The Leeds Teaching Hospitals NHS Trust

LTHT Policy for the Labelling of Request Forms and Specimens

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1 Staff Summary & Introduction

This is a Trust policy that mandates the minimum standard required for requesting and labelling of biological specimens.

It applies to all staff who are involved in the collecting and labelling of any biological specimens to be analysed and/or stored by LTHT Pathology Services.

This includes ALL locations sending specimens to LTHT Pathology, from both within and outside the Trust.

The policy also covers the essential requirement for the requesting clinician to duly notify the laboratory in instances where there is an intention to dispatch samples from patients with known or suspected infection with a hazard group 3 pathogen. Suspicion is based on clinical risk factors that are detailed in this policy.

Individuals collecting biological specimens for analysis must also be aware of:

- Guidelines on the positive identification of patients
  Mandates that patients are positively identified prior to any clinical activity, including the collection of pathology [laboratory medicine] specimens.

- Guidance on labelling samples that present a danger of infection to Healthcare Professionals, and/or are collected from patients suspected of being infected by Hazard Group 3 organisms/pathogens (Leeds Health Pathways website)
  This is a requirement under health and safety (H&S) legislation.

- http://www.hse.gov.uk/safetybulletins/clinicalinformation.htm
  HSE Safety Alert on the provision of information on specimen request forms to staff in clinical diagnostic laboratories, to enable them to apply the correct safety measures to control any risk. Recent investigations have identified a lack of sufficient relevant clinical details being provided on specimen request forms. This has resulted in samples being handled at the wrong biological containment level, with a subsequent increase in risk of infection to laboratory staff.

  https://intranet.leedsth.nhs.uk/departments/pathology/hospital-transfusion-team/transfusion-guidelines-hospital-transfusion-team/
  The LTHT Policy on Safer Transfusion Procedures is available via the above intranet weblink. This includes procedure relating to unknown patients.

2 Purpose and Effect

The purpose of the policy is to ensure that all specimens received by LTHT Pathology have been obtained from the correct patient and that sufficient information has been provided to ensure that specimens can be processed safely, in a manner that provides an unequivocal link with the originating patient.

In the interests of patient safety, BOTH request form and associated specimens, MUST meet the minimum acceptance criteria defined in this policy. Requests failing to comply with these requirements will therefore be rejected.

It also serves to ensure that specimens that may present a risk of infection with a hazard group 3 pathogen are processed safely at the correct containment level, ensuring that risks presented to laboratory personnel are mitigated as much as possible.

3 Key Definitions

Although authors should make the effort to use simple accessible language throughout the policy and avoid abbreviations, it may be helpful to include some key definitions at the start to support staff understanding of what follows.

Key word/Term	**Definition**
Unique Identifier	An identifier that must be unique to each patient, normally their NHS number. For Transfusion request forms, PAS number is regarded as equivalent to 'hospital number', both of which are regarded a unique identifier.
Specimen	Any fluid, tissue, organ or body part removed from a patient that is sent to LTHT Pathology for analysis and/or storage
Positive Identification	Asking the patient (or carer if the patient lacks capacity) to state the patient's name and date of birth and matching this information against the patient's identification band and any other associated paperwork. Asking the patient/carer to confirm information (with a yes/no response) is not acceptable.

4 Key Staff and Committees/Groups

Staff Group/Committee	**Key Roles and Responsibilities in Policy Enactment**
Chief Executive	• Ultimate accountability for ensuring that appropriate systems and processes are in place for managing the requirements of this policy • Responsibility is delegated through Clinical Directors and CSU Managers

