Liverpool Clinical Laboratories Minimum Data Standard Policy for Laboratory Investigations

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Significant changes from previous version:
Included ISO 15189 requirement regarding recording the identity of the person collecting the sample and the collection date and if applicable, the collection time. Added section regarding requests accepted will be considered an agreement. Amended Consultant/GP/Requesting Practitioner information to a mandatory requirement for all requests.

1. INTRODUCTION/BACKGROUND

1.1. Background

Most errors involving laboratory tests are caused by problems in the pre-analytical phase, including:

- patient identification on request form and/or sample.
- sample collection e.g. wrong sample, wrong tube, 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.
- errors in transcription into laboratory computer system due to illegible or incorrect data supplied.

1.2. Summary

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.

To ensure patient safety and compliance with data protection, laboratory tests must be assigned to the correct patient and the results must be received in the correct location. The requesting clinician has responsibility for providing the data on the form or electronic request. The sample collector 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.

1.3. Scope of the Policy

The policy applies to all users with whom Liverpool Clinical Laboratories (LCL) has an agreed Service Level Agreement (SLA), involved in the requisition, collection and reception of patient samples processed and analysed by LCL. It defines the minimum criteria that must be in place for the receipt and identification of patient samples and request forms.

Each request accepted by Liverpool Clinical Laboratories for investigation will be considered an agreement to undertake the relevant analysis.

The aims of the policy are:

- to ensure that results of Pathology tests are assigned to the correct patient.
- to reduce the number of repeat samples required due to mislabelling or inadequate information.
- to ensure laboratory and clinical personnel have accurate clinical and sampling information for result interpretation.
- to ensure that results (electronic and paper) are received at the correct location.
- to comply with the Data Protection Act 1998 with respect to accuracy of patient data and confidentiality.
- to enable activity data to be credited to the right consultant/clinical team.

- to support laboratory staff when the decision to reject samples has to be made.

The LCL MDS policy is an overarching document however departmental procedures are also in use describing specific requirements and should be followed in conjunction with this policy.

2. MINIMUM DATA STANDARD REQUIREMENTS

Information contained in charts 2.1 – 2.4 in **bold type** will comply with the minimum data standard required for **samples and request forms.**

Samples that do not meet the minimum criteria for unequivocal identification of the patient will be rejected by laboratory staff in accordance with guidelines produced by the professional bodies to which they belong and the requirements of the United Kingdom Accreditation Service (UKAS). Samples that are not processed or where there is no location given for the results to be received can present a serious patient safety issue.

Additional information marked * are always important, and sometimes essential for some investigations and for the correct clinical interpretation for results - refer to the Royal Liverpool and Broadgreen University Hospital Trust (RLBUHT) Electronic Laboratory Handbook and Aintree University Hospital Foundation Trust (AUHFT) Clinical Laboratories Handbook, see links below:

LCL website
http://www.liverpoolcl.nhs.uk/laboratory-handbooks/

RLBUHT intranet
http://rlbuhtnet/jps/

AUHFT
http://nww.ahtpathology.nhs.uk/index.php?title=Main_Page

A copy of this policy is also available in the laboratory handbooks and on each Trust's intranet.

2.1 Minimum data standard requirements - Blood Sciences, Medical Microbiology, Routine Virology and Immunology

REQUEST FORM (PAPER/ELECTRONIC)	SAMPLE	REASON	FAILURE TO COMPLY
Surname and First name	**Surname and First name**	Unequivocal patient identification	Rejection of sample
Date of Birth	**Date of Birth**		
Unique patient identifier: NHS Number or Hospital Number	**NHS/ Hospital Number**		
Tests required	N/A	To perform relevant tests	Rejection of sample
Location (ward/clinic/surgery)	Location	Return of results to clinician	Rejection of sample
Consultant/GP/Requesting Practitioner	N/A	Return of results to clinician	Rejection of sample
Identity / signature of sample collector	**Identity / signature of sample collector**	To confirm patient ID	Rejection of sample
*Gender	N/A	Correct interpretation of results and/or further investigations	Incorrect interpretation of results possible
*Name / Bleep No of requesting Medical Officer	N/A	To contact if necessary	Delay in results
Date and Time of Collection	**Date and Time of Collection**	Chronological tracking of results, essential in some cases Correct interpretation of results	Incorrect interpretation of results possible
*Sample Type (if not venous blood)	*Sample Type (if not venous blood)		
*Patient preparation (fasting, time of dose)	*Time and/or number of sample		
* Sampling site	*Sampling site		
*Time post clinical event(mandatory for some investigations e.g. forTroponin)	N/A		
*Relevant clinical details including relevant medication and travel history	N/A	To enable addition of interpretative comments and / or further investigations	Incorrect interpretation of results possible
*Ethnicity for ANC Haemoglobinopathy samples	N/A	Correct interpretation of haemoglobinopathy screening	Delay in partner testing decision

