Reference Number: UHB 452 **Version Number:** 2	**Date of Next Review: 16/05/2026** **Previous Trust/LHB Reference Number:** UHB 452

LABELLING OF SPECIMENS SUBMITTED TO MEDICAL LABORATORIES PROCEDURE

Introduction and Aim

Accurate labelling of specimens and accompanying laboratory request forms is very important for safe and effective patient care.

This policy describes the requirements for accurate positive identification of the patient from whom the specimen was taken, the clinical details surrounding the patient and the person and location where the result should be sent. These are the minimum requirements for accepting a specimen and logging it onto the laboratory database in line with the Right First Time Requesting Initiative launched in April 2013. Some laboratory tests have very specific requirements about how the specimen should be obtained, the preservative used (or not used) and the clinical information required to perform the correct test and interpret the results properly.

In some circumstances, e.g. where sequential specimens are taken, it is important to identify not only the patient but also the individual specimen (by date and time taken). Each laboratory produces a user guide, which should be consulted before sending specimens for specialist tests.
Laboratory Medicine Test Knowledge Base

Cardiff and Vale University Health Board is committed to achieving excellence in providing safe, effective, efficient and compassionate care. In order to achieve this it is necessary to ensure that effective procedures are in place to ensure that all samples taken for laboratory investigations can be accurately and unambiguously assigned to the correct patient, and that all necessary information for analysis, interpretation and reporting is provided.

Cardiff and Vale University Health Board is also committed to the health, safety and welfare of all its staff, by providing a safe workplace and systems of work. In order to achieve this it is necessary to ensure that staff have the necessary information when obtaining, transporting and processing hazardous biological materials

Objectives

The aim of this policy is to ensure that robust arrangements are in place to ensure that samples taken for laboratory analysis or storage can be -

- accurately and unambiguously identified
- all necessary information is supplied for appropriate and timely analysis, interpretation and reporting
- issues arising from the non-conformance with this policy will be reported via UHB 138 Incident, Hazard and Near Miss Reporting Policy and Procedure to establish the root-cause of the issue to avoid recurrence.

Scope

This policy relates specifically to the labelling of **specimens** submitted to Cardiff and Vale University Health Board medical laboratories for investigation and/or storage for subsequent investigation, and encompasses all body fluids and tissues, except blood components, blood products, cells or tissues for the purposes of transfusion or transplantation, or for storage for possible subsequent transfusion or transplantation.

Requirements for such transfusion related samples are described in the UHB 348 Blood Component Transfusion Procedure. Samples taken for point of care testing should follow the UHB 062 Point of Care Testing Policy.

Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has been completed and this found there to be a no impact.
Documents to read alongside this Procedure	This Policy and the supporting procedures describe the following with regard to sample labelling requirements. . **Other supporting documents are:** • UHB 017 Labelling of specimens policy (EQIA) • UHB 350 Data Protection Act procedure • UHB 301 Information governance • UHB 053 Major Incident Plan • UHB 062 Point of Care Testing (POCT) Policy • UHB 068 Blood and Component Transfusion Policy • UHB 100 Consent to Examination or Treatment Policy • UHB 101 Patient Identification Policy • UHB 138 Incident, Hazard and Near Miss Reporting Policy • UHB 149 Standard Infection Control Precautions Procedure • UHB 348 Blood Component Transfusion Procedure • Infection Control Procedure for Needlestick and Similar Sharps Injuries • UHB 089 Control of Substances Hazardous to Health (COSHH) Procedure

Approved by	Laboratory Medicine Quality meeting

Accountable Executive or Clinical Board Director	Chief Operating Officer
Author(s)	Laboratory Medicine Quality group

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	16/04/19	08/05/19	New procedure to replace previous UHB 017 Labelling of Specimens Submitted to Medical Laboratories Policy, including additional guidance on management of high risks samples.
2	16/05/23		Links throughout the document updated Changed name of Clinical board Director

Contents

1.0 Introduction

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In some circumstances, e.g. where sequential specimens are taken, it is important to identify not only the patient but also the individual specimen (by date and time taken). Each laboratory produces a user guide, which should be consulted before sending specimens for specialist tests.
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Cardiff and Vale University Health Board is also committed to the health, safety and welfare of all its staff, by providing a safe workplace and systems of work. In order to achieve this it is necessary to ensure that staff have the necessary information when obtaining, transporting and processing hazardous biological materials

2.0 Aims and Objectives

The aim of this policy is to ensure that robust arrangements are in place to ensure that samples taken for laboratory analysis or storage can be -

- accurately and unambiguously identified
- all necessary information is supplied for appropriate and timely analysis, interpretation and reporting
- staff that are involved in or detect issues arising from the non-conformance with this policy, that result in (near) patient harm, will be expected to report to the organisation in line with UHB 138 Incident, Hazard and Near Miss Reporting Policy and Procedure to establish the root-cause of the issue to avoid recurrence. Incident reporting may be undertaken by the receiving laboratory but the investigation will remain the responsibility of the referring clinical area

3.0 Definitions

For the purposes of this document, **a specimen** means the quantity of tissue, fluid, or other sample submitted for testing, together with its container and the request form.

3.1 Inappropriate labelling describes any situation where the information provided on the specimen container or request form is incorrect or not adequate for the purposes of the laboratory investigation requested. This includes the following categories:

- **Unlabelled specimens** have an absence of labelling on either the container or the request form, or have no request form.