Staff Group/Committee	Key Roles and Responsibilities in Policy Enactment
Trust Board	• Ensuring that a robust system of risk management is in place within the organisation which includes the identification of patients and labelling requirements for pathology sample and specimen testing
CSU Managers and Clinical Directors	• Ensuring adequate and appropriate dissemination and implementation of this protocol within their areas of responsibility. • Ensuring appropriate and adequate training of staff to perform the tasks covered by this policy and the continual review of associated competence. • Identifying the underlying causes of non-compliance with this policy and taking all necessary measures to introduce corrective and remedial actions as required.
IPC Subcommittee	• Support the Pathology CSU in ensuring that high risk specimens are being managed in accordance with the requirements of this policy. Failure to do so constitutes a breach of HSE regulatory requirements and all such incidents are RIDDOR-reportable.
Heads of Department, Managers and Supervisors overseeing services who dispatch biological specimens to LTHT Pathology services	• Ensure that all staff that they line manage exercise full conformity with the requirements of this policy. • Ensure that breaches of the labelling requirements defined in this policy are robustly investigated, applying causal factor analysis and instigating appropriate corrective measures to prevent recurrence. • Ensure that all members of the team who collect specimens are aware of this policy and competent in sample collection, requesting and labelling (appropriate training has been completed and reviewed at an appropriate interval).
ALL staff involved in the collection and labelling of biological specimens to be analysed/stored by LTHT Pathology Services. Applies to locations both within and outside of LTHT.	• To ensure that samples are collected and labeled in the manner described in this policy and the supporting Trust Policy on Positive Patient Identification. • It is the responsibility of the person collecting the specimen from the patient to ensure that the patient is correctly (positively) identified and that the specimen container is correctly labelled. • It is the responsibility of the person requesting an investigation or storage of specimens to ensure that the necessary informed consent has been obtained. • In all instances where ‘high risk’ specimens are being dispatched (defined below), relevant clinical risk factors must be provided on request cards and all specimens labelled with a danger of infection sticker, with contact made with the microbiology laboratory clinicians via switch board.
Pathology CSU Quality Assurance Group	• Review and update the policy • Formally approve policy updates
Trust Policies and Procedures Group	• Approve policy updates and authorize updates to the policy hosted on Leeds Health Pathways

Staff Group/Committee	Key Roles and Responsibilities in Policy Enactment
Pathology CSU Administrators	• Request updated versions of the policy to replace existing on the Pathology Website (liaison with Trust web-development team).
Specialty (department-level) Governance Groups within Pathology	• Review ongoing compliance with the policy and ensure that breaches are robustly followed up and reported as DATIX incidents. • Monitor rejected sample data to identify trends/themes and ensure that action is taken where appropriate.
Laboratory Teams (Pathology CSU)	• Accept/reject specimens in strict accordance with the requirements and stipulations of this policy. • Report labelling policy breaches using the electronic quality management system or, if the incident has escaped detection and resolution by the Quality Management System and resulted in incorrect results being issued in relation to a sample/request form labelling error (irrespective of harm caused), via DATIX.

5 Equality and Diversity Impact

This Policy has been assessed for its impact upon equality. The Leeds Teaching Hospitals NHS Trust is committed to ensuring that the way that we provide services and the way we recruit and treat staff reflects individual needs, promotes equality and does not discriminate unfairly against any particular individual or group.

6 Requirements

6.1 Request forms

It is the responsibility of the requestor to ensure that request forms are completed correctly, even if these duties are delegated.

- The use of ICE-printed labels on request forms is strongly encouraged
- In exceptional cases where request forms are filled in by hand, they **must be clear, legible and completed in full**.
- If a patient is confirmed as positive for a Hazard Group/Category 3 pathogen, or where there is strong clinical suspicion, request forms must contain relevant travel history and occupational risk factors. **Forms and samples must be labelled with yellow Danger of Infection stickers. These measures act to ensure that laboratory personnel are able to ensure that sample processing takes place at the correct laboratory containment level, protecting their safety.**

6.2 Specimen Collection

It is the responsibility of the person collecting the sample from the patient to ensure that the patient is correctly identified, and that the specimen container is correctly labelled.

Samples MUST be labelled with the patient present, with labelling taking place immediately after the sample has been collected.

