

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Sample Collection and Acceptance Policy

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Ratified By:	Clinical Policy Group

1 Introduction

- 1.1 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. Members of staff working in the laboratories should not compromise patient safety by working outside the policy.
- 1.2 Submission of a request and specimen(s) to Integrated Laboratory Medicine Directorate constitutes a contract between the service user (on behalf of the patient) and the service provider to perform investigations. Both parties are required to fulfil their obligations under this policy to ensure that the quality of the diagnostic testing remains focused on the patient.
- 1.3 The policy applies to all samples and tissue specimens that are collected from a patient in any clinical area of the Trust and labelling is regarded as a formal identification procedure. The most essential step in any diagnostic testing or treatment process is to establish positively and beyond doubt, the correct patient identity. Failure to do so can lead to the patient being misdiagnosed, wrongly treated and potentially harmed.
- 1.4 Accurate patient 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 Individual staff member responsibilities for ensuring correct patient identification are described in more detail in the Trust's [Patient Identification Policy](#). This was introduced to facilitate the highest level of patient safety and ensure that all patients are positively and correctly identified on every occasion. It is intended to ensure that all staff involved in patient identification processes, are fully aware of their responsibilities and understand the significance and importance of using wristbands for identification.

2 Policy Scope

- 2.1 This policy covers the requirements for ensuring that the identity of a patient is correctly established before any Integrated Laboratory Medicine diagnostic tests are ordered and subsequently performed. The principles however apply to all Trust areas that undertake diagnostic/treatment processes, where failure to positively identify the patient would have detrimental consequences.
- 2.2 This policy applies to all Trust staff, of all grades, who have been fully trained and deemed competent to collect and/or label, and process samples and specimens from patients anywhere in clinical areas of the Trust.

2.3 Service Agreement

Laboratory practices are subjected to comprehensive regulation and legislation and are accredited against ISO 15189 Requirements for Quality and Competence for Medical laboratories, which require all requests for 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:

2.3.1 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 the Trust Patient Identification policy relating to this.
- iii. The sample must be fully and correctly labelled with the minimum essential information before sending this to the laboratory.
- iv. Specimens/samples must be collected under the correct conditions. Refer to the Laboratory Medicine area on the Clinical Directorates tab of the intranet homepage or contact the laboratory where uncertainty exists.
- v. Specimens/samples must be collected 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.
- vi. 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.

- 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. Please note, UN 3373 standard containers must be used to transport specimens.
- 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).

2.4 Service User expectations of the Laboratories

Provided that all of the expectations in 2.3.1 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 Practitioners 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 or Medical Practitioners.
- 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 Integrated Laboratory Medicine Discipline involved.

- vii. Laboratories will ensure high quality of examination testing that will be subjected to continued external proficiency testing and regulatory assessment.
- viii. The laboratories will provide instructions and advice to service users through the Laboratory Medicine area on the Clinical Directorates tab of the intranet homepage.
- ix. The laboratory will make results available to service users within the turnaround times stated on the intranet pages. Service users will be notified as soon as possible of any circumstances that adversely affect this.
- x. The laboratories will inform service users as quickly as possible of circumstances that could impact on the reliability of examination results.
- xi. The laboratories will inform services users of any changes to sample requirements or testing processes that impact on examination results and/or reference ranges.
- xii. Laboratory Management will maintain processes that ensure and assess ongoing competence of all grades of staff employed in the Directorate.
- xiii. 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 made by telephone.

3 Aim of the policy

- 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 collected for diagnostic testing, that the Trust Patient Identification policy is completely followed on every occasion at the patient's side.
- 3.3 To raise awareness that diagnostic testing performed by the laboratory on behalf of a service user constitutes 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 implementing a robust system of corporate governance within the organisation. This includes having a systematic process for the development, management and authorisation of strategies, policies, and procedures.

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, measuring, and recording 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

- i. They comply fully with the policy requirements and remain competent to carry out the required tasks.
- ii. They must notify their line manager immediately if they feel that they are unable to comply with the requirements.
- iii. They must not deviate from protocol and must undertake training as required and ensure that this applied as reflective practice.

5 Definitions

5.1 The Trust

The Newcastle upon Tyne Hospitals NHS Foundation Trust.

5.2 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.

