obtained consent. Any manual forms should be signed by the requesting Practitioner to indicate that consent has been obtained.

4.4 Sample and Test Requirements

Before collecting patient samples please refer to the Pathology webpage for information on the type and amount of the sample required and the type of the collection container including any additives if required. The Pathology webpage will also outline any special timing for the sample and instructions for the inclusion of clinical information relevant to or affecting sample collection, test performance or result interpretation (e.g. History of administration of drugs, fasting sample).

4.5 Labelling of Samples

All samples **MUST** be clearly and unequivocally labelled with the identifiers listed within **Appendix 1** and 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. Pre-labelling of sample tubes and pots is poor practice and increases risks of misidentification.

All printed sample identification labels (MEDITECH/ICE/addressograph) must be fully readable i.e. no information is missing/unreadable due to printer alignment or label damage. It is the responsibility of the person collecting the sample to ensure all the patient identifiers are all fully legible before sending the sample to the laboratory.

All Blood Transfusion samples MUST be hand labelled

4.6 Completing Request Forms

The use of paper handwritten request forms within the Trust is mandatory for Blood Transfusion and Histopathology. To reduce transcription errors Laboratory Medicine prefers the use of MEDITECH or CliniSys ICE electronic order communication systems to request Pathology tests. The ICE system interfaces with the Trust patient administration system, MEDITECH, to ensure that the request form and sample label will print with full demographic and request details, ensuring compliance with the labelling criteria in **Appendix 1**. Handwritten request forms for Blood Sciences (Biochemistry/Haematology/Immunology) and Microbiology are available for periods of downtime. The reverse of the ICE form can also be completed manually during periods of system downtime. However, in both of these instances, staff completing the request form and sample label must ensure adherence to the criteria within **Appendix 1**.

MEDITECH requests do not print a request form, instead a barcoded label is printed and placed on the sample bag, which contains the following:

- First Name and Surname
- MEDITECH order number
- Tests Requested
- Date of sample

When a Pathology test is requested electronically, an order number is printed on the sample label, and the same number is printed on the request form (ICE request) or on the barcoded label (MEDITECH request).

When completing paper handwritten requests, the requesting Practitioner and location stated on the form by the requesting Practitioner will be where the patient report will be sent, or telephoned, if critically abnormal. Whilst a copy of the results can be sent to another location, it remains the responsibility of the requesting practitioner to act on the results.

It is the responsibility of the requesting Practitioner to act on Pathology results. A Practitioner cannot request tests on behalf of another Practitioner, unless this has been delegated to a person with the appropriate authority.

The requesting Practitioner and requesting location MUST be provided in full on the request form to ensure the result is communicated to the intended recipient in a timely manner. Failure to provide both the requesting Practitioner and requesting location on the request form may result in a delay in the communication of a critically abnormal result.

Barcoded MEDITECH or ICE labels MUST be printed at the time of sample collection to ensure 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’ incidents.

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. 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.

4.7 Department Specific Requirements- Blood Transfusion

The request form must be fully completed by a registered medical practitioner or designated practitioner. It is the requesting practitioner's responsibility to ensure that any special requirements, e.g. CMV negative, irradiated products, bone marrow transplant or solid organ transplant are communicated to the Blood Transfusion Department. The clinical indication for transfusion should be written in the patient's case notes and on the request form.

The department operates a zero tolerance policy to accurate form and sample labelling to comply with UK guidelines and best practice for Blood Transfusion. As a result of this, samples not meeting the sample and request labelling criteria in **Appendix 2** will be rejected.

- Addressograph labels **MUST NOT** be used to label the sample.
- The request form **MUST** be clearly handwritten. (An addressograph label may be used on the request form for the patient identifiers but all other details/information must be handwritten).
- All handwritten data must be legible.
- Transfusion samples **MUST** be accompanied by a request form, and **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 **AND** sample.
- Sex of the patient must be indicated on both the request form and sample.
- If the sample is labelled with both NHS and hospital number, and one of these is incorrect the sample will be rejected.
- Request forms and blood specimens once received by the Blood Transfusion laboratory **CANNOT** be amended.
- Failure to comply with these requirements will result in the rejection of the sample.

