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**Pathology Policy**

**Sample Acceptance and Rejection**

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**INTRODUCTION**

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**Purpose of the policy**

This policy is based on the requirements set out in the ISO 15189:2022 Standards for Medical Laboratories – Requirements for Quality and Competence, the IBMS (Institute of Biomedical Science) – Guidance on Patient sample and Request Form Identification Criteria and The Guidelines for the Blood Transfusion Service.

**Scope of the policy**

This policy is to ensure that all results are for a specific, identifiable individual and are suitable for testing based on the date and time of collection. This policy applies to all clinical areas of Dartford and Gravesham NHS Trust, Medway NHS foundation Trust, all General Practices covered by the ICS’s and any other external users of the North Kent Pathology Service.

This document should be read by all medical staff, nursing staff, midwifery and phlebotomists and shall be used in conjunction with their own protocols for patient identification.

This policy should be used in conjunction with SOP.PAT.6 Primary sample collection and handling to ensure compliance to ISO 105189:2022 requirements.

**DEFINITIONS AND ABBREVIATIONS**

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IBMS Institute of Biomedical Science

NKPS North Kent Pathology Service

ICS’sIntegrated Care Systems

**RESPONSIBILITIES**

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The responsibility for requesting a laboratory service or test lies with an authorised, trained and competent practitioner. It is the responsibility of the individual taking the sample to ensure that samples are correctly labelled and request forms (paper or electronic) are completed to agreed standards and that the sample type taken for the request is compliant with that listed in the Departments User Handbook. Where there is any doubt about what sample type is required it is the duty of the practitioner to contact the Laboratory for advice.

The responsibility for receipting the sample lies with suitably trained staff employed by NKPS. Before accepting a clinical specimen, laboratory staff shall ensure that certain minimum criteria for sample identifications are met. Criteria for sample identification are given in this document. Departmental Standard Operating Procedures (SOPs) concerning identification shall not conflict with this procedure.



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**PROCEDURE**

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When requesting a Pathology test, please ensure consideration of the following has occurred:

The need for the test request has been established and is in the patient’s best interest and that the patient has given consent in line with Trust policy for this to occur.

Please ensure that the Pathology service is able to undertake the test.

* + If in doubt please refer to discipline specific departmental handbooks located on: Dartford and Gravesham NHS Trust: [https://www.dgt.nhs.uk/services/a-z-services/pathology/pathology-users-handbooks](https://www.dgt.nhs.uk/services/a-z-%20services/pathology/pathology-users-handbooks)

Medway NHS foundation Trust: [Pathology (medway.nhs.uk)](https://www.medway.nhs.uk/services/pathology.htm)

Ensure that the patient is aware of any specific requirements that they may need to take for the test e.g. fasting (if in doubt please refer to \*).

Order the test and if sample collection is not occurring immediately ensure that method of collections is organised and the patient is aware of any actions they may need to take e.g. booking a phlebotomy appointment.

When collecting a specimen, please ensure that the following steps are adhered to:

Ensure that the patient’s identity is confirmed and matches the request form (electronic or paper).

Confirm with the patient that they meet any applicable specific requirements for the test e.g. fasting (if in doubt please refer to \*).

Ensure only trained staff or those under appropriate supervision collect the specimen from the patient.

Ensure appropriate quantity of specimen is obtained and placed in the appropriate container (if in doubt please refer to \*).

Ensure all consumables used are within expiry date.

Ensure where OrderComm labels are being used , they are printed just prior to the sample being taken

Ensure containers are labelled in line with Pathology specimen acceptance criteria immediately following the collection in the presence of the patient.

Ensure that all sharps are disposed of in line with Health and Safety processes.

Ensure the specimen is placed in the agreed method for transportation to Pathology; whilst these are awaiting transport, these shall not be placed where patient confidentiality may be compromised, in direct sunlight or near heaters to ensure specimen integrity.

