Document Control

Title			
Pathology Specimen Acceptance Policy			
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Directorate Clinical Support & Specialist Services		**Department** Pathology	
Version	**Date Issued**	**Status**	**Comment / Changes / Approval**
3.0	Jun 2011	Final	Formally approved at the Pathology Operational Group meeting on 24th May 2011.
3.1	Jun 2012	Revision	(i) One of the two key identifiers on a specimen must be the full patient name, (section 5.1). (ii) 'Hospital number' now reads 'a NDDH hospital number', (throughout). (iii) New request form information added (section 3.6).
3.2	Jun 2012	Revision	Minor amendments by Corporate Governance to update document control report, equality impact assessment and automatic hyperlinked table of contents.
3.3	April 2014	Revision	Added a reference to not using PAS labels on blood tubes. Amended requirements for requests from A/E – all requests and specimens must include a NDDH hospital number. Added key identifier: Major Incident patient number as detailed in Major Incident Plan action card 49. Included reference to electronic requesting of pathology tests due to the implementation of Order Comms. Updated policy into the new Trust policy template. Submitted to relevant stakeholders for consultation on 30/04/14. Approved at the Pathology Operational Group Meeting on 27/05/14.
4.0	Jul 14	Final	Approved at the Pathology Operational Group Meeting May 2014 and published on Bob.
5.0	May 2017	Final	Removed all references to using the 6 digit ND case note number as a key identifier, as these are not present on the patients' wristband. Included a sentence that establishes the Pathology Lead Clinician as having the overall responsibility when results are occasionally issued on unrepeatable Microbiology specimens (e.g. blood cultures), that have been mis/unlabelled. Included the requirement that when any mis/unlabelled, unrepeatable specimen that has been processed and had results issued the report includes a warning comment alerting the user to interpret the results with caution, as the patient identity could not be unequivocally identified.
6.0	Dec 2020	Final	Included specific reference to requests for Sickle Cell & Thalassaemia and andrology samples as required by UKAS accreditation. Removed reference to NHS never events list, as no longer relevant. General review for accuracy.
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Superseded Documents Pathology Specimen Acceptance Policy v5.0 Pathology Specimen Acceptance Policy v4.0 Pathology Specimen Acceptance Policy v2.1 Completion of Pathology Request Forms and Labelling of Specimen Containers (April 2005)	

Issue Date	**Review Date**	**Review Cycle**
February 2021	February 2024	Three years

Consulted with the following stakeholders: (list all)

- Associate Medical Director – Surgery
- Associate Medical Director – Medicine
- Associate Medical Director – Clinical Support & Specialist Services
- Divisional Nurse – Surgery
- Divisional Nurse – Medicine
- Divisional Nurse - Clinical Support & Specialist Services
- Lead Consultant – Emergency Care
- Midwife Manager
- Outpatient Department Manager

Approval and Review Process

- Pathology Operational Group

Local Archive Reference
Q-Pulse (document No. TRUST-POLICY-1)
Filename
Pathology Specimen Acceptance Policy

Policy categories for Trust's internal website (Bob)	**Tags for Trust's internal website (Bob)**
Pathology	Labelling, Sample, Specimen, Patient, Identification, Rejected, Pathology

CONTENTS

1. Purpose

1.1. The purpose of this document is to ensure that the Trust meets best practice to ensure patient safety and the effective reporting of pathology results and reports, ensuring compliance with (i) International standard, ISO 15189:2012: 'Medical Laboratories – Requirements for Quality and Competence', (ii) Good Practice Guidelines for Blood Establishments and Hospital Blood Banks, and (iii) NHS Sickle Cell and Thalassaemia Screening Programme - Handbook for antenatal laboratories

Implementation of this policy will ensure that:

- Pathology specimens are unequivocally identified to a patient
- Results are reported to the requester at the correct location
- Where there are problems with patient or sample identification and when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report shall indicate the nature of the problem and that caution is required when interpreting the result.

1.2. The policy applies to all users of the North Devon Pathology Service who are involved in the collecting and labelling of pathology specimens and forms: Trust clinical, medical and administration/clerical staff as well as certain external organisations such as RMB Chivenor Medical Centre and North Devon Hospice.

2. Definitions

Specimen

2.1. Consists of or includes human cells (including subsequent relevant pathological preparations), which have come from a person's body in the course of his/her:-

2.2. (a) Receiving medical treatment,

2.3. (b) Undergoing diagnostic testing, or

2.4. (c) Participating in research.