4.8 Department Specific Requirements- Cervical Cytology

The Cervical Cytology service is provided by Gateshead Health NHS Foundation Trust, please see Cytology web page for the contact details to direct any queries regarding this service: https://www.barnsleyhospital.nhs.uk/pathology/cellular-pathology/cervical-cytology/

4.9 Department Specific Requirements- Andrology

The sample container and specific Andrology sample request form and patient collection information is provided to the patient by the requesting Practitioner. Further information on the Andrology service is available on the Pathology webpage:
https://www.therotherhamft.nhs.uk/Histopathology/Histopathology/
Information sheets designed to assist the interpretation of results; together with detailed instruction sheets for patients requiring Post Vasectomy and Infertility investigations are available from the Laboratory upon request.

- If the pot provided becomes un-useable/damaged, the patient must contact the laboratory for another. Any specimen received in another type of sample container will be rejected.
- The request form and sample container must be labelled in line with the criteria listed in **Appendix 1**
- The patient **MUST** fully complete the 'Information Required from Patient' section on the request form, including the time of sample collection and information on recent illness, time of last ejaculation etc.
- Missing information may result in the request being rejected.
- Laboratory staff will check the sample and request form on arrival at the Laboratory and staff may need to interview the patient to confirm information on the request form if this has not been fully completed.
- The specimen and attached request form must be delivered to the laboratory reception **within 1 hour of collection**.

4.10 Integrated Sexual Health/GUM Samples

Due to the sensitive nature of Genitourinary Medicine (GUM) or Integrated Sexual Health (ISH) requests, patient information is anonymised. This means that patient demographics such as NHS number and address are not available.
GUM request forms and samples must have the GUM number, Date of birth and patient sex.

4.11 Sample Rejection

Forms and samples failing to meet the minimum labelling criteria in **Appendix 1** (for Blood Sciences, Microbiology and Cellular Pathology samples) and **Appendix 2** (for Blood Transfusion samples) for unequivocal identification of the patient, will not be processed. The final decision to accept or reject a sample rests with Laboratory Medicine staff.

The Laboratory Medicine Service will not process unlabelled or mislabelled samples which can be repeated. Local laboratory procedures will be followed for issuing a report and notifying the requesting Practitioner/location that a repeat sample collection is necessary. Due to the high volume of requests received, the requestor will not normally be contacted directly when samples for routine tests are rejected. A Datix incident report will be completed for the rejection of ''precious'' samples, as defined below, or when ''high risk''

samples are not labelled This information will be communicated via the Pathology report on the MEDITECH or ICE systems. Samples will, however be held for the standard retention period for the sample type in case of any query.

It is recognised that some samples cannot be easily re-collected and are classed as ‘’precious’’. Examples of precious samples would include (this list is not intended to be exhaustive):

- All histology and non-gynae cytology samples
- Bone marrow, CSF samples, tissues and other fluids obtained by invasive procedures (not blood samples)
- Any samples that are part of a dynamic function test

Processing of incorrectly or unlabelled samples may only take place after discussion with the requesting Practitioner who must attend the laboratory and complete a “Precious Specimen Declaration Form”. Where specimens failing to meet these minimum criteria are processed, the responsibility for these results will rest with the requesting Practitioner and reports will contain the following comment:

“Due to inadequate labelling of the sample/request form the responsibility for these results lies solely with the requesting physician”.

When a completed “Precious Specimen Declaration Form” is received:

- The sample will be processed
- A Datix incident report will be raised by laboratory staff to enable investigation into the inadequate labelling by the clinical area.
- All precious specimen declaration forms will be collated for analysis and areas of continued non-compliance with the Policy will be contacted.

Failure to meet the Blood Transfusion sample labelling criteria in **Appendix 2** will result in rejection of the sample. Request forms and blood specimens once received by the Blood Transfusion laboratory **CANNOT** be amended. If an urgent sample does not meet the criteria, the requesting Practitioner will be contacted as soon as possible. In life threatening situations the patient should be supported with group O blood, AB FFP and A platelets. At the earliest opportunity a fresh sample should be obtained.

4.12 Patient Results

The responsibility for acting on Pathology results lies with the requesting Practitioner.

Critically abnormal results will be telephoned to the requesting Practitioner and location defined on the request form, in line with the Trust Policy for The Management of Deranged Blood Results and local Pathology procedures.

