The Newcastle upon Tyne Hospitals NHS Foundation Trust

Sample Acceptance and Rejection Policy

<table>
<thead>
<tr>
<th>Version No.:</th>
<th>3.7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective From:</td>
<td>22 December 2015</td>
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<tr>
<td>Expiry Date:</td>
<td>22 December 2017</td>
</tr>
<tr>
<td>Date Ratified:</td>
<td>18 December 2015</td>
</tr>
<tr>
<td>Ratified By:</td>
<td>Laboratory Medicine Board</td>
</tr>
</tbody>
</table>

1 Introduction

1.1 Submission of a request and specimen(s) to NUTH Laboratories constitutes a contract between the service user (on behalf of the patient) and the service provider (NUTH Medical Laboratories) to perform investigations. Both parties are required to fulfil their obligations under this policy to ensure that the quality of the support diagnostic testing remains focused on the patient.

1.2 This document sets out the Trust’s policy for submitting specimens to the Laboratory for diagnostic tests and investigations. It is intended to ensure the safety of the patient and to confirm the correct investigation is performed on the right sample. Laboratory members of staff are not permitted to endanger the patient by working outside the policy.

1.3 The policy applies to all samples and tissue specimens that are taken from a patient in any clinical area of the Trust and labelling is regarded as a formal identification procedure.

1.4 Accurate identification details on laboratory samples are vital for patient safety. It is the responsibility of the person requesting a laboratory investigation (i.e. medical, nursing and phlebotomy staff etc.) to ensure that samples are correctly labelled and request details (forms or electronic requests) are completed to the required standard. Sample and request details must be compatible.

1.5 In some circumstances typically in accident and emergency departments, full patient details are not available. In these cases local policy for labelling of unknown patients and their samples must be followed.

1.6 Before a clinical specimen is accepted, laboratory staff must ensure that the minimum criteria for sample identification are met and that the sample and request form match correctly. It is important that the requesting medical officer/practitioner is identified on the form and that a contact number is given in case there is a problem with the sample or request form or there is a critically abnormal result. It therefore is strongly recommended that a contact number is given.
2 Scope

2.1 This policy applies to all Trust staff of all grades who take samples and specimens from patients anywhere in clinical areas of the Trust. Although not exhaustive, specimens and samples are biological materials that can be broadly classified as follows:

i. Blood
ii. Urine
iii. Tissues
iv. Bone
v. Faeces
vi. Non-blood bodily fluids (e.g. synovial, pleural, ascitic, C.S.F.)
vi. Swabs and cultures
viii. Nails
ix. Hair

2.2 Samples and specimens must be taken by staff who are competent to do so and although not exhaustive would include the following grades:

i. Qualified Doctors
ii. Trained Medical Students
iii. Qualified Nurses
iv. Qualified Midwives
v. Qualified Dental Practitioners
vi. Qualified Dental Nurses
vii. Qualified Operating Department Practitioners
viii. Qualified Phlebotomists (this group is not eligible to label tissue samples)
ix. Healthcare Assistants

All the above staff groups, with the exception of Phlebotomists, can label tissue samples but it is important to note that all tissue samples must be formally checked and labelled by two members of staff from the above list that are eligible to do so.

3 Aims

3.1 To provide guidance to Trust staff who request laboratory tests and take samples for pathology investigations on obtaining, correctly labelling, preserving, packaging and transporting samples requiring pathology tests.

3.2 To ensure that the correct patient is identified before any specimens are taken for diagnostic testing, that the Trust labelling policy is completely followed on every occasion.

3.3 To raise awareness that every test that is performed by the laboratory on behalf of a service user is a service agreement between the two parties. This is now a
stipulated requirement to conform to Pathology Quality requirements and comply with the ISO 15189 standard for quality and competence in Medical Laboratories.

4 Duties (Roles and responsibilities)

4.1 Trust Board

The Trust Board is responsible for ensuring that a robust system of risk management is in place within the organisation which includes the identification of patients and labelling requirements for pathology sample and specimen testing.