2.2 Minimum data standard requirements - Histopathology / Non-gynae Cytology

REQUEST FORM (PAPER/ELECTRONIC)	SAMPLE	REASON	FAILURE TO COMPLY
Surname and First name	**Surname and First name**	Unequivocal patient identification	Rejection of sample
Date of Birth	**Date of Birth**		
Unique patient identifier: **NHS Number or Hospital Number**	**NHS / Hospital Number**		
Investigations required	N/A	To perform relevant investigations	Rejection of sample
Location (ward/clinic/surgery)	Location	Return of results to clinician	Rejection of sample
Sampling Site	**Sampling Site**	Correct interpretation of results	Rejection of sample
Consultant / Requestors name and signature	N/A	Named contact for clinical discussions. Signature verifies responsibility for request	Rejection of sample
Identity / signature of sample collector	**Identity / signature of sample collector**	To confirm patient ID	Rejection of sample
Date and Time of collection	**Date and Time of Collection**	Correct interpretation of results	Incorrect interpretation of results possible
*Sample Type	*Sample Type		
*Relevant clinical details	N/A	Correct interpretation of results	Incorrect interpretation of results possible

2.3 Minimum data standard requirements - Cervical Cytology

REQUEST FORM (PAPER/ELECTRONIC)	SAMPLE	REASON	FAILURE TO COMPLY
*Surname *First name *Date of Birth *Hospital / Clinic number *NHS number 3 points from the above list must match between sample and request form	*Surname *First name *Date of Birth *Hospital / Clinic number *NHS number 3 points should match between sample and request form	Unequivocal patient identification	Rejection of sample according to North West Region Cervical Screening Quality Assurance Reference Centre Zero Tolerance Guidance.
*Sender	N/A	Return of results to correct clinician	Report sent to GP listed on Open Exeter database.
*GP if not sender	N/A	Copy of report sent to GP	Report sent to GP listed on Open Exeter database.
*Requestors name or signature, alternatively GMC or NMC number	N/A	Named contact for clinical discussions. Signature verifies responsibility for request. GMC or NMC number required to provide notification of inadequate sample monitoring data.	Monitoring of specimen taker performance compromised.
*Relevant clinical details *Date of last test *Reason for smear *LMP	N/A	Correct interpretation of results. Ensures patient management is correct and any reflex HPV testing undertaken as appropriate.	Management based on available information with risk of inappropriate HPV testing or colposcopy referral.
*Date of Request	N/A	Correct interpretation of results in some cases. Date of request enables monitoring of turnaround time as required by NHSCSP.	Performance against 14 day turnaround time based on information provided. Investigation of breaches as appropriate.

2.4 Minimum data standard requirements - Blood Transfusion

REQUEST FORM	SAMPLE	REASON	FAILURE TO COMPLY
Surname and First name	**Surname and First name**	Unequivocal patient identification	Rejection of sample
Date of Birth	**Date of Birth**		
Unique patient identifier: **Hospital Number and NHS Number if available (RLBUHT)** *See below* **NHS Number or Hospital Number (AUHFT)**	**Unique patient identifier:** **Hospital Number (RLBUHT)** *See below* **NHS Number or Hospital Number (AUHFT)**		
Patient's address	**Patient's address (RLBUHT)**		
Gender	N/A	To ensure correct components issued	Rejection of sample
Location (ward/clinic/surgery)	Location	Issue of blood products to correct location	Rejection of sample
Identity / signature of collector	**Identity / signature of collector**	To confirm patient ID	Rejection of sample
Consultant/GP/Requesting Practitioner	N/A	Return of results to clinician / used for audit	Rejection of sample
Date and Time of Collection	**Date and Time of collection**	To ensure integrity of sample	Rejection of sample
*Transfusion history	N/A	To ensure safety of component provision	Sample only valid for 72 hours
*Name / Bleep No of requesting Medical Officer	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 required. Pre op not sufficient	N/A	To ensure the appropriate use of blood products and that blood products are available when required.	May cause delay in providing blood products
Any Special Requirements i.e. Irradiated, CMV negative, HEV negative components	N/A	To ensure appropriate component selection	May result in clinical incident if patient receives inappropriate components

RLBUHT - NHS numbers (on request forms and samples) are used for patients in the community and from 121 antenatal patients.

