

Clinical Sample Acceptance Procedure

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1 Laboratory Handbooks

Information regarding each laboratory and the tests offered can be found on the Laboratory Medicine webpage <http://www.barnsleyhospital.nhs.uk/pathology/>
 Information regarding referral sites used for tests is available upon request.

2 Principle

Correct sample identification and handling is a mark of good medical practice and samples that cannot be properly identified are a risk to the patient and will **NOT** be analysed.
 The responsibility for requesting laboratory investigations lies with the patient's clinician. The person responsible for taking the specimen (whether medical, nursing or phlebotomy staff) **MUST** ensure that the information on both the request and sample is legible, adequate and includes necessary labelling for biological hazard.

3 Responsibilities of Staff

The responsibility for requesting a laboratory service or test lies with an authorised and trained healthcare practitioner. It is the responsibility of the requester to ensure that the identity of the patient is confirmed at sample collection and that all samples are correctly labelled and request

forms are completed to agreed standards in accordance with the Laboratory Medicine Clinical Sample Acceptance Procedure, failure to do so may result in the sample being rejected.

Medical, nursing and other healthcare professionals must be familiar with and understand the rationale of laboratory procedures and standards. There should be clear written guidelines for those who obtain blood samples from a patient on behalf of the requesting practitioner.

Before accepting a clinical specimen laboratory staff must ensure that certain minimum criteria for sample identification are met.

4 Risk assessment/Safety controls

4.1 Correct sample identification

Correct sample identification and handling is a mark of good medical practice and samples that cannot be properly identified are a risk to the patient and will NOT be analysed, with the exception of “precious” samples (refer to section 10.4). The responsibility for requesting laboratory investigations lies with the patient’s clinician. The person responsible for taking the specimen (whether medical, nursing or phlebotomy staff) MUST ensure that the specimen is taken from the correct patient and that the information on both the request and sample is legible, adequate and includes necessary labelling for biological hazard.

4.2 Danger of Infection

Samples from patients with blood borne virus diseases constitute a particular hazard to laboratory staff. All infectious or potentially infectious specimens and their accompanying request forms should be clearly marked with “Danger of Infection” stickers are available from Specimen Reception. The range of investigations available on such specimens may be limited. Please contact the laboratory for further information.



Provision of clear Clinical Details with sufficient detail to inform laboratory staff of the safety precautions they need to take in order to process the specimen without risk of infection e.g. recent history of relevant foreign travel that may increase the likelihood of exotic agents being present.

4.3 Correct Sample Handling

Any person requesting examination of material sent to the laboratories will, for the purposes of Section 7 of Health and Safety at Work Act, 1974, be assumed to be familiar with the instructions relating to danger of infection.

All samples must be sent in sealed plastic bags and the request form attached to the outside, to prevent damage in case of sample leakage.

The procedure complies with the Carriage of Dangerous Goods Regulations (2009)

Samples transported to the laboratory must comply with UN3373. Further Information on the packaging of specimens and the transportation to the laboratory can be found on the Laboratory Medicine webpage <http://www.barnsleyhospital.nhs.uk/pathology/pathology-general/>

5 Urgent Samples

Sample requiring urgent processing must be identified as such. Procedures for requesting urgent tests are located within departmental handbooks located on the laboratory Medicine website.

6 Patient preparation

Any special considerations for the preparation of a patient, e.g. fasting, or requirements for the sample e.g. sample timing or site are provided in the test repertoire within the departmental handbooks.

Certain tests require patient consent to be given due to the nature of the testing and the consequences of the results. Any genetics testing requested must have the patient's informed consent prior to taking the sample. When electronic requests are generated, it is assumed that the requesting Clinician named on the form has discussed the consequences of the results with the patient and obtained consent. Any manual forms must be signed by the requesting Clinician to indicate that consent has been obtained.

7 Type of container and additives

Before collecting Patient samples please refer to the department user handbook for information on the type and amount of the sample required and the type of the collection container including any additives if required. The handbook will also outline any special timing for the sample and instructions for the inclusion of clinical information relevant to or affecting sample collection, test performance or result interpretation (e.g. History of administration of drugs, fasting sample).

8 Multiple forms with only one lot of samples

When a patient attends with multiple request forms for bleeding, staff are instructed to treat each request separately and take all of the samples requested. Failure to provide all of the samples will result in one of the requests being rejected as we cannot ensure that we are able to get clinically critical results to the appropriate requesting clinician for action.

