Policy

Pathology Sample Acceptance

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Table of Contents

	Section heading		Page
1.0	Introduction		7
2.0	Objective		7
3.0	Scope		8
4.0	Pathology Sample Acceptance		8
	4.1	General	8
	4.2	Urgent Samples	8
	4.3	Patient Preparation	9
	4.4	Sample and Test Requirements	9
	4.5	Patients Attending the Phlebotomy Outpatients Department	9
	4.6	Labelling of Samples	9
	4.7	Completing Request Forms	11
	4.8	Department Specific Requirements- Blood Transfusion	12
	4.9	Department Specific Requirements- Cervical Cytology	15
	4.10	Department Specific Requirements- Andrology Samples	15
	4.9	GUM Samples	15
	4.10	Sample Rejection	15
	4.11	Pathology Results	15
5.0	Roles and responsibilities -		17
	5.1	Trust Board	17
	5.2	Medical Director	17
	5.3	CBUs	17
	5.4	Consultant Medical Staff	17
	5.5	Ward and Department Leads	18

	5.6	Requesting Practitioner	18
	5.7	Practitioner taking the sample	18
	5.8	Pathology Staff	19
	5.9	Patient	19
6.0	Associated documents and references		19
7.0	Training and resources		20
8.0	Monitoring and audit		20
9.0	Equality, diversity and inclusion		21
	9.1	Recording and monitoring of equality, diversity and inclusion	21
Appendix 1	Equality impact assessment		22
Appendix 2	Glossary of terms		27
Appendix 3	Document history/version control – must be the last appendix		28

1.0 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 Barnsley Hospital NHS Foundation Trust's Policy for the acceptance process for samples requiring analysis by the Pathology Service. It provides a robust framework to ensure that all samples are correctly and unambiguously identified.

2.0 Objective

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), ISO 15189:2022 (subclause 7.2.6) and the British Committee for Standards in Haematology (BCSH) 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).

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 Pathology Service. This Policy is to ensure that staff within the Trust understands the minimum criteria that must be in place for the receipt and identification of patient samples and request forms. Each request sent to Pathology and accepted for investigation will be

considered an agreement to undertake the relevant analysis and Pathology will expect compliance with this Policy from all users. Implementation of this Policy will ensure that:

- Pathology samples are unequivocally traceable/identified to a patient
- The number of repeat samples required due to mislabelling 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.
- 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 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 ClinSys ICE electronic order communication system is not permitted for the requesting of Blood Transfusion tests.

3.0 Scope

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

4.0 Pathology Sample Acceptance

4.1 General

All requests received and accepted by the Pathology 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.barnsleyhospital.nhs.uk/Pathology/

The CliniSys ICE Order Communications system will prompt the user regarding 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.barnsleyhospital.nhs.uk/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 sexual health and genetics 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 Patients attending the Phlebotomy Outpatients Department or Community Diagnostic Centre (CDC)

Patients attending the Hospital Phlebotomy Outpatient Department or Community Diagnostic Centre (CDC) for sampling must attend with either a postponed ICE request, or a handwritten request. Patients attending without a valid request form will be unable to be bled. It is the requestor's responsibility to ensure they select the correct patient details on ICE when making a postponed request, any patients attending with another patient's information are unable to be bled and a Datix incident report will be raised due to the breach in information governance.

4.6 Labelling of Samples

All samples **MUST** be clearly and unequivocally labelled with the identifiers listed within **Table 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 (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 fully

legible before sending the sample to the laboratory. **All Blood Transfusion samples MUST be hand labelled.**

Table 1: 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
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	
Consultant/GP/Requesting Practitioner- Written in Full	N/A	Return of results to Practitioner	
High Risk Sticker if patient has a blood borne virus	N/A	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
Gender	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	Incorrect

Minimum Data Set - Request Form (Paper or Electronic)	Minimum Data Set – Sample (Handwritten or Electronic)	Reason	Action by Laboratory if requirement not met
		of interpretative comments and / or further investigations	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 samples 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”.