Please note: Certain tests have specific transport requirements e.g. on ice/ within 10 minutes of collection to remain suitable for analysis by the laboratory and this shall be considered before taking specimen so that this criteria can be met (if in doubt please refer to Pathology test catalogues in\*). For further information on the requirements needed to meet ISO 15189:2022 please refer to SOP.PAT.6 Primary sample collection and handling

Clinical Governance demands that a sample shall be uniquely labelled and uniquely associated with a test request. The information which appears on the specimen and on the



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accompanying request form SHALL match.

It is the responsibility of the individual collecting the samples from the patient to ensure that the sample container is correctly labelled.

Pre-labelling of sample containers SHALL NOT be performed prior to phlebotomy as this is a common source of error.

Printing of OrderComm labels shall occur just before the sample is taken. Failure to comply with this may result in rejection of the sample due to the date and time stamp on the label, being taken as the true date and time of sample collection.

In cases where an OrderComm label has been printed, but there has been a significant delay in sample collection, the label MUST be clearly updated with the actual time and date of collection.

Samples shall not be collected if the request form is not fully completed. Samples shall not be collected if the patient cannot be uniquely identified. If a patient’s surname is double barrelled, both names shall be used.

If a patient’s first name is hyphenated, both names shall be used.

For locations where OrderComm is available the system shall be used to request a laboratory test. This provides auditable proof of the location and the phlebotomist who collected the samples. The individual printing the labels shall be the same person who collected the samples.

For locations where Blood track is available, its use is auditable proof of the time, date and phlebotomist who collected the samples. The individual ordering the blood track labels shall be the same person who collected the samples.

All handwritten samples shall have the initials of the staff member collecting the sample and the location, written on the sample container.

Failure to meet the requirements set out in this policy may result in the rejection of the request or significant delay.



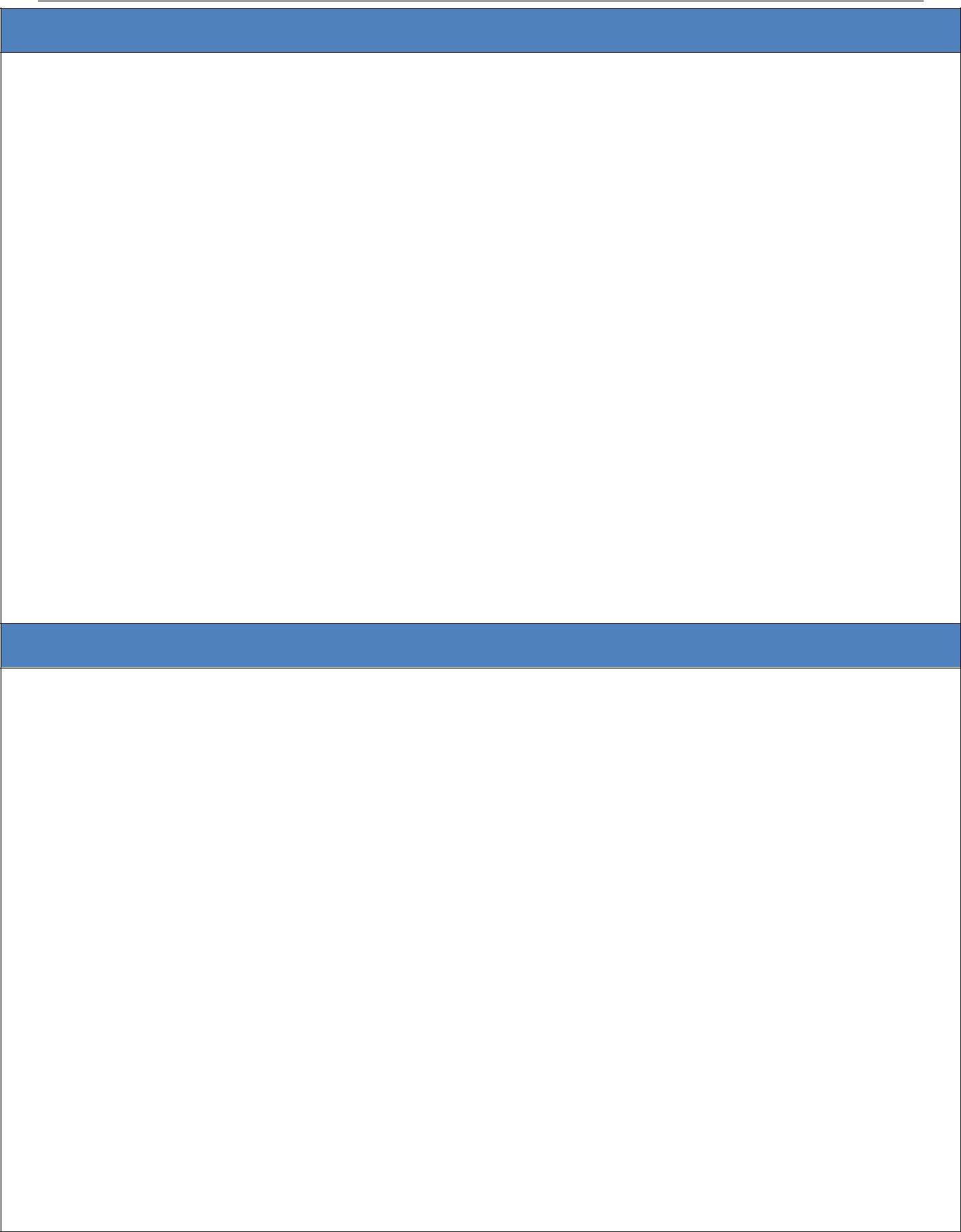
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**Request form information**