- **Mislabelled specimens** have a mismatch between the patient information on the specimen container and the accompanying form, or between the information supplied and information from another source (e.g. a previous specimen from the same patient, or data on PMS)

- **Inadequately labelled specimens** have insufficient information on the tube or request form for either the proper identification of the patient or the specimen, or for the correct performance, interpretation and communication of the analysis.

4.0 Scope of the Policy

This policy relates specifically to the labelling of **specimens** submitted to Cardiff and Vale University Health Board medical laboratories for investigation

and/or storage for subsequent investigation, and encompasses all body fluids and tissues, except blood components, blood products, cells or tissues for the purposes of transfusion or transplantation, or for storage for possible subsequent transfusion or transplantation.

Requirements for such transfusion related samples are described in the UHB 348 Blood Component Transfusion Procedure. Samples taken for point of care testing should follow the UHB 062 Point of Care Testing Policy.

5.0 Stakeholder Responsibilities

The responsibility for requesting a laboratory investigation lies with an authorised practitioner (normally a medical clinician). It is the responsibility of the requester to ensure that specimen containers are correctly labelled and request forms completed to an acceptable standard (see below). If another person, e.g. a phlebotomist, obtains specimens from a patient on behalf of a requesting practitioner they must ensure that the labelling meets these standards (see below). All staff who take Pathology specimens are responsible for ensuring they are collected in a manner that meets the requirements of the tests requested. It is also the responsibility of the person requesting an investigation or storage of a sample to ensure that they have obtained the necessary informed consent for all procedures requested (refer to UHB 100 Consent to Examination or Treatment Policy).

Managers and senior staff in clinical areas are responsible for ensuring that staff who collect samples are aware of this policy and are competent in sample collection, requesting and labelling. Managers and senior staff in clinical areas must also ensure that appropriate action is taken where incidents arising from breaches of this policy occur, including responding to or reporting incidents on Datix, conducting root cause analysis and assessing any feedback provided to them.

Phlebotomists and Laboratory staff are required to adhere and enforce this policy; they should therefore be treated in accordance with the UHB Dignity at Work Process. Laboratory staff who receive samples which cannot be processed due to breaches in this policy must ensure that departmental procedures for acceptance of samples are followed, incidents that result in (near) patient harm may be reported to Datix if appropriate.

The Lead Executive for Patient Quality and Safety is the Executive Director of Nursing, who in conjunction with the Executive Medical Director and the Executive Director of Therapies and Health Science have ultimate responsibility for ensuring effective clinical governance arrangements and the quality of patient care. This responsibility is discharged within the Clinical Boards and Directorates via the Clinical Board Directors, Laboratory/Clinical Directors, and appropriate senior managers.

It is the responsibility of Clinical Board Quality, Safety and Experience Groups to implement this policy, ensuring that appropriate up-to-date guidance is available and implemented at directorate level, and that compliance is audited at departmental level. Outcomes from audit and monitoring must be fed back to Directorates through the Clinical Board clinical governance structure.

6.0 Procedure for Labelling Specimens

6.1 Specimen Collection

6.1.1 Phlebotomists will not bleed a patient without a completed and signed request form. The form must include full patient identification, Consultant's initial and surname, location and clinical details. Incomplete request forms will be returned for completion before blood is collected.

6.1.2 Staff must ensure they have positively identified the patient, following the relevant UHB 101 Patient Identification Policy, before taking a sample.

6.1.3 Specimen labelling should be performed in the presence of the patient. Pre-labelling empty sample containers and leaving filled containers unlabelled for any period of time is extremely poor clinical practice which poses a high risk of mislabelling and must not be tolerated under any circumstance. In the event of the requesting clinician, or other member of staff, becoming aware of any errors in sample identification discovered after the specimen has been sent for processing, this must be reported immediately to the laboratory to prevent incorrect information remaining on the laboratory databases with the potential for an adverse clinical incident.

6.1.4 When using an addressograph label, staff should take special care that they are the correct ones for the patient.

6.1.5 The person who takes the sample should sign the request form and record the date and time the sample was taken.

6.1.6 The UHB is currently implementing electronic test requesting. The system allows clinicians to order requests electronically and print test labels to attach to specimens to facilitate the booking in process and improve legibility. The same principles must be employed, with regard to patient safety, when utilising an electronic request form.

6.2 Labelling the Request Form

6.2.1 Specimens will not be processed by the laboratory without an appropriate request form.

6.2.2 Laboratories require a minimum data set before a specimen can be registered to ensure safe and accurate retrieval of data. It is the requesting clinician's responsibility to enter these details **legibly** on the appropriate form.

6.2.3 In certain special situations, e.g. where patient anonymity must be protected, there are agreed protocols for specific investigations which do not require patient names.

6.2.4 In an emergency situation where the identity of the patient cannot be established or Patient Management Systems (PMS) are not working, the requesting clinician must notify the laboratory in order that temporary arrangements can be made, in compliance with the agreed protocol.

6.2.5 Minimum Data Set (excluding Blood Transfusion samples)

An addressograph label should be used whenever possible**.**
The following information is essential for patient identification:

1. Patient's NHS number and/or hospital number, AND
2. Patient's name (surname and first name – not initial), AND EITHER
3. Patient's address (minimum first line), including postcode, if known, OR[1]
4. Patient's date of birth

[1]If the patient is from a communal address, the date of birth is required

6.2.6 The following is essential for prompt and accurate reporting and to comply with Right First Time:

5. Clinician's Initial and Surname with overall responsibility for the patient (usually a Consultant or GP)
6. Ward / Department and Hospital, or other address to which the report should be sent
7. Relevant clinical information

6.2.7 The following information is required for scientific and clinical interpretation:

8. Date and time specimen **taken** (NOT when requested)
9. Patient's gender.

6.2.8 The following Information is required to contact the requestor (e.g. for critical results or in the event of problems with the sample):

10. Legible name and extension/bleep number of requesting clinician

6.3 Addressograph Labels

Addressographs must only be used for specimens taken from the person whose details are on them. They **must not** be modified or altered for use for other people's specimens, e.g. partners or siblings. The only exception to this is for certain requests regarding fetuses, when the mother's addressograph may be used with the fetal origin of the specimen clearly stated.