a. **Never pre-label sample tubes.** The practice of pre-labelling specimen containers, either by hand or with printed labels prior to the sample being taken is a well-established cause of error.
b. The patient must have their identity confirmed against the information on the request form (electronic or paper) in accordance with the LTHT positive patient identification policy. If the request form is incomplete, or does not match the information given by the patient, **specimens must not be taken**.
c. The request form details must be checked against details on the patient's wristband. If the wristband information is found to be incorrect, the wristband must be removed and a new one generated with the correct information, immediately.
d. In all instances where it is possible to do so, the patient must be asked to provide their full name and date of birth verbally and their response compared to the information provided on the request form. If the patient lacks capacity to provide this information, the patient's carer must be asked to provide it.
e. The specimens must be labelled **immediately** after being collected at the patient's side, with information taken from the request form (if ICE labels are not available) and at the point at which the specimens are taken.
f. All specimen containers must be clearly labelled, ideally with ICE labels. The use of printed addressograph labels is NOT permitted and will result in the rejection of the sample, as these do not contain all the requisite information.
g. When ICE-printed labels for specimens are used, they must:
    - Be generated before sample collection - taken to the patient prior to phlebotomy
    - Be checked against the request form for accuracy
    - NOT be used to confirm the identity of the patient. Patient identification must be done from the **request form**
h. If for some reason, the specimen container does not have a label, write on a blank label and attach to the tube/container.
i. HIGH RISK SAMPLES – in ALL instances where infection with a hazard group 3 pathogen is either known or suspected (based on clinical risk factors), the procedure detailed in appendix 1 (which includes relevant clinical risk factors) must be followed to ensure the safety of laboratory personnel and avoid HSE-enforceable regulatory action.

6.3 Labelling standards

Completion of the following fields is mandatory, and where information is missing or illegible the request will be rejected.

The **REQUEST FORM** **must** contain the following:

ALL Patients
i. **Forename & Surname** in full, initials are not permitted ii. **Date of Birth (DoB)** iii. **Any one of the following: PAS Number* / NHS Number / ED (A&E) number (identifier used must be on both request form and sample** iv. **Consultant/ GP (or Requesting Officer within Pathology for referrals from other hospitals)** v. **Location: GP Surgery/ Ward/OPD/Unit (or hospital/department for referrals from other hospitals). This is essential - a location is required to ensure that the report is issued to the correct location.** vi. **Date of request** vii. **Time of sample collection (where relevant)** viii. **Clinical details e.g. presenting complaint, relevant medication, procedure etc.** ix. **Investigation/Tests required** x. **Infection status (where relevant)** xi. **Handwritten requests only: Signature, printed name and contact number of the person taking responsibility for completing the request card). N.B. This information is provided in digital format on all ICE requests based on the requestor's login.** xii. **HIGH RISK SAMPLES -** in ALL instances where infection with a hazard group 3 pathogen is either known or suspected (based on clinical risk factors), **relevant clinical risk factors must be provided on the request form (clinical details)** to enable laboratory staff to isolate such requests and ensure that they are processed safely at the correct containment level. Refer to the procedure in appendix 1. * see transfusion service-specific requirement (section 2.4) relating to PAS number provision
The details on the request form MUST match those on the specimen container

Labelling of the **SPECIMEN**:

ALL Samples
i. **Forename & Surname** in full, initials are not permitted ii. **Date of Birth (DoB)** iii. **Date and time of collection** iv. **NHS number, and where applicable, the ED (A&E) number (same identifier must be used on request form).** See below transfusion service-specific requirement (section 2.4) relating to PAS number provision v. **Blood Sciences & Microbiology ICE Requests only: the ICE accession number on the sample must match that on the form** vi. **HIGH RISK SAMPLES -** in ALL instances where infection with a hazard group 3 pathogen is either known or suspected (based on clinical risk factors), a **danger of infection (DOI) sticker** must be affixed to all specimens to enable laboratory staff to isolate such requests and ensure that they are processed safely at the correct containment level. Refer to the procedure in appendix 1.
The details on the specimen container MUST match that on the request form: The same identifiers must be used on both the form and sample

Reminder: In the interests of patient safety, where any of the information is missing or illegible, the request will be rejected.

6.4 Allowable Service-Specific Exceptions and Requirements

i. Samples collected for the Centre for Sexual Health and patients with anonymised Sexual Health Service numbers (all sites) will be accepted when labelled with Sexual Health Service-printed labels; this reflects national guidance.

ii. Occupational Health - these requests do not always have an NHS number e.g. if the member of staff is not yet registered at a healthcare establishment in the Leeds/West Yorkshire area.

iii. Date and time of collection on samples referred to LTHT from other hospitals - allowances will be made when the date and time of collection are not provided, with the caveat that the referring hospital accepts full responsibility for the results.