4.2 Chief Executive

The chief Executive has ultimate accountability for ensuring that there are appropriate processes in place for effective and reliable management of the requirements of this policy but delegates this responsibility through Clinical Directors and Directorate Managers within the organisation.

4.3 Directorate Managers and Directorate Directors

All Clinical Directors and Directorate Managers are responsible for ensuring

i. Adequate and appropriate dissemination and implementation of this policy within their areas of responsibility.

ii. Ensuring appropriate and adequate training of staff to perform the tasks covered by this policy and maintaining and measuring continuing competence in this respect.

iii. Identifying the root causes of non-compliance with this policy and taking all necessary measures to introduce corrective and remedial actions as required.

4.4 Heads of Department, Junior Managers and Supervisors

Have a responsibility to ensure that all staff that they line-manage that undertake the activities covered by this policy, perform the tasks in full compliance with requirements. They must take appropriate actions to correct and report non-conformances with requirements as they present.

4.5 All staff

All staff members who perform the tasks covered within this policy are personally responsible for their own actions and must ensure that they are comply fully with the policy requirements and remain competent to carry out the required tasks.
They must notify their line manager immediately if they feel that they are unable to comply with the requirements.

The list above is not exhaustive and there may be occasion where additional stakeholders/specialist personnel with a specific role and or responsibility should be listed.

5 Definitions

The following definitions apply in the context of this policy:

5.1 Service Agreement

A statement that defines the pre analytical requirements of the laboratory from service users and provided that these are met fully, what the service users in turn can expect with the examination results provided by the laboratory.

5.2 Valid

A sample and/or request that is acceptable for examination by the laboratory. Although not exhaustive, this will require a sample of appropriate quality, with positive and correct labelling. The request process should conform to the exact requirements whether hardcopy or electronic and should follow the exact progression steps.

5.3 Sample or specimen

A portion of biological fluid or tissue that is removed from a patient, placed into appropriate container (s) for the purpose of laboratory examination.

5.4 Request

A formal approach made verbally, in writing or electronically that asks the laboratory to perform an examination process on accompanying biological fluid(s) or tissue (s).

5.5 Reports

The representation of collated examination results, with appropriate technical, scientific, clinical and medical interpretations, in a single electronic or hard copy document. It is intended to assist service users in the diagnosis and/or clinical management of disorders and ailments.
5.6 The laboratory

One of a number of facilities or areas within the Directorate of Laboratory Medicine that is equipped for performing diagnostic testing, experiments, research and teaching. The laboratories are split into the following specific disciplines:

i. Blood Sciences (on both Freeman Hospital and RVI sites)
ii. Blood Transfusion (on both Freeman Hospital and RVI sites)
iii. Cellular Pathology (RVI)
iv. Microbiology (Freeman Hospital)
v. Public Health England-Molecular (RVI)
v. Public Health England – Tuberculosis (Freeman)

5.7 Service users

These are any party with the appropriate authority to request that the laboratories perform diagnostic testing of biological fluids or tissues on their behalf. Service users will need to consider the appropriateness of all requests made and should contact the laboratories to discuss where uncertainty occurs. Although not exhaustive this includes the following groups:

i. Qualified Doctors
ii. Qualified Nurses (delegated responsibility from a doctor or some specialist nurses in their own right)
iii. Qualified Midwives
iv. Qualified Dental Practitioners
v. General Practitioners or representatives acting on their behalf.

5.8 The Trust

The Newcastle upon Tyne Hospitals NHS Foundation Trust.

6 Procedure

6.1 Service Agreement

Laboratory practices are subjected to comprehensive regulation and legislation and the Medical Laboratories – Requirements for Quality and Competency Standard (ISO 15189) requires all requests and tests to be deemed a service agreement between the laboratories and service users. As such there are expectations that fall on both parties and it is a requirement that these are understood and strictly adhered to. They are summarised as follows:
6.1.1 Laboratory expectations and requirements of service users

Service users are responsible for ensuring that all of the following points are met and they must:

i. Provide a specimen/sample that is valid and of acceptable quality for testing.

ii. The patient must be correctly identified at the time of the sample taking and the service user is referred to Trust policies relating to this.