6.4 Labelling the Specimen Container

Each specimen container (**NOT** the lid or cap) must be labelled **by the person taking the specimen** with:

1. Patient's name (surname and first name – not initial)
2. Patient's date of birth
3. Patient's hospital number or NHS number (if available)

In addition it is desirable for the time and date the sample was collected to be annotated.

An addressograph is the preferred method of labelling in all areas of the laboratory service **except the blood transfusion laboratory** where hand-written details are required.

6.5 Recording the Collection of Specimens

When a blood sample is taken the date and time of collection and the name of the person who took the sample should be entered into the appropriate places on the request form. This information is important for ensuring the suitability of samples for analysis and appropriate interpretation of data. It is also useful in the event of enquiries about sample collection.

6.6 Biohazard Specimens

For specimens from patients who are known or suspected to be infected with a Hazard Group (HG) 3 agent (primarily blood-borne viruses) the container (and ideally the request form also) **must** be clearly identified with a yellow hazard 'danger of infection' warning sticker. This policy acknowledges the requirements to maintain patient confidentiality in addition to inform and protect staff, Appendix 1 provides a detailed literature review of the current guidance. Appendix 2 provides a detailed list of biological agents where there is a legal requirement for additional or enhanced precautions above Containment Level (CL) 2 and biological agent which pose a danger to an unborn child. If the referring clinician refers a sample which is suspected or known to contain a non-derogated HG 3 organisms or a biological agent

which poses a danger to an unborn child (appendix 2) then this must be clearly labelled with a 'danger of infection' sticker so that the laboratories can handle the samples safely. Although COSHH sets out the minimum requirements for each level of containment, certain HG3 agents can be worked with under reduced containment in particular circumstances.

N.B. hazard group 4 agents can only be handled by specialist laboratories.

All infectious or potentially infectious samples should also be double bagged. For samples other than blood, all UHB Procedures (especially UHB 149 Standard Infection Control Precautions Procedure) and National Guidelines relevant to the infectious agent (e.g. MRSA, TSE) should be followed. If in doubt, guidance should be sought from the laboratories or Infection Prevention and Control Team before taking samples. Failure to identify hazardous specimens is a breach of the duty of care under Health and Safety legislation. Patient confidentiality should be preserved by ensuring that the identity of patients is kept confidential in its packaging while being transported to the laboratory.

Forms and sample containers must be kept separated and **not** placed into the same plastic bag/compartment.

6.7 Procedure for Handling Inappropriately Labelled Specimens

(For definitions see 6 above)

6.7.1 Feedback to Requestors

A member of laboratory staff will attempt to contact the requesting clinician when practicable, and/or a report will be sent requesting a repeat sample.

6.7.2 Unlabelled Specimens

All unlabelled specimens will need to be retaken. Only rarely will exceptions be made when retaking is not a **reasonable** option, there are compelling clinical reasons, and there is clear evidence of patient identity. Such a specimen will need to have the patient's identity confirmed by the person responsible for collecting the specimen and that person will have to sign a laboratory record confirming this, thereby accepting responsibility for the identity of the specimen. A comment will be added to the Laboratory Information Management System (LIMS) to acknowledge the labelling error and any potential authorisation from clinician to proceed to analysis.

6.7.3 Mislabelled Specimens

All specimens with different patient's details on the request form and the container, will have to be retaken. Only rarely will exceptions be made when retaking is not a **reasonable** option, there are compelling clinical reasons, and there is clear evidence of patient identity. Such a specimen will need to have the patient's identity confirmed by the person responsible for collecting the specimen and that person will have to sign a laboratory record confirming this, thereby accepting responsibility for the identity of the specimen. A comment will be added to the Laboratory Information Management System (LIMS) to acknowledge the labelling error and any potential authorisation from clinician to proceed to analysis.

6.7.4 Inadequately Labelled Specimens

Where specimen labelling falls short of the full requirements of patient identification, initial and surname of Medical Practitioner, location and clinical details, samples will not be analysed, except, at the discretion of the laboratory, when:

- repeat sampling is not feasible, and
- not analysing could seriously compromise patient care (e.g. unrepeatable samples, such as CSF), and
- patient identity can reasonably certainly be deduced.

A member of laboratory staff will attempt to inform the requesting clinician either by telephone or report (if that person can be identified from the form) and:

- If there is an overriding clinical reason for processing the specimen, offer the opportunity to come to the laboratory and complete the labelling. The person completing or correcting the labelling must be the person who took the specimen, must be able to satisfy themselves of the identity of the specimen and must sign a laboratory record confirming this, thus accepting responsibility for the identity of the specimen.
- Inform the clinician that if this is not done within one day (or shorter period if the analyte is less stable), the specimen may be discarded. Cellular pathology specimens may be retained unprocessed for a limited period.
- Keep the specimen in a designated place for the agreed period of time.
- If specimens have to be discarded (or retained unprocessed for longer than one day) a record will be made in the laboratory computer system and an appropriate notification made to the requesting ward/department/practice.