iv. Unknown patients**,** where the surname and/or forename are not known e.g. unconscious patients brought into LTHT. In such instances the LTHT Accident and Emergency Department Unknown Patient Policy must be followed. The PAS or ED (A&E) number must be on the sample and request form. Details on the request form and sample must also match.

v. Neonatal patients **–** In the absence of an assigned forename, "Baby" or "Twin 1"/"Twin 2" etc. can be used in place of the forename, but must additionally include: **surname, date of birth** and one of the following identifiers: PAS/A&E/NHS number on both the sample and request form.

vi. Cord samples-

- Cord samples must be handwritten at the patient's side immediately at the point of taking them.
- Cord samples must be labelled with forename, surname and date of birth. In the absence of an assigned forename, "Baby" can be used in place of the forename, but must also additionally include: surname, date of birth.
- For multiple births, separate cord samples are required from each infant. In the absence of an assigned forename, these must be labelled as "Baby 1/ Baby 2" or "Twin 1/Twin 2" etc. in place of the forename, and must also additionally include: surname, date of birth.
- The staff member who obtains the sample must sign/initial the sample tube, and detail the date and time the sample was collected
- The unique ID number must be added to the sample tube (handwritten) once one has been generated.
- Once all identifiers are present for the cord sample, **do not** produce a BloodTrackTx® label.

- Cord samples labelled with BloodTrackTx® will be rejected.

- Request Form must be labelled with the baby's details - maternal details must be annotated on the request form **only**.

- Samples must not be labelled as "Baby of" with maternal details.

vi. Microbiology service-specific exceptions:

- Clinical details are essential for correct and safe processing. If not supplied on the request card from blood cultures collected in **ED only,** these can be obtained by telephone, and will not be rejected. It is not essential to provide clinical details on the request form for MRSA screens and NAAT requests, as the reason for requesting is implicit from the request.

- Requests from external hospitals are acceptable with the requestors lab number as an identifier, as long as this is present on both the request form and the sample. The requesting hospital laboratory takes responsibility for the labelling of the referred samples.

- Where a sample is rejected on the basis of no clinical details being provided, where this involves a critical sample, the case will be discussed with senior clinical staff, and ***may*** be processed if it is agreed that rejection will adversely affect patient care.

vii. Genetics Laboratory service-specific exceptions:

- Sample Labelling and acceptance.

  Full name and at least one of the following identifiers should be indicated on both the sample and referral card:

  Date of birth
  NHS number
  Patient number

  Poorly labelled or unlabelled samples and request cards must be referred to the relevant Head of Section or Duty Scientist immediately.

- Blood samples from anonymous sperm donors

  In rare circumstances where a female patient has an inheritable condition (autosomal dominant or x-linked) that is licensed by the HFEA for pre-implantation genetic diagnosis (PGD) and is undergoing such treatment, the DNA of the sperm donor would be required. In such instances, Leeds reproductive medicine unit will send 3x 3ml EDTA blood tubes labelled with the patient's date of birth and unit number (F number).

viii. Research study samples

- Requests will only be rejected by R&D personnel; **all** requests will be processed/analysed irrespective of the patient identifiers provided, and rejection will be instigated by R&D staff where processing has been determined to compromise the validity of the study.

- Samples collected from patients recruited into non-blinded (non-anonymised) clinical trials will be accepted if the patient's first name, surname, DOB, date and time of sample collection are provided on both the sample and the request form. Additionally, the study ID, tests required and visit number must be clearly identified on the request form.

- Anonymised samples arriving as part of a clinical trial will only be accepted if the following 3 pieces of information are provided on both the form AND the sample: the patient's unique study ID number, the patient's date of birth and the date and time of sample collection. Additionally, tests required and visit number must be clearly identified on the request form.

ix. Transfusion service Key Requirements

- As per Trust Positive Patient Identification Policy described above, the request form must be used to confirm identifiers provided verbally by the patient (wherever possible) and these details must also match all the details displayed on the patient's wristband prior to a transfusion sample being taken

- The use of ICE-printed labels on request forms is strongly encouraged

- Any transfusion request form received with a handwritten amendment on an ICE label will be rejected

- Handwritten request forms must include the printed name, signature and contact number of the person taking responsibility for completing the request form. This information is provided in digital format on all ICE requests based on the requestor's login.