9 Patients attending Hospital Phlebotomy departments

If you are sending a patient to the Hospital Phlebotomy department you must send them with either a postponed ICE request on the ICE system (and ideally a printed copy of the request form), or a handwritten request. Patients attending without a valid request form or postponed request on the system will be unable to be bled. It is the requestor's responsibility to ensure they select the correct patient details on ICE when making a postponed request, any patients attending with another patient's information are unable to be bled and a Datix will be raised due to the breach in IG.

10 Minimum standards for acceptance of clinical samples and requests

10.1 Information required on Request Form

All request forms must be completed with the information highlighted in **bold** as a **minimum**.

NB. Please see section 11 of this document for Blood Transfusion specific requirements.

- 1. Patient Surname**
- 2. Patient Forename**
- 3. Date of birth**
- 4. One of the following Unique Numerical Identifiers**
 - **Hospital Number**
 - **NHS number**
 - **GUM number**
 - **A/E number**
 - **Full address and postcode if unique numerical identifier cannot be provided**
- 5. Ward / Location**
- 6. Clinician / GP Details**
7. Sex (failure to provide will prevent the reporting of appropriate reference ranges)
8. Investigation required
9. Clinical Details with sufficient detail if additional safety precautions are required by laboratory staff to process the sample.
10. Sample type / site and times where applicable (essential for Histology and Microbiology requests)
11. Signature of requester and phlebotomist
12. Bleep number of requesting doctor is applicable or an appropriate contact phone number

Note: Orders via ordercomms are accepted as the information requested above is all accessible via the barcode printed on the request label.

Ideally, it is preferable to send requests via the electronic ordercomms system. This is beneficial for a number of reasons; it prompts for mandatory information required by the laboratory to carry out testing and it speeds up the sample receipt process, advises staff of the correct sample requirements and reduces clinical risk associated with transcription errors. When handwritten forms must be used it is vital that the request form is completed accurately in accordance with the clinical acceptance policy and the requesting clinician's name and location or address fully written.

Please note that abbreviations may result in the incorrect clinician or location being selected and as a consequence, the results for the patient may be sent back to another clinician. Whilst the laboratory staff make every effort to minimise errors, staff can only book samples into the system with the information they are provided with.

10.2 Information required on specimen

All specimens must be labelled using the **four identifiers** (1-4) highlighted in **bold** as a **minimum**.

NB. Please see section 11 of this document for Blood Transfusion specific requirements.

- 1. Patient Surname**
- 2. Patient Forename**
- 3. One of the following Unique Numerical Identifiers**
 - **Hospital Number**
 - **NHS number**
 - **A/E number**
 - **GUM number**
 - **Laboratory accession number for electronic requests**
- 4. Date of birth**
5. Date and time
6. Ward/location
7. Signature of person taking the sample

Note: Orders via ordercomms are accepted as the information requested above is all accessible via the barcode printed on the sample label.

Specimen labels electronically generated by the ordercomms system meet the requirements and are acceptable in Blood Sciences and Microbiology.

Blood Transfusion specimens must be hand labelled.

Where multiple samples are collected as part of an investigation (e.g. glucose tolerance test -GTT) **ALL** samples must be labelled in accordance with the minimum data stated above, **Note:** for some ICE orders this may require handwriting the remaining bottles if insufficient labels are printed.

10.3 GUM Patients

Due to the sensitive nature of GUM requests Patient information is anonymised. This means that patient demographics such as NHS number and address are not available.

GUM request forms and samples must have the GUM number, Date of birth and patient gender.

10.4 Insufficient Information provided

Forms and specimens failing to meet these minimum criteria for identification will not be processed. If no tests are requested then the sample will be rejected.

It is recognised that some samples cannot be easily re-collected and are classed as "precious". Processing of incorrectly or unlabelled samples may only take place after discussion with the requesting clinician who must attend the laboratory and complete a "Precious Specimen Declaration

Form". Where specimens failing to meet these minimum criteria are processed the responsibility for these results will rest with the requesting clinician and reports will contain the following comment:

"Due to inadequate labelling of the sample/request form the responsibility for these results lies solely with the requesting physician".