A similar procedure will apply to all specimens that have been received in the laboratory for which, during processing, a member of the laboratory staff has good reason to doubt the identity of the specimen. A comment

will be added to the Laboratory Information Management System (LIMS) to acknowledge the labelling error and any potential authorisation from clinician to proceed to analysis.

6.7.5 Recording of Labelling Incidents

The laboratory will keep a record of all inappropriately labelled specimens. This record will include:

- precise details of the inappropriate labelling
- the name and address of the patient
- the name of the requesting clinician
- the ward, unit, or practice
- Consultant in charge of the case where possible

Where the laboratory agrees to analyse an inadequately labelled specimen, the name and department/section of the person taking responsibility for the specimen will also be recorded.

Labelling incidents that result in (near) patient harm will be treated as clinical incidents and dealt with according to the UHB 138 Incident, Hazard and Near Miss Reporting Policy and Procedure.

When repeated labelling incidents can be identified as originating from a single Unit or Practice, an appropriate Consultant, General Practitioner or Practice Manager will be informed.

7.0 Resources

No resources are being made available specifically in response to the revision of this policy. The procedures described are already best practice in the UHB. This revision represents a more rigorous application of those practices, and decreased tolerance of substandard practice in the interest of patient safety. Some re-sampling of patients is anticipated.

8.0 Staff Training and Education

All new medical practitioners and other health care professionals should be made aware of local guidance and the importance of correct patient and sample identification. It is the responsibility of Clinical Boards to ensure that staff have access to appropriate training, and observe all UHB Policies and Procedures. Training of new medical practitioners and other health care professionals in laboratory usage should continue at induction. No facilities for any additional formal training required as a result of this policy will be available.

9.0 Review

This policy will be reviewed at least every 3 years and more frequently if any developments or changes in practice inform the Health Board otherwise.

10.0 Monitoring and Audit

The quality of information supplied with specimens will be audited regularly as part of the Laboratory Medicine internal audit programme and results reported to the Clinical Board Quality Safety and Experience Group.

11.0 Distribution

This policy will be available for viewing via the UHB share point pages.

12.0 Equality

An equality impact assessment has been undertaken to assess the relevance of this policy to equality and potential impact on different groups, specifically in relation to the General Duty of the Race Relations (Amendment) Act 2000 and the Disability Discrimination Act 2005 and including other equality legislation. The assessment identified that the policy presents a positive impact as all patients and colleagues will be treated equally under this policy.

Appendix 1 High risk labelling policy: Literature review

The Health and Safety Executive's (HSE) "*Approved List of Biological Agents*" states as a fundamental principle of good laboratory safety systems that:

> *"where there is a high risk of staff exposure to a hazard group 3 biological agent, laboratory staff may need additional information."*

The HSE builds on this advice in their *"Safe working and the prevention of infection in clinical laboratories and similar facilities"* guidance by suggesting that:

> *"The most common method of providing information on specimens known or suspected of posing a risk of infection is to use a 'danger of infection' label. Use of a standard label for all such specimens coming into the laboratory reduces scope for confusion. Reception staff need to send specimens bearing a danger of infection label directly to the appropriate laboratory department, unopened"*

This is a legal requirement. This is further supported by another legal requirement imposed by the Control of Substances Hazardous to Health Regulations (2002) (COSHH) to record exposure to Hazard Group (HG) 3 or HG 4 organisms:

> "Under COSHH employers must keep details about employees exposed to hazard group 3 or 4 biological agents, where there is a deliberate intention to work with or use the group 3 or 4 agent or, in the case of an incidental exposure, a risk assessment shows there is a significant risk. Employees should be considered as having been exposed unless exposure has been prevented, and not merely controlled. The details recorded should include:
>
> - the type of work the employee does;
> - the biological agents to which they have been exposed (where this is known);
> - records of accidents and incidents involving exposure to the biological agents concerned.
>
> These details should be kept for at least 10 years after the last known exposure, except in the case of certain exposures which may give rise to infections with longer-term implications, where they should be kept for 40 years."

Management of Health and Safety at Work Regulations 1999 (MHSW) also establishes the requirement to manage infection risks to new and expectant mothers in the workplace. Specific pathogens require the employer to make suitable adjustments to protect new and expectant mothers in pathology laboratories:

- Chlamydia psittaci
- Cytomegalovirus

Appendix 1 High risk labelling policy: Literature review

- Hepatitis A
- Hepatitis B
- Human immunodeficiency viruses
- Listeria
- Parvovirus
- Rubella
- Toxoplasma
- Varicella-zoster (chickenpox)

Advisory Committee on Dangerous Pathogens (ACDP) Guidance "INFECTION RISKS to new and expectant mothers in the workplace" also lists a range of microbes cause infections in the human population and may also infect pregnant women. These may or may not have an adverse effect on the baby

- Borrelia burgdorferi (Lyme disease);
- Coxiella burnetii (Q fever);
- Campylobacter spp. and Salmonella spp (gastroenteritis);
- Lymphocytic choriomeningitis virus (LCM),
- Mycobacterium tuberculosis (TB),
- Treponema pallidum (syphilis)

Accidents or incidents which result in or could result in the release or escape of a biological agent likely to cause severe human disease, i.e. a HG3 or HG4 agent (defined as a dangerous occurrence) also have to be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (2013) (RIDDOR).

