East Kent Hospitals University NHS Foundation Trust

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NHS Foundation Trust

TRUST POLICY

Pathology Sample and Request Form Acceptance Policy

Version:	6.0
Author (Title and Care Group):	Head of Quality, Clinical Governance& Risk Management Pathology Clinical Support Services Care Group
Approving committee:	Head of Quality, Clinical Governance& Risk Management Pathology
Date approved:	24 May 2022
Date ratified by Policy Authorisation Group:	22 June 2022
Date issued:	04 August 2022
Next scheduled review date:	May 2023

Applies to (include subsidiary companies):	
Trust staff (specify groups e.g. clinical/non-clinical):	All clinical staff that take and label pathology samples
Subsidiaries	No - Beautiful Information Yes - Spencer Private Hospitals
2gether Support Solutions Ltd. as a service provider (hard and soft facilities services)	No

Includes references to children/young people	No
Includes references to medicines	No

We care

Version Control Schedule

Version	Date	Author	Status	Comment
1	August 2013	Allison Bunkall, Head of Quality, Clinical Governance& Risk Management Pathology	Approved	
2	April 2015	Allison Bunkall, Head of Quality, Clinical Governance& Risk Management Pathology	Approved	Amendment to sample labelling instruction. Section 6 page 5.
3	April 2017	Allison Bunkall, Head of Quality, Clinical Governance& Risk Management Pathology	Approved	Amendment to section 5, addition of explanation re self-requesting
4	May 2019	Head of Quality, Clinical Governance& Risk Management Pathology	Approved	Incorporated information regarding Cellular Pathology and unrepeatable samples Updated appendices 1 Amendment to section 5, expansion of explanation re self- requesting
5	February 2022		Not Issued	Version never issued – next live version is version 6
6	February 2022	Head of Quality, Clinical Governance& Risk Management Pathology		

Policy Reviewers

Name and Title of Individual	**Date Consulted**
Pathology General Manager	09/02/2022
Pathology Clinical Director	09/02/2022
Name of Committee	**Date Reviewed**
Pathology Management and Governance Committee	21/03/2022
Clinical Support Services Care Group Quality and Risk Meeting	24/03/2022

Summary of Key Changes from Last Approved Version

Expanded table to state pre- printed labels accepted with full patient demographics in pathology with exception of Blood Transfusion samples.

Added that identifier could be mortuary number

Added that for electronic order requests, request forms do not now always accompany sample.

Added to rejection of request forms that if sample and form demographics do not match, rejection of request will be made against both patient records.

Associated Documentation

Policy for Patient Identification

Blood Transfusion Policy

Contents

1. Policy Description

1.1. Clinical governance demands that a sample **must** be uniquely labelled and accompanied by a test request. The information that appears on specimens and their accompanying request **must** match and fulfil a set of minimum criteria defined by pathology professional bodies.

1.2. This document sets out the requirements for correct sample labelling and request details for all test requests received by laboratories within pathology.

1.3. In the interests of patient safety, both request and samples **must** contain an adequate minimal amount of information. Any sample, which does not conform to the essential labelling requirements will be rejected by pathology.

2. Introduction

2.1. Pathology **must** ensure that all patient results are for a specific, identifiable individual. It is therefore essential that samples are labelled accurately and completely and that request forms are completed adequately for samples to be accepted for testing.

2.2. Before accepting a clinical specimen, laboratory staff **must** ensure certain minimum criteria for sample identification are met. Criteria for sample identification are given in this document.

2.3. The responsibility for requesting a laboratory service/test lies with the patient's clinical team. Thus, it is the responsibility of the requestor to ensure that samples are correctly labelled and that request forms are completed to the agreed standard. If samples or requests are not labelled/completed with the essential requirements they will be reported to the user with the reason why the sample was rejected

2.4. Laboratory staff are not permitted to endanger patients by working outside this policy, so non-compliant samples or requests will not be accepted.

2.5. This document should be read by pathology, medical, nursing, midwifery and phlebotomy staff and **must** be used in conjunction with their own protocols for patient identification.

3. Definitions

3.1. **Blood sciences** encompasses the disciplines of clinical biochemistry (including immunology), haematology (including blood transfusion) and haemophilia.

3.2. **Cellular pathology** encompasses histology (including immunohistochemistry), cytology (gynaecological and non-gynaecological) and andrology.

3.3. **DartOCM** is the electronic order communications solution used by the primary care providers served by EKHUFT Pathology.

3.4. **GUM** represents the genitourinary medicine service.

3.5. **Indexor** is a sample transport and receipt solution used for electronic pathology order requests in the primary care setting.