Once Pathology results are authorised, these will be released electronically to the MEDITECH and ICE systems for review, action and filing by the

requesting Practitioner, in line with local procedures for the actioning & filing of Clinical Reports.

4.13 Additional Add-On Requests

Requests to perform additional testing on samples that have already been received by Blood Sciences or Microbiology must be accompanied by an electronic ICE form, handwritten ICE form or 'add-on request form', located on the Pathology Webpage: https://www.therotherhamft.nhs.uk/Pathology/Pathology/.

The form must contain all the required patient demographics listed in **Appendix 1** and indicate that it is an add-on request, clearly stating the additional Pathology tests required.

Urgent add-on requests can be telephoned to the Laboratory, but must be accompanied by a request form as soon as possible. This will ensure that there will be no delay in analysis and will therefore not compromise patient treatment.

It may not be possible to add on some additional tests to existing samples as a result of sample volume. In addition, some tests are time sensitive and the ability to perform the test will be restricted by when the sample was taken. Please contact the laboratory for further guidance.

5. DEFINITIONS AND ABBREVIATIONS

5.1 Definitions

Requesting Practitioner: Authorised and trained personnel who has responsibility for the appropriate requesting of investigations, and timely review and action of Pathology results.

High Risk Sample: Samples from patients with blood borne virus diseases constitute a particular hazard to laboratory staff. All infectious or potentially infectious specimens and their accompanying request forms should be clearly marked with "Danger of Infection" stickers.

Precious Sample: Samples that cannot be easily re-collected are classed as ''precious''. Examples of precious samples would include (this list is not intended to be exhaustive):

- All histology and non-gynae cytology samples
- Bone marrow, CSF samples, tissues and other fluids obtained by invasive procedures (not blood samples)
- Any samples that are part of a dynamic function test

5.2 Abbreviations

ACB Association of Clinical Biochemists and Laboratory Medicine
BCSH British Committee for Standards in Haematology

BMA	British Medical Association
BSH	British Society of Haematology
BRILS	Barnsley and Rotherham Integrated Laboratory Services
BSQR	Blood Quality Safety Regulations
CMV	Cytomegalo Virus
CSF	Cerebrospinal fluid
GP	General Practitioner
GUM	Genito-Urinary Medicine
HEV	Hepatitis E Virus
HIV	Human Immunodeficiency Virus
HTA	Human Tissue Authority
IBMS	Institute of Biomedical Science
ICE	Integrated Clinical Environment
ISH	Integrated Sexual Health
MHRA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health Service
RCPath	Royal College of Pathologists
TRFT	The Rotherham NHS Foundation Trust
UK	
UKAS	United Kingdom Accreditation Service

6. REFERENCES

- Pathology Webpage https://www.therotherhamft.nhs.uk/Pathology/Pathology/
- Institute of Biomedical Science Policy on Patient Sample and Request Form Identification Criteria, Version 3 (March 2016) Institute of Biomedical Science
- Provision of key clinical information on laboratory specimen request forms http://www.hse.gov.uk/safetybulletins/clinicalinformation.htm
- British Medical Association (BMA), Duty of care regarding communication of investigation results, (December 2016) https://www.bma.org.uk/advice/employment/gp-practices/service-provision/duty-of-care-to-patients-regarding-test-results
- Medical laboratories — Requirements for quality and competence (ISO 15189:2012)
- Royal College of Pathologists (RCPath)- The Communication of Critical and Unexpected Pathology Results, G158, October 2017
- Association of Clinical Biochemists and Laboratory Medicine (ACB)
- British Society of Haematology (BSH)
- BSH Guideline on Administration of Blood Components (2009)
- BSH Guidelines on Pre Transfusion Compatibility Procedures in Blood Transfusion Laboratories (2004)
- The Blood Safety and Quality Regulations (BSQR) (2005)
- The Good Laboratory Practice Regulations 1999 (SI 1999 3106)
- The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 (SI 2004 No. 994)

7. ASSOCIATED DOCUMENTATION

Trust Policies:

- Patient Identification Policy
- Venepuncture Procedure
- Blood Transfusion Policy
- Management of Deranged Blood Results
- Consent Policy
- Health Record Policy
- Incident and Serious Incident Management Policy

Pathology Internal Policies and Procedures:

- Barnsley and Rotherham Integrated Laboratory Services (BRILS) Clinical Sample Acceptance Procedure (Internal reference: QA-COMP-002)
- Pathology Confidentiality Policy: (Internal reference: MPL-PP-007)
- Transmission of laboratory results Policy (Internal reference: QPL-PQ-004)
- Biochemistry Validation and Telephoning Procedure: (Internal reference: LP-BIO-ADM-002)
- Haematology Telephoning Guidelines Internal Reference: LPL-HAE-LAB-001)
- Immunology Action Limits and Telephoning of Results (internal Reference: LP-IML-042)
- Telephoning Results in Microbiology (LP-MIC-ADM-012)
- Telephoning Results procedure in Blood Transfusion (LP-BB-LAB-045)
- Histopathologist Reporting Procedures (LP-HIS-ADM-045)

Request and Sample Labelling Requirements - Blood Sciences, Microbiology and Histopathology

Minimum Data Set - Request Form (Paper or Electronic)	Minimum Data Set – Sample (Handwritten or Electronic)	Reason	Action by Laboratory if requirement not met
MEDITECH requests do not have a request form. A barcoded label is attached to the sample bag, containing: • First Name and Surname • MEDITECH order number • Tests Requested • Date of sample	Data Set on printed label as below, with corresponding MEDITECH order number on the request label.	Unequivocal identification of patient	**Sample Rejection***
First Name and Surname	First Name and Surname	Unequivocal identification of patient	**Sample Rejection***
Date of Birth	Date of Birth		
One of the following Unique Numerical Identifiers • Hospital Number • NHS number • GUM number • Full address and postcode if unique numerical identifier cannot be provided	One of the following Unique Numerical Identifiers • Hospital Number • NHS number • GUM number		
Tests required	N/A	To perform relevant tests	
Location (ward/clinic/surgery)- Written in Full	N/A	Return of results to Practitioner	Delay in results
Consultant/GP/Requesting Practitioner- Written in Full	N/A	Return of results to Practitioner	Delay in results
High Risk Sticker if patient has a blood borne virus	High Risk Sticker if patient has a blood borne virus	Samples from patients with blood borne virus diseases constitute a particular hazard to laboratory staff	If it is identified that a known infectious sample is not appropriately labelled a Datix must be raised by laboratory staff to allow investigation by the clinical area
Name / Bleep No of requesting Consultant or Practitioner	N/A	To contact if necessary	Delay in results

Minimum Data Set - Request Form (Paper or Electronic)	Minimum Data Set – Sample (Handwritten or Electronic)	Reason	Action by Laboratory if requirement not met
Sex	N/A	Correct interpretation of results and/or further investigations	Failure to provide will prevent the reporting of appropriate reference ranges
Clinical Details	N/A	To enable addition of interpretative comments and / or further investigations	Incorrect interpretation of results possible
Identity and signature of sample collector	Identity and signature of sample collector	Audit trail of clinical practice	N/A
Date, Time and location of Collection	Date and Time of Collection	Chronological tracking of results, essential in some case to ensure correct interpretation of results	Incorrect interpretation of results possible
Patient preparation (fasting, time of dose)	Time and/or number of sample		
Sample Type (if not venous blood)	Sample Type (if not venous blood)		
Sample Site (Histopathology)	Sample Site (Histopathology)		

Forms and specimens failing to meet these minimum criteria for patient identification will not be processed.

*It is recognised that some samples cannot be easily re-collected and are classed as ‘’precious’’. Processing of incorrectly or unlabelled precious samples may only take place after discussion with the requesting Practitioner who must attend the laboratory and complete a “Precious Specimen Declaration Form”.