When a completed "Precious Specimen Declaration Form" is received, the sample will be processed and a Datix raised by laboratory staff to enable investigation into the inadequate labelling by the clinical area. All precious specimen declaration forms will be collated for analysis

11 Specific requirements for Blood Transfusion

Suitably trained and competency assessed Phlebotomists, Healthcare Assistants, Nursing and Medical Staff may collect samples for pre-transfusion testing. Positive patient identification and attention to detail is vital when labelling sample tubes, in order to ensure safe transfusion practice. Inadequate patient identification and/or sample labelling may lead to fatal ABO incompatible transfusions. **The department operates a zero tolerance policy to comply with UK guidelines and best practice. As a result of this, samples not meeting the sample labelling criteria will not be accepted. Addressograph labels must not be used to label the sample.**

11.1 Sample Requirements

The sample required is 4.9mls of blood in a blue EDTA Sarstedt Blood Transfusion bottle (NHS supply number KCM 131). Minimum blood required for processing is 2ml. Paediatric samples must also be collected in the same tube, a minimum of 0.5 ml is required. The sample bottle **MUST** be within expiry date.

Inadequate, clotted and haemolysed samples will not be tested as they prevent accurate interpretation of results. Also, blood specimens must **NOT** be obtained from the tubing of an IV set or from a vein in which an IV solution is flowing.

11.2 Information required on Specimen

Immediately the sample has been taken, it must be hand-written, legibly and accurately, in ball point pen to avoid smudging by the person taking the blood at the site of collection. The sample tubes should never be pre-labelled.

All samples **MUST** be labelled with the following information:

- Surname and Forename
- Hospital Number
- Date of Birth
- Ward/Location.
- Gender.
- Date and time of sample collection
- Signature of person taking the specimen.
- Please use a "High Risk" sticker if appropriate.

11.3 Check Group or Two Sample Rule

From **Monday 5th February 2018**, Bloodbank introduced the two-sample rule for requests for blood and blood components (red blood cells (RBC), fresh frozen plasma (FFP), cryoprecipitate, platelets & granulocytes).

What is the two-sample rule?

Bloodbank must ensure that there are **TWO** distinct samples from a patient that have generated the same blood group from both samples. If Bloodbank have seen the patient before and already have a historic blood group, then you only need to make a request for group and save and/or X-match as you normally do. If the patient has no previous records in Bloodbank then you **MUST** repeat the

group and save or X-match with a *second sample (using a specific request form & sample bottle that will be provided by Bloodbank – if within 8 hours of original bleed)*. This national recommendation is based on the evidence from –

- The BEST studies as referenced in BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories.
- National data from the IBCT and the Near Miss chapters in recent SHOT reports (SHOT, 1996 to 2010) – 386 cases of “wrong blood in tube” (WBIT) were reported as near misses in 2010.
- Local data confirms an unacceptable number of WBIT cases among patients where it can be detected due to having a historical group on record.

Why is this rule being introduced?

Wrong blood in tube (WBIT) is a 'never event', it should not happen, however on occasions it does. The consequences of transfusing somebody with blood of the incorrect blood group is very serious and can lead to death. In the 6 months prior to its introduction, there had been 4 WBIT incidents within the Trust, 2 of which would have resulted in a major ABO incompatible transfusion if blood products had been requested. WBIT is a SHOT (Serious Hazards of Transfusion) reportable incident.

The two-sample rule is a national guideline to improve patient safety when receiving transfusions and has been routinely adopted by the majority of NHS Trusts across the UK.

How does the two-sample rule work?

If the patient is not known to Bloodbank then the two-sample rule is invoked. The two samples must come from separate venepuncture events and ideally should be carried out by two different people. A specific request form & sample will be issued by the laboratory and should be collected from Bloodbank upon delivery of the 1st G&S sample in urgent situations or as required for routine requests. If >8 hours has passed since the first G&S sample was taken then it is acceptable to send a second routine request (in this instance a specific bottle is not required). It is **NOT** acceptable to take two samples at one venepuncture event and send them to Bloodbank on separate request forms. This will not negate the possibility of WBIT.

How will I know if a second sample is required?