iii. The sample must be fully and correctly labelled before sending this to the laboratory.

iv. Specimens/samples must be taken under the correct conditions (refer to the Laboratory Medicine intranet page or contact the laboratory where uncertainty exists).

v. The sample container must be sealed in order to prevent spillage. Failure to do so may result in loss of sample or the container being returned for appropriate repackaging.

vi. Specimens/samples must be taken into the correct containers and be filled to the correct levels. The laboratory must be contacted if this cannot be done and they will advise as to whether alternatives would be acceptable.

vii. Specimens must be correctly packaged, preserved and transported in a timely manner to the laboratory for testing. The laboratory must be contacted if this cannot be done and they will advise as to whether alternatives would be acceptable.

viii. Requests- Full information must be provided on all requests. This will include both patient and clinical details and any other information that will ensure that the correct tests and follow up tests are performed as required.

ix. Where electronic requesting is used, the service user must ensure that the exact process of ordering and escalation takes place before any samples are sent off for testing. This is absolutely critical to the process and service users must understand the process and should refer to all Trust policies and procedures for electronic ordering (e-Record).

6.1.2 Service User expectations of the Laboratories

Provided that all of the expectations in 6.1.1 above are fully met, the service users can in return expect the following levels of service from the laboratories:
i. Requests and tests will be received, registered and processed by trained and competent Health Care Science Assistants (HCSA’s) or higher grades of laboratory staff.

ii. Examination testing will be performed by qualified and competent Biomedical Scientists (BMS), Health Care Scientists (HCS)/ Clinical Scientists or if appropriate by HCSA’s under direct supervision.

iii. Validation of examination testing will be performed by qualified and competent BMS, HCS /Clinical Scientists.

iv. Authorisation of examination results will be performed by qualified and competent BMS/HCS /Clinical Scientists and Medical Staff as appropriate to the test.

v. Where appropriate, scientific/technical interpretation will be given verbally and/or in writing by qualified and competent HCS /Clinical Scientists.

vi. Where appropriate, clinical advice and interpretation will be given verbally and/or in writing by qualified and competent clinical or medical practitioners (HCS/Clinical Scientists, Consultants, Specialist Registrars, and F2 grades). The provider of this information differs depending on the Laboratory Medicine Discipline involved.

vii. Where appropriate, medical advice and interpretation will be given verbally and/or in writing by qualified and competent Medical Practitioners (Consultants, Specialist Registrars and F2 grades).

viii. Laboratories will ensure high quality of examination testing that will be subjected to continued external proficiency testing and regulatory assessment.

ix. The laboratories will provide instructions and advice to service users through the Trust Intranet and Web services.

x. The laboratory will make results available to service users within the turnaround times stated on the intranet and web pages. Service users will be notified as soon as possible of any circumstances that adversely affect this.

xi. The laboratories will inform service users as quickly as possible of circumstances that could impact on the reliability of examination results.

xii. The laboratories will inform services users of any changes to sample requirements or testing processes that impact on examination results and/or reference ranges.

xiii. Laboratory Management will maintain processes that ensure and test on going competence of all grades of staff employed in the Directorate.

xiv. When samples are rejected the laboratory shall issue a report that details the reason(s). Where the request is deemed to be urgent the communication may also be by telephone.
6.2 Specimens/Samples

If the requirements detailed in 6.1.1 of this policy (service agreement) are not completely met, the specimen(s)/sample(s) may be rejected by the laboratories.

6.2.1 Laboratory Medicine (Excluding Cellular Pathology)

6.2.1.1 Sample Labels

Samples must be labelled promptly in close vicinity to the patient, e.g. bedside or out-patient phlebotomy room.

**Essential information for the sample label:**

- Patient’s Full Name
- Date of birth
- Hospital Number or NHS number or other agreed unique identifier.