Cellular Pathology Specimens

2.5. Includes Histology – tissue samples e.g. an appendix, Non-Gynaecological Cytology – fluid samples e.g. cyst fluid and Mortuary Departments – e.g. bodies and limbs and fluids.

Blood Transfusion Specimens

2.6. Specimens collected from patients for the purpose of providing blood and blood products to patients of road traffic accidents, those with acute blood loss, anaemia, clotting problems and specimens associated with leukaemia cases during chemo- and radiotherapy. Examples include cross match and group and save specimens.

Antenatal Serology Specimens for the Screening for Infectious Diseases in Pregnancy (IDIP) Programme

2.7. Requests for maternal Hepatitis B, HIV and Syphilis. Such requests are part of the Infectious Diseases in Pregnancy Screening (IDPS) Programme, responsible for ensuring that screening to identify these infectious diseases is offered early in pregnancy. This screening programme has specific requirements for specimen and request form labelling.

NHS Sickle Cell & Thalassaemia Screening Programme

2.8. The aim of the antenatal screening programme is to offer timely antenatal sickle cell and thalassaemia screening to all women (and couples), to enable informed decision making. This screening programme has specific requirements for specimen and request form labelling.

Key Identifier

Under no circumstances should the old style ND case note number be used on specimens or request forms, as these are not present on the patients' wristband.

2.9. Key Identifiers include:

- 10 digit NHS number OR TrakCare registration number (these can be 7 or 8 digits long)
- Name in full (not preferred or 'known as' names)
- Date of birth
- Unknown Male/Female – only in conjunction with TrakCare registration number or GUM number
- GUM number
- Major Incident patient number, e.g. MI001 (only in circumstances where a major incident has been declared – See *Incident Response Plan*, card nos. 33, 34 and 35, available on the BOB policies website.)

2.10. In the case of an unknown/unresponsive patient presenting as an emergency admission, the Pathology Department will accept Unknown Male/Female along with a TrakCare registration number.

Request Form

2.11. Hardcopy request forms accompany the specimen(s), electronic request forms are sent electronically and are matched up with the specimens in the laboratory. Both types of request form and are completed by the requesting practitioner (or team member) to identify:

- The patient
- The requestor and location to send the results/reports
- The specimen type and/or analysis required
- Clinical and other relevant information as required

2.12. There are different request forms available:-

- Electronic request forms (for GPs requesting Biochemistry, Haematology and Microbiology analysis)
- Paper request form: White background with green printing and bag – **Biochemistry & Haematology**
- Paper request form: White background with blue printing – **Microbiology**
- Paper request form: White background with blue & red printing and bag – **Infectious Diseases in Pregnancy Screening**
- Paper request form: White background with blue & orange printing – **Covid-19 testing** (Microbiology)
- Paper request form: White background with blue printing & some yellow highlighted instructions – **Andrology (semen analysis** – Microbiology)
- Paper request form: White background with black printing – **Histology**
- Paper request form: Yellow background with black printing – **Non-gynae cytology**
- Paper request form: White background with red printing and bag– **Blood Transfusion**
- Non-NDDH request forms are also available e.g. for chromosomal analysis requests and Downs Syndrome screening. Contact the laboratory for supplies of request forms.

3. Responsibilities

Role of Requesting Practitioner

3.1. Where the requesting practitioner is not directly able to label specimens and request forms and package them for transportation themselves, these tasks will be considered to have been delegated to a person within the requesting practitioner's team. For a summary of the requirements see page 12. However the requesting practitioner has overall responsibility for:-

- Ensuring that pathology specimens have been labelled according to this policy
- Ensuring that the request form is completed correctly, in full, according to this policy
- Ensuring that the specimens are packaged and transported to the laboratory according to the guidance given and relevant legislation in force.
- Ensuring that where specimens have been rejected, either repeat specimens are collected or unrepeatable specimen results are reviewed with caution as the identity of the patient was not able to be confirmed.

Role of Pathology Lead Clinician

3.2. The Pathology Lead Clinician has the overall responsibility when results are occasionally issued on unrepeatable Microbiology specimens that have been mis/unlabelled, specifically blood cultures.