3.6. **Request forms** are the mechanisms for ordering pathology investigations on patients incorporating patient details, tests required and relevant clinical information. Please note that request forms can be either in paper copy form or electronic e.g. for DartOCM requests submitted using Indexor. Note that it is the policy of EKHUFT that electronic requesting processes should be used in all cases unless there are specific reasons why this is not possible e.g. requestor is working remotely without electronic access.

3.7. **Sunrise** is the electronic order communications solution used for secondary care requests and results within EKHUFT.

3.8. **Q-Pulse** is an electronic quality management system.

4. Purpose and Scope

4.1. This document aims to ensure the safety of the patient and to ensure the right investigation is performed on the right sample.

4.2. This document **must** be used in conjunction with the Policy for Patient Identification and Blood Transfusion Policy as specimen labelling will only be accurate if the patient has been correctly identified.

5. Duties

5.1. All staff collecting samples for analysis hold a duty of care to patients and should comply with this policy. The ward/department manager **must** ensure that this policy is fully implemented within their areas of responsibility.

5.2. The laboratory will **not** accept self-requests for pathology investigations, or requests where the patient and requestor are in a close personal relationship (family/friend): all investigations **must** be requested by the patient's treating healthcare professional and the report destination **must** be different from that of the patient.

5.3. It is the responsibility of the pathology quality manager to update and revise this document.

6. Labelling criteria

6.1. Essential criteria

6.1.1. Samples **must** never be pre-labelled: labelling should be on the body of the container and never on the lid.

6.1.2. All samples **must** be clearly labelled in the presence of the patient.

6.2. Sample labelling (not blood transfusion)

6.2.1. Samples should be labelled with the following:

6.2.1.1. Full last name/surname (or coded identifier as in genitourinary medicine [GUM] patients);

6.2.1.2. Full first name;

6.2.1.3. Date of birth (DOB) and or NHS/hospital number;

6.2.1.4. Date and time of sample (essential for certain tests e.g. glucose tolerance tests);

6.2.1.5. Cytology samples only – sample takers number and signature;

6.2.1.6. Initials of person who took sample (blood tubes only);

6.2.1.7. Source/location of patient;

6.2.1.8. Specimen type(s) and anatomical site(s) on all samples (essential for histology and microbiology).

6.2.2. If samples are not labelled with the following details the request will be rejected:

6.2.2.1. Three out of four of the following identifiers: patient's full first name, surname, DOB and NHS/hospital number/mortuary number.

6.2.2.2. For cytology samples: additionally the number and signature of the individual who collected the sample **must** be documented on the sample.

6.2.2.3. If there is evidence of re-labelling (e.g. two sticky labels or crossing out of information on the sample) then the sample will be rejected.

6.3. **Request form labelling** (not blood transfusion)

6.3.1. Request forms should include the following information:

6.3.1.1. Full last name/surname (or coded identifier as in GUM patients);

6.3.1.2. Full first name;

6.3.1.3. Date of birth (DOB) and or NHS/hospital number/mortuary number;

6.3.1.4. Date and time of sample (essential for certain tests e.g. glucose tolerance tests);

6.3.1.5. Tests required;

6.3.1.6. Source/location of patient;

6.3.1.7. Address/location for report (if different to source/location of patient);

6.3.1.8. Specimen type(s) and anatomical site(s) on all samples (essential for histology and microbiology);

6.3.1.9. Clinical details (essential for some haemostasis/coagulation/cellular pathology/specialised clinical biochemistry tests);

6.3.1.10. Consultant/GP name;

6.3.1.11. Contact information/bleep number of the requestor;

6.3.1.12. Urgency of request.

6.3.2. Please note that request forms can be either in paper copy form or electronic e.g. for DartOCM requests submitted using Indexor.

6.3.3. Rejection criteria

If request forms do not include the following details the request may be rejected

6.3.3.1. Three out of four of the following identifiers: patient's full first name, surname, DOB and NHS/ hospital number;

6.3.3.2. Date of sample;

6.3.3.3. Tests requested;

6.3.3.4. Clinical details appropriate to the requested investigation (essential for some haemostasis/coagulation/cellular pathology/specialised clinical biochemistry tests).

6.3.3.5. If the information on the samples and request forms which are received together do not match. In these instances, the requests will be made on both patients records and rejected stating that there was patient identification discrepancy.