- If known biohazard a biohazard sticker or other alert must be attached to both request and sample

- A single unique identifier is permitted only for specific agreed services such as:
  - Sexual Health.
  - Health Surveys
  - Unknown Patients that are emergency admissions
  - Clinical Research and Trials
  - Where prior arrangements have been made with and agreed by the laboratory

- A specifically generated number is allowed for unknown unidentified patients seen in emergency departments. The label and request detail should state unknown male or unknown female together with the unique and specific emergency number.

**Desirable information:**

- Date and Time of sample is essential for certain dynamic tests, i.e. is one of a series

- Date and Time of sample is essential for Tissue Specimens and where the sample is perishable or the analyte is unstable (e.g. serum potassium).

Please consult the laboratory for information regarding individual tests.
6.2.1.2 Request Information

**Essential information for all samples:**

- Patient’s Full Name
- Date of birth
- Hospital Number or NHS number or other agreed unique identifier.
- Sex of patient
- Date of sample
- Patient’s location
- Responsible Consultant or GP
- Name of requesting Medical Officer/practitioner
- Investigations required
- Clinical Information

- If known biohazard a biohazard sticker or other alert must be attached to both request and sample.
- Essential requirements for Specific Sample type/test e.g. fasting
- Time of sample: All cellular pathology requests. Selected dynamic function tests
- Patient’s address (for Cytology)
- Handwritten sample tube details for all blood group/cross-match samples or samples for referral to the NHSBT.
- Where requests are not made electronically, the exact official name of the investigation and/or the approved abbreviation should be written legibly in block capitals on the request form.

**Desirable information:**

- Time sample collected
- Date and Time of sample is essential for Tissue Specimens and where the sample is perishable or the analyte is unstable (e.g. serum potassium), or is one of a series (e.g. dynamic tests).
- Clinical Information
- Requesting Medical Officer/Practitioner’s contact telephone or pager number
6.2.1.3 Rejection Criteria

_Samples may be rejected in the following circumstances:_

- The minimum essential information is missing from the sample or request.
- The sample and request form information do not match.
- The sample is unlabelled or otherwise unsuitable (e.g. wrong tube type).

6.2.1.4 Samples Where the Essential Information Is Missing

- Where essential information is missing from a sample or request form, the laboratory will attempt to contact the requesting medical officer/practitioner identified on the request using the contact number, where this is given.
- The laboratory may require the requesting medical officer/practitioner to attend the laboratory to complete or amend details before the request is accepted.
- If the laboratory is unable to contact the requesting medical officer/practitioner or colleague the sample will be rejected or analysis deferred until contact is made.
- When samples are rejected due to insufficient information, a report will be issued through the laboratory information system as soon as practicable, stating that the sample has not been processed and giving details.
- Where the missing information includes the Patient’s Consultant and/or the GP Patient’s location and destination for report, a printed report may be delayed or unavailable. In this case, the report may be issued to a default source (Unknown Consultant/Unknown Location) on the laboratory information system. Samples that have been rejected and not processed may be stored in the laboratory for up to one week to allow the requesting practitioner time to get in touch. This storage will be at the discretion of individual departments.

6.2.1.5 Blood Transfusion

- The minimum label requirements for transfusion specimens are a unique identification number (Hospital, NHS or A&E), surname, first name and date of birth.
- The sample tube label must be _hand written_ at the bedside. An addressograph label on the sample tube will not be accepted.
- Electronically generated sample labels must be affixed to the request form and not to the sample. Electronically generated
requests still require a request form. The person taking the sample must complete and sign the 'sample taking declaration' on the form.

- If details on samples for blood transfusion are incorrect or incomplete the samples will not be processed until the details are amended by the person who obtained the samples (minor errors only). In the event of major errors, new samples will be requested.

6.2.1.6 The Human Tissue Act 2004

- This Component of the Human Tissue Act (HTA) came into effect on 1st September 2006. It is no longer acceptable to store human tissue or cells for research use without patients' consent. Once a diagnosis has been made, tissue or cells may still be used for education, audit and quality assurance activities.

- **Consent for research storage** of cells/tissue should be discussed with patients (a detailed patient leaflet is available for information, if required) and the outcome of their decision appropriately represented on the specimen request form. A clearly identifiable specific section has been added to Histopathology and Cytology request forms to record this information. It is the responsibility of clinicians sending specimen to the laboratory to ensure that this section is completed correctly.

