THE DEPARTMENT OF LABORATORY HAEMATOLOGY HANDBOOK HANDBOOK V 10.7 Date issued 28/04/2024.

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Changes in this document since last version

- Updated EQA participation table
- Updated reference ranges
- Removal of reference to molecular services
- Information on neonatal screening service

Laboratory Haematology

About the Oxford University Hospitals NHS Foundation Trust (OUH)

One of the largest NHS teaching trusts in the country. It provides a wide range of general and specialist clinical services and is a base for medical education, training, and research. The Trust is one of the largest employers in Oxfordshire, primarily based in Headington, Oxford and comprises:

The John Radcliffe Hospital

- Accident and Emergency
- Acute medical and surgical services, trauma, intensive care, cardiac, infectious diseases, women's services, and children's services.

The Churchill Hospital

- Non-emergency specialist services
- Renal medicine and transplant, clinical and medical oncology, dermatology, chest medicine, and palliative care.

The Horton Hospital (Banbury)

- · Accident and emergency services
- General hospital service, maternity, and paediatric services.

The Nuffield Orthopaedic Centre (NOC)

- Orthopaedics, rheumatology, and rehabilitation.
- Specialist haemophilia care

About us:

The main Haematology Department, including Blood Transfusion, is situated on Level 4 of the **John Radcliffe Hospital**, Headington, Oxford, and provides a comprehensive service to Oxfordshire and other, more distant referring laboratories.

This service includes the following:

- 1. Routine Haematology,
- 2. Antenatal and neonatal haemoglobinopathy screening service in line with NHSE screening guidance
- 3. Routine Haemostasis
- 4. Blood Transfusion service
- 5. Morphology and Leukaemia Immunophenotyping service

On the **Horton General Hospital** site, the department is located in the Pathology building and provides the following services:

- 1. Routine Haematology and Morphology
- 2. Routine Haemostasis
- 3. Blood Transfusion service

This provides a comprehensive service to the hospital as well as local GPs in the North of Oxfordshire, and South of Northamptonshire.

On the **Churchill Hospital site**, the department provides the following services:

Routine Haematology, haemostasis, and blood product issue support, 8am-7pm Monday to Friday, from the Laboratory Medicine Building. Located opposite Car Park 5. Use Air Tube Station 14 to send samples. This laboratory is referred to as Laboratory Medicine (LM)

On the **Nuffield Orthopaedic Centre** site there is no routine Haematology or Blood Transfusion laboratory, and all these services are supported from the John Radcliffe. However, from March 2022 Specialist Haemostasis and Thrombophilia diagnostic and monitoring service for patients with inherited haemostatic defects. (The Oxford Haemophilia and Thrombosis Centre, OHTC). The OHTC is located to the rear of the NOC campus near to Old Road in Headington.

24/7/365 services are maintained on both the John Radcliffe and the Horton sites.

Policies - Dept. of Laboratory Haematology Oxford University Hospitals Foundation Trust

Policy Statements

Animal Specimens

We do **not** accept animal specimens for laboratory testing.

Billing

- Work to support NHS care of OUH patients will be managed following Trust budget setting process, with cross-charging from Directorate of Pathology and Laboratory Medicine to appropriate Division / Directorate based on monthly outcome against plan.
- Work to support Oxfordshire CCG NHS workload will be billed by OUH commissioning according to the agreed overall Contract on a monthly basis.
- In the absence of a specific exceptional contract, the standard Laboratory Medicine Terms and conditions will apply. (link to OUH website, laboratory medicine page).
- In case of initial referral of work for the first time to the laboratory, or a significant change (considered to be an increase of greater than 20 percent by activity), please contact the laboratory prior to referral, so that the laboratory can assure you that they have the capacity and resources to meet your request.
- Receipt of a sample for testing will be deemed to be acceptance of a contract with OUH Foundation Trust, the work will be invoiced within 30 days of completion and payment is expected within 30 days of invoice being raised. It is the sender's responsibility to manage the process of raising purchase order numbers, if that is required by the sending organisation.
- Private Patients:
 - The OUH sees a variety of Private Patients, they need to be registered with the OUH Private Patient Office (<u>link to OUH website</u>, <u>private patients</u>), and the bills for the Laboratory Medicine fraction of their care will be raised as part of their overall care. If insurance is involved, they need to sign a Pre-authorisation with the relevant Insurance Company.
 - Non-OUH patients, the Department is happy to provide services for other organisations that provide care to Private Patients, but as the Department will have no relationship with the individual patient, any bill will be the responsibility of the sending organisation. The Department will not bill individual patients.

Clinical Trials:

- Clinical Trials at OUH if there is a laboratory component to the Trial should have agreed the financial aspects of the study with the Joint R&D office based at the Churchill Hospital, while obtaining ethical approval. Details of any support required from OUH laboratories should be agreed in advance of the Trial commencing, contact <u>LabTrials.OUH@ouh.nhs.uk</u>
- o Individual projects can be agreed directly with the laboratory on a case-by-case basis, please contact Laboratory Manager, Haematology and <u>LabTrials.OUH@ouh.nhs.uk</u> well in advance.