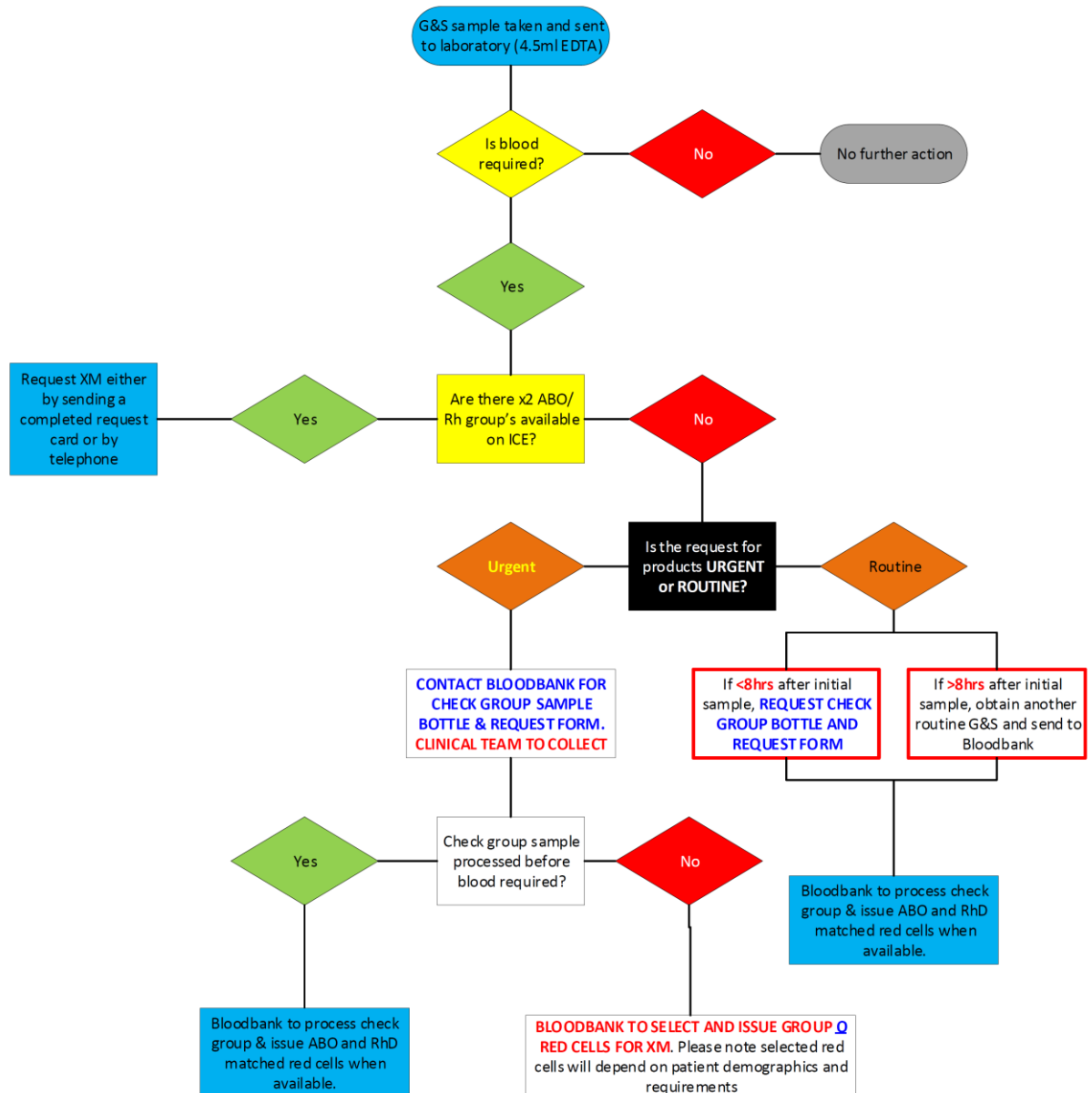
If you are unsure if Bloodbank already have a historic blood group, you can check ICE for previous requests or contact the laboratory to confirm.

What happens in an emergency situation?

If blood is required in an emergency e.g. Major Haemorrhage procedure activated, the two-sample rule will not apply however a second sample should be sent as soon as possible. Blood will be issued as per the MH protocol and will not be delayed. The Bloodbank will only be able to issue Group O red cell products in the absence of a check group sample (and Group AB Plasma and/or Group A platelets)

If Clinical teams identify an urgent patient who requires blood products, ensure a Group & Save sample is sent to the laboratory ASAP, the laboratory staff will then identify if a **CHECK GROUP SAMPLE** is also required. Ideally for patients with no history, the first G&S sample should be hand-delivered to the bloodbank where it will be exchanged for a **CHECK GROUP SAMPLE**. It is essential for cases where there is clinical urgency for blood and blood product provision that clear communication is maintained between the clinical and laboratory teams to ensure efficient working.

Flowchart for 2 sample rule



11.4 Completing the Blood Transfusion Request Form

Request forms and blood specimens once received by the laboratory cannot be amended. The request form must be fully completed by a registered medical practitioner or designated practitioner. It is the clinician’s responsibility to ensure that any special requirements, e.g. CMV negative, irradiated products, bone marrow transplant or solid organ transplant are communicated to the Blood Transfusion Department. The clinical indication for transfusion should be written in the patient’s case notes and on the request form – please NBTC indication for transfusion codes.