- The Trust supports the importance of access to stored diagnostic tissue and cells for research. Currently, a supplementary consent form for research storage of these specimens must be completed at the time of obtaining consent to biopsy and other surgical procedures.

6.2.1.7 Samples Which May be Processed Even If the Essential Information Is Missing

- Certain types of specimen are considered 'precious' or are extremely difficult to repeat (e.g. CSF samples, biopsies, aspirates, etc., or where the sample forms part of a series or dynamic test).

- In such cases, a senior member of the laboratory staff will be responsible for deciding if the analysis is justified. The requesting medical officer/practitioner will be contacted and may be asked to come to the department to complete the details.
• If samples are accepted under these circumstances, the details will be recorded on the form or in the computer. The report will include a clear disclaimer detailing the shortcomings of the sample and/or request.
• The disclaimer will identify the requesting practitioner who has agreed to take responsibility for the results and for any action taken as a result of the report.

6.2.1.8 Requests generated using an electronic system, e.g. powerchart or ICE will print a label for use on the sample container. Other samples will either be labelled in hand writing or using pre-printed addressograph labels.

6.2.2 Labelling

• Labelling of tissue specimens must be conducted by two members of staff in order to minimise the likelihood of error and ensure patient safety. This policy details the requirements for labelling both the specimen pot and the corresponding request form for tissue specimens and must include all necessary relevant information as a mandatory requirement.
• Requests generated using an electronic system, e.g. powerchart or ICE will print a label for use on the sample container. Other samples will either be labelled in hand writing or using pre-printed addressograph labels.
• Ensure that this procedure is done at the same time or just after the specimen is taken and whilst the patient is still present.
• Only the identified patient’s notes must be in the clinical area.
• The patient must have an identity wristband if anaesthetised or sedated (please refer to the Patient Identification Policy).
• Specimen container(s) or request form(s) must not be pre labelled

6.2.2.1 Labelling of Tissue Specimen(s) and request form

**Important Note:** This must be done by two members of staff, who will:
• Check the details of the specimen with the operator/surgeon
• Label the specimen pot accurately with patient details using a handwritten (handwriting MUST be legible) or current addressograph label. Using the patient’s notes complete the request form legibly to include all the following essential information:
✓ Patient’s Full Name (or coded identifier where applicable e.g. specimens from GUM clinics) (most recent name)
✓ Date of Birth
✓ Hospital Number
✓ Patient’s location and destination for report
✓ Patient’s Consultant
✓ Name of requesting doctor/practitioner and contact number
✓ Clinical information
✓ Potential risk of infection
✓ Date and time sample collected

In the case of placentas sent for histology, all the above details will be those of the mother, not the baby.

• Check the details on the specimen label and on the request form via one of the three methods:
  • If the patient is conscious and competent, by asking the patient their full name, address and date of birth and checking with their identity wristband if present
    Or
  • If the patient has no identity wristband and is considered incompetent to give these details these should be provided by the accompanying parent/guardian/carer who has signed the consent form for the procedure
    Or
  • If the patient is anaesthetised/sedated details on the labelling should be checked with the full name, address, date of birth and hospital number on the identity wristband
  • Where multiple specimens are obtained from a single patient, both the specimens and the request forms need to be clearly labelled to identify the different areas of origin of the separate samples.
  • When slides for cytological examination are submitted, the slide itself needs to have written on it the patients initial, surname, hospital number and date of birth.

6.2.3 Preparation for Transport of Specimens
The same two members of staff are responsible for ensuring that the labelling of specimen(s), completion of request form and bagging for transport are completed. This duty must not be ‘handed off’ to a third party. For further information please refer to the Transport of Clinical Specimens policy.
6.2.4 Tissue Specimen Log

All clinical areas where tissue specimens are taken must keep a record of specimens sent, recording the surname, forename, MRN, date and time of sending and department sent to.