**Request forms shall include:**

\*NHS number and/or hospital number

\*Full Surname – *if hyphenated should include both names*

\*Full First name(s) – *if hyphenated should include both names*

\*Date of Birth (dd/mm/yyyy)

Gender (Gender is mandatory for blood transfusion) 1st line of patient address

Full post code of patient address

Patient Contact Telephone number (mobile or landline - required by GP On Call Care service) Surgery Location (Mnemonic or National Practice Code)

GP Code (prescribing number)/Cytology Sample Taker Code (ST number) & legible name of requestor (if not GP)

Relevant clinical details including drug therapy, recent travel abroad Date & Time of sample collection

Sample Type (where not blood) Sample Site (if applicable)

Test(s) required and for antenatal requests- Estimated Date of Delivery (EDD) and completion of the consent for testing section.

(If the test is not available to be selected electronically, add this to the request form manually) Patient category – NHS or Private shall be indicated clearly

The four key identifiers\* shall be present on both sample and form and match, otherwise the sample will be rejected.

Note: Where OrderComms are available it is imperative that this system is used. Noncompliance in the use of this system may result in delay to patient results.

**Sample requirements**

Do not generate specimen labels for more than one patient in advance, or pre-label the container before obtaining the sample.

Label sample in patient’s presence after positive identification has occurred (when can; use OrderComm generated label).

Do not relabel container if an error is made: discard specimen and begin again, unless sample is unrepeatable e.g. histology samples - Specimen should be transferred to another container.

Sign the label

**Handwritten labels shall be legible and include:**

\*NHS or hospital number

\*Full Surname - *if hyphenated should include both names*

\*Full First name(s) – *if hyphenated should include both names*

\*Date of Birth (dd/mm/yyyy)

Location Code i.e. Ward or GP code (Mnemonic or National Practice) Date & Time of collection

Initials of person labelling sample Sample type (where not blood)

**NB**: In circumstances where the patient’s name/details are not known or should remain anonymous, specimens **shall** be labelled with a patient identification number (e.g. GUM clinic number, Family Planning clinic number ,A/E number) **and** the gender of the patient (i.e. Unknown Male)

Samples sent with a request form should be bagged. The bag shall only contain the sample(s) and request form(s) from one patient.

**Transfusion specimens:**

**These shall all be hand written labels unless using a full vein to vein traceability system and use the Hospital number e.g BloodTrack**

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**Consequences of the labelling criteria not being met for repeatable samples**

Unlabelled samples with no request form

Unlabelled samples submitted without an accompanying laboratory request form will be rejected. No testing will be performed, no report generated and the sample will be discarded.