Therefore samples which are known, or suspected to contain HG 3 or HG 4 organisms must be labelled as such to allow employers to comply with the legal requirement established by a number of statutory implements.

It is anticipated that the revised General Medical Council (GMC) guidance "Confidentiality: good practice in handling patient information" read in conjunction with "Confidentiality: disclosing information about serious communicable diseases" will provide the following advice:

> *"If a patient who has been diagnosed with a serious communicable disease refuses to allow you to tell others providing their care about their infection status, and you believe that failing to disclose the information will put healthcare workers or other patients at risk of infection, you should explain to the patient the potential consequences of their decision and consider with the patient whether any compromise can be reached.*
>
> *Like everyone else, healthcare workers are entitled to protection from risks of serious harm. But disclosure of information about a patient's infection status without consent is unlikely to be justified if it would make no difference to the risk of transmission – for example, if the risk is likely to be managed through the use of universal precautions that*

Appendix 1 High risk labelling policy: Literature review

> *are already in place. If the patient continues to refuse to allow you to tell other members of the healthcare team about their infection status, you must abide by their wishes unless you consider that disclosing the information is necessary to protect healthcare workers or other patients from a risk of death or serious harm."*
>
> *"If it is not practicable to seek consent, and in exceptional cases where a patient has refused consent, disclosing personal information may be justified in the public interest if failure to do so may expose others to a risk of death or serious harm. The benefits to an individual or to society of the disclosure must outweigh both the patient's and the public interest in keeping the information confidential.*
>
> *If you consider that failure to disclose the information would leave individuals or society exposed to a risk so serious that it outweighs patients' and the public interest in maintaining confidentiality, you should disclose relevant information promptly to an appropriate person or authority. You should inform the patient before disclosing the information, if it is practicable and safe to do so, even if you intend to disclose without their consent."*

The overarching legal principle contained within this guidance is that you must disclose information if it is necessary to protect healthcare workers or other patients from a risk of death or serious harm. Safety considerations always takes primacy over information governance. This requirement is explicitly laid out in COSSH and HSE guidance *"Safe working and the prevention of infection in clinical laboratories and similar facilities".*

In the context of the GMC guidance universal precautions, otherwise known as standard infection control precautions, are the basic infection prevention and control measures necessary to reduce the risk of transmitting infectious agents. The HSE clarify the standing of the term 'universal precautions' in their document *"Safe working and the prevention of infection in clinical laboratories and similar facilities"*:

> *"The use of the term 'universal precautions' is not helpful with regard to the*
> *measures needed for handling biological agents, as it is not clearly defined.*
> *Adopting universal precautions may result in a standard of practice which is not high enough. The precautions needed must be based on an assessment of the risks involved, which may be influenced by several factors, such as the biological agents known or suspected to be present and the type of work being carried out."*

Universal precautions in the context of pathology facilities would be dependent on the containment level of the laboratory. Therefore any sample

Appendix 1 High risk labelling policy: Literature review

known or suspected to contain HG 3 or HG 4 organisms cannot be handled with the universal precautions deployed at CL2.

The HSE's "Approved List of Biological Agents" states that:

> *"working with HG 2 biological agents requires a minimum of Containment Level CL 2; HG3 agents being handled at a minimum of CL3"*
>
> *"CL3 or CL4 must be used, where appropriate, if the employer knows or suspects that such a containment level is necessary even if there is no intention to deliberately propagate and concentrate biological agents"*

Therefore there is a legal requirement for additional or enhanced precautions above CL 2 if the laboratory is referred a sample which is suspected or known to contain a non-derogated HG 3 organisms (appendix 2).

Although COSHH sets out the minimum requirements for each level of containment, certain HG3 agents can be worked with under reduced containment in particular circumstances. In order to be able to do this the employer must follow the relevant ACDP guidance agreed or approved by the Health and Safety Commission (HSC). The HG3 agents eligible for reduced containment are listed in the latest edition of the HSC's "*Approved list of biological agents".* In the Approved List, the agents for which this is relevant are indicated in the hazard group column with an asterisk (*) and are listed in Appendix 2. These are known as derogated organisms.

Derogation from CL3 does not imply that the work can be carried out at CL2, it simply allows certain physical containment requirements, normally expected at CL3, to be dispensed with. All other aspects of the work, in particular supervision and training, should reflect the high standards expected at CL3. Any decision to reduce containment measures should be made on the basis of a local risk assessment which takes into account the specific nature of the work.

Appendix 2

Biological Agent	Human Pathogen Hazard Group	Notes
BACTERIA		
Bacillus anthracis	3	Classified under Specified Animal Pathogens Order (SAPO)
Brucella abortus	3	Classified under SAPO Danger to unborn child
Brucella canis	3	Classified under SAPO
Brucella melitensis	3	Classified under SAPO
Brucella suis	3	Classified under SAPO
Burkholderia mallei (formerly Pseudomonas mallei)	3	Classified under SAPO
Burkholderia pseudomallei (formerly Pseudomonas pseudomallei)	3	
Chlamydophila psittaci (avian strains)	3	Danger to unborn child
Chlamydophila trachomatis	2	Danger to unborn child
Coxiella burnetti	3	
Escherichia coli, verocytotoxigenic strains (eg O157:H7 or O103)	3*	Toxigenic
Francisella tularensis (Type A)	3	
Listeria monocytogenes	2	Danger to unborn child
Mycobacterium africanum	3	
Mycobacterium bovis	3	
Mycobacterium leprae	3	
Mycobacterium malmoense	3	
Mycobacterium microti	3*	
Mycobacterium szulgai	3	
Mycobacterium tuberculosis	3	Danger to unborn child
Mycobacterium ulcerans	3*	
Rickettsia akari	3*	
Rickettsia canada	3*	
Rickettsia conorii	3	
Rickettsia montana	3*	
Rickettsia prowazekii	3	
Rickettsia rickettsii	3	
Rickettsia sennetsu (Ehrlichia sennetsu)	3	
Rickettsia spp	3	
Rickettsia tsutsugamushi	3	
Rickettsia typhi (Rickettsia mooseri)	3	
Salmonella paratyphi A	3*	
Salmonella paratyphi B/java	3*	
Salmonella paratyphi C/Choleraesuis	3*	

Appendix 2.