6.2.5 Health and Safety

For histology requests, samples with known or suspected risk of infection, e.g. hepatitis, HIV or tuberculosis must be labelled as a biohazard. A lack of sufficient clinical detail provided on the request form regarding potential risk of infection may result in the sample being handled in the wrong biological containment level with resulting increased risk of infection to laboratory staff.

See: Health and Safety Executive 9/12/2011
“Provision of key clinical information on laboratory specimen requests”
http://www.hse.gov.uk/safetybulletins/clinicalinformation.htm

6.3 Anonymised and Unknown Patients

Some requests will require that the anonymity of the patient be maintained due to the nature of the tests and/or clinical details that will be required. This is necessary to preserve the dignity of the patient. Although not exhaustive an example would be requests that require sexual health testing. In these cases the required minimum labelling would be:

i. A unique reference number or identifier, printed or clearly written on both sample and request form.
ii. Sex of patient
iii. Date of sample
iv. Patient’s location/destination for report
v. Responsible Consultant or GP

6.4 Complaints and Enquiries

6.4.1. Enquiries can be made directly to the appropriate laboratory and the contact details are available through the Laboratory Medicine intranet and web pages.

6.4.2. Complaints should be directed to the appropriate Laboratory Manager or Clinical head of service. The contact details are available through the Laboratory Medicine intranet and web pages.

6.4.3 The laboratories will undertake full investigations of all complaints and endeavour to determine root causes where possible and to ensure that remedial actions are take. The outcomes will be made available to complainants where ever possible.
6.4.4 If service users are dissatisfied by the way that the laboratories handle complaints, they should contact the Clinical Director of Laboratory Medicine to progress the matter. The contact details are available through the Laboratory Medicine intranet and web pages.

7 Training

7.1 All staff who request specimens to be sent to the laboratory for tests or investigations should be appropriately trained in both the methods of collecting each type of specimen and in the requirements of making a request to the laboratory, whether this be on paper request forms or by electronic means.

7.2 Details of the use of the laboratories and requirements for specimen collection, labelling and transport to the laboratory are available on the trust intranet.

8 Equality and diversity

The Trust is committed to ensuring that, as far as reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This policy has been appropriately assessed.

9 Monitoring compliance

<table>
<thead>
<tr>
<th>Standard / process / issue</th>
<th>Monitoring and audit</th>
<th>Method</th>
<th>By</th>
<th>Committee</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance will be monitored by Laboratory staff.</td>
<td>When non-compliance is noted, appropriate codes are placed in the computer records and a report printed. Computer searches can monitor the numbers of each type of non-compliance.</td>
<td>Laboratory Staff</td>
<td>Laboratory Medicine Executive Committee</td>
<td>Annually</td>
<td></td>
</tr>
<tr>
<td>Providing the information required will ensure the health and safety of laboratory personnel and will lead to accurate and timely reports.</td>
<td>Department of Cellular Pathology. The Department will arrange update meetings with those users who fail to comply with this Trust policy.</td>
<td>Clinical Policy Group and the Trust Communication Meeting</td>
<td>Monthly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All incidents, accidents or near misses, related to the labelling of tissue specimens should be reported on DATIX</td>
<td>Clinical Governance and Risk Department</td>
<td>Clinical Risk Group</td>
<td>Six monthly reports on themes and trends</td>
<td></td>
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</table>
10 Consultation and review

This policy has been reviewed by the Laboratory Medicine Executive Committee prior to ratification and implementation. The policy will be reviewed three yearly by the Laboratory Medicine Executive Committee.

11 Implementation (including raising awareness)

This policy will be communicated to all Trust staff who undertakes this procedure. The policy will be made available on the intranet.