Unlabelled samples with an accompanying request form

Unlabelled samples received with a laboratory request form will be rejected. No testing will be performed, a report will be generated and the sample will be discarded. The requestor shall take a fresh sample, label it correctly and send it to the laboratory together with a new request form.

Labelled samples with no request form

The laboratory will contact the requestor, if the requestor can be identified, to inform them that the labelled sample has been received without an accompanying request form. The requestor shall send a request form before the laboratory proceeds with any testing. A report will be generated. If the requestor cannot be identified, the sample will be rejected and discarded.

Samples with a clearly different name from that on the request form

Samples with labelling discrepancies received with a laboratory request form will be rejected. No testing will be performed, a report will be generated and the sample will be discarded. The requestor shall take a fresh sample, label it correctly and send it to the laboratory together with a new request form.

Mixed Samples received in one sample bag (more than one patient)

Where there is any doubt regarding the identity of the samples, the laboratory will reject the samples and the patients will need to be re-bled.

Bagged unlabelled samples with specimen request labels

Request stickers dropped into specimen bags with unlabelled samples will be rejected as specimen unlabelled and the patient will need to be re-bled.

Laboratory staff will reject these samples because the integrity of the samples cannot be established due to non-conformance to this procedure.

If the sample or request is received without a collection date (or collection time for some tests) then the sample may be rejected. If it cannot be established that the sample has been collected within the stated acceptable time limits for the particular tests requested, then it will be rejected.



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In rare circumstances, minor discrepancies may be allowed. This is always at the discretion of senior laboratory staff and their decision is final. Individual circumstances will be taken into account, for example, samples that were difficult to collect or taken in emergency situations.

In exceptional circumstances, the individual who collected the sample (and only that individual) will be given the option to come to the laboratory to correct the labelling rather than take a fresh sample.

Any deviation from the established collection procedures will be clearly recorded in the Laboratory Information System (LIMS) and will appear as a comment on the patients report. The potential risk and impact on the patient outcome of acceptance or rejection of the sample shall be assessed, recorded and communicated to the appropriate personnel.

Blood Transfusion

If a sample is received for blood transfusion without a request form the sample will be rejected. The requestor will be contacted where possible and a fresh sample requested. No testing will be performed, a report will be generated and the sample will be discarded.

If the sample or form are not labelled fully and correctly in line with this labelling procedure, then the sample will always be rejected. The reason for the rejection will be documented in the report shown on iLab-web.

**Blood Transfusion has a Zero tolerance policy with regards to sample acceptance and rejection**.

Gynae Cytology and Urine for Cytology

Full patient demographics are required for acceptance of these samples. This includes full name, DOB, Hospital number and most importantly NHS number.

Exceptions

Where samples are unable to be repeated and are considered precious: all cellular pathology samples (excluding Gynae-Cytology and Urine samples), CSF (Cerebro Spinal Fluid), Bone Marrow samples, pre antibiotic blood cultures (requested from ward patients) and any samples that have been signed for and are not correctly labelled.

Every effort will be made to identify the requestor and where possible ask a member of staff from that ward to come to pathology, with the patient’s notes and complete the missing patient details on the sample. In cases where this is not possible the samples may be returned to the requestor for correct labelling. If it is not possible to identify the requestor it will only be processed if authorised by the Head of Department. Under these circumstances, an identify disclaimer will be added to the iLab-web report.



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Monitoring

Sample rejection is monitored within each department within pathology by:

Data Quality Audits

Non-conformance Monitoring

**REFERENCES**

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IBMS (Institute of Biomedical Science) – Guidance on Patient sample and request Form Identification Criteria (wwww.ibms.org/publications)

Use of the NHS, CHI or Health and Care Number on paper and electronic patient records is a mandatory requirement included within the NHS Operating Framework 2008/9

ISO 15189:2022 Medical laboratories – requirements for quality and competence SOP.PAT.6 Primary sample collection and handling

**APPENDICES**

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None



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