4.7 Completing Request Forms

The use of paper handwritten request forms within the Trust is now limited to Blood Transfusion and Histopathology. The rest of the Pathology Department requires the use of the CliniSys ICE electronic order communication systems to request Pathology tests. The ICE system interfaces with the Trust patient administration system to ensure that the request form and sample label will print with full demographic and request details, ensuring compliance with the labelling criteria in **Table 1**. The reverse of the ICE form can be completed manually during periods of system downtime, however, staff completing the request form and sample label must ensure adherence to the criteria within **Table 1**.

When completing paper handwritten ICE 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 by

both electronic reporting via the ICE System, and verbal telephone communication from the laboratory if the result falls within the critically abnormal limits of the laboratory. Failure to provide both the requesting Practitioner and requesting location on the request form **will result in rejection** on the grounds of patient safety.

Barcoded 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.

4.8 Department Specific Requirements- Blood Transfusion

The request form must be fully completed by a registered medical Practitioner or designated Practitioner. It is the 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 **Table 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.
- Gender 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. The correct request form must be used, there are three request forms as follows, Antenatal Serology, Neonatal Request form and Blood Transfusion Request Form.
- Failure to comply with these requirements will result in the rejection of the sample.

Table 2: 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 • Hospital Number • NHS number	One of the following Unique Numerical Identifiers • Hospital Number • NHS number		
Gender	Gender	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. *Clinical diagnosis and reason for transfusion	N/A	To ensure the Appropriate use of blood products and that blood products are available	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
required. Pre-op not sufficient		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.

4.9 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/

4.10 Department Specific Requirements- Andrology

The sample container and specific Post Vasectomy sample request form and patient collection information is provided to the patient post-procedure by the requesting Practitioner. Further information on the Andrology service is available on the Pathology webpage: https://www.barnsleyhospital.nhs.uk/pathology/blood-sciences/andrology/

- 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 **Table 1**
- The Patient **MUST** write the time of sample collection on the request form and sample container.
- Missing information may result in the request being rejected.
- The specimen and attached request form must be delivered to the laboratory reception **within 1 hour of collection**.

4.11 GUM/ISH 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 gender.

4.12 Sample Rejection

Forms and samples failing to meet the minimum labelling criteria in **Table 1** (for Blood Sciences, Microbiology and Cellular Pathology samples) and **Table 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 Pathology.

The Pathology 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, this information will be communicated via the Pathology report on the ICE system. 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 **Table 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.

4.13 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 Telephoning Pathology Results and Blood Products and local Pathology procedures.

Once Pathology results are authorised, these will be released electronically to the ICE system for review, action and filing by the requesting Practitioner, in line with the Trust Policy for Actioning & Filing of Paperless Clinical Reports Using ICE.

4.14 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.barnsleyhospital.nhs.uk/pathology/

The form must contain all the required patient demographics listed in **Table 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.

5.0 Roles and 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 samples (including near miss events) using the Trust's Incident Reporting procedures

Any such issues should be discussed at relevant Clinical 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.

5.1 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.

5.2 Medical Director: is responsible for implementing patient management strategies throughout the Trust that include appropriate requesting of investigations, and timely review and action of Pathology results.

5.3 Clinical Business Units (CBU): are 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 Practitioner is not available/away.

5.4 Consultant Medical Staff: are 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.

5.5 Ward and Department Leads: are responsible for ensuring implementation within their area and for ensuring all staff who work within the area adhere to the principles at all times.

5.6 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 the appropriate authority. Where these tasks are delegated, the responsibility for 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 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.

5.7 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 communications (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.

5.8 Pathology Staff: Pathology Laboratory staff have the responsibility for conducting analysis only on samples that have been correctly identified and can be unequivocally traceable to a patient and for the communication of critically abnormal results in a timely manner.