12 References

- Institute of Biomedical Sciences. IBMS Professional Guidance. Patient Sample and Request Form Identification Criteria. (Version 2, 2009)

13 Associated documentation

The following Trust policies are associated:

- Patient Identification - Establishment and Confirmation Prior to Investigative Testing and Treatment
- Patient Identification Policy
- Transport of Clinical Specimens policy
The Newcastle upon Tyne Hospitals NHS Foundation Trust

Equality Analysis Form A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

PART 1

1. **Assessment Date:** 18/12/2015

2. **Name of policy / strategy / service:**
   - Sample Acceptance and Rejection Policy

3. **Name and designation of Author:**
   - Ian Mellors, Quality Manager Blood Sciences

4. **Names & designations of those involved in the impact analysis screening process:**
   - Ian Mellors, Quality Manager Blood Sciences
   - Clinton Blackburn, Laboratory Manager Blood Sciences
   - Dave Evans, Laboratory Manager Cellular Pathology
   - Malcolm Holliday, Laboratory Manager Microbiology
   - Dr. Jonathan Wallis, Clinical Director Laboratory Medicine

5. **Is this a:**
   - Policy [x]
   - Strategy [ ]
   - Service [ ]

   **Is this:**
   - New [ ]
   - Revised [x]

   **Who is affected**
   - Employees [x]
   - Service Users [x]
   - Wider Community [x]

6. **What are the main aims, objectives of the policy, strategy, or service and the intended outcomes?** *(These can be cut and pasted from your policy)*
   - This policy provides a system for ensuring that the correct processes are applied for processing, retention and storage of pathological records and materials (specimens and samples).
   - To ensure that conformance with guidelines, directives and legislation is applied and maintained for this procedure.
   - To ensure that codes of ethical conduct and expected behaviours are maintained in all procurement and business matters.
7. Does this policy, strategy, or service have any equality implications? Yes [ ] No [X]

If No, state reasons and the information used to make this decision, please refer to paragraph 2.3 of the Equality Analysis Guidance before providing reasons:
The policy applies equally and fairly to all users of the Laboratory Medicine services and is intended to ensure a consistent approach to sample acceptance and labelling for all staff, patients and other service users at all times and under all circumstances. Laboratory Medicine is a support diagnostic service that will perform all tests in its repertoire upon request from service users and will do so impartially and without prejudice, ensuring equal and fair application to every such approach made from whatever authorised and approved source.

8. Summary of evidence related to protected characteristics

<table>
<thead>
<tr>
<th>Protected Characteristic</th>
<th>Evidence, i.e. What evidence do you have that the Trust is meeting the needs of people in various protected Groups</th>
<th>Does evidence/engagement highlight areas of direct or indirect discrimination? If yes describe steps to be taken to address (by whom, completion date and review date)</th>
<th>Does the evidence highlight any areas to advance opportunities or foster good relations. If yes what steps will be taken? (by whom, completion date and review date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race / Ethnic origin (including gypsies and travellers)</td>
<td>The department does not reject requests on this basis</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sex (male/ female)</td>
<td>The department does not reject requests on this basis</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Religion and Belief</td>
<td>The department does not reject requests on this basis</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Sexual orientation including lesbian, gay and bisexual people</td>
<td>The department does not reject requests on this basis</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Age</td>
<td>The department does not reject requests on this basis</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Disability – learning difficulties, physical disability, sensory impairment and mental health. Consider the needs of carers in this section</td>
<td>The department does not reject requests on this basis</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Gender Re-assignment</td>
<td>The department does not reject requests on this basis</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Marriage and Civil Partnership</td>
<td>The department does not reject requests on this basis</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Maternity / Pregnancy</td>
<td>The department does not reject requests on this basis</td>
<td>No</td>
<td>No</td>
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</table>
9. Are there any gaps in the evidence outlined above? If ‘yes’ how will these be rectified?

No

10. Engagement has taken place with people who have protected characteristics and will continue through the Equality Delivery System and the Equality Diversity and Human Rights Group. Please note you may require further engagement in respect of any significant changes to policies, new developments and or changes to service delivery. In such circumstances please contact the Equality and Diversity Lead or the Involvement and Equalities Officer.

Do you require further engagement? Yes  No  x

11. Could the policy, strategy or service have a negative impact on human rights? (E.g. the right to respect for private and family life, the right to a fair hearing and the right to education?)

No

PART 2

Name: Ian Mellors

Date of completion: 18/12/2015

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified, please refer to the Policy Author identified above, together with any suggestions for action required to avoid/reduce the impact.)