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Standards covered by this document

ISO 15189:2012	5.4	Pre-Examination Processes
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Related documents

Title	Q-Pulse No.
COSHH Assessments	
Risk Assessments	
Others	
BS EN ISO 15189:2012 (Medical laboratories — Requirements for quality and competence)	QMS-EXTD-2
LCL Laboratory Handbook - UHA	QMS-EXTD-160
LCL Laboratory Handbook - RLBUHT	QMS-EXTD-161
Virology Specimen Verification	I&1-VI-SOP-54
Returns Policy SOP	CP-SPE-SOP-27
Fine Needle Aspiration Cytology SOP	CP-NCER-SOP-1

Significant changes from previous version:

Updated to reflect CC-190 Removal of address from Transfusion sample bottle. Address will no longer be required on the sample bottle however is still mandatory on the request form.

Updated to reflect CC-210 Removal of acceptance of REM hospital number at AUH. All LUHFT patients are required to have an RQ6 number and the use of the historic AUH hospital number has been removed.

Pre-printed identification labels are no longer accepted on any Transfusion request forms including from The Walton Centre

Introduction

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.

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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.

Purpose and scope

The policy applies to all users involved in the requisition, collection and reception of patient samples processed and analysed by LCL, including those with whom Liverpool Clinical Laboratories (LCL) has an agreed Service Level Agreement (SLA) and those that use LCL services as a referral laboratory. Note that each request sent to LCL and accepted by LCL for investigation will be considered an agreement to undertake the relevant analysis and LCL will expect compliance with this policy from all users.

It defines the minimum criteria that must be in place for the receipt and identification of patient samples and request forms.

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 2018 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.

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Roles and responsibilities

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.

Policy Approval

The policy will be approved at the LCL Quality and Safety Group which includes representatives from the Clinical Governance and Risk Teams of the Liverpool University Hospitals Foundation Trust who will support its implementation throughout the organisations.

Service / Laboratory Managers

It is the responsibility of the service managers and laboratory managers to ensure that this policy is adhered to and that any deviations are recorded as per documented procedure. Service and Laboratory managers shall be responsible to ensure that each department section reflects the requirements of their departments and if necessary, inform the Quality Practitioner and/or Quality Manager of any changes via the change request stage on Q-Pulse.

Any deviations from this policy must be discussed with the Clinical Director of the Directory and Quality Practitioner, deviations must be risk assessed and appropriately documented.

Quality manager

It is the responsibility of the Quality Manager to ensure this policy is up to date, including review of the change requests raised and ensure the policy is in line with regulatory and accreditation requirements. It is the quality manager responsibility to ensure the most up to date version of this policy is available to the requesting clinicians via the Laboratory Handbook available on the Trust Intranet.

All staff

Laboratory staff has 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.

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- 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.

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/ Registrar and or speciality doctor.
- 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)

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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:

It is good working practice to ensure that request forms sent with patients for phlebotomy **must** also be fully completed before leaving the surgery or clinic. It is not **appropriate** for patients to write their own details, or for phlebotomy staff to complete them. The phlebotomist **should** 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.

[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. Please refer to order of draw <http://rhlabcomm01/handbook/orderofdraw.pdf>
- 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.**
- ALL transfusion samples and request forms must be handwritten.
- Recording their details on the request form along with the date and time of sample collection and, when possible, record this on the sample. *Note: It is collector responsibility to ensure the identity of the collector is recorded. LCL will accept samples without this information, however, at any point we can ask user for this information. This could be during the investigation of an error and/or during an audit to ensure compliance. This requirement is in line with ISO 15189:2012 clause 5.4.4.3 f) that states*

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“The laboratory’s instructions for collection activities should include (...) recording of the identity of the person collecting the primary sample and collection date, and, when needed, recording of the collection time;”

- 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 accordance with specimen/sample requirements. Please refer to the laboratory handbook for further details.

[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.

Terms and definitions

Term	Definition
MDS	Minimum Data Set
GDRP	General Data Protection Regulation

Policy

[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.

[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.

[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

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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. Trust Specific Hospital number is essential for Transfusion requests e.g., LUFHT RQ6 however NHS numbers are used for patients in the community
- 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.

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.

Location/ Consultant/ GP

The correct location for any 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

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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.

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 LUHFT 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.

Exceptions

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.

For samples received from patients currently in prison, due to confidentiality, the prison number will be accepted instead of the NHS number.

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

In Biochemistry urine and faecal samples that are collected by the patient will be accepted even if there is no date or time of collection on the sample or request card.

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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 Aintree site 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. The Association of Chief Police officers (ACPO) numbers would be used for a major mass mortality.

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.

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.

Diagnostic 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.

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.

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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.

[Rejection of Samples](#)

Samples will 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
- If patients details have been amended on sample. i.e different patient details then amended (either by crossing out and/or tippex over)
- The information provided is not legible

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 requests/samples arrive in the same bag.

Note:

For Histopathology and Non-Gynae Cytopathology samples, due to the precious nature of the sample, LCL will not reject or dispose of samples but samples will not be processed until sufficient information is provided.

For further details please refer to Appendix 1, 2 and 3.

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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.

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.

A 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.

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.

Monitoring and review

Implementation

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

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.