Business Continuity and Contingency Plans

In the event of a local, regional, or national disaster, Oxford University Hospitals NHS Trust have comprehensive contingency plans in place to ensure the impact on care and specifically on laboratory services is minimised. With standardisation of testing across our various sites we have worked to ensure most of the common workload can be performed from more than one site.

Chain of Custody

Chain-of-Custody is a record of disposition of a specimen to document who collected it, who handled it, who performed the analysis, is often required when results are to be used in a court of law, (e.g., in Paternity testing cases). The Dept. of Laboratory Haematology does NOT provide this service. In certain appropriate

cases with relevant consent, samples or test results originally used for clinical care would be released if no longer required for clinical testing.

Confidentiality of Results

OUH Hospitals Laboratory Haematology Department is committed to maintaining the confidentiality of patient information. To work towards this goal, we aim to minimise the transmission of results by telephone and aim to maximise the use of electronic transmission of results to systems with audit trail of access to the results. The Department follows the policy of the Oxford University Hospitals Foundation Trust, with regards to patient confidentiality and as such all staff are required to complete training in Information Governance and maintain competence.

Phone Enquiry Policy (SOP Gen 001)

Results will only be released to a referring clinician or their approved representative. Third parties including patients, or their relatives will be referred to the ordering clinician. We will want to ensure anyone phoning has legitimate authority to receive the results. Patients would need to be clearly identified by use of NHS or MRN number AND full name or date of birth. Provision of appropriate information before enquiring will assist prompt and accurate response to enquiries and reporting.

Complaints / feedback

Although we always like to hear about the things we have done well, we would also like to hear about the things we could do **better**.

The Oxford University Hospitals NHS Foundation Trust (OUH) is committed to providing the very highest standards of care.

We will always try our best to get things right, but sometimes mistakes happen. When they do, it is vitally important to put things right as soon as possible, and to ensure that the same mistakes do not happen again. If as a user you feel that the department has not fulfilled its obligations to you, please contact the department as below. These contact details can also be used for feedback and questions about services provided.

- Laboratory Manager: Dan Smith (email to Dan.smith@ouh.nhs.uk) 01865 220337
- Quality Manager: Andrew Platt (email to Andrew.platt@ouh.nhs.uk) 01865 857663

Making a Formal Complaint

Please put your complaint in writing to:

Chief Executive
Oxford University Hospitals NHS Foundation Trust
Headley Way
Headington
Oxford OX3 9DU

Email: complaints@ouh.nhs.uklink to OUH website, complaintscom

Telephoning of Critical Values

The Critical Values policy is described below:

Definition of a Critical Value: A Critical Value is defined as one which is such at variance with normal (expected values) as to be life threatening unless something is done promptly and for which some corrective action could be taken.

Abnormal results are not considered Critical Values: Most laboratory tests have established reference ranges which are the results that are typically seen in a group of healthy individuals. While results outside these ranges may be considered abnormal, that is different from "critical".

Action taken when a result exceeds the Critical Values: In addition to normal reporting staff will attempt to telephone or otherwise contact the ordering clinician as quickly as possible. For this reason, each request should be accompanied by contact details to allow the laboratory to contact a referring clinician. The following limits apply to inpatients and primary care.

Critical Values for FBC include:

- WBC >25.0x10⁹/I (if not post op)
- Haemoglobin < 75 g/l (when unexplained by clinical data/diagnosis)
- Platelet count < 30 x 10⁹/l (when unexplained by clinical data/diagnosis)
- Neutrophil count < 0.8 x 10⁹/l (when unexplained by clinical data/diagnosis)

Critical Values for Coagulation testing include:

- INR > 7.9 (patients on Warfarin)
- PT > 25.0 seconds (unless known to be receiving anti-coagulation therapy)
- APTT >50.0 seconds (unless known to be receiving anti-coagulation therapy)
- Fibrinogen <1.0 g/l (new presentation)

The appearance of significant features on a blood film (not diagnosed / unexpected change) to include but not limited to:

- New diagnosis of Malaria infection
- New diagnosis of Acute Leukaemia
- New diagnosis of red cell fragmentation syndrome (HUS, DIC, TTP)

Disclosure of Results

Results will only be released to a referring clinician or their approved representative. Third parties including patients, or their relatives will be referred to the ordering clinician.

Infectious Material

All samples will be treated by the department as potentially hazardous; however, samples from patients who are known to pose an infection risk should have this information appropriately recorded on the request form and all samples should have an approved danger of infection sticker on them. It is the duty and responsibility of the sender to be aware of the risks and to arrange for appropriate packaging, labelling and transportation.

- Both the form (if available) and the specimen label must carry a common warning label indicating in black on a yellow background.
- The label must be clearly visible to anyone handling the specimen but should not carry clinical details.