Role of Pathology Department Specimen Reception Staff

3.3. Staff in each of the pathology departments are responsible for:-:

- Checking request forms and electronic requests against specimen identification
- Labelling paper request forms and specimens with laboratory accession numbers
- Entering pathology requests into the computer system, where these are not received in electronic format
- Referring incorrectly labelled specimens and request forms to a designated member of pathology staff

Role of Designated Members of Pathology Staff

3.4. Designated members of pathology staff are responsible for:

- Checking available patient databases (e.g. TrakCare and the NHS Summary Care Record) for the presence of incorrect or out of date patient identifiers
- Amending the Pathology computer system where data has been confirmed to be incorrect or out of date
- Confirming a non-compliance against this policy
- Rejecting non-compliant specimens
- Including a warning comment (e.g. 'Interpret results with caution'), with results that have been issued from mislabelled or unlabelled specimens that are unrepeatable

4. Labelling of Specimens

General

Specimens must be labelled immediately after collection, at the patient's side. They should not be transferred to a central area to be labelled later. All specimens must be dated and preferably signed. (See below for specific requirements for Blood Transfusion, Antenatal Serology, Sickle Cell & Thalassaemia and Andrology specimens).

All specimens must be clearly and unequivocally identified with a minimum of two of the key identifiers, one of which must be the full name. Key identifiers must be correct and match the information given on the request form.

Whenever possible, the NHS and/or TrakCare registration number should be used as one of the key identifiers. The NHS number is a unique identifier and its use will minimise clinical risk and improve data entry times.

Patients wearing hospital I.D. wristbands

The identity of the patient must be confirmed by checking the patient's wrist band. Do not rely on the information on the headboard of the bed or on pre-

printed sticky labels. All hospital inpatient specimens must be labelled after checking the patient's wristband and, where possible, at the patient's bedside.

Only patient identification numbers found on patients' wristbands should be used for labelling pathology requests, these are the NHS number or the TrakCare registration number

Patients NOT wearing hospital I.D. wristbands

The identity of the patient must be confirmed by asking them to confirm their full name, date of birth and address. If positive identification of the patient cannot be confirmed by asking the patient for these details, refer to a parent/ carer or partner who can confirm the patient's identity before collecting the specimen(s).

New Born Babies

When requesting Pathology investigations on new born babies, to prevent specimen rejection the baby's NHS or a TrakCare registration number, date of birth, name and birth order **must** be used, **not** the mother's details.

Please do not use the 5 day blood spot labels, which include both mother and baby's ID, on pathology request forms.

Specimens not conforming to these criteria will be rejected by the Pathology Department.

Specimens may be also be rejected if they have leaked.

Unrepeatable Specimens

All cellular pathology specimens and the following other specimen types are considered by the laboratory to be unrepeatable:

Fluids from sterile sites: CSF, Ascitic fluid, pleural fluid, joint fluid and other fluids. Tissue samples, bronchial washings, CVP tips, blood cultures, bone marrow/intraosseus specimens, pre-dose level blood specimens, QUAD/NT specimens (where the time window has passed) and specimens from deceased patients.

Almost all specimens which do not meet these requirements must be verified by the requesting practitioner (or team member), an appropriate clinician or manager.

Following verification, and completion of a 'Record of Verification Form for Rejected or Unrepeatable Specimens', the specimen will be accepted

However occasionally some Microbiology specimens, (e.g. blood cultures) which do not meet these requirements will still be processed but results will be issued with a warning comment informing that the patient's identity could not be unequivocally confirmed and that the results should be viewed with caution. The lead clinician for Pathology holds ultimate responsibility for issuing results on any unrepeatable specimens that have been mislabelled or unlabelled.

In the event of a life-threatening or time critical situation, the consultant or team member in charge of patient care will discuss with the laboratory staff that they will accept the analysis of a specific, repeatable sample and

acknowledge in doing so acceptance of any governance issues involved. This exception will not include samples for blood transfusion which are governed by national legislation.

Blood Transfusion and Antenatal Serology (IDIP) Specimens

All blood transfusion and antenatal serology screening specimens (HIV, Hep B and Syphilis) must be labelled by hand. No sticky labels can be used. The specimen must be identified with a minimum of full name, date of birth and a patient number that can match one on the patient wristband, i.e. NHS or Trakcare registration number.

Under no circumstances should the old style ND case note number be used solely on specimens or request forms, as these are not present on the patients' wristband.

Specimens from unknown, unconscious patients must be labelled with a Trakcare registration number and gender. The specimen(s) must be signed by the person taking the specimen.

Specimens not conforming to these criteria have to be rejected by the Pathology Department.

Sickle Cell & Thalassaemia (SCT) Screening Specimens

Requests for these tests should consist of a correctly labelled EDTA (purple top tube) sample for a FBC test. This should be accompanied by a correctly completed blood sciences request form and a completed Family Origin Questionnaire (FOQ) form which must include three key patient identifiers.