Biological Agent	Human Pathogen Hazard Group	Notes
BACTERIA (continued)		
Salmonella typhi	3*	
Shigella dysenteriae (Type 1)	3*	Toxigenic
Treponema pallidum (syphilis)	2	Danger to unborn child
Yersinia pestis	3	
FUNGI		
Blastomyces dermatitidis (Ajellomyces dermatitidis)	3	
Cladophialophora bantiana (formerly Xylohypha bantiana, Cladosporium bantianum)	3	
Coccidioides immitis	3	Allergen
Coccidioides posadasii	3	Allergen
Histoplasma capsulatum var capsulatum (Ajellomyces capsulatus)	3	
Histoplasma capsulatum var duboisii	3	
Histoplasma capsulatum var farcinimosum	3	
Paracoccidioides brasiliensis	3	
Penicillium marneffei	3	Allergen
Rhinocladiella mackenziei (formerly Ramichloridium)	3	
HELMINTHS		
Echinococcus granulosus	3*	
Echinococcus multilocularis	3*	
Echinococcus vogeli	3*	
Taenia solium	3*	
PROTOZOA		
Leishmania brasiliensis	3*	
Leishmania donovani	3*	
Naegleria fowleri	3	
Plasmodium falciparum (malaria)	3*	
Toxoplasma gondii	2	Danger to unborn child
Trypanosoma brucei rhodesiense	3*	
PRIONS - unconventional agents associated with transmissible spongiform encephalopathies (TSEs)		
Sporadic Creutzfeldt-Jakob disease agent	3*	Restrictions on post mortem examinations
Sporadic fatal insomnia agent	3*	Restrictions on post mortem examinations
Variably protease-resistant prionopathy agent	3*	Restrictions on post mortem examinations
Familial Creutzfeldt-Jakob disease agent	3*	Restrictions on post mortem examinations

Appendix 2.

Biological Agent	Human Pathogen Hazard Group	Notes
PRIONS - unconventional agents associated with transmissible spongiform encephalopathies (TSEs) (continued)		
Fatal familial insomnia agent	3*	Restrictions on post mortem examinations
Gerstmann-Sträussler-Scheinker syndrome agent	3*	Restrictions on post mortem examinations
Variant Creutzfeldt-Jakob disease agent	3*	Restrictions on post mortem examinations
Iatrogenic Creutzfeldt-Jakob disease agent	3*	Restrictions on post mortem examinations
Kuru agent	3*	Restrictions on post mortem examinations
VIRUSES		
Absettarov virus	3	Strain of Central European tick-borne encephalitis virus (Far Esatern subgroup)
Alkhurma haemorrhagic fever virus	3	Subspecies of Kyasanur Forest disaes virsu
Andes virus	3	
Australian bat lyssavirus	3	Classified under SAPO
B virus (Macacine herpesvirus 1)	4	
Banna virus	3	
Belgrade (Dobrava) virus	3	
Bhanja virus	3	
Borna disease virus	3	
Bundibugyo ebolavirus 4	4	
Bunyavirus germiston	3	Synonym: Germiston virus Subspecies of Bunyamwera virus
Central European tick-borne encephalitis virus	3	
Chapare virus	4	
Chikungunya virus	3*	
Crimean/Congo haemorrhagic fever virus	4	
Dengue viruses types 1–4	3	
Duvenhage virus	3	Classified under SAPO
Eastern equine encephalomyelitis encephalitis virus	3	Classified under SAPO
European bat lyssaviruses 1 and 2	3	Classified under SAPO
Everglades virus	3*	
Far Eastern tick-borne encephalitis virus (Russian spring–summer encephalitis virus)	4	
Flexal virus	3	

Appendix 2.

Biological Agent	Human Pathogen Hazard Group	Notes
VIRUSES		
Getah virus	3	
Guanarito virus	4	
Hantaan virus (Korean haemorrhagic fever)	3	
Hanzalova virus	3	
Hendra virus (formerly equine morbillivirus)	4	Classified under SAPO
Hepatitis B virus	3*	Danger to unborn child
Hepatitis C virus	3*	Danger to unborn child
Hepatitis D virus (delta)	3*	Synonym: Deltavirus Hepatitis delta virus Danger to unborn child
Hepatitis E virus	3*	Danger to unborn child
Herpesvirus simiae	4	
Human cytomegalovirus (Human herpsevirus 5)	2	Danger to unborn child
Human herpes simplex viruses 1 and 2	2	Danger to unborn child
Human immunodeficiency viruses	3*	Danger to unborn child
Human parvovirus 4, 5, B19	2	Danger to unborn child
Human pegivirus	3*	Formerly known as GB virus C; or Hepatitis G virus Danger to unborn child
Hypr virus	3	
Israel turkey meningitis meningoencephalomyelitis virus	3	
Japanese encephalitis virus	3	Classified under SAPO
Junin virus	4	
Kumlinge virus	3	
Kyasanur Forest disease virus	4	
La Crosse virus	3	Subspecies of California encephalitis virus
Lagos bat virus	3	Classified under SAPO
Lassa fever virus	4	
Louping ill virus	3*	
Lujo virus	4	
Lymphocytic choriomeningitis virus LCMV (all strains other than Armstrong)	3	
Machupo virus	4	
Marburg marburgvirus	4	
Mayaro virus	3	
Measles virus	2	Danger to unborn child
Middelburg virus	3	
Mobala virus	3	
Mokola virus	3	Classified under SAPO
Monkeypox virus	3	
Mucambo virus	3*	
Mumps virus	2	Danger to unborn child

Appendix 2.