• Apart from the common warning label, the electronic order or request form must give sufficient clinical information to enable laboratory staff to know which precautions to take.

Because of the extra work and stress involved in processing 'high risk' specimens it is important that the category is limited to those specimens where it is a matter of medical opinion that the patient concerned is likely to be carrying a hazard group-3 pathogen.

- Each specimen must be sealed in a double plastic bag.
- Place labels:
 - One on the specimen container
 - o One EPR specimen envelope or on the request form.
- Please ensure that the correct number of samples are sent, as no decanting will be possible on high-risk samples.

Blood taken from the following patient's must be treated as "high-risk" specimens:

- Patients known to be HIV positive.
- Patients known to be HTLV1 positive.
- Patients who are known to be Hepatitis B or C positive
- Intravenous drug abusers.
- Patients from other known high-risk groups.
- Please contact the department before sending samples from patients suspected of having any form of Viral Haemorrhagic fever (VHF), as these will require special processing and only minimal tests will be performed.
- Samples from patients with confirmed VHF must not be sent to the department, as we are not equipped to handle them.

For further information see *ACDP. 2013.Categorization of biological agents according to hazard and categories of containment London. HMSO.* (link to HSE document on approved list of biological agents)

Labels are available from: Oxuniprint, stock code – DOIL0001, Danger of Infection Label pk 250.

Radioactive Samples

Specimens from patients receiving radioactive tracers or material should be marked as such. Please include the date and time of receipt and the isotope used. These samples will be handled in such a way as to protect the health and safety of our staff while meeting the needs of the patient. This may involve some delay in the processing of the sample. Please ensure testing is truly necessary before requesting testing on patients immediately after such treatment.

Record Retention

The Department retains requests, sample material and test results for the retention periods recommended by the Royal College of Pathologists, in "Retention and Storage of pathological records and specimens 5th edition 2015" link to RCPath website, retention of clinical material

Referral of Tests to another Laboratory

Although the vast majority of the analytical methods that the department offers are performed on one of the three sites, there are a number of tests that are referred to other external laboratories. This will happen for one of the following reasons:

- 1. The test requires expertise or equipment that the department does not have access to.
- 2. The low number of requests is such that, it would not be possible to maintain suitable skills or competence in the analytical method, so they are referred to another referral laboratory.

3. In extremis, routine tests may be referred in the case of catastrophic analyser failure, as part of the departmental service contingency plan

Referring laboratories are chosen that provide equal performance to our own and are regularly asked to provide evidence of continuing UKAS ISO 152189 accreditation, and acceptable EQA performance. For very specialist testing, the laboratory will endeavour to identify the most suitable testing laboratory. A list of the referring laboratories is held in the department and is available on request to the quality manager.

Referred samples will be sent off by the laboratory using appropriate postal or courier methods and the laboratory will manage the dispatch and return of results process. A process of monitoring TAT for these samples is in place.

Where reports will be sent out using similar mechanisms used for internal processing; however, they will contain the name of the processing laboratory and reference ranges where appropriate.

OUH will invoice for samples referred to another laboratory at the price charged to OUH, plus a small administrative charge plus if required any courier costs.

Distribution of testing on various sites within the department of laboratory Haematology

The department operates four laboratories on four sites within the OUH FT. this document describes the scope of practice on each site.

Churchill site

- FBC (including Retic)
- Clotting screen / INR / D-Dimer
- Electronic issue of blood products (blood, platelets, plasma)

NOC site

- Clotting screen / INR / D-Dimer
- Factor assays.
- VWD investigations
- DOAC testing (Dabigatran)
- Emicizumab testing
- Lupus screening
- Thrombophilia investigations
- · Haemostatic investigations
- Platelet function investigations
- HIT screening.
- TTP investigations

Horton site

- FBC (including Retic)
- ESR
- Malaria investigations
- Glandular Fever
- Sickle Screen
- Blood film examination (manual and digital)
- G6PD assay
- Clotting screen / INR / D-Dimer
- Blood Group and antibody screening / investigation
- Issue of blood products (blood, platelets, plasma)

JR site

- FBC (including Retic)
- ESR
- Malaria investigations
- Glandular Fever
- Sickle screen
- Plasma viscosity
- Blood film examination (manual and digital)
- Bone marrow examination
- Clotting screen / INR / D-Dimer
- LMW Heparin testing
- DOAC testing (Rivaroxaban, Apixaban Edoxaban testing)

- Blood Group and antibody screening / investigation
- Issue of blood products (blood, platelets, plasma)
- Foetal-maternal haemorrhage estimation
- ABO titres
- Haemoglobinopathy diagnosis, including AN & NN screening service.
- Flow cytometry: acute / chronic leukaemia investigations, MRD analysis & PNH.

Quality

Scope of Accreditation

The Department attained ISO 15189:2012 accreditation in July 2016 after assessment by UKAS against the Standard ISO-15189 *Medical laboratories—Requirements for quality and competence.* The department is assessed on an annual basis.