6.4. Blood transfusion samples

6.4.1. The British Society for Haematology (BSH) have produced guidelines on requesting blood and collecting samples for testing by transfusion departments. EKHUFT's transfusion policy conforms to these and **must** be adhered to when requesting or collecting samples for transfusion. Transfusion samples **must** adhere to the following:

6.4.2. Sample tubes **must** be hand written, with all sections completed in legible hand writing.

6.4.3. The following is an extract from EKHUFT Blood Transfusion policy:

"The person taking the sample **must**:

Bleed one person at a time.

Verify the identity of the patient by asking the patient to state their full name and date of birth where possible. This **must** be compared and found to be identical to the request form and in the case of inpatients also identical to the identity bracelets. Note: The request form **must** be taken to the patient and **not** obtained after the blood sample has been collected.

Label the sample immediately at the patients' side by hand using a minimum of three points of patient identification (NHS number, full name, and full DOB) for all patients to minimise risk of error. All samples **must** be signed, labelled, timed and dated by the person taking the sample.

In the event of an NHS number not being available then a hospital number, major incident number or other unique identifier is to be used. Whichever of the aforementioned alternatives is used it **must** also be present on the patient identity bracelets."

6.5. Cellular pathology samples

6.5.1. If the sample(s) does not match essential sample acceptance criteria (e.g. incorrect name, site discrepancy on pot & form), it **must** be booked in and an interim report issued with the reason why the sample has been rejected using either Snomed code, MIS (mismatch) or KIM (key identifier missing). This interim report should be authorised by a senior biomedical scientist (Band 7 or above) and the sample and request form then returned to the sender for amendment with a clear explanation as to why the sample has been rejected.

6.5.2. If samples are received from within William Harvey Hospital and are unlabelled the person responsible for the sample should be contacted to come to pathology in person to label the specimen container.

6.5.3. If the samples are received from any other area; they **must** be returned to the person responsible for the sample to label the specimen container.

6.5.4. If the requestor attends pathology and labels the container within 24 hours from request, then the sample is no longer 'rejected' and an interim report is not necessary. If the requestor does not attend within 24 hours, then the sample will be rejected and treated as above.

6.5.5. If there are minor errors in the labelling (e.g. for single samples, if the form is labelled with specimen site but there is no indication of site on the sample container and errors requiring clinical advice), the sample and form should be reviewed by the sub-speciality consultant of the day.

6.6. Rejected samples

6.6.1. Any samples received within pathology which do not meet the minimum required labelling criteria will be rejected

6.6.2. Any sample that is rejected will have a report issued with an appropriate comment and the sample will be retained within the laboratory for a minimum of 5 days (N.B. coagulation samples are not viable after six hours and therefore are not retained).

6.7. Unrepeatable samples

6.7.1. In the case of 'precious' or unrepeatable samples, (e.g. all cellular pathology samples excluding gynaecytology and urine, bone marrow, cerebrospinal fluid, dynamic function tests and post-mortem samples, certain paediatric samples), the requestor will be contacted as soon as the error has been identified.

6.7.2. Samples may be returned to the requestor for labelling. If it is not possible to identify the sample it will only be processed if authorised by a medical/clinical consultant of the appropriate discipline. An identity disclaimer would then be added to the computer record.

6.7.3. Where several samples are received in the same bag, and all match up except one sample or one form (e.g. six samples and five forms, all match with an extra sample, or vice versa) all matching samples can be accepted.

7. Policy Development, Approval and Ratification

7.1. This policy has been developed in line with guidance from the Institute of Biomedical Science and the British Society for Haematology

This policy was approved by the Pathology Management and Governance Committee in April 2022

This policy was approved by the Clinical Support Services Care Group Quality and Risk Meeting

7.2. This policy will be ratified by the Policy Authorisation Group.

8. Review and Revision Arrangements

8.1. This policy will be reviewed as scheduled in one years' time unless legislative or other changes necessitate an earlier review.

8.2. It will be ratified by the Policy Authorisation Group every year, or when there are significant changes and/or changes to underpinning legislation in accordance with section 9.3 of the policy for the Development and Management of Trust Policies

9. Policy Implementation

9.1. Refer to Appendix C.

10. Document Control including Archiving Arrangements

10.1. Archiving of this policy will conform to the Trust's Information Lifecycle and Records Management Policy, which sets out the Trust's policy on the management of its information.

10.2. This policy will be uploaded to the Trust's policy management system.

10.3. Version 4 of this policy, which this document supersedes, will be retained within the Trust's policy management system for future reference. Version 5 was never issued.

11. Monitoring Compliance

11.1. Compliance is monitored for each sample on acceptance within pathology. An electronic record is kept on APEX of all rejected samples

12. References

12.1. Patient Sample and Request Form Identification Criteria, Council of the Institute of Biomedical Science (IBMS hds/2000).