Request and Sample Labelling Requirements - Blood Transfusion

Minimum Data Set - Request Form (Paper - Handwritten Only)	Minimum Data Set – Sample (Handwritten only)	Reason	Action by Laboratory if requirement not met
First Name and Surname	First Name and Surname	Unequivocal identification of patient	**Sample Rejection**
Date of Birth	Date of Birth		
One of the following Unique Numerical Identifiers • Complete Hospital Number (Including RU and 0's) • NHS number	One of the following Unique Numerical Identifiers • Hospital Number • NHS number		
Sex	Sex	To ensure correct components issued	
Tests required	N/A	To perform relevant tests	
Location (ward/clinic/surgery)- Written in Full	Location (ward/clinic/surgery)	Issue of blood products to correct location	
Consultant/GP/Requesting Practitioner- Written in Full	N/A	Return of results to Practitioner	
Identity and signature of sample collector	Identity and signature of sample collector	To confirm patient identification	
Date, Time and location of Collection	Date and Time of Collection	To ensure integrity of sample	
High Risk Sticker if patient has a blood borne virus	High Risk Sticker if patient has a blood borne virus	Samples from patients with blood borne virus diseases constitute a particular hazard to laboratory staff	If it is identified that a known infectious sample is not appropriately labelled a Datix must be raised by laboratory staff to allow investigation by the clinical area
Full address and postcode	N/A	Unequivocal identification of patient	N/A
Name & Bleep No of requesting Consultant or Practitioner	N/A	To contact if necessary	May cause delay in providing blood products
Date &Time blood products are required.	N/A	To ensure the appropriate use of blood products and that blood	May cause delay in providing blood products

Minimum Data Set - Request Form (Paper - Handwritten Only)	Minimum Data Set – Sample (Handwritten only)	Reason	Action by Laboratory if requirement not met
*Clinical diagnosis and reason for transfusion required. Pre op not sufficient		products are available when required.	
Transfusion history and pregnancy status/history including expected date of delivery if appropriate	N/A	To ensure safety of component provision	Sample only valid for 72 hours
Haemoglobinopathy status Previous Antibody history	N/A	To ensure appropriate component selection	May result in clinical incident if patient receives inappropriate components
Treatment with drugs known to effect Transfusion	N/A	To ensure that the correct component specification is selected or to ensure that laboratory staff are aware of drugs that affect blood group/antibody screening serology	May result in clinical incident if patient receives inappropriate components, or may cause a significant delay in the provision of blood components due to delay in referral to Red Cell Immunohaematology department at NHS Blood & Transplant
Anti-D administration within 12/52	N/A	To ensure an understanding of anomalous serological results within the laboratory.	May cause a significant delay in the provision of blood components due to unnecessary investigations or a delay in referral to Red Cell Immunohaematology department at NHS Blood & Transplant
Any Special Requirements e.g. Irradiated, CMV negative, HEV negative components	N/A	To ensure appropriate component selection	May result in clinical incident if patient receives inappropriate components

Forms and samples failing to meet these minimum criteria for patient identification will not be processed.

POLICY FOR LABORATORY MEDICINE SAMPLE ACCEPTANCE

SECTION 2
DOCUMENT DEVELOPMENT, COMMUNICATION, IMPLEMENTATION AND MONITORING

8. CONSULTATION AND COMMUNICATION WITH STAKEHOLDERS

This document was developed in consultation with:

Laboratory Medicine Business and Governance
Division of Clinical Support Services Governance Committee
Patient Safety Group

9. APPROVAL OF THE DOCUMENT

This document was approved by:

Laboratory Medicine Business and Governance on 20/01/2021
Division of Clinical Support Services Governance Committee 09/02/2021
Patient Safety Group 08/04/2021

10. RATIFICATION OF THE DOCUMENT

This document was ratified by the Trust Document Ratification Group.

11. EQUALITY IMPACT ASSESSMENT STATEMENT

An Equality Impact Assessment has been carried out in relation to this document using the approved initial screening tool; the EIA statement is detailed at Appendix 1 to this section of the document.

The manner in which this policy impacts upon equality and diversity will be monitored throughout the life of the policy and re-assessed as appropriate when the policy is reviewed.

12. REVIEW AND REVISION ARRANGEMENTS

This document will be reviewed every three years unless such changes occur as to require an earlier review.

The Laboratory Medicine Quality Manager is responsible for the review of this document.