In addition, for blood transfusion requests:

- **Pre-printed identification labels must not be used on the sample.**
- **At RLUH pre-printed identification labels must not be used on the request form.**
- **All handwritten data must be legible.**
- **Under BCSH guidelines one character difference between sample and request constitutes failure i.e. no additions, omissions or substitutions.**

2.5. Compliance with national targets

Delays in the receipt of results where samples cannot be processed or where results cannot be sent to the requesting clinician have the potential to affect the Trust's compliance with current national targets.

2.6. Correct sample

In order to provide meaningful test results, samples must be of the correct type, collected into the correct container, at the appropriate time and be in good condition when they are delivered to the laboratory.

2.7. Identification of patient, request form and sample

Unequivocal identification of samples and correlation with the request forms for the correct patient is essential. It is a serious patient safety issue if results are attributed to the wrong patient, and, particularly in the case of transfusion of blood and/or its products, misidentification of the patient can be fatal. Strict adherence by all staff to minimum data for unequivocal patient, sample and request form identification will minimise errors of this type.

Unique Patient Identifier:

For GP and other Primary Care requests the unique patient identifier is the NHS number.

For inpatients and outpatients, the unique patient identifier is the NHS number or Hospital number if the NHS number is not available. Hospital number is essential for Transfusion requests at RLBUHT (see chart 2.4 for exceptions).

The same unique identifier must be used on both the request form and the sample.

Request forms may be in paper or electronic format and must be completed so that it is possible to unequivocally identify the patient. Sample and request form information must be compatible and clear and legible.

Only laboratory approved versions of paper request forms that have been designed to comply with the relevant laboratory's requirements and quality standards should be used.

2.8. Clinical details

Medical staff and Clinical Scientists in the laboratory are available to give expert clinical advice and interpretation of results. The inclusion of relevant clinical information assists in the appropriate interpretation and actioning of results, including commenting, discussion with the requesting clinical team, and addition of relevant further testing on samples already received where appropriate and possible, thus reducing the need for further samples and providing benefit for the patient, medical, nursing and phlebotomy staff.

Details of relevant medication e.g. dose and timing, antibiotic therapy etc. should be provided.

Users must ensure the provision of sufficient information on request forms to staff in LCL to enable them to apply the correct safety measures to control the risk. Health and Safety Executive investigations have identified there has been lack of sufficient relevant clinical details being

provided on request forms. This has resulted in samples being handled at the wrong biological containment level with resulting increased risk of infection to laboratory staff. Clinicians should ensure that appropriate information, including relevant travel history is provided in order to alert laboratory staff of potential dangers.

2.9. Location/ Consultant/ GP

The correct location for any hard copy report to be sent must be included so that the results can be dispatched to the right place. Failure to include this can result in delay in patient treatment, and a breach of data protection if sent to an incorrect location. The name of the Consultant responsible for the current episode of care is a requirement to allow results for outpatients and those already discharged from wards to be sent to the relevant secretary, and the Trust to be provided with activity data by Consultant. The name of the General Practitioner on the request form is a requirement for samples sent from the community.

2.10. Labelling samples

For reasons of patient safety, it is mandatory to **hand write** (not addressograph) sample labels for **transfusion** requests**.**

The only adhesive labels that can be used for blood samples from AUHFT and RLBUHT hospital patients are those generated on a dedicated printer following electronic requesting.

Electronic ordering generates adhesive labels at the point of request. These are incorporated into the request form for use at specimen collection.

Pre-printed labels from other Hospitals may be used for other samples provided that the details are verified prior to attaching to the container and are placed so that they do not affect the stability of the container, obstruct its safe opening or prevent the assessment of sample quality.

2.11. Exceptions

2.11.1. Unique identifier

In some cases where confidentiality is an issue, such as samples from patients attending sexual health clinics, it may be agreed that a single unique identifier be used on both request form and sample. Due to the potential social and legal implications of results, great care must be exercised to prevent transcription errors, as there is no other means of verifying patient identity.

It should also be noted that Virology may accept Chlamydia and Gonorrhea (CT/GC) specimens with less than the Minimum Data Standard as outlined in the relevant Virology SOP due to the fact that many samples are self-taken by patients.

2.11.2. Patients of unknown identity

Occasionally patients are admitted who are not able to give any identification. In such cases samples will only be accepted if they are labelled as ‘Unknown male’ or ‘Unknown female’, together with a unique identifier which may be a newly assigned hospital number or AED number.

At AUHFT unknown patients are given a unique number and identified as surname Unknown XXXX / forename Unknown DOB 01/01/1901 and a hospital number. The patient’s gender is identified on the request form.