5.9 Patient collecting own sample: Patients collecting their own sample are responsible for the labelling and transport to the laboratory of the sample in line with information provided by the Requesting Practitioner.

6.0 Associated documents and references

Trust Policies:

- Patient Identification Policy
- Venepuncture Procedure
- Telephoning Pathology Results and Blood Products Policy
- Blood Transfusion Policy
- Actioning & Filing of Paperless Clinical Reports Using ICE Policy

Pathology Internal Policies and Procedures:

- Barnsley and Rotherham Integrated Laboratory Services (BRILS) (Internal reference: QA-COMP-002)
- Pathology Confidentiality Policy: (Internal reference: QA-COMP-015)
- Management of urgent sample requests (Internal reference: SOP-BS-064)
- Transmission of laboratory results Policy (Internal reference: SOP-CR-020)
- Blood Sciences Telephoning Procedure: (Internal reference: SOP-BS-005)
- Blood Bank Telephone Procedures: (Internal reference: SOP-HAE-BB-D-19)
- Authorisation, Transmission and Amendment of Microbiology Results Procedure: (Internal reference: SOP-MC-GEN-006)
- Reporting Procedure, Consultant Histopathologists (Internal Reference: SOP-CP-HIST-D-36)

External References:

- Pathology Webpage https://www.barnsleyhospital.nhs.uk/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 Committee for Standards in Haematology (BCSH)
    - 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)

7.0 Training and resources

Each staff member is accountable for their practice and should always act in such a way as to promote and safeguard the well-being and interests of patients. Staff will receive instructions and direction regarding the requesting of Pathology tests from a number of sources:-

- Corporate Induction
- Trust Policies and Procedures available on the internet
- Ward/departmental/line managers

8.0 Monitoring and audit

The Pathology Services Management Team will review this Policy in the following circumstances:-

- When new national or international guidance is required
- When newly published evidence demonstrates need for change to current practice
- Every three years routinely

Responsibility for implementation of this Policy lies with the CBUs.

Incidents where non-compliance with this Policy is noted and are considered an actual or potential risk should be on DATIX.

Audit of compliance will be undertaken as part of the internal audit programme. Feedback to users will be given. Where it is ascertained that some areas have high non-compliance rates, they will be contacted directly with a view to improving performance**.**

What is being monitored?	Who will carry out the monitoring?	Frequency of monitoring?	Who and where reported to?
Audit of compliance and the use of precious sample declaration forms via Datix	Pathology Quality Manager	Quarterly	Pathology Business and Governance and CBU3 Business and Governance (if escalation required)

9.0 Equality and Diversity

The Trust is committed to an environment that promotes equality and embraces diversity in its performance as an employer and service provider. It will adhere to legal and performance requirements and will mainstream equality, diversity and inclusion principles through its policies, procedures and processes. This Policy should be implemented with due regard to this commitment.

To ensure that the implementation of this Policy does not have an adverse impact in response to the requirements of the Equality Act 2010 this Policy has been screened for relevance during the Policy development process and a full equality impact assessment is conducted where necessary prior to consultation. The Trust will take remedial action when necessary to address any unexpected or unwarranted disparities and monitor practice to ensure that this Policy is fairly implemented.

This Policy can be made available in alternative formats on request including large print, Braille, moon, audio, and different languages. To arrange this please refer to the Trust translation and interpretation Policy in the first instance.

The Trust will make reasonable adjustments to accommodate any employee/patient with particular equality, diversity and inclusion requirements in implementing this Policy. This may include accessibility of meeting/appointment venues, providing translation, arranging an interpreter to attend appointments/meetings, extending Policy timeframes to enable translation to be undertaken, or assistance with formulating any written statements.

9.1 Recording and Monitoring of Equality & Diversity

This section is mandatory for all Trust Approved Documents and must include the statement below:

The Trust understands the business case for equality, diversity and inclusion and will make sure that this is translated into practice. Accordingly, all policies and procedures will be monitored to ensure their effectiveness.