For accredited scope of practice please see below (Current UKAS scope of accreditation)

Any tests referred to in this handbook which are not explicitly covered in the scope of practice above are by definition NOT part of the laboratory's external accreditation. They should as far as practicable still be covered by the Laboratory Quality Management system, including QC and initial verification.

The department may offer a small number of analytical tests that are defined to be out of accredited scope; in the majority of cases the reason will be that the test method has undergone changes to improve performance, and these are awaiting assessment by UKAS. On the OUH website there is a list of these tests, this can be found on the front page in a section titled out of scope tests – this list will be updated as needed.

- The Department takes part in a wide variety of National External Quality Assurance Schemes.
- The Department is annually assessed by the MHRA for conformance with the Blood Safety and Quality Regulations.
- The Department contributes as required to the Foundation Trusts assessment by CQC against relevant standards.

Proficiency Testing

The laboratory is committed to participation at least forty different external Quality assurance schemes as well as a variety of internal quality control process to ensure the consistent quality of results produced. External QA schemes selected are chosen based on suitability of the laboratory's needs. Where possible EQA schemes will be accredited to ISO 17043 international standard or hold equivalent markers of quality, participation in individual schemes is kept under regular review.

Schemes we participate in as of January 2024 include:

Scheme	Site	Frequency	Section
NEQAS FBC	all	Every 1 month	Core automated
NEQAS Automated WBC differential (& NRBC)	all	Every 2 months	Core automated
NEQAS Reticulocytes	all	Every 2 months	Core automated
NEQAS Sickle	JR2, HGH	Every 2 months	Core automated
NEQAS G6PD assay	HGH	Every 2 months	Core automated
NEQAS Plasma Viscosity	JR2	Every 1 month	Core automated
NEQAS ESR	JR2, HGH	Quarterly	Core automated
NEQAS GF	JR2, HGH	Quarterly	Core automated
NEQAS Malaria RDT	JR2, HGH	Quarterly	Core automated
NEQAS Haemoglobinopathy Adult	JR2	Every 2 months	Haemoglobinopathy
NEQAS Haemoglobinopathy Neonate	JR2	Every 1 month	Haemoglobinopathy
NEQAS Haemoglobinopathy Liquid Capillary	JR2	Every 2 months	Haemoglobinopathy
NEQAS Routine Coagulation	all	Every 2 months	Core automated
NEQAS DOAC programme	JR, NOC	Quarterly	Haemostasis
NEQAS Lupus programme	NOC	Every 6 months	Haemostasis
NEQAS FXIII assay programme	NOC	Every 6 months	Haemostasis
ECAT Post analytical platelet function	NOC	Every 6 months	Haemostasis
ECAT PFA	NOC	Every 6 months	Haemostasis
NEQAS Thrombophilia	NOC	Quarterly	Haemostasis
NEQAS ADAMTS 13	NOC	Every 6 months	Haemostasis
NEQAS Coagulation supplementary	NOC	Variable	Haemostasis
NEQAS FVIII inhibitor (pilot)	NOC	Every 6 months	Haemostasis
NEQAS HIT programme (pilot)	NOC	Every 6 months	Haemostasis
NEQAS Emicizumab (pilot)	NOC	Quarterly	Haemostasis
WFH Haemophilia	NOC	Quarterly	Haemostasis
NEQAS Morphology (Films)	JR2, HGH	Every 6 weeks	Morphology
NEQAS Morphology (Malaria)	JR2, HGH	Quarterly	Morphology
NEQAS Morphology (manual WBC differential)	JR2, HGH	Quarterly	Morphology
NEQAS Digital Morphology (pilot)	JR2, HGH	Every 6 weeks	Morphology
NEQAS Immunophenotyping (part 1)	JR2	Every 2 months	Morphology
NEQAS Immunophenotyping (part 2)	JR2	Every 2 months	Morphology
NEQAS ALL MRD by Flow	JR2	Every 4 months	Morphology
NEQAS AML MRD by flow (not accredited)	JR2	Every 4 months	Morphology
NEQAS CSF flow (not accredited)	JR2	Quarterly	Morphology
NEQAS PNH	JR2	Every 2 months	Morphology
NEQAS Special Stains (Iron stain only)	JR2	Every 6 months	Morphology
NEQAS ABO & Rh D testing	JR2, HGH	Every 2 months	Blood Transfusion
NEQAS Antibody screening and identification	JR2, HGH	Every 5 weeks	Blood Transfusion

NEQAS Crossmatching	JR2, HGH	Every 2 months	Blood Transfusion
NEQAS Red cell phenotyping	JR2, HGH	Every 12 weeks	Blood Transfusion
NEQAS Foetal Maternal Haemorrhage	JR2	Quarterly	Blood Transfusion
NEQAS Extended phenotype (Pilot)	JR2	Quarterly	Blood Transfusion
NEQAS ABO titration	JR2	Quarterly	Blood Transfusion
NEQAS DAT (Pilot)	JR2, HGH	Quarterly	Blood Transfusion

For the rare tests where there is no external quality assurance scheme available, the laboratory will pursue alternative means to provide assurance; this will include the use of inter-trust sample sharing schemes to provide evidence of comparability.