In the event of a major incident where there may be many unknown casualties, patients will be assigned a unique Major Civilian Disaster (MCD) Number, which will be the only method of identifying such patients until after 'stand down' and the patient has been properly identified. It is important that following this at least one request form is received that contains the full patient details **and** the unique identifier to enable a single patient record to be produced (with the exception of SIGMA requests). The Association of Chief Police officers (ACPO) numbers would be used for a major mass mortality.

2.11.3. Staff attending Health and Well-being Centre (Occupational Health)

It may not be appropriate in terms of confidentiality to supply a hospital number or NHS number for Trust staff who attend for employment related tests. In these cases the sample will be processed if the minimum identification details are full Name and Date of Birth provided that this location is clearly given.

2.11.4. Primary Care patients without an NHS number

If a request is made from Primary Care for a patient who does not have an NHS number this fact must be clearly stated on the request form.

2.11.5. Smears

Smears of material on microscope slides must be labelled with the patient's **full name** and **Date of Birth** as the minimum. Labelling must be in **pencil** only as ink dissolves in the processing reagents. Ensure slide labelling is on the same side of the glass slide as the specimen.

2.11.6. Extreme cases

Cases where the criteria for correct labelling of request and sample **cannot** be met are very rare. Laboratory staff must not be coerced into accepting incorrectly or inadequately labelled requests and/or samples.

For urgent and/or 'precious' samples (those that cannot be repeated, or it would put patients **at greater risk** to do so), the Consultant in charge of the laboratory discipline involved or a Clinical Scientist /Senior member of staff (or appropriate deputy) may request that the sample is processed in an appropriate manner. The procedures to follow in these circumstances are defined in departmental procedures.

In the case of 'precious' samples in Transfusion local procedures must be adhered to.

2.12. Rejection of Samples

2.12.1. Criteria for rejection

Samples <u>will</u> be rejected:

- when the **minimum criteria** are not met.
- if they are fully labelled, but **not reliably identified**, e.g. where two samples with the same details are from different patients both may be rejected.

In addition, samples that will be rejected because they cannot produce reliable results or present a safety risk include:

- clots present in blood bottles where an anticoagulant is required in the sample.

- containers that are not filled to the correct level where it is critical (e.g. coagulation studies).
- time from clinical event to collection of sample is not within published guidelines (e.g. Troponin).
- time from collection to testing is outside the limits where reliable results can be obtained (e.g. - inappropriate storage before receipt in the laboratory).
- gross contamination of the outside of the container.
- 2 patients' Sigma requests arrive in the same bag.

2.12.2. Recording information

Where there is sufficient information on the request, but sample labelling is inadequate, patient details will be entered into the laboratory computer system. There will be a coded entry for the test that will generate a report stating the test has not been performed, together with a reason for the rejection. This will form part of the patient record.

2.12.3. Informing requestor

Due to the high volume of requests received the requestor will **not** normally be contacted directly when samples for routine tests are rejected.

At the RLBUHT a laboratory report will be issued if a location has been provided, indicating the sample was unsuitable for analysis due to a non-compliance with the policy. At AUHFT, for inpatients and outpatients the information will be available electronically via the patient record, only where a hospital number is available, and via a hard copy report, only where a valid location or Consultant is given.

The information for community requests will be available via the GP messaging service and /or hard copy reports only where the GP location is given. Samples will, however be retained for as long as those samples that have been tested in case of any query.
For urgent and/or 'precious' samples (those that cannot be repeated, or it would present a greater risk to the patient to do so) the requestor may be contacted by telephone and asked to amend inadequate details as appropriate and accept responsibility. This must be recorded according to laboratory procedures. In the absence of the requestor, and except for transfusion requests, the laboratory Consultant, Clinical Scientist or a Senior/Experienced BMS may action as above.

3. DUTIES AND RESPONSIBILITIES

3.1. LCL Medical Director/ Laboratory Clinical Directors

It is the responsibility of the LCL Medical Director to authorise the policy and in conjunction with the Speciality Clinical Directors and the LCL Quality Manager to review and amend this policy in line with best practice, and to support laboratory staff in their implementation of it.

3.2. Policy Approval

The policy will be approved at the LCL Quality and Governance Committee which includes representatives from the Clinical Governance and Risk Teams of the Royal Liverpool and Broadgreen University Hospitals NHS Trust and Aintree University Hospital NHS Foundation Trust who will support its implementation throughout the organisations.