Monitoring information will be collated, analysed and published on an annual basis as part of Equality Delivery System. The monitoring will cover the nine protected characteristics and will meet statutory employment duties under the Equality Act 2010. Where adverse impact is identified through the monitoring process the Trust will investigate and take corrective action to mitigate and prevent any negative impact.

Appendix 1

EQUALITY IMPACT ASSESSMENT TEMPLATE

INITIAL ASSESSMENT STAGE 1 (part 1)

<table>
<tr><td>Department:</td><td colspan="3">Trust Wide</td><td>Division:</td><td>Corporate</td></tr>
<tr><td>Title of Person(s) completing this form:</td><td colspan="3">Daniel Firth</td><td>New or Existing Policy/Service</td><td>New</td></tr>
<tr><td>Title of Policy/Service/Strategy being assessed:</td><td colspan="3">Pathology Sample Acceptance Policy</td><td>Implementation Date:</td><td>01/04/2023</td></tr>
<tr><td>What is the main purpose (aims/objectives) of this Policy/service?</td><td colspan="5">This Policy sets out Barnsley Hospital NHS Foundation Trust’s Policy for the acceptance process for samples requiring analysis by the Pathology Service. It provides a robust framework to ensure that all samples are correctly and unambiguously identified.</td></tr>
<tr><td rowspan="5">Will patients, carers, the public or staff be affected by this service?</td><td></td><td>Yes</td><td>No</td><td colspan="2" rowspan="5">If staff, how many individuals/which groups of staff are likely to be affected?

All staff involved in the requesting and labelling of Pathology samples.</td></tr>
<tr><td>Patients</td><td>X</td><td></td></tr>
<tr><td>Carers</td><td></td><td>X</td></tr>
<tr><td>Public</td><td></td><td>X</td></tr>
<tr><td>Staff</td><td>X</td><td></td></tr>
<tr><td rowspan="6">Have patients, carers, the public or staff been involved in the development of this service?</td><td>Patients</td><td></td><td>X</td><td colspan="2" rowspan="6">If yes, who did you engage with? Please state below:

Engagement with Trust Patient Safety and Harm Group and CBU3 Business and Governance</td></tr>
<tr><td>Carers</td><td></td><td>X</td></tr>
<tr><td>Public</td><td></td><td>X</td></tr>
<tr><td>Staff</td><td>X</td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td>What consultation method(s) did you use?</td><td colspan="5">Benchmarking with other Trusts.</td></tr>
</table>

Equality Impact Assessment Stage 1 PART 2

Based on the data you have obtained during the consultation what does this data tell you about each of the above protected characteristics? Are there any trends/inequalities?

Information provided by requesting Practitioner and stored on Laboratory Information Management System for diagnostic purposes only.

What other evidence have you considered? Such as a ‘Process Map’ of your service (assessment of patient’s journey through service) / analysis of complaints/ analysis of patient satisfaction surveys and feedback from focus groups/consultations/national & local statistics and audits etc.

Policy benchmarked against other Trusts (regional and National)

Equality Impact Assessment Stage 1 PART 3

ACCESS TO SERVICES

What are your standard methods of communication with service users?

Communication Methods	Yes	No
Face to Face Verbal Communication	X	
Telephone	X	
Printed Information (E.g. leaflets/posters)	X	
Written Correspondence	X	
E-mail	X	
Other (Please specify)		

If you provide written correspondence is a statement included at the bottom of the letter acknowledging that other formats can be made available on request?

Please tick as appropriate.

Yes	No
	X

Are your staff aware how to access Interpreter and translation services?