Please note: the schemes marked in the table above as pilot or not accredited are in development by the EQA scheme and therefore may not be ISO 17043 accredited; however, they are currently the "best fit" for the laboratory's needs.

Measurement of Uncertainty

The department produces results from a wide range of tests, some of which have a measurement of uncertainty associated with the result. This does not infer an inaccurate test but does highlight that these tests produce a result that is accurate within certain parameters. This information can sometimes be useful if a specific test has a target range that may be included in a clinical treatment algorithm. Although not published here, measurement of uncertainty estimates for tests are available on result from the quality manager (Haematology quality manager email link)

The Quality Policy of the Department of Laboratory Haematology.

Within the Directorate of Pathology and Laboratories; Oxford University Hospitals NHS Foundation Trust.

The Department of Laboratory Haematology provides a diagnostic and routine monitoring service for the OUH NHS Foundation Trust; local CCGs and acts as a referral centre for referring hospitals. The analytical profile of the department includes both routine tests and specialist analysis. In addition, the department provides blood transfusion support for the trust and certain surrounding hospitals. The department is committed to providing a service of highest quality and is aware and takes into consideration the needs and requirements of its users. In order to ensure that the needs and requirements of users are met, the department of laboratory haematology will:

- Operate a quality management system in an impartial manner to integrate the organisation, procedures, processes, and resources required.
- Obtain and monitor data on user satisfaction and complaints.
- Review the existing services in relation to the needs and requirements using data gathered from the users
 of the service in order to achieve continual quality improvement.
- Set quality objectives and plans in order to implement this quality policy and to ensure that it is suitable and effective.
- Ensure that all personnel are familiar with this quality policy to ensure user satisfaction.
- Treat patients and visitors with due care and respect,
- Commit to the health, safety, and welfare of its entire staff. Visitors to the department will be treated with respect and due consideration will be given to their safety while on site.
- Uphold professional values and remain committed to good professional practice and conduct.
- Comply with any relevant environmental legislation.
- Where such appropriate controls exist, comply with any relevant or appropriate national or international product storage legislation.

The Department of Laboratory Haematology will comply with the requirements of ISO 15189:2012 and 2022; other relevant national and international standards and where appropriate, other regulatory bodies and is committed to:

- Staff recruitment, training, development, and retention at all levels sufficient to provide a full and effective service to its users.
- Ensuring that all staff are familiar with the contents of the Quality manual and all procedures relevant or appropriate to their work.
- The correct and proper procurement and maintenance of such equipment and other resources as are needed for successful provision of service.
- The collection, transport, and handling of all specimens where appropriate in such a way as to ensure the correct performance of laboratory examinations and where appropriate in compliance with relevant legislation.
- The selection and use of examination procedures that are fit for purpose and provide the highest achievable quality of all tests performed.
- Reporting results of examinations in ways that are timely, confidential, accurate and clinically useful.
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.

This policy is a controlled document and is reviewed annually within the department. Signed copies will be displayed within the laboratory.

Working Hours

- JR & Horton sites: core services are available 24 hours per day, 7 days a week.
- OHTC on NOC site: routine service is available Monday to Friday, 08:30 17:00, with a limited emergency service available out of these hours (please see below for information).
- Lab Med lab on Churchill site: routine service is available Monday to Friday 08:00 19:00

While the Routine laboratories are open for the receipt of samples and processing the most common tests some of the more specialist work will only be available when the more specialist staff in individual sections are on duty.

There is only one qualified Biomedical Scientist on duty at the following times:

	JR2 site	Horton site	Churchill site	NOC site
Saturday	20:30 hr – 8.30 hr	08:30 hr – 08:30 hr	N/A	See notes below
Sunday	20:30 hr – 8.30 hr	08:30 hr – 08:30 hr	N/A	
Monday –Friday		17:00 hr – 08:30 hr	8:00-10:30 hr	
			17:00 – 19:00 hr	

The OHTC unit offer an on-call service, available outside of routine opening hours, if this service is required; please contact the on-call Haemostasis consultant via switchboard to discuss your requirements before taking any samples from patients.

Specialist units:

Staffed 08:30-17:00 Monday to Friday:

- Oxford Haemophilia and Thrombosis Centre, NOC
- Immunophenotyping Service, JRH
- Ante-Natal and Neonatal Screening Services, JRH

General Enquiries please see appendix II.

Transfer of Specimens to the Laboratory

In the majority of clinical areas at John Radcliffe, Churchill and Horton Hospitals, samples may be sent to the laboratory in the Pneumatic tube system. Staff are encouraged to use the Air Tube system were available for all relevant samples. Use of the Air Tube system is covered by OUH policy, a copy of which is available on the OUH intranet site:

Portering services on the four hospital sites are marginally different and local policies should be followed but while there are some routine collections of samples from the *retained estate* of the Churchill Hospital in most areas there is no routine collection of samples and a portering job needs to be logged with the helpdesk on each occasion.