Biological Agent	Human Pathogen Hazard Group	Notes
VIRUSES		
Murray Valley encephalitis virus	3	
Ndumu virus	3	
Negishi virus	3	
Ngari virus	3	Subspecies of Bunyamwera virus
Nipah virus	4	Classified under SAPO
Omsk haemorrhagic fever virus	4	
Oropouche virus	3	
Piry virus	3	
Powassan virus	3	
Primate T-cell lymphotropic viruses types 1 and 2	3*	Synonyms: Human T-cell lymphotropic viruses (HTLV) types 1 and 2
Rabies virus	3*	
Reston ebolavirus 4	4	Includes strain Siena
Rift Valley fever virus	3	Classified under SAPO
Rocio virus	3	
Rubella virus	2	Danger to unborn child
Sabia virus	4	
Sagiyama virus	3	Subspecies of Ross River virus
Sal Vieja virus	3	
San Perlita virus	3	
SARS-related coronavirus	3	
Seoul virus	3	
Severe fever with thrombocytopoenia syndrome virus (SFTS)	3	
Siberian tick-borne encephalitis virus	3	
Simian immunodeficiency virus	3*	
Sin Nombre virus (formerly MuertoCanyon)	3	
Snowshoe hare virus	3	Subspecies of California encephalitis virus
Spondweni virus	3	Subspecies of Zika virus
St Louis encephalitis virus	3	Classified under SAPO
Sudan ebolavirus 4	4	
Tai Forest ebolavirus 4	4	Previously known as Ebola Cote d'Ivoire virus
Tick-borne encephalitis virus	3	
Tonate virus	3*	
Variola virus (major and minor)	4	All strains including Whitepox virus
Venezuelan equine encephalitis virus	3	Classified under SAPO
Wesselsbron virus	3*	
West Nile fever virus	3	Classified under SAPO
Western equine encephalitis virus	3	Classified under SAPO
Yellow fever virus	3	
Zika virus	3	See Spondweni virus

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National Patient Safety Agency (NPSA) Safer Practice Notice (SPN) 14; Right Patient, Right Blood 2006

Public Health Wales information regarding service provision (e.g. microbiology, virology, gynaecology cytology) to C&V via a Service Level Agreement can be sought from -
http://www.publichealthwales.wales.nhs.uk/

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Equality & Health Impact Assessment for

Labelling of Specimens Submitted to Medical Laboratories

Please read the Guidance Notes in Appendix 1 prior to commencing this Assessment

1	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	No proposed change to Laboratory Medicine Service delivery. Document reviewed to provide clarity on sample labelling acceptance criteria and actions in the event of non-conformance with the policy.
2	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact details	Clinical Diagnostics and Therapeutics Clinical Board Director Dr Adam Christian Interim Director of Nursing and Multi-disciplinary Teams Helen Luton
3	Objectives of strategy/ policy/ plan/ procedure/ service	The aim of this policy is to ensure that robust arrangements are in place to ensure that samples taken for laboratory analysis or storage can be accurately and unambiguously identified, and that all necessary information is supplied for appropriate and timely analysis, interpretation and reporting. In addition, any issues arising from the non-conformance with this policy will be reported via UHB 138 Incident, Hazard and Near Miss Reporting Policy and Procedure to establish the root-cause of the issue to avoid recurrence.
4	Evidence and background information considered. For example • population data • staff and service users data, as applicable • needs assessment • engagement and involvement findings	Cardiff and Vale University Health Board (UHB) is one of the largest NHS organisations in the UK, providing healthcare services for 475,000 people living in Cardiff and the Vale of Glamorgan. There are currently approximately 558 staff employed within Laboratory Medicine that are involved in the collection, processing, testing, storage, reporting or management of patient specimens from both internal or external sources. On an average day we carry out 13,715 blood tests.

	• research • good practice guidelines • participant knowledge • list of stakeholders and how stakeholders have engaged in the development stages • comments from those involved in the designing and development stages Population pyramids are available from Public Health Wales Observatory[1] and the UHB's 'Shaping Our Future Wellbeing' Strategy provides an overview of health need[2].	There are many papers that present the importance of accurate patient identification to the prevention of medical errors and demonstrate improvement after introducing and enforcing sample labelling procedures. Patient Sample and Request Form Identification Criteria - Institute of Biomedical Science (ibms.org) The Laboratory Medicine service has dedicated share point and internet pages that explain the service, the testing repertoire and turn-around times. Laboratory Medicine - Home (sharepoint.com) Laboratory Medicine undertakes engagement with service users via user surveys, responding to compliments and concerns, incident management and service user engagement days.
5	Who will be affected by the strategy/ policy/ plan/ procedure/ service	Service users, patients, staff.