Interpreter & Translation Services	Yes	No
Telephone Interpreters (Other Languages)	X	
Face to Face Interpreters (Other Languages)	X	
British Sign Language Interpreters	X	
Information/Letters translated into audio/braille/larger print/other languages?	X	

EQUALITY IMPACT ASSESSMENT – STAGE 1 (PART 4)

Protected Characteristic	Positive Impact	Negative Impact	Neutral Impact	Reason/comments for positive or negative Impact Why it could benefit or disadvantage any of the protected characteristics
Men	No	No	Yes	
Women	No	No	Yes	
Younger People (17 – 25) and Children	No	No	Yes	
Older people (60+)	No	No	Yes	
Race or Ethnicity	No	No	Yes	
Learning Disabilities	No	No	Yes	
Hearing impairment	No	No	Yes	
Visual impairment	No	No	Yes	
Physical Disability	No	No	Yes	
Mental Health Need	No	No	Yes	
Gay/Lesbian /Bisexual	No	No	Yes	
Trans	No	No	Yes	
Faith Groups (please specify)	No	No	Yes	
Marriage & Civil Partnership	No	No	Yes	
Pregnancy & Maternity	No	No	Yes	
Carer Status	No	No	Yes	
Other Group (please specify)				

INITIAL ASSESSMENT (PART 5)

Have you identified any issues that you consider could have an adverse (negative) impact on people from the following protected groups? **NO**

IF 'NO IMPACT' IS IDENTIFIED Action: No further documentation is required.

IF 'HIGH YES IMPACT' IS IDENTIFIED Action: Full Equality Impact Assessment Stage 2 Form must be completed.

(c) Following completion of the Stage 1 Assessment, is Stage 2 (a Full Assessment) necessary? NO

Assessment Completed By: …Dan Firth……...**Date Completed:** …07/02/2023

Line Manager ……Annette Davis-Green…….. Date……07/02/2023……..

Head of Department ……Dr Dominique Chan-Lam Date……07/02/2023……..

When is the next review? Please note review should be immediately on any amendments to your Policy/procedure/strategy/service.

1 Year	**2 year**	**3Year X**

STAGE 2 – FULL ASSESSMENT & IMPROVEMENT PLAN

MUST be completed if any high negative issues have been identified at stage 1

Protected Characteristic	**What adverse (negative) impacts were identified in Stage 1 and which groups were affected?**	**What changes or actions do you recommend to improve the service to eradicate or minimise the negative impacts on the specific groups identified?**	**Lead**	**Timescale**
• **Men** • Younger People (17-25) • and Children • Older People (50+) • Race or Ethnicity • Learning Disability • Hearing Impairment • Visual Impairment • Physical Disability • Mental Health Need • Gay/Lesbian/Bisexual • Transgender • Faith Groups (please specify) • Marriage & Civil Partnership • Pregnancy & Maternity • Carers • Other Group (please specify) • Applies to ALL Groups				
How will actions and proposals be monitored to ensure their success? Which Committee will you report to? (i.e. Divisional DQEC / Governance Meeting).				
Who will be responsible for monitoring these actions?				

Appendix 2
Glossary of terms

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

ACB: Association of Clinical Biochemists and Laboratory Medicine
BHNFT: Barnsley Hospital NHS Foundation Trust
BSQR: Blood Quality Safety Regulations
BCSH: British Committee for Standards in Haematology
BRILS: Barnsley and Rotherham Integrated Laboratory Services
CMV: Cytomegalo Virus
CSF: Cerebrospinal fluid
GUM: Genito-Urinary Medicine
HTA: Human Tissue Authority
ICE: Integrated Clinical Environment
IBMS: Institute of Biomedical Science
ISH: Integrated Sexual Health
NHS: National Health Service
MHRA: Medicines and Healthcare Products Regulatory Agency
RCPath: Royal College of Pathologists
UKAS: United Kingdom Accreditation Service