Transfer between the sites of the Trust during routine hours is by vehicles operated by the South-Central Ambulance Service (SCAS). A vehicle operates at xx:10 from Laboratory Medicine on the Churchill site via the NOC and arriving at the John Radcliffe laboratories at xx:45, between the hours of 8:10 and 17:45 Monday to Friday. Most Haematology samples generated at the Churchill are processed on the Churchill site, but some specialist work will be sent to the John Radcliffe, all of the routine NOC workload will be sent to the John Radcliffe.

Between 7pm and 8am, Monday to Friday, and all-day Sat, Sun and Bank Holidays a Commercial Courier "CitySprint", provides an hourly service between Churchill, and NOC receptions and the Labs at the John Radcliffe. Acute clinical areas at the Churchill site can book additional CitySprint collections direct from the clinical areas and staff working there should make themselves familiar with the local process.

SCAS provides four routine collections from the Horton Laboratories at 8:00, 10:35, 14:25, and 16:30 to bring specialist work to the JRH. If necessary, the Laboratory Staff can organise additional deliveries using a local Taxi firm. Most Haematology samples generated at the Horton site will be processed at the Horton site, but specialist work will be sent to the JRH.

A twice a day service from most Oxfordshire G.P.'s operates for collection of samples and delivers to both the laboratories at the JRH and the Horton.

All samples that are transported by these services must be appropriately packaged and labelled. Transport of all samples should be such to guard against unauthorized access to specimens. These are examples of the approved transport boxes currently in use. The green bags (of varying size) are used to transport samples from GP surgeries into the labs and also to transport samples around the various Trust sites. Please note the dark blue bag is for internal use, transporting samples from JR site to the Horton site and return. There are other coloured bags in use.





Samples sent by either Royal Mail or other courier services are the responsibility of the sender until the arrival in the Laboratory. It is their responsibility to ensure packaging meets the standard *for the transport of specimens through the post.* Royal Mail Group plc will accept Category B diagnostic specimens provided they are packaged to Packaging Instruction 650 requirements. Full details may be accessed on the Royal Mail website: (Royal Mail track and trace)

Specialist Samples:

Most samples can be sent by the best available means to arrive in the Laboratories as quickly as possible, but some will be required to be processed in specialist areas of the laboratory which may not provide a 7-day service and may not be able to be stored. In most cases it is strongly advised that requesters contact the relevant section before sending the sample.

Examples include but are not limited to:

- Platelet Investigations including those linked to potential Non-Accidental Injury investigation, these samples
 must be tested within <u>2 hours of being bled</u>. Please contact the laboratory (01865 2) 25311 in routine
 hours, or contact Duty SpR, via switchboard, <u>before taking the samples</u>. In some cases, arrangements
 can be made to bleed the patient at the OHTC.
- Cold Agglutinins testing in Blood Transfusion must arrive while still at 37°C, and only between 08.30 and 13.00 Mon-Friday. Contact laboratory on (01865 2) 20339 if sending sample.

Requesting of Tests

Blood should be correctly collected into vacutainers if at all possible (including children). The anticoagulant / sample tube required is listed in the section on normal ranges at the end of this handbook. Samples that have been damaged by poor phlebotomy technique may not be processed if excessively haemolysed. Please remember to fully label samples with the following as a strict minimum

- Full Name (first name and surname)
- Date of birth or another unique numerical identifier (e.g., NHS number)

Samples that do not meet these criteria will not be routinely processed.

(Blood Transfusion samples will require a higher standard of patient Identification please see the relevant section of this handbook, and there is a Trust "Blood Transfusion Policies and Procedures", a copy should be available on all wards or from on the intranet:

Blood Transfusion pages on OUH intranet

You must make yourself familiar with it if you need to request blood for transfusion.)

Date and time of collection should be provided on all samples (or associated request card if used) as certain assays can only be performed on fresh samples.

Please use the patient's hospital number (MRN) or NHS number and give a location for the report and relevant clinical details. It is most important that requests for immediate investigations are reserved for those that are truly urgent; we will prioritize investigation of samples using information from request forms. Hospital In-patients are given priority followed by some outpatient clinics.

OUH Requests

The OUH Trust routine method of ordering tests is via Cerner Millennium EPR. The Trust has almost completed implementation of the EPR system, samples requested using this method do not require request cards. When implementation is complete, only samples requested via EPR will be accepted from OUH users.

Use of Cerner Millennium is therefore strongly recommended where possible.

Please do not use paper forms if EPR is available, paper requests are manually entered into the laboratory LIMS system and these requests are therefore at greater risk of data entry errors.

Information about correct positioning of these labels can be found on the reverse of the specimen bags.

