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**Standard Operating Procedure (Non-Examination) QMS**

**Primary Sample Collection and Handling**

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| **Applicable to:** | Phlebotomists, nurses, general practitioners and other clinical staff |
| **This document is only valid for use on: (delete as appropriate)** | Darent Valley Site / Medway Site |
| **Related Documents:** | POL.PAT.27 Sample acceptance and rejection |



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**INTRODUCTION**

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**Purpose of the procedure**

The purpose of this procedure is to inform those responsible for the primary collection of samples (e.g. phlebotomists, nurses, general practitioners and other clinical staff) of the correct methods to be used for the proper collection and handling of patient samples.

**Principle of the procedure**

The principle of this procedure is to ensure adherence to the ISO 15189:2022 standards 6.3.5: Sample collection facilities and 7.2.4: Primary sample collection and handling which when used aides in ensuring that the pre-examination process of sample collection is of optimum quality.

**PROCEDURE**

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**Type of sample**

This procedure is relevant to all types of sample collection including the following as examples:

Blood

Cerebral Spinal Fluid Bone Marrow

Urine Faeces

Human tissue for histology Swabs

**Sample collection facilities (ISO standard 6.3.5)**

When collecting samples from a patient the collection facilities shall enable collection to be undertaken in a manner that does not invalidate results or adversely affect the quality of the tests requested.

Consideration should be given to privacy, comfort and needs (e.g. disabled access, toilet facilities) of patients, and accommodation of any accompanying person (guardian or interpreter) that may need to be present at the time of sample collection.

The reception area should be separate from the collection area.

First aid materials should be available for both patients and personnel.

**Primary sample collection and handling (ISO standard 7.2.4)**

There are two key areas for patient preparation that must occur before the collection and handling of primary samples can occur:

Consent (ISO standard 7.2.4.3)

All procedures carried out on a patient need the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents themselves



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at a laboratory/ phlebotomy service with a request form and willingly submits to the usual collecting procedure, for example, venepuncture.

Special procedures, including more invasive procedures (collection of bone marrow biopsies) or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent.

In emergency situations, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided that they are in the patient’s best interest.

Consent is also essential for certain genetic tests such as Haemoglobinopathy screening where additional forms to the request must be completed. Antenatal screening requires the consent box on the request form to be ticked in order for the analysis to be performed. The requirement for completion of this extra documentation is stated in the departmental handbooks and further information can be found by referring to Trust policies on an individual basis for these. For example Antenatal sickle cell and Thalassaemia screening guidelines: <https://www.dgt.nhs.uk/download_file/3106/506>

Preparation of the patient (ISO standard 7.2.4.2)

All patients must be adequately prepared for the collection of the sample which can include discussion of what will occur (e.g. for biopsies - a potential anaesthetic) and whether or not the patient must fast before having the sample collected (e.g. fasting glucose). For specific patient pre collection activities which include:

The type and amount of primary sample to be collected with descriptions of the containers and any necessary additives, and when relevant the order of collection of the samples

Special timing of collection where relevant

Provision of clinical information relevant to, or affecting sample collection, examination performance or result interpretation ( e.g. history of administration of drugs)

Please refer to the relevant departmental user handbooks listed below

Via Adagio on the Dartford and Gravesham NHS Trust (DGT) website:

DGT Blood Transfusion User Handbook: <https://www.dgt.nhs.uk/download_file/view/6485/1576> Haematology User Handbook: <https://www.dgt.nhs.uk/download_file/view/394/1576> Chemical Pathology Users Handbook: <https://www.dgt.nhs.uk/download_file/view/6484/1576> Microbiology Users Handbook: <https://www.dgt.nhs.uk/download_file/view/396/1576>

Via the Clock tower on the Medway Foundation Trust (MFT) website:



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

MFT Blood transfusion User Handbook:

Haematology User Handbook:

Chemical Pathology Users Handbook:

Microbiology Users Handbook:

For more involved investigations please refer to the Trust policies/procedures/guidelines for example there is a specific document for the performing a Glucagon stimulation test: <https://www.dgt.nhs.uk/download_file/4065/1915>

**Environmental and safety controls**

Ensure compliance to the Trust health and safety policies including disposal of sharps and handling of clinical material.

Dependent on the type of sample being taken and for pathology examination; varying degrees of personal protective equipment must be worn. Follow trust protocols or seek advice from Infection Control or Health and Wellness/Occupational Health.