- It is gold standard practice that samples should be labelled at the patient's side using BloodTrackTx® to promote positive patient ID and reduce the number of rejected samples due to mislabelled samples. See section 6.4.6 for guidance on labelling cord samples.

- Samples must be labelled by the same trained practitioner that confirms the patient details and takes the sample.

- Handwritten samples will not be rejected by the Transfusion laboratory staff. Staff responsible for taking and labelling transfusion samples must adhere to

the Safer Transfusion Policy and ensure that the sample is labelled at the bedside and all positive ID checks are performed throughout the process.

- For all handwritten samples the request form must include the printed name and signature of the person taking responsibility for collecting the sample. This information is provided in digital format on all samples collected by BloodTrackTx® based on the collector's login.

- Whilst not mandated, it is very important to include the LTHT PAS number on the blood transfusion request form whenever it is possible to do so. PAS numbers are Trust specific.

- Including the PAS number on the request form is the only way to identify instances where a patient has transferred from another Trust and the wristband has not been changed on their admission to LTHT

- Wristbands from other Trusts must be removed and a LTHT wristband generated and applied on admission

- This is important as the BloodTrackTx® electronic labelling system for blood transfusion samples will generate a label from the QR code on the patient wristband.

- The label includes the following details:- Full name, DOB, NHS no, PAS No, Date and time label was produced, name of staff member who produced the label and the location the PDA is allocated to.

- Handwritten samples must be labelled with Full name, DOB, unique patient ID number (NHS, PAS). Handwritten samples must also include date and time collected, signature/initials of person collecting the sample.

- Any mismatches in the patient identification details on the request form/label/laboratory information management system (LIMS) will result in the transfusion sample being rejected

- The rejection of blood transfusion samples due to mismatched patient details is wholly preventable but is dependent on staff obtaining and labelling transfusion samples in accordance with LTHT Safer Transfusion Policy and LTHT Positive Patient ID Policy.

6.5 Rejection of specimens and requestor notification

Where specimens are from Acute Medicine, or are defined as critical by the requesting healthcare provider, laboratory staff will, so far as is reasonably practicable, contact the sender by telephone to inform them that a request has been rejected, giving the reason(s) why.

A report will be issued, stating the reason for rejection, on all samples.

If, in exceptional circumstances a specimen is unrepeatable e.g. CSF, bone marrow aspirate & trephine, ascitic, pleural and peritoneal dialysis fluids, the requestor may make provision for the sample to be processed. In such cases, the requestor will be asked to sign a 'declaration form' accepting personal responsibility for the results issued.

The declaration form can be found on the Pathology website:
https://www.leedsth.nhs.uk/a-z-of-services/pathology/.

Completion of declaration forms creates delays to sample processing. To prevent this from occurring, all staff are reminded to take due care to ensure all samples are collected and labelled correctly.

The use of declaration forms varies between disciplines in Pathology, due to the geographical location of some laboratories.

- Declaration forms from Trust locations are to be completed by the **REQUESTOR,** in the laboratory (requestor to attend in person). Forms will **NOT** be sent out to other locations, unless attendance is geographically impossible.

- Declaration forms for GPs or external hospitals can be found on the Pathology website and sent to the department via transport or post, **ONLY** if the sample is deemed to be unrepeatable.

- **Microbiology only**: Declaration forms can be emailed to the department (microbiologydept@nhs.net) when the sending location is not based on the same site as the Microbiology Department.

- **Blood Transfusion only**: Declaration forms are **never** accepted. Where the requirements of this policy are not met, a repeat specimen is always required.

- **Genetics Laboratory only**: Head of Sections and Duty Scientists will make contact the referring clinician, and if they insist the specimen is unrepeatable a decision will be made about processing the sample.

  Examples of unrepeatable samples include:
  - Prenatal samples
  - Tumour samples
  - Bone marrow
  - Post-mortem samples

If the sample is to be processed, the clinician must complete a declaration form before processing begins. If the sample is being sent from a location external to St James' Hospital, the form must be emailed to the department, with the original sent by post.

In ALL instances where results are issued following the completion of the declaration form, a qualifying comment will appear on the printed report.

6.6 Monitoring

In instances where incorrect results have been issued in relation to a sample/request form labelling error, OR a 'near-miss has resulted, an incident will be raised using the DATIX system and assigned to the appropriate manager to investigate further.