- Always check patient identification before labelling samples.
- Only put specimens from a single patient in each primary bag.
- Stick the specimen label directly over the tube label.
- Labels should be straight, vertical and as close to the cap as possible.
- If using paper forms, please ensure that on each request form, the individual collecting blood, signs the form.

If Cerner cannot be used: a fully completed request form must accompany all samples (please see Appendix III, Examples of Haematology Request forms). Please ensure that the correct form is used. Information about the service and sample collection is printed on reverse of request form. It is very important to complete the request form fully and correctly. The use of Addressograph labels on request forms is encouraged, but all samples should be handwritten. Samples labelled with addressograph labels are unlikely to be processed, due to technical difficulties with the analytical equipment in use in the department.

Oxfordshire CCG GP Practices:

Locations are equipped to use the GP electronic requesting system (Sunquest-ICE). The system will identify which bottles are required for each test and produce labels suitable for use on the requests bottles and a larger label to go on the request card including eye-readable information in case of an IT-Link failure and eye readable clinical details. The date and time the patient was bleed should be added on each occasion.

Use of this ordering system is strongly recommended.

It is CCG and OUH policy that all requests should include a valid NHS number.

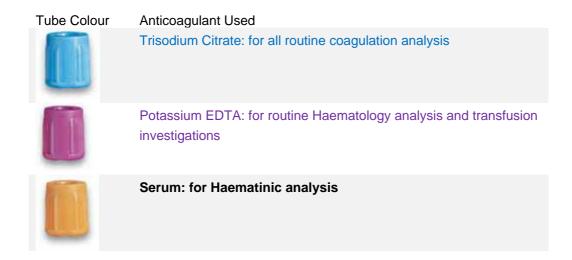
All other locations (including referrals from other trusts):

Each request should be accompanied by a fully completed request form see <u>Appendix III</u> for examples. Patient demographics should include:

- Full name (first name and surname)
- Date of Birth
- Hospital Number
- NHS Number (or CHI number for Scottish requests)
- If your referral site expects the laboratory number to be reflected back to them, it must be included at this point.
- If your Trust has a policy of demanding Purchase Order Number for all external work, it must be included at this point.
- Relevant clinical details

Use of addressograph labels on request cards is encouraged, but is strongly discouraged on bottles, as some designs of larger labels will interfere with the automated flow of samples through the analysers, and some referral sites (NHSBT) will only accept handwritten samples.

Sample Requirements



Sample Types for Commonly Requested Tests.

The trust supplies BD Vacutainer tubes for the collection of adult samples, these contain a variety of different additives, either to stabilize an analyte, or to make a sample suitable for testing. It is very important that the correct tube is taken for the correct test requested. In all cases, if the wrong tube is received, the laboratory cannot provide a correct result. The table below displays the commonly encountered sample tube types.

Sample Type	Tube lid Colour (BD Vacutainer tubes)	Tube lid Colour (BD Vacutainer tubes)
EDTA		
Citrate		
Clot		
Heparin		

If possible, please use BD vacutainer tubes for the collection of all samples, regardless of patient age. If this is not possible, there is a selection of paediatric tubes available, these may have different lid colours to the adult tubes, so some degree of care is needed in selection. As with adult tubes, please send correctly filled samples for clotting studies.

Paediatric tube types in use.

Sample Type	Tube Lid Colour		Sample Type	Tube Lid Colour	
EDTA	Red	10 2401 3	Clot	Clear	To the second se
Citrate	Green	51 2011 ²	Heparin	Orange	215-08

Please note we still receive a number of paediatric EDTA tubes with Heparin lids on them, care must be taken not to mix up the red and orange lids.

These samples will be rejected as unsuitable to process.

Neonatal Haemoglobinopathy screening

This process uses neonatal blood spot cards, shared with the Biochemistry screening laboratory. There are national guidelines relating to sampling and completion of request cards. These can be found on the Clinical Biochemistry webpage on the OUH website (<u>Making a Neonatal screening request</u>)

General Haematology Tube requirements

For FBC, the department requires an EDTA sample, if possible, this should be in a properly filled, well-mixed purple top vacutainer; 4.5- and 1.8-ml tubes are available for use. For paediatric use, there is a 1.3 ml screw top sample tube available. Please send full samples, if possible, this allows for supplementary requested tests to be performed on the same sample. For other commonly requested tests please see the normal range section of this document.

The laboratory does not have the facility to process larger (6 ml or 10 ml) EDTA tubes for routine Haematology investigations. Any larger samples like this will be rejected and not processed.

As part of the Full Blood Count profile, results will be produced and reported for:

- White Blood Cell Count
- Haemoglobin
- Haematocrit
- Red Cell Count
- Mean Cell Volume (MCV)
- Mean Cell Haemoglobin (MCH)
- Mean Cell Haemoglobin Concentration (MCHC)
- Platelets
- Nucleated Red Cell Count

There is no need to request these tests in addition to a Full Blood Count.