The details on the request form are important and could have medico-legal implications. The request form should be clearly handwritten. (An addressograph label may be used on the request form for the patient identifiers but all other details/information must be handwritten). The correct request form must be used, there are three request forms as follows, Antenatal Serology, Neonatal Request form and Blood Transfusion Request Form.

Specimens and Request forms for Blood Transfusion / Antenatal Serology / Kleihauer requests **MUST** meet minimum labelling requirements that are:

Essential Information

The request form **must** contain the following information:-

- Patient details e.g. Surname, Forename, gender, DOB and patient identification number.
- Ward/Location and Consultant.
- Diagnosis/operation and reason for transfusion
- “High Risk” sticker if appropriate.
- Previous pregnancies (if relevant)
- Number and type of blood components required or batch products, including any special requirements.
- Date and time products are required
- Signature of person authorising the request (Medical staff or authorised practitioner ONLY)
- The person collecting and labelling the blood sample **MUST** also sign the request form.

The request form **MUST** be signed by a medical officer responsible for the patient and ALL details must be completed.

12 Specific requirements for labelling post vasectomy samples

The specimen pot and specific post vasectomy sample request form, including all the patient collection information is be provided to the patient post-procedure by the Clinician. If the pot provided becomes un-useable/damaged, the patient must contact the laboratory for another. Any specimen received in another type of pot will be rejected.

- All the details on the request form must be completed. Missing information may result in the request being rejected.
- The sample pot must contain patient full name, date of birth, date and time of production on the specimen pot.
- Any mis-information provided may affect the results provided by the laboratory, therefore results are supplied on the understanding that the information provided is accurate and truthful and the specimen has been produced and collected as per the instructions on the request form.
- The specimen and attached request form must be delivered to the laboratory reception *within* 1 hour of collection. This is crucial as staff must prepare and process the sample within 4 hours of collection.

13 Specific requirements for labelling Bone Marrow Slides

Information required on the specimen

- | |
|--|
| <ol style="list-style-type: none">1. Patient Surname2. Unique Numerical Identifier: (Hospital number)3. Date Taken |
|--|

14 Specific requirements for All Requests using Near Patient Testing Analysers

All Analysers are interfaced indirectly to the Laboratory Information System (LIMS) and the results and demographics received by the LIMS automatically register and record these results in the system prior to presenting them to the ward reporting system.

Failure to provide accurate data and complete data for the patient could publish results to the wrong electronic patient record. A unit number alone is secure providing the patient details have been verified against it.

The interface is set up to trap mis-matched data and prevent this passing in to the LIMS. Therefore it is essential that the following data is keyed in to the analyser:

1. Hospital number* - this should bring up the appropriate patient data for positive verification.
2. Patient Surname
3. Patient Forename
4. Date of birth

* Where this is not available (new-borns or A/E) input the surname in both the hospital number and surname fields.

15 Inconsistencies Detected at Validation of Results

Laboratory staff should be aware of the importance of relevant clinical information when validating results, especially when cumulative records are available. An unexpected test result can highlight the possibility of an incorrectly labelled sample and request form; this will be reported on Datix for investigation by the clinical area.

16 References

Institute of Biomedical Science Policy on Patient Sample and Request Form Identification Criteria, Version 3 (March 2016) Institute of Biomedical Science

Provision of key clinical information on laboratory specimen request forms
<http://www.hse.gov.uk/safetybulletins/clinicalinformation.htm>

British Medical Association (BMA), Duty of care regarding communication of investigation results, (December 2016) <https://www.bma.org.uk/advice/employment/gp-practices/service-provision/duty-of-care-to-patients-regarding-test-results>

Medical laboratories — Requirements for quality and competence (ISO 15189:2012)

17 Summary of Revision

Version	Summary of change
2.0	Updated format of document. Expanded information on responsibilities of staff (responsibility of the requester to ensure that the identity of the patient is confirmed); risk assessments; patient preparation; types of container; specific sections relating to standard samples, BT requests, post vasectomy samples, bone marrow slides and blood gas samples taken by near patient testing analysers; references and summary of revisions
3.0	Updated Blood Transfusion Information to reflect changes in practice. Updated Near Patient Testing to reflect all Near Patient Tests. Updated Bone Marrow Slides. Added section 15, Inconsistencies Detected at Validation of Results.
4.0	Added in that if no tests are requested then sample will be rejected. Amended Phlebotomy practice to state the requirement for a postponed request on the system, and ideally patient sent with a printed postponed request.