A new pair of gloves must be worn for each patient that is bled and hands must be washed at the start of each sample collection session.

**Procedural steps**

Before commencing collection of a primary sample, ensure that adequate privacy (when possible) during reception and sampling is available and appropriate to the type of information being requested and primary sample being collected.

Instructions for pre-collection activities (ISO standard 7.2.4.2)

All procedures carried out on a patient must involve the completion of the relevant request form or OrderComm and the correct completion of the sample bottle label. Instructions on how to complete these are within the relevant departmental user handbooks and POL.PAT.27 Sample acceptance and rejection criteria available on Adagio (DGT) and the Clock Tower (MFT), websites.

Instructions for collection activities (ISO standard 7.2.4.4)

1. Confirm identification of the patient

The patient’s identity must be checked before attempting venepuncture, this is accomplished by asking the patient their full name and date of birth or checking the patient’s wristband if they are not able to respond. Check that this information corresponds with that on the request form/ order comm.



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2. Verify that the patient meets the pre-examination requirements for the requested assay

This includes ensuring the request form/ OrderComm is completed in full and that for the assay requested the patient has consented and meets requirements (if any e.g. fasting/ drug dosage explained below) set out in the relevant user handbook (check the departmental handbook to confirm).

Fasting patients

These are for patients requiring fasting profiles e.g. lipid profiles or fasting Glucose and is indicated on the request form.

Check with the patient that they have fasted for 12 hours.

If they confirm that they have fasted, mark the request form with a letter ‘F’

Where patients have not fasted they will be advised that they need to fast for 12 hours before returning for the tests to be performed.

If a patient has fasted except for a cup of tea as an example. this must be written on the request form

Recording Drug Dosage times

If drug levels are being monitored, it may be important to know the time of the last dose.

The time of last dose must be written on the request form.

There are instances where blood needs to be taken at a particular time after the last dose to obtain a meaningful test result. Where these specific times have lapsed between drug dose and a blood sample being taken the patient must be advised accordingly i.e. to wait until the time is appropriate for the blood sample to be taken or return on another occasion.

In situations which are unclear relating to drug dosage / timing of blood samples, please speak to a qualified Biomedical Scientist in the appropriate pathology discipline via the Trust switchboard.

3. Take the sample

Collect the sample as directed using applicable protocols.

Note that blood samples must be gently mixed at the earliest opportunity to ensure anti-coagulation effectiveness and the order of drawer for blood collection must be followed to ensure accurate results which are described here:

Blood Culture – **Light Blue** (Sodium Citrate) – **Red** (clotting accelerator no gel)

– **Gold** (clotting accelerator with gel) – **Green** (Lithium Heparin) – **Navy blue** (sodium

heparin) **Lavender** (EDTA) – **Pink** (EDTA) – **Grey** (Fluoride Oxalate)

Ensure that the sample lids are correctly tightened; leaking samples may be rejected by the laboratory.



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Note that some primary samples (e.g. CSF, pleural fluid) need to be split into separate sample containers for biochemistry and microbiology.

1. Labelling of the sample
	1. Manual labelling (for non-OrderComm requests and transfusion samples)

Label all samples with the patient’s surname, forename, date of birth, hospital /NHS number in the presence of the patient at the time of collecting the sample.

* 1. Labelling using OrderComm process

Label the sample with the printed sticker (details patient’s surname, forename, date of birth, hospital /NHS number) number in the presence of the patient at the time of collecting the sample.

1. Recording the details of the sample collection
	1. Manual recording (for non-OrderComm requests and transfusion samples)

Label all samples and request form with the date and time of sample collection and the member of staff must also sign the request form.

* 1. Recording using OrderComm process

The OrderComm process will ensure that the member of staff who has completed the order will be auditable using the system which also includes a barcode on the printed sticker stating date and time sample taken.

1. Storing the sample prior to transportation to the laboratory

Place the samples into the sealable portion of the designated sample bag (Blood Science/ Cellular Pathology or Microbiology) and the corresponding pathology request form placed in the dedicated pocket of the same bag.

Samples that are not able to be transported using the pneumatic tube system or from areas without access to the tube, should be placed in the designated collection point (which is not in direct sunlight or temperature extremes and not accessible to the general public) to await collection by driver or porter.

Note: some specimen types require refrigeration whilst awaiting collection by driver or porter (refer to user handbooks for details).

If the sample collection is from an external source to Darent Valley Hospital, ensure that the relevant transport materials are utilised that are provided by the laboratory.