A DATIX incident will also be raised in all instances where one or more specimens obtained from patients that are either known to be infected with a hazard group 3 pathogen, or suspected to be infected (based on clinical risk factors), are dispatched to the laboratory without following the notification process detailed in appendix 1.

7 Consultation and Review Process

All updates/revisions will be reviewed by the Pathology CSU Quality Assurance Group and thereafter, the LTHT Policies and Procedures Group.

Approval via the former ensures that all Pathology Leadership Teams are fully consulted and able to ensure that the policy meets the local (department-level) requirements before being introduced into routine use.

Changes to the policy which impact directly or indirectly on the work undertaken by staff working within the Pathology CSU require review and approval at the Pathology Joint Consultation Committee which is attended by Trade Union representatives.

On-going review of policy effectiveness is reviewed through speciality (department-level) quality assurance group meetings which review specimen rejection data, labelling policy breach data and report to the CSU-level Quality Assurance Group which oversees policy delivery, on an exceptional basis.

8 Monitoring Compliance and Effectiveness

Policy element to be monitored	Standards/ Performance indicators	Process for monitoring	Individual or group responsible for monitoring	Frequency or monitoring	Responsible individual or group for development of action plan	Responsible group for review of assurance reports and oversight of action plan
Compliance with sample acceptance criteria	Review of rejected sample set data	Data review in specialty governance meetings	Speciality Leadership Teams	Monthly	Specialty Governance Group	Specialty Governance Group
	Review of DATIX incidents	Data review in specialty governance meetings	Speciality Leadership Teams	Monthly	Specialty Governance Group	Specialty Governance Group; annual trend review in CSU QA Group
	Internal audit of samples vs. request form vs. report	Examination Audits within all specialties	Speciality Leadership Teams	As per risk-based audit schedule	Specialty Governance Group	Specialty Governance Group
Compliance with IPC requirements (duly notify laboratory when infection with hazard group 3 pathogen suspected/known). Failure to do so represents a breach of HSE regulatory requirements and can lead to enforcement action.	Review of laboratory audit data (lab information management system and DATIX incidents)	Periodic audit by Microbiology team	Microbiology Executive Group IPC Subcommittee	Monthly	Microbiology Executive Group IPC Subcommittee	Pathology QAG IPC Subcommittee

9 Plan for Communication and Dissemination of Policy

This policy applies to all staff sending specimens for analysis/storage to LTHT Pathology.

This policy will be made available to all LTHT Pathology Staff via the electronic quality management system software (currently Q-Pulse) which provides version control and provides an audit trail of document acknowledgment for all staff to whom the document has been distributed.

It will be made available to other staff working within the Trust and Staff working within external locations via:

- The Trust Website
- The Pathology Website

Appendix 1. Procedure for Labelling High Risk Specimens and Request Forms

In instances where infection with a hazard group 3 pathogen is either known or suspected (based on clinical risk factors), the requesting clinician is responsible for ensuring that a danger of infection (DOI) sticker is affixed to all specimens (irrespective of type), AND relevant clinical risk factors are provided on the request form as clinical details.

These measures will collectively enable laboratory staff to isolate such requests and ensure that they are processed safely at the correct containment level (Category 3 Laboratory with all relevant PPE measures applied). Failure to do this means that laboratory staff are placed at significantly increased risk of acquiring a potentially life-threatening infection.

Yellow labels with black print need to be used and can be obtained from the print unit (code WRN502) or via the Pathology Supplies team (email: leedsth-tr.pathologysupplies@nhs.net).

High Risk Labelling is NOT routinely required for Blood-borne Virus (BBV) positive samples

Blood samples from BBV positive patients no longer routinely require the addition of Danger of Infection labels. The laboratories follow 'universal precautions' and treat all blood samples as potentially hazardous.

People with HIV infection who achieve and maintain viral suppression by taking their HIV treatment as prescribed pose no greater risk to laboratory workers or other health care professionals than anyone else in the population.

It is, however, very important to provide clear clinical details, including those relating to BBVs, as this will assist the laboratory in selecting the right tests and processing the sample correctly and safely, so please provide as much detail as possible.