12.2. British Society for Haematology (2017) The administration of blood components. URL **https://b-s-h.org.uk/guidelines/guidelines/administration-of-blood-components/** (Accessed 21/01/19)

13. Appendices

Appendix A – Sample and Form acceptance and rejection guide

The below table depicts what information should be available on the sample and form and when sample rejection can be triggered.

Labelling criteria	Sample	Form	Comments
Full Last name/Surname (or coded identifier as in GU patients)	✓	✓	This will trigger rejection if not present.
Full First name	✓	✓	This will trigger rejection if not present.
Date of Birth (DOB) and or NHS/hospital number/ Mortuary number	✓	✓	This will trigger rejection if not present. Both **must** be available for blood transfusion samples (or use of major incident number).
Date and time of sample (essential for certain assays)	✓	✓	If the date is not available on the request form; the sample will be rejected.
Cytology samples only – sample takers number and signature	✓		This will trigger rejection if not present.
Source/location of patient	✓	✓	
Specimen type(s) and anatomical site(s) on all samples (essential for Histology and Microbiology)	✓	✓	
Tests required		✓	This will trigger rejection if not present.
Address/ location for report (if different to source/ location of patient)		✓	
Clinical details appropriate to the investigation (essential for some haemostasis/coagulation/cellular pathology/specialised clinical biochemistry assays)		✓	This will trigger rejection if not present.
Consultant/GP name		✓	
Urgency of request		✓	

- Pre-printed labels with full patient demographics are acceptable in pathology with the exception of Blood Transfusion where labels **must** be hand written or obtained using 360 labels.
- Samples will be rejected in the following conditions: there is evidence of re-labelling i.e. two sticky labels or crossing out of information on the sample, the information on the sample and request form do not match or the sample is unlabelled or otherwise unsuitable for processing (e.g. in wrong tube type).

- Any rejected samples will be retained within the laboratory for 5 days (7 days for Microbiology)

Appendix B – Equality Analysis

An Equality Analysis not just about addressing discrimination or adverse impact; the policy should also positively promote equal opportunities, improved access, participation in public life and good relations.

Person completing the Analysis		
Name	Emma Sutton	
Job title	Head of Quality, Clinical Governance& Risk Management Pathology	
Care Group/Department	Pathology, Clinical Support Services	
Date completed	20th January 2022	
Who will be impacted by this policy	[x] Staff (EKHUFT) [x] Staff (Other) [x] Service Users	[ ] Carers [x] Patients [ ] Relatives

Assess the impact of the policy on people with different protected characteristics. When assessing impact, make it clear who will be impacted within the protected characteristic category. For example, it may have a positive impact on women but a neutral impact on men.		
Protected characteristic	**Characteristic Group**	**Impact of decision** Positive/Neutral/Negative
e.g. Sex	Women Men	Positive Neutral
Age	None	None
Disability	None	None
Gender reassignment	None	None
Marriage and civil partnership	None	None
Pregnancy and maternity	None	None
Race	None	None
Religion or belief	None	None

Sex	None	None
Sexual orientation	None	None

If there is insufficient evidence to make a decision about the impact of the policy it may be necessary to consult with members of protected characteristic groups to establish how best to meet their needs or to overcome barriers.	
Has there been specific consultation on this policy?	This policy has been reviewed by the Head Biomedical Scientists and Heads of Services within pathology prior to approval.
Did the consultation analysis reveal any difference in views across the protected characteristics?	No

Mitigating negative impact: Where any negative impact has been identified, outline the measures taken to mitigate against it.	

Conclusion: Advise on the overall equality implications that should be taken into account by the policy approving committee.	It is believed that there is no discrimination through implementation of this policy.

Appendix C – Policy Implementation Plan

To be completed for each version of policy submitted for approval.

Policy Title:	Pathology Sample and Request Form Acceptance Policy
Version Number:	6
Director Responsible for Implementation:	Operations Director, Clinical Support Services Care Group
Implementation Lead:	Head of Quality, Clinical Governance and Risk Management (Pathology)

Staff Groups affected by policy:	All pathology service users
Subsidiary Companies affected by policy:	SPH
Detail changes to current processes or practice:	None applicable
Specify any training requirements:	None applicable
How will policy changes be communicated to staff groups/ subsidiary companies?	To all requestors of pathology services: To be placed onto the Pathology intranet page, placed in policy centre on trustnet and published in the pathology app To all pathology staff: To be distributed using Q-Pulse once approved