Appendix 3

Version	Date	Comments	Author
1a (Draft)	31/07/2020	First Draft of Policy	Dan Firth
1b (Draft)	02/09/2020	Policy updated following comments within Pathology. Approved at Pathology Business and Governance Meeting 02/09/2020.	Dan Firth
1c (Draft)	01/10/2020	Policy updated following review and comments from Clinical Director for CBU3.	Dan Firth
1d (Draft)	16/02/2021	Policy updated following review and comments from Clinical Director for CBU3 and comments made during CBU3 Business and Governance 25/11/2020. Version updated to state Requesting Practitioner/Consultant/GP and location must be provided, but samples will not be rejected if not provided. Approved at Pathology Business and Governance 16/02/2021.	Dan Firth
1 (Final)	02/12/2021	Approved at CBU3 Business and Governance Meeting 28/04/2021, Patient Safety and Harm 23/09/2021 and Quality and Governance Committee 27/10/2021. Endorsed by the Trust Board of Directors 02/12/2021.	Dan Firth
2a (Draft)	07/02/2023	Decision by Executive Team on 18/01/2023 to amend Pathology Sample Acceptance criteria to reject samples where a clinician and/or location is not provided on the handwritten request form from 01/04/2023. Approved by Clinical Director for CBU3 and approved at CBU3 B&G 22/02/2023. Approved by PSH 23/03/2023	Dan Firth

Review Process Prior to Ratification:

Name of Group/Department/Committee	Date
Pathology Business and Governance Meeting	15/02/2023
CBU3 Business and Governance Meeting	22/02/2023
Patient Safety and Harm Group	23/03//2023

Trust Approved Documents (policies, clinical guidelines and procedures)

Approval Form

Please complete the following information and attach to your document when submitting a policy, clinical guideline or procedure for approval.

Document type (policy, clinical guideline or procedure) **Detail any section headings that have been removed from the template and the reason for this**	Policy
Document title	Pathology Sample Acceptance Policy
Document author (Job title and team)	Barnsley and Rotherham Integrated Laboratory Services (BRILS) Integrated Quality Manager
New or reviewed document	Reviewed
List staff groups/departments consulted with during document development (including BFS, & any other stakeholders)	Pathology Service Clinical Director, CBU3 Executive Team Medical Director and Deputy Medical Director Barnsley PLACE Quality and Safety Committee
If this document deviates from published national guidance please state the reasons for this and the impact this may have on patient safety (include relevant risk ID).	N/A
Approval recommended by (meeting and dates):	Pathology Business and Governance Meeting- 15/02/2023 CBU 3 Business and Governance Meeting- 22/02/2023 Patient Safety and Harm Group- 23/03/2023
Date of next review (maximum 3 years)	01/04/2026
Key words for search criteria on intranet	Pathology Sample Acceptance Request Results Results Transfusion Blood Microbiology Histopathology
Key messages for staff (consider changes from previous versions and any impact on patient safety)	This is an updated version of the Pathology Sample Acceptance Policy. 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 Pathology Service. This Policy is to ensure that staff within the Trust understands the minimum criteria that must be in place for the receipt and identification of patient samples and request forms. Each request sent to Pathology

	and accepted for investigation will be considered an agreement to undertake the relevant analysis and Pathology will expect compliance with this Policy from all users. Following approval from the Executive Team on the 18/01/2023, The Policy has been updated to reflect that a requesting Practitioner and requesting location **MUST** be provided in full on the request form. This is to ensure the result is communicated to the intended recipient in a timely manner by both electronic reporting via the ICE System, and verbal telephone communication from the laboratory if the result falls within the critically abnormal limits of the laboratory. Failure to provide both the requesting Practitioner and requesting location on the request form **will result in rejection** on the grounds of patient safety.
I confirm that this is the <u>FINAL</u> version of this document	**Name: Dan Firth** **Designation: Quality Manager**

FOR COMPLETION BY THE CLINICAL GOVERNANCE TEAM

Approved by (group/committee): PSH **Date approved: 23/03/2023** **Date Clinical Governance Administrator informed of approval: 04/04/2023** **Date uploaded to Trust Approved Documents page: 06/04/2023**