SCT specimen requests not conforming to these criteria will be rejected by the Pathology Department.

Andrology (Semen Analysis) Specimens

Semen Analysis is carried out by APPOINTMENT ONLY. Samples should be collected in a non-toxic container, and accompanied by an Andrology request form. Samples for fertility investigations must be delivered to the laboratory within 1 hour of collection and samples for post vasectomy analysis can be delivered within 4 hours of the sample being taken.

A link to the full guidance can be found in the Associated Documentation section, below. Semen analysis request packs (Fertility Kits) are available from the Pathology Supplies Department

5. Completing Pathology Request Forms

General

5.1. If an electronic order communications system has not been used to generate a pathology request, pathology specimens must be accompanied by the appropriate paper pathology request form.

5.2. All paper and electronic pathology request forms must be completed in full and include a minimum of **three key identifiers** which must be correct and match the information given on the specimen(s). The NHS and/or Trakcare registration number must be used as one of the key identifiers.

5.3. The electronic request or paper request form must also include the report destination, the name of the requesting practitioner and the analysis required.

5.4. Relevant clinical details must be included on paper and electronic request forms. If these are not included, the laboratory may not analyse some specimens such as Histopathology, Non-Gynae Cytology, culture and sensitivity and some specialist, expensive, or referred tests.

5.5. Pre-printed labels are accepted on paper request forms as a means of identification but they must contain all relevant information. Poorly printed or misaligned labels (where ID cannot be interpreted), will result in such requests being rejected. Labels must be attached to all copies of the request form. Request forms should also include relevant clinical information and the requesting practitioner's contact details.

5.6. Request forms and accompanying specimens not conforming to these criteria will be rejected by the Pathology Department.

Blood Transfusion Request Forms

5.7. The request form for blood transfusion specimens must be signed by the person taking the specimen.

5.8. Request forms and accompanying blood transfusion specimens not conforming to this criterion will be rejected by the Pathology Department.

6. Rejecting Specimens

6.1. Specimens will be rejected by the Pathology Department if they do not comply with the criteria detailed above. The final decision to accept or reject a specimen rests with the Pathology Department.

6.2. Where a specimen is rejected, the Pathology Department will inform the requesting practitioner (or team member) that the specimen has been rejected; this can be by contacting the location where the request originated or by means of a laboratory comment in lieu of the results, attached to the pathology report.

6.3. For mislabelled or unlabelled unrepeatable specimens, the Pathology Department will, in occasional circumstances process these specimens (e.g. blood cultures), but issue a warning comment along with the results informing the users that the patient's identity could not be unequivocally identified and therefore the results must be interpreted with appropriate caution.

7. Monitoring Compliance with and the Effectiveness of the Policy

Standards/ Key Performance Indicators

7.1. Daily and monthly data extractions from the pathology computer system of numbers of rejected pathology specimens due to unlabelled or mislabelled specimens and/or request forms

Process for Implementation and Monitoring Compliance and Effectiveness

7.2. Monitoring compliance with this policy is well established.

- Monitoring compliance is the responsibility of the Pathology Quality Manager.
- This will be undertaken by monitoring incident reports and identifying trends on an on-going basis. Where non-compliance is identified, support and advice will be provided to improve practice.
- In practice, a list is extracted daily of rejected specimens from the pathology computer to check for legitimacy of rejection and developing rejected specimen trends. Noticeable trends of rejected specimens are reported back to the locations they originate from, e.g. GP practice or NDDH ward.
- Quarterly Incident reports are published which review the numbers of 'Wrong Blood in Tube', (WBIT), specimens received – these are reviewed at the Pathology Operational Group Meetings. WBIT data is fed back to the Trust Patient Safety and governance meetings as each of these incidents can potentially carry a significant risk to the safety of two patients.
- Each year the total number of rejected specimens is extracted and this is included as part of the Pathology Management Review.

8. Equality Impact Assessment

8.1. The author must include the Equality Impact Assessment Table and identify whether the policy has a positive or negative impact on any of the groups listed. The Author must make comment on how the policy makes this impact.