High Risk Labelling IS REQUIRED

While blood samples from BBV positive patients no longer routinely require the addition of Danger of Infection labels, if a patient is known or suspected to have a raised viral load (e.g. new diagnosis, not on HIV treatment / not engaging with HIV care, poor treatment adherence or treatment failure) then these samples **should** be labelled as high risk with a Danger of Infection label. A raised viral load is considered to be: HIV > 200 copies/mL, HBV > 200 IU/mL, HCV detected at any level.

Samples other than blood for patients with diagnosed blood borne virus infection should be labelled as Danger of Infection

There is a table on the Leeds Health Pathways website which lists frequently suspected hazard group 3 pathogens and for each, highlights the mandatory

requirement to provide relevant risk factor information on the request and add DOI stickers to all specimens:

https://nww.lhp.leedsth.nhs.uk/common/guidelines/detail.aspx?ID=1671

A full list of Hazard Group 3 Pathogens can be accessed via The Approved List of biological agents - MISC208 (hse.gov.uk)

If the laboratory isolates a potential HG3 Pathogen, they will notify the clinical area. Any subsequent samples sent on the patient MUST include details of the pathogen that has been isolated. The ward must have a mechanism to ensure that this happens.

All biological agents causing infection are classified into hazard groups 1-4 as defined by the Advisory Committee on Dangerous Pathogens (ACDP), advisor to the HSE. Those in groups 3 and 4 are deemed to be a serious hazard and samples taken from patients suspected of infection with one of these pathogens should be considered high risk and Danger of Infection labels applied.
While not exhaustive, below is a summary of the more common clinical conditions when high risk labelling would be appropriate.

It is very important that the request form contains clear clinical details so staff can help identify which samples may require additional precautions when processing.

Clinical details that should alert the clinician to the possibility of a 'high risk' pathogen

Clinical Symptom or Condition	Clinical History	Pathogen	Hazard group
Bloody diarrhoea	Farm/animal exposure Foreign travel	E coli 0157 * Shigella	HG3 HG3
Stool with "worms" visible	History of foreign travel	Taenia solium, Echinococcus	HG3
Necrotic injection site Cough, necrotising pneumonia	Person who injects drugs (PWID) Foreign travel, exposure to animal hide, wool or skins, occupations with animal exposure	Bacillus anthracis	HG3
Fever, Sepsis	Recent travel to India	Salmonella typhi *	HG3
Fever, Haemorrhage/coagulopathy	Recent travel to Africa	Viral Haemorrhagic fever (various agents) * Malaria	HG4 HG3
Fever, abscesses	History of foreign travel and	Brucella *	HG3

Clinical Symptom or Condition	Clinical History	Pathogen	Hazard group
	consumption of unpasteurised milk, occupations/pastimes with animal exposure		
Haemoptysis	Contact of case of TB	Mycobacterium tuberculosis	HG3
Swollen lymph nodes, fever, weakness, chest pain	Foreign travel: Africa, North West America, Asia	Yersinia pestis	HG3
Glanders, fever, chills, muscle aches	Occupations with exposure to horses, donkeys and mules	Burkholderia mallei	HG3
Melioidosis, pain, swelling, fever, abscess, cough	Foreign travel: Far East & Northern Australia, Mexico , Middle East and Africa	Burkholderia pseudomallei	HG3
Respiratory symptoms, cough, fever	Contact with dead or dying birds or poultry	Avian Influenza	HG3
Respiratory symptoms, cough, fever	Recent travel to the Middle East or contact with camels	MERS-CoV	HG3
Vesicular skin lesions	Recent travel to sub-Saharan Africa	Monkeypox	HG3

* Highly infectious to laboratory staff. Numerous cases of laboratory acquisition.

Foreign travel

High risk pathogens may be endemic in one country but rare in another. Generally, Western Europe has a similar risk to the UK. A detailed history of foreign travel helps the laboratory select the correct test for the patient. Please provide as much information relating to the travel as possible (e.g. countries visited; areas visited - city, rural; when returned; what prophylaxis taken; onset of symptoms etc.)