5.3 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.

5.4 Unique Patient Identifier

This is the patient's unique 10-digit NHS number or their Medical Record Number (MRN).

5.5 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.

5.6 Request

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

5.7 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.

5.8 The laboratory

One of a number of facilities or areas within the Integrated Laboratory Medicine Directorate 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 -including Cytology (RVI)
- iv. Microbiology and Virology (Freeman Hospital)
- v. Yorkshire and North East Genomic Laboratory Hub - YNEGLH (Centre for Life)

5.9 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.

6 Sample Collection and Acceptance Process

The person taking any specimen is directly responsible for ensuring that the patient is positively and correctly identified and that patient details correspond to the information given on both the specimen/s and any accompanying request form.

If the requirements detailed in 2.3.1 of this policy are not completely met, the specimen(s)/sample(s) may be rejected by the laboratories.

Please consult the Laboratory Medicine area via the Clinical Directorates tab on the intranet homepage for information regarding individual tests.

6.1 Sample Collection

- 6.1.1 If the patient is conscious and capable and able to communicate verbally, then labelling must be done by receiving verbal confirmation of details from 'open' questions. The patient should be asked to state their full name, address, and date of birth. Their MRN and/or NHS number should be obtained from their wristband if present.
- 6.1.2 If the patient is conscious and capable, but unable to provide verbal confirmation due to a medical condition and/or disability, then labelling must be done by receiving confirmation of details from 'open' questions using the patient's preferred communication method, e.g. sign language, interpretation, advocate or communication aids. The patient should be

asked to state their full name, address, and date of birth. Their MRN and/or NHS number should be obtained from their wristband if present.

- 6.1.3 Where the patient is anaesthetised, sedated or not capable to answer questions, specimen labelling should be checked against the wristband or photo identification badge and should include all of details described in point 6.1.1 above.
- 6.1.4 In the case of Cellular Pathology specimens, if the patient has no wristband or is not deemed to be competent, as per the guidance of the Consent for Examination or Treatment Policy, to give reliable details then they should be provided by an accompanying parent/guardian/carer who has signed the consent form for the procedure.

6.2 Sample Labelling

6.2.1 All samples

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

Specimen container(s) must not be pre labelled for any specimens.

Essential information for the sample label:

- **Patient's Full Name**
Plus
- **Date of birth**
Plus
- **Hospital Number (MRN) or NHS number or other agreed unique identifier (Only specimens with an MRN will display on eRecord).**

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 desirable; however, it 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)
- The date and collection time is desirable for tissue samples so that the laboratory is fully informed about how long the sample has been in fixative as this will allow them to prioritise the processing of samples.

6.2.2 Blood Transfusion

- The sample tube label must be **handwritten** 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.
- This includes any samples for referral to the NHSBT.

6.2.3 Cellular Pathology

- 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 handwriting or using pre-printed addressograph labels.
- Ensure that this procedure is done at the same time or just after the specimen is collected and whilst the patient is still present.
- Only the identified patient's notes must be on screen in the clinical area.
- All details of the specimen must be checked with the operator/surgeon.
- In the case of placentas sent for histology, all the essential details will be those of the mother, not the baby.

- 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 forename, surname, MRN number and date of birth. The site and pass information (sample sequence) must also be included.
- All clinical areas where tissue specimens are collected must keep a record of specimens sent, recording the surname, forename, MRN, date and time of sending and department sent to.

6.3 Request Information

Sample requests can be made electronically or with the correct paper request form. For electronic requesting please refer to the E-record guides available on the Trust intranet.

6.3.1 *Minimum Essential information for all paper requests:*

- **Patient's Full Name**
- **Date of birth**
- **Hospital Number or NHS number or other agreed unique identifier.**
- **Investigations required**
- **For Blood Transfusion forms all request form declarations must be signed by the person who took the sample.**

6.3.2 *Essential information for all paper requests:*

- **Sex of patient**
- **Date of sample**
- **Patient's location**
- **Responsible Consultant or GP**
- **Name of requesting Medical Officer/practitioner (Contact Number desirable)**
- **Clinical Information**
- 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 screening samples only)
- The exact official name of the investigation and /or the approved abbreviation should be written legibly.