7. Disposal of materials used in the collection of the sample

Adhere to Trust protocol of the disposal of clinical and confidential waste and the sharps policy.



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Potential Difficulties

The patient may not have an acceptable request form; this must be rejected and a request made for the patient to return once they have a revised/ correct request form.

Amending request form information:

Because of the Medico-legal implications of request forms they must not be amended in any significant way by phlebotomy/reception staff. The exceptions are: -

Where there are errors with patient details e.g. if patient says that their name has been misspelt or that their date of birth on the request form is inaccurate.

o Write the amended detail next to the incorrect detail on the form e.g. patient says that DOB is \*\*/\*\*/\*\*

o Do not obliterate the original details, it must be obvious what amendments have been made and why.

o The revised details may then be written on patient samples. Where there has been an obvious omission of the requesting location

e.g. clinician’s handwriting/signature is recognised by staff, but no requesting location has been recorded on the request form.

o Append the requesting location.

If there is a doubt about which tests are required for a patient, such as when no test request has been written on a request form, or the patient claims that additional tests are required by their doctor refer the patient back to the referring clinician to establish what tests are required. If possible, directly contact the clinical requestor by the telephone to establish the examination assays required.

Patients may/do not speak English; arrangements must be made for a translator to ensure that informed consent is given

Occasionally, patients suffer from collapsed veins affecting the ability to draw blood. On occasion the sample tube may not have a vacuum and not draw blood from the

patient, in which case a new sample tube should be used and the defective tube discarded into the clinical waste bin.

Problems with the procedure, e.g. missing of a vein, puncturing an artery, should be explained to the patient and the appropriate action taken.

Special considerations/general comments

Do not be over familiar with the patient by using their first name.

Never bleed a patient with a baby on their lap as any sudden movement may cause injury to the patient / baby / phlebotomist.

A patient may have a disability such as deafness or may be in a wheel chair. Allowances must be made for these patients.

Certain religions forbid the removal of clothing in the presence of others, please make reasonable accommodation for this.



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If a patient needs to undress to expose a vein, then ensure that they cannot be seen by other patients by drawing a curtain or arranging the phlebotomy to be performed elsewhere.

If patients request information regarding on how to make a complaint; refer to the complaints procedure.

If OrderComm labels are printed in advance; the date and time of sample collection will be the time this occurred and can give rise to samples rejected as they appear to be too old to be processed or a report issued based on the sample date which can cause confusion for clinical teams. This is poor practice.

If the sample is not labelled at point of venepuncture; there is an element of risk and potential incorrect patient identified which can give rise to incorrect results issued on a patient history and therefore action taken on the incorrect patient.

If the patient is not identified correctly and assumptions are made on identity without confirmation using wrist band/ asking patient their details; there is an element of risk and potential incorrect patient identified which can give rise to incorrect results issued on a patient history and therefore action taken on the incorrect patient.

Occasionally a patient may feel unwell during some stage of the phlebotomy process particularly if the patient has been fasting for their blood test. It is important to give assistance to these patients appropriately i.e. initially ask the patient to lie down where possible (e.g. on a bed or couch in outpatients) or if the patient is unable to walk to an area to lie down or one is not available; chairs can be used and where possible adjusted to a reclining position. Ensure that the patient is comfortable and that they have a disposable bowl available in the event of vomiting.

If the patient is having a Glucose Tolerance Test:

If vomiting occurs more than 30 minutes after drinking the Polycal the test must be completed if possible.

If vomiting occurs less than 30 minutes after drinking the Polycal then the Glucose

Tolerance Test must be cancelled and re-booked.

If the patient shows no sign of feeling better or becomes acutely unwell or unconscious urgent medical attention must be obtained either:

1. A nurse/doctor must be asked to attend the patient. o Bleep the On Call Medical Doctor.

o A porter can be called via 8888 to attend with a wheel chair to escort the patient to the AE Department.

**IN THE EVENT OF A CARDIAC ARREST CALL FOLLOW YOUR TRUST PROTOCOL**

Please note: if users deviate from the procedures defined in this document or in the user handbooks, please record what occurred on a form/ piece of paper and send this with the sample to the laboratory.



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Once received in the laboratory the sample will be evaluated by the specimen reception teams to ensure compliance with the acceptability criteria relevant to the requested examinations and the requirements stated in POL.PAT.27 Sample acceptance and rejection policy

**REFERENCES**

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ISO 15189:2022 Standards

**APPENDICES**

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None



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