3.3. Requestor

The authorised person making the request is responsible 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.
- the accuracy of patient information on the request form or electronic request.
- attaching correct addressograph labels (where allowed) to the request form.
- indicating the location for results to be sent.
- identifying the Consultant/GP.
- indicating tests required on the form.
- determining any specific requirements for the tests being performed, e.g. fasting, timed samples, and informing the patient where necessary.
- being aware of requirements for specialist assays by consulting the laboratory handbooks, available on the relevant Trust's intranet site or LCL website, or contacting the appropriate department if the information cannot be found.
- providing sufficient relevant and legible clinical information on the form to enable correct interpretation of results.
- obtaining valid consent for the test where required, e.g. HIV or genetic testing.
- identifying the person making the request.
- signing the paper request form (where the form is completed on behalf of the requestor, this signature may be of the person completing the form provided that the requestor is also identified as above).
- informing patients collecting their own samples, such as urine, that the sample must be adequately labelled before sending it for testing.
- This policy is to be referenced in all Service Level Agreements (SLAs)

Note 1:
Tests on members of staff within the Trust or its external users must only be requested via their General Practitioner, Occupational Health Department or the clinical team responsible for their medical care.

Note 2:
Request forms sent with patients for phlebotomy **must** also be fully completed before leaving the surgery or clinic. It is not acceptable for patients to write their own details, or for phlebotomy staff to complete them. The phlebotomist is required to confirm with the patient that the details given are correct. Failure to include full patient demographics at the point of request should result in the sample not being collected, and also presents a risk that patients may attend for tests requested on a family member for example.

3.4. Sample Collector

The sample collector is responsible for:

- checking the correct identity of the patient and ensuring correlation with patient demographic information documented on the request form.
- where possible, and prior to collection, confirming that the specific preparatory requirements for the test to be undertaken, e.g. fasting, have been complied with.
- taking sufficient sample for the requested tests to be carried out.
- collecting from the appropriate site, e.g. away from intravenous lines.
- collecting samples in the correct order and into the appropriate container. Blood must not be transferred from one container to another.
- filling sample bottles with the correct volume if indicated.

- labelling sample containers with at least the minimum data required, at the time of collection. **CONTAINERS MUST NOT BE PRE-LABELLED OR TAKEN AWAY FOR LABELLING.**
- handwriting labels on samples for transfusion.
- recording their details on the request form along with the date and time of sample collection.
- taking steps to ensure that the requestor is informed where insufficient or no sample is obtained.
- sealing the sample (or samples from the same patient with one form) in the bag attached to the request form or as supplied for order comms (exceptions for large samples).
- ensuring that samples are transported to the Laboratory in a timely manner

3.5. Staff receiving patient samples

Staff, such as GP practice staff or clinic staff, receiving samples that patients have collected themselves must check that the samples are correctly labelled before forwarding them to the laboratory.

3.6. Laboratory Staff

Laboratory staff have the responsibility for:

- conducting analyses only on samples that are unequivocally identified and suitable for the tests requested.
- keeping sample and request form together until unequivocal identification and correlation of both is determined or sample rejected as below.
- preserving the integrity of rejected or 'spare' samples in case they are required subsequently.
- where permitted, and according to local laboratory standard operating procedures, requesting that missing data on request forms or samples is completed by the authorised requestor or deputy.
- when taking an aliquot of a sample for further testing, labelling it with at least the minimum patient identification and unique laboratory number.
- preserving as much sample as possible for additional or further testing.

This is a brief overview of the roles and responsibilities of Laboratory staff. Each department has its own complement of Standard Operating Procedures detailing the precise course of action for each task performed.

4. MONITORING EFFECTIVENESS

4.1. Implementation

This policy will be available on the RLBUHT and AUHFT intranet sites and distributed to CCGs and other external service users. It is a controlled document on Q-Pulse, LCL's document management system.

4.2. Audit

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**.**

4.3. Reporting

Some instances of failure to comply with the policy will result in reporting through the Trust's incident reporting procedure. These will include, but not limited to:

- Unlabelled or mislabelled samples for transfusion requests.
- Samples that have been fully labelled but are from the wrong patient.
- Persistent failure of individuals or clinical areas to adhere to the procedure.

5. TRAINING

This policy must be incorporated into the planned relevant staff training programmes within the Trusts.

6. REFERENCES

- British Committee for Standards in Haematology Guidelines on the Administration of Blood and Blood Components
- BS EN ISO 15189:2012 Medical laboratories – Requirements for quality and competence
- Guidelines for the Blood Transfusion Services in the UK March 2013
- Health and Safety Executive - Safety Notice HID 5-2011 Provision of key clinical information on laboratory specimen request forms http://www.hse.gov.uk/safetybulletins/clinicalinformation.htm
- Institute of Biomedical Science Patient Sample and Request Form Identification Criteria March 2016
- North West Region Cervical Screening Quality Assurance Reference Centre Zero Tolerance Guidance