6.3.3 *Paper Request Forms*

To ensure that the specimen is handled correctly, please ensure that the correct paper request form for the sample is used e.g., cytology samples must be sent on a cytology

paper request form, Blood Sciences samples must be sent on a Blood Sciences paper request form.

6.4 Rejection Criteria

6.4.1 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).

6.4.2 Samples Where the Minimum 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.

6.4.3 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.
- Cellular Pathology samples will not be rejected but will not be processed until any error has been corrected, and this may lead to a delay in diagnosis.

6.5 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.

6.6 Health and Safety

- 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.

- All samples must be correctly packaged, especially those being sent via the air tube system. Please refer to the Trust Transport of Clinical Specimens policy.

6.7 Legislation

- All blood transfusion incidents that are attributable to incorrect patient identification have to be reported by law to the Serious Hazards Of Transfusion (SHOT) in compliance with the Blood Safety and Quality Regulations 2005 which formulate United Kingdom law.
- The Trust is inspected for compliance with this need by the Medical and Healthcare Regulatory Agency (MHRA) and has to declare continued compliance with the requirements annually.

6.8 Complaints and Enquiries

- Enquiries can be made directly to the appropriate laboratory and the contact details are available through the Laboratory Medicine area on the Clinical Directorates tab of the intranet homepage.
- Complaints should be directed to the appropriate Laboratory Manager or Clinical head of service. The contact details are available through the Laboratory Medicine area on the Clinical Directorates tab of the intranet homepage.
- The laboratories will undertake full investigations of all complaints and endeavour to determine root causes where possible and to ensure that remedial actions are taken. The outcomes will be made available to complainants wherever possible.
- If service users are dissatisfied by the way that the laboratories handle complaints, they should contact the Directorate Manager of the Integrated Laboratory Medicine Directorate to progress the matter. The contact details are available through the Laboratory Medicine area on the Clinical Directorates tab of the intranet homepage.

7 Training

- 7.1 It is essential that all practitioners taking specimens are fully trained in procedure and deemed competent in both the methods of collecting each type of specimen and in the requirements of making a request to the laboratory, whether this is on paper request forms or by electronic means.
- 7.2 They should be able to clearly demonstrate this to their manager or supervisor if requested to do so. Should a member of staff be unable to demonstrate competence, their ward/department manager must arrange re-training before the individual can collect samples in a clinical environment independently.

- 7.3 All training should be provided by a practitioner that is documented as being fully competent in the procedure and should be subjected to periodic competence reassessment.
- 7.4 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 is 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 the compliance/effectiveness of this policy

Standard process issue	Monitoring and audit			
	Method	By	Committee	Frequency
Compliance will be monitored by Laboratory staff.	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.	Laboratory Staff	Laboratory Medicine Executive Committee	Quarterly
	Providing the information required will ensure the health and safety of laboratory personnel and will lead to accurate and timely reports.	Department of Cellular Pathology. The Department will arrange update meetings with those users who fail to comply with this Trust policy.	Clinical Policy Group and the Trust Communication Meeting	Monthly
	All incidents, accidents or near misses, related to the labelling of tissue	Clinical Governance	Clinical Risk Group	Six monthly reports on

Standard process issue	Monitoring and audit			
	Method	By	Committee	Frequency
	specimens should be reported on DATIX	and Risk Department		themes and trends

10 Consultation and review of this policy

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 of policy (including raising awareness)

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

12 References

- NPSA (2005) Wristband for hospital inpatients improves safety. Safer Practice No. 1. November 2005.
- Institute of Biomedical Sciences. IBMS Professional Guidance. Patient Sample and Request Form Identification Criteria. (Version 4, 2019).
- Health and Safety Executive. HID 5-2011. Provision of Key Clinical Information on Laboratory Specimen Request Forms. (Dec 2011).
- Medical Laboratories Requirements for Quality and Competence (ISO 15189). BSN EN ISO 15189:2012.
- Provision of Key Clinical Information on Laboratory Requesting Forms. Health and Safety Executive Safety Notice. December 2009.
- WHO Theatre checklist.

13 Associated documentation

The following Trust policies are associated:

- [Patient Identification Policy](#). October 2018
- [Transport of Clinical Specimens Policy](#). October 2017.
- [Consent for Examination or Treatment Policy](#). July 2022.