Table 1: Equality impact Assessment

Group	Positive Impact	Negative Impact	No Impact	Comment
Age			X	
Disability			X	
Gender			X	
Gender Reassignment			X	
Human Rights (rights			X	

Group	Positive Impact	Negative Impact	No Impact	Comment
to privacy, dignity, liberty and non-degrading treatment), marriage and civil partnership				
Pregnancy			X	
Maternity and Breastfeeding				
Race (ethnic origin)			X	
Religion (or belief)			X	
Sexual Orientation			X	

9. References

- International Standard ISO 15189:2012
- Laboratory Handbook – NHS Infectious Diseases in Pregnancy Screening Programme available at http://infectiousdiseases.screening.nhs.uk/standards
- Laboratory Handbook – Sickle Cell and Thalassaemia Screening available at https://www.gov.uk/government/publications/sickle-cell-and-thalassaemia-screening-handbook-for-laboratories

Major Incident Plan – Action Cards at http://ndht.ndevon.swest.nhs.uk/emergency-planning/emergency-business-continuity-plans/incident-response-plan/

10. Associated Documentation

- Patient Identification Policy
- Information on Obtaining a Semen Sample for analysis
- Pathology Supplies (request forms and specimen containers) Order Form

Summary of the NDHT Pathology Specimen Acceptance Policy

This summary of the key points of the policy is applicable to every specimen and request form.

Pathology Requests Not Complying With This Policy Will Be Rejected

Key Identifiers Include:

- NHS or Trakcare registration number
- Date of birth
- Name in full (not calling or preferred names)
- Genito-urinary medicine number (GUM No.)
- Unknown or Alias Male/Female – (see 'Main Exceptions' below).
- Major incident patient number (e.g. MI001)

NOTE: Old style ND case note numbers are no longer a key identifier and must not be used.

Labelling of Specimens

- All specimens must be clearly and unequivocally identified with a minimum of **two** of the key identifiers **(one of which must be full name),** and must match with the request form I.D.
- Specimens not conforming to these criteria will be rejected by the Pathology Department.
- Specimens may also be rejected if they have leaked.

Transfusion & Antenatal Serology Specimens Only – Additional Requirements:-

- Must be identified with a minimum of **three** of the key identifiers.
- Must be labelled by hand, not with sticky labels.
- Must be signed by the person collecting the specimen.

Completing Pathology Request Forms (Paper and Electronic)

- The request must contain a minimum of **three** key identifiers and must match with the specimen The NHS or Trakcare registration number should be used as one of the key identifiers.
- The report destination, the name of the requesting practitioner and the analysis required must also be included, along with relevant clinical information.
- Pre-printed labels are accepted on request forms as a means of identification but they must contain all relevant information. Poorly printed or misaligned labels (where ID cannot be interpreted), will result in affected requests being rejected. Labels must be attached to all copies of the request form. Large patient ID labels are not acceptable on blood tubes.
- Without the presence of relevant clinical details, some specimens will not be processed*****

Additional Requirements for Blood Transfusion, SCT, IDIP and Andrology (Semen Analysis)

- Request forms for blood transfusion specimens must be signed by the person taking the specimen.
- For specific requirements relating to (i) Sickle Cell & Thalassaemia, (ii) Infectious Diseases in Pregnancy and (iii) Andrology specimens, refer to the full policy details above.

Main Exceptions to the above	GUM specimens	Minimum required is GUM (Alias) number & DOB *****
	A/E unknown (unconscious) patient	Minimum required is Trakcare registration number & Gender*****

criteria:	In the event of a life-threatening or time critical situation, the consultant in charge of patient care will discuss with the laboratory staff that they will accept the analysis of a specific, repeatable sample and acknowledge in doing so acceptance of any governance issues involved. This exception will not include samples for blood transfusion which are governed by national law.

*** Refer to policy for full policy wording and all exceptions.**

Unrepeatable Specimens

All cellular pathology specimens and the following other specimen types are considered by the laboratory to be non-repeatable:

Fluids from sterile sites: CSF, Ascitic fluid, pleural fluid, joint fluid and other fluids. Tissue samples, bronchial washings, CVP tips, blood cultures, bone marrow/intraosseus specimens, pre-dose level blood specimens, QUAD/NT specimens (where the time window has passed) and specimens from deceased patients.

Almost all specimens which do not meet these requirements must be verified by the requesting practitioner (or team member), an appropriate clinician or manager.

However occasionally some Microbiology specimens, (e.g. blood cultures) which do not meet these requirements will still be processed but results will be issued with a warning comment informing that the patient's identity could not be unequivocally confirmed and that the results should be viewed with caution. The lead clinician for Pathology holds ultimate responsibility for issuing results on any unrepeatable specimens that have been mislabelled or unlabelled.