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:

- Unlabeled or mislabeled 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

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References

Title	Q-Pulse No.
BS EN ISO 15189:2012 (Medical laboratories — Requirements for quality and competence)	QMS-EXTD-2
British Committee for Standards in Haematology Guidelines on the Administration of Blood and Blood Components	Online
Guidelines for the Blood Transfusion Services in the UK March 2013	Online
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	Online
Blood Safety and Quality Regulations 2005	Online
HTA Codes of Practice and Standards	Online
FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration	QMS-EXTD-171
Institute of Biomedical Science Patient Sample and Request Form Identification Criteria March 2016	Online
North West Region Cervical Screening Quality Assurance Reference Centre Zero Tolerance Guidance	Online

Appendix 1 - Minimum data standard requirements - Blood Sciences, Medical Microbiology, Routine Virology and Immunology

Request Form (Paper or Electronic)	Sample	Reason	Failure to comply	Exceptions
Surname and First name	Surname and First name	Unequivocal patient identification	Rejection of Sample	GUM specimens will be anonymised and only GUM/DOB is required
Date of Birth	Date of Birth (DOB)			No exceptions, all samples must contain DOB
Unique patient identifier: NHS Number or Hospital Number	NHS/ Hospital Number			Self-taken Samples & Precious samples (CSF, Biopsies, FNA)
Tests required	N/A	To perform relevant tests		Precious samples (CSF, Biopsies, FNA)
Location (ward/clinic/surgery)	N/A	Return of results to clinician		Self-taken Samples & Precious samples (CSF, Biopsies, FNA)
Consultant/GP/Requesting Practitioner	N/A	Return of results to clinician		Self-taken Samples & Precious samples (CSF, Biopsies, FNA)
Date, Time and location of Collection (preferable but not mandatory)	Date and Time of Collection (Mandatory)	Chronological tracking of results, essential in some case to ensure correct interpretation of results	Rejection of Sample	Self-taken Samples & Precious samples (CSF, Biopsies, FNA)

Identity / signature of sample collector	Identity / signature of sample collector	As per clause 5.4.4.3 f) of ISO 15189:2012	Samples accepted however LCL may periodically audit compliance	Not applicable
Gender	N/A	Correct interpretation of results and/or further investigations	Incorrect interpretation of results possible	Not Applicable
Name / Bleep No of requesting Medical Officer	N/A	To contact if necessary	Delay in results	Not Applicable
Sample Type (if not venous blood)	Sample Type (if not venous blood)	Chronological tracking of results, essential in some case to ensure correct interpretation of results	Incorrect interpretation of results possible	Not Applicable
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. for Troponin)	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	Not Applicable

Appendix 2 - Minimum data standard requirements - Histopathology / Non-gynae Cytology

Request Form (Paper/Electronic)	Sample	Reason	Failure To Comply	Exceptions
Surname and First name	Surname and First name	Unequivocal patient identification	LCL will not reject or dispose of samples but samples will not be processed until sufficient information is provided	Not Applicable
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	If correct request form used (Histology or Cytology) sample will be processed as per usual. If wrong request form samples will not be processed until sufficient information is provided	
Location (ward/clinic/surgery)	Location	Return of results to clinician	Clarify on PAS system and record as error	
Sampling Site	Sampling Site	Correct interpretation of results	Clarify on PAS system and record as error	

Consultant name and signature	N/A	Named contact for clinical discussions. Signature verifies responsibility for request	LCL will not reject or dispose of samples but samples will not be processed until sufficient information is provided	Not Applicable
Identity / signature of sample collector	Identity / signature of sample collector	clause 5.4.4.3 f of ISO 15189:2012	Samples accepted however LCL may periodically audit compliance	
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	

Appendix 3 - Minimum data standard requirements - Blood Transfusion

REQUEST FORM	SAMPLE	REASON	FAILURE TO COMPLY
Surname and First name	Surname and First name		Rejection of sample
Date of Birth	Date of Birth		
Unique patient identifier: Trust specific Hospital Number (and NHS Number if available) NHS numbers (on request forms and samples) are used for patients in the community	Unique patient identifier: Trust specific Hospital Number NHS numbers (on request forms and samples) are used for patients in the community	Unequivocal patient identification	
Patient's address	N/A		
Gender	N/A	To ensure correct components issued	
Location (ward/clinic/surgery)	Location	Issue of blood products to correct location	
Identity/Signature of collector	Identity / signature of collector	To confirm patient ID	
Consultant/GP/Requesting Practitioner	N/A	Return of results to clinician / used for audit	

REQUEST FORM	SAMPLE	REASON	FAILURE TO COMPLY
Date and Time of Collection	Date and Time of collection	To ensure integrity of Sample	Rejection of sample
*Transfusion history and pregnancy status/history including EDD if appropriate	N/A	To ensure safety of component provision	Sample only valid for 72 hours
Haemoglobinopathy status Previous Antibody history	N/A	To ensure appropriate component selection	May result in clinical incident if patient receives inappropriate components
Treatment with drugs known to effect Transfusion	N/A	To ensure that the correct component specification is selected or to ensure that laboratory staff are aware of drugs that affect blood group/antibody screening serology	May result in clinical incident if patient receives inappropriate components, or may cause a significant delay in the provision of blood components due to delay in referral to Red Cell Immunohaematology department at NHS Blood & Transplant
Anti-D administration within 12/52	N/A	To ensure an understanding of anomalous serological results within the laboratory.	May cause a significant delay in the provision of blood components due to unnecessary investigations or a delay in referral to Red Cell Immunohaematology department at NHS Blood & Transplant
*Name / Bleep No of requesting Medical Officer	N/A	To contact if necessary	May cause delay in providing blood Products

REQUEST FORM	SAMPLE	REASON	FAILURE TO COMPLY
*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

In addition, for blood transfusion requests:

- **Pre-printed identification labels must not be used on the sample or request form.**
All handwritten data **must** be legible.
- **Under BSH guidelines one character difference between sample and request constitutes failure i.e. no additions, omissions or substitutions.**
- **Antenatal Clinic (ANC) samples can use addressograph labels on the form only, as these samples have no validity and cannot be used for blood issue. The sample must be handwritten, and the form/sample must be signed by the phlebotomist**

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