13. DISSEMINATION AND COMMUNICATION PLAN

To be disseminated to	Disseminated by	How	When	Comments
Document Ratification Group via policies email	Author	Email	Within 1 week of ratification	Remove watermark from ratified document and inform Document Ratification Group

				if a revision and which document it replaces and where it should be located on the intranet. Ensure all documents templates are uploaded as word documents.
Communication Team (documents ratified by the Document Ratification Group)	Document Ratification Group	Email	Within 1 week of ratification	Communication team to inform all email users of the location of the document.
All email users	Communication Team	Email	Within 1 week of ratification	Communication team will inform all email users of the policy and provide a link to the policy.
Key individuals Staff with a role/responsibility within the document Heads of Departments /Matrons	Author	Meeting/E mail as appropriate	When final version completed	The author must inform staff of their duties in relation to the document.
All staff within area of management	Heads of Departments /Matrons	Meeting / Email as appropriate	As soon as received from the author	Ensure evidence of dissemination to staff is maintained. Request removal of paper copies Instruct them to inform all staff of the policy including those without access to emails

14. IMPLEMENTATION AND TRAINING PLAN

What	How	Associated action	Lead	Timeframe
Full Policy	Via Clinical Directors with support and leadership	Dissemination of Policy, with communications to all clinical areas.	Laboratory Medicine Quality Manager	1 week after ratification

	from Medical Director			

15. PLAN TO MONITOR THE COMPLIANCE WITH, AND EFFECTIVENESS OF THE TRUST DOCUMENT

15.1 Process for Monitoring Compliance and Effectiveness

Audit/Monitoring Criteria	Process for monitoring e.g. audit, survey	Audit / Monitoring performed by	Audit / Monitoring frequency	Audit / Monitoring reports distributed to	Action plans approved and monitored by
Audit of use of precious sample declaration forms via Datix	Datix Records	Pathology Quality Manager	Quarterly	Laboratory Medicine Business and Governance Division of Clinical Support Services	Laboratory Medicine Business and Governance Division of Clinical Support Services

15.2 Standards/Key Performance Indicators (KPIs)

Adherence to this Policy supports compliance with:
Medicines and Health care regulatory Agency (MHRA)
Blood Safety and Quality Regulations (2005)
UKAS Accreditation to ISO 15189:2012

The Rotherham NHS Foundation Trust

EQUALITY IMPACT ASSESSMENT (EIA) INITIAL SCREENING TOOL

Document Name: Laboratory Sample Acceptance Policy | Date/Period of Document: 3 years

Lead Officer: Quality Manager, BRILS | Job title: Quality Manager, BRILS

☐ Function	☒ Policy	☐ Procedure	☐ Strategy	☐ Other:_____

Describe the overall purpose / intended outcomes of the above: The purpose of this Policy is to ensure that the Trust meets best practice to ensure patient safety and the effective reporting of Pathology results and reports.

*You must assess **each** of the 9 areas separately and consider how your policy may affect people of different groups within those areas.*

1. Assessment of possible adverse (negative) impact against a protected characteristic

	Does this have a **significant** negative impact on equality in relation to each area?	**Response** Yes	**Response** No	**If yes, please state why and the evidence used in your assessment**
1	Age		X	
2	Disability		X	
3	Gender reassignment		X	
4	Marriage and civil partnership		X	
5	Pregnancy and maternity		X	
6	Race		X	
7	Religion and belief		X	
8	Sex		X	
9	Sexual Orientation		X	

You need to ask yourself:

- Will the policy create any **problems** or **barriers** to any community or group? ☐ Yes ☒ No
- Will any group be **excluded** because of the policy? ☐ Yes ☒ No
- Will the policy have a negative impact on **community relations**? ☐ Yes ☒ No

If the answer to any of these questions is Yes, you must complete a full Equality Impact Assessment

2. Positive impact:

	Could the policy have a **significant** positive impact on equality by reducing inequalities that already exist? Explain how will it meet our duty to:	**Response** Yes	**Response** No	**If yes, please state why and the evidence used in your assessment**
1	Eliminate discrimination, harassment and / or victimisation		X	
2	Advance the equality of opportunity of different groups		X	
3	Foster good relationships between different groups		X	

3. Summary

On the basis of the information/evidence/consideration so far, do you believe that the policy will have a positive or negative adverse impact on equality?

Positive						**Negative**
HIGH ☐	**MEDIUM** ☐	**LOW** ☐	**NEUTRAL** ☒	**LOW** ☐	**MEDIUM** ☐	**HIGH** ☐

Date assessment completed: 09/02/2021	Is a full equality impact assessment required? ☐ Yes ☒ No
Date EIA approved by Equality and Diversity Steering Group: 18/06/2021	