6. EQIA / How will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
6.1 Age For most purposes, the main categories are: • under 18; • between 18 and 65; and • over 65	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
6.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
6.3 People of different genders: Consider men, women, people undergoing gender reassignment **NB** Gender-reassignment is anyone who proposes to, starts, is going through or	Negative, there may be an assumption that a name belongs to a specific gender traditionally but the gender recorded may be opposed to this and the conflict may be seen as an		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender	error in the absence of qualifying supporting information.		
6.4 People who are married or who have a civil partner.	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
6.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
6.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
6.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
6.8 People who are attracted to other people of: • the opposite sex (heterosexual); • the same sex (lesbian or gay); • both sexes (bisexual)	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
6.9 People who communicate using the Welsh language in terms	Policy applied to all samples but for paediatric samples,	Disseminate policy and encourage use of user hand	Mitigation captured in introduction –

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
of correspondence, information leaflets, or service plans and design Well-being Goal – A Wales of vibrant culture and thriving Welsh language	precious samples professional discrepancy can be applied within the appropriate laboratory.	books.	Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
6.10 People according to their income related group: Consider people on low income, economically inactive, unemployed/workless, people who are unable to work due to ill-health	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
6.11 People according to where they live: Consider people living in areas known to exhibit poor economic and/or health indicators, people unable to access services and facilities	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
6.12 Consider any other groups and risk factors relevant to this	Policy applied to all samples but for paediatric samples,	Disseminate policy and encourage use of user hand	Mitigation captured in introduction –

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate. Make reference to where the mitigation is included in the document, as appropriate
strategy, policy, plan, procedure and/or service	precious samples professional discrepancy can be applied within the appropriate laboratory.	books.	Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.

7. HIA / How will the strategy, policy, plan, procedure and/or service impact on the health and well-being of our population and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people and on the impact on our population. Specific alignment with the 7 goals of the Well-being of Future Generations (Wales) Act 2015 is included against the relevant sections.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
7.1 People being able to access the service offered: Consider access for those living in areas of deprivation and/or those experiencing health inequalities Well-being Goal - A more equal Wales	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
7.2 People being able to improve /maintain healthy lifestyles: Consider the impact on healthy lifestyles, including healthy eating, being active, no smoking /smoking cessation, reducing the harm caused by alcohol and /or non-prescribed drugs plus access to services that support disease prevention (eg immunisation and vaccination, falls prevention). Also consider impact on access to supportive services including smoking cessation services, weight management services etc Well-being Goal – A healthier Wales	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
7.3 People in terms of their income and employment status: Consider the impact on the availability and	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
accessibility of work, paid/ unpaid employment, wage levels, job security, working conditions Well-being Goal – A prosperous Wales	appropriate laboratory.		and under heading Mislabelled Specimens, Page 11.
7.4 People in terms of their use of the physical environment: Consider the impact on the availability and accessibility of transport, healthy food, leisure activities, green spaces; of the design of the built environment on the physical and mental health of patients, staff and visitors; on air quality, exposure to pollutants; safety of neighbourhoods, exposure to crime; road safety and preventing injuries/accidents; quality and safety of play areas and open spaces Well-being Goal – A resilient Wales	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Action taken by Clinical Board / Corporate Directorate Make reference to where the mitigation is included in the document, as appropriate
7.5 People in terms of social and community influences on their health: Consider the impact on family organisation and roles; social support and social networks; neighbourliness and sense of belonging; social isolation; peer pressure; community identity; cultural and spiritual ethos Well-being Goal – A Wales of cohesive communities	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.
7.6 People in terms of macro-economic, environmental and sustainability factors: Consider the impact of government policies; gross domestic product; economic development; biological diversity; climate	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.

How will the strategy, policy, plan, procedure and/or service impact on:-	**Potential positive and/or negative impacts and any particular groups affected**	**Recommendations for improvement/ mitigation**	**Action taken by Clinical Board / Corporate Directorate** Make reference to where the mitigation is included in the document, as appropriate
Well-being Goal – A globally responsible Wales			

Please answer question 8.1 following the completion of the EHIA and complete the action plan

8.1 Please summarise the potential positive and/or negative impacts of the strategy, policy, plan or service	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory. Patient identification may be misinterpreted in the case of a transgender patient presenting with opposite gender name and gender recorded on same episode.

Action Plan for Mitigation / Improvement and Implementation

	Action	**Lead**	**Timescale**	**Action taken by Clinical Board / Corporate Directorate**
8.2 What are the key actions identified as a result of completing the EHIA?	Policy applied to all samples but for paediatric samples, precious samples professional discrepancy can be applied within the appropriate laboratory.	Disseminate policy and encourage use of user hand books.	Complete on issuing policy.	Mitigation captured in introduction – Laboratory Medicine Test Knowledge Base and under heading Mislabelled Specimens, Page 11.

	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
8.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment required? This means thinking about relevance and proportionality to the Equality Act and asking: is the impact significant enough that a more formal and full consultation is required?	N/A			
8.4 What are the next steps? Some suggestions:- • Decide whether th strategy, policy, plan, procedure an • d/or service propo ○continues unchanged as there are no significant negative impacts ○adjusts to account for the negative impacts ○continues despite potential for adverse impact or missed opportunities to advance equality (set out the justifications for doing so)	continues unchanged as there are no significant negative impacts			

	Action	Lead	Timescale	Action taken by Clinical Board / Corporate Directorate
○stops. Have your strategy, policy, plan, procedure and/or service proposal approved • Publish your report of this impact assessment • Monitor and review				