Summary of Actions to Take where a HG3 Infection is Suspected/Known

Scenario	What to do
Known blood borne virus positive – blood samples	• Include virus name in clinical details on all requests. • Yellow DOI stickers on forms and samples from patient known or suspected to have a raised viral load (e.g. new diagnosis, not on treatment, not engaging with care, poor treatment adherence or treatment failure) • If patient moves location ensure new area is aware of this requirement • Samples can be transported via the POD system
Known blood borne virus positive – non blood samples e.g, Tissue, wounds, sputum	• Include virus name in clinical details on all requests

Scenario	What to do
	• Yellow DOI stickers on all forms and samples from patient • If patient moves location ensure new area is aware of this requirement • Samples can be transported via the POD system
Ward notified from lab that patient has a HG3 pathogen	• Include HG3 pathogen name in clinical details on all requests. • Yellow DOI stickers on all forms and samples from patient • If patient moves location ensure new area is aware of this requirement • Samples should be hand delivered to the laboratory – do not use the POD system
Ward notified on admission that patient has diagnosed or suspected named HG3 pathogen. High risk of HG3 pathogen diagnosis (symptoms and clinical history both indicate risk).	• Include HG3 pathogen name in clinical details on all requests. • Yellow DOI stickers on all forms and samples from patient • If patient moves location ensure new area is aware of this requirement • Samples should be hand delivered to the laboratory – do not use the POD system • Inform the Microbiology medics via switchboard
Clinical details obtained during assessment that indicate a risk (refer to above clinical risk factors table)	• Include all relevant details on request form • If unsure if details are relevant contact laboratory for advice • Yellow DOI stickers on all forms and samples from patient • If patient moves location ensure new area is aware of this requirement • Samples should be hand delivered to the laboratory – do not use the POD system

If a High │Risk Hazard Group 4 pathogen is suspected:

- **Contact the on-call Infectious Disease physician immediately**
- **Do not collect any samples from the patient unless instructed to do so**
- **Do not send any samples via the POD system**

Checklist for the Review and Approval of Policy

LEEDS TEACHING HOSPITALS NHS TRUST

Approving Body Checklist for the Review and Approval of Trust Policy or Procedure

To be completed and attached to the policy when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Format and Content**		
	Is it in the correct format?	Yes	
	Is the staff summary clear and adequate?	Yes	
	Are the intended outcomes clearly described? (the Policy/Procedure Effect)	Yes	
	Is there a Definitions section giving an explanation of key terms used.	Yes	
	Has the policy's impact on Equality and Diversity been fully considered?	Yes	
2.	**Consultation and Review**		
	Has there been appropriate consultation with stakeholders and users?	Yes	
	Has an appropriate governance group reviewed and supported the document prior to submission for formal approval?	Yes	
	For HR Policies only, has the TCNC approved the document?	N/A	
	If it is a clinical policy/procedure has it been reviewed by the Clinical Guidelines Group?	Yes	
	Has it been reviewed by the counter fraud team?	n/a	
3.	**Dissemination and Implementation**		
	Is there a communications plan to identify how it will be communicated and implemented? The Communications Team can help you with advice.	n/a	
4.	**Process to Monitor Compliance and Effectiveness**		
	Is there a monitoring table setting out measurable standards or KPIs together with clear monitoring and reporting mechanisms (to ensure there is assurance of implementation)	Yes	
5.	**Review Date**		
	Is the review date in 2 years? If not is there a justified reason?	Yes	

If the document needs urgent approval before all of the above are satisfactorily addressed, please bring this to the attention of the appropriate committee so conditional approval can be given.

Endorsement from appropriate group(s) **(This will vary depending on content and nature of policy)** For example, a policy relating to radiation should be considered by the radiation safety committee. A staff policy should be reviewed by TCNC.			
If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			
Group		Date	
Group		Date	

Version Control Sheet

This document to be maintained by the Policy/Procedure/Protocol Lead, and a copy attached to each version as it is circulated for consultation/input.

Version	Date	Author	Status	Comment (including actions taken)
4.4	20/7/23	Dan Carless	draft	Re-indexed (new electronic quality management system) Information incorporated into Trust Policy Template to enhance compliance, as per recommendation from Trust P&P Review Group. Minor clarifications added to section 5.4 (ix) relating to Blood Transfusion Service. No material changes to other content.
4.4	4/9/23	Dan Carless	Draft	Additions relating to management of high risk samples including appendix 1 (response to round 2 feedback from Trust Policies and Procedures team).