As part of the Full Blood Count profile the aim will be to produce a 5-part White Cell Differential.

- Neutrophil
- Lymphocyte
- Monocyte
- Eosinophil
- Basophil

In most cases an accurate differential will be produced and reported by the analyser, in a minority of cases either the analyser will not produce a differential or will produce a report suggesting the presence of other cells in the circulation. In these cases, a Blood Film will be produced and examined by microscopy. There is no need to request a Blood Film to receive a White Cell Differential.

There are circumstances were examining a Blood Film will add value to the report if so, please include clinical circumstances and why the Film is requested.

Examples which would generate a Film request regardless of FBC result would include:

- ? Sezary Cells
- ? DIC
- ? Haemolysis
- ? Haemolytic Anaemia
- Persistent/ Unexplained Anaemia
- Persistent/ unexplained Thrombocytopenia

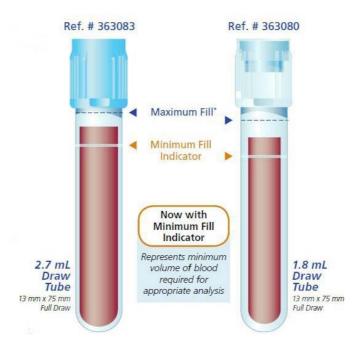
General Coagulation Tube requirements

- For a coagulation screen request PT and APTT or "Coagulation screen" in EPR or if EPR is not available on form
- For patients anticoagulated with warfarin request an INR
- For patients anticoagulated with unfractionated heparin request an APTT
- Patients anticoagulated with LMW heparin do not normally need monitoring.

Please take care with ordering on EPR and select the correct test, as due to the way electronic orders are handled in the lab, errors may not be spotted prior to processing of samples.

Coagulation citrate samples (blue top) need to be correctly filled due to the nature of the anticoagulant used. Partially filled, clotted or overfilled specimens will not be processed.

For patients that are difficult to bleed paediatric (1.3 ml) or short draw (1.8 ml) vacutainers tubes are recommended. Please ensure that all samples are adequately labelled. Please see figure below for correct filling.



Some conditions where it is appropriate to request a coagulation screen.

- Unexplained bleeding or bruising
- · Personal or family history of bleeding disorder
- Liver disease
- Prior to anticoagulant therapy
- Conditions associated with DIC e.g., septicaemia.
- Massive transfusion
- Suspected non-accidental injury.

Coagulation screens before surgery or invasive procedures

In 2008 the British Committee for Standards in Haematology (BCSH) published guidance on the assessment of bleeding risk prior to surgery.

(Chee et al Guidelines on the assessment of bleeding risk prior to surgery or invasive procedures

These recommendations can be summarized as follows:

- Indiscriminate coagulation screening prior to surgery or other invasive procedures for prediction of bleeding risk is **not recommended**.
- A comprehensive bleeding history should be taken in all patients prior to surgery and invasive procedures.
- If the bleeding history is negative, no further coagulation testing is indicated.
- If the bleeding history is positive or there is a clear clinical indication (e.g., liver disease), a comprehensive assessment guided by the clinical features is required.

Some reasons not to request coagulation screen.

The use of coagulation screens has increased over recent years as a routine screen for haemostatic abnormalities. The tests were not designed for this purpose and their use in this manner is inappropriate for several reasons:

- 1. By definition, 2.5% of normal healthy subjects will have prolonged clotting times. This is likely to be higher in the patient population. A large proportion of such results will require further investigations, causing delayed operations, unnecessary anxiety to the individual, and unnecessary and expensive laboratory investigations. There are also occasions when this can erroneously precipitate the use of blood products.
- 2. All inherited bleeding disorders (and many acquired ones) have low prevalence. Indiscriminate screening results in low positive predictive value, and a high number of false positives.
- 3. The coagulation screen is insensitive to factor XIII deficiency, mild von Willebrand disease (the commonest congenital bleeding disorder in Caucasians) and platelet disorders and may give false reassurance.
- 4. Some factor deficiencies causing prolongation of the APTT are clinically irrelevant, e.g., factor XII deficiency. This and the lupus anticoagulant may suggest a bleeding risk when none exists, causing unnecessary postponement of surgical procedures.
- 5. Evidence in the literature shows that coagulation tests have both low sensitivity and specificity to predict bleeding.
- 6. 95% of potentially clinically significant abnormalities of coagulation or haemostasis in medical and surgical patients can be detected through a comprehensive history and physical examination.
- 7. Despite a large number of abnormal results being generated through indiscriminate use of the coagulation screen, studies have shown that patient management is rarely altered.

Requests for specialized bleeding investigations (especially those in patients where there is a suspicion of non-accidental injury) should be discussed with the clinical staff at the OHTC <u>before taking the samples</u>. The majority of these samples need to be fresh (<4-6 hours) in order to process, so should be sent direct to the OHTC on the NOC site.

Samples delayed in transit outside of this time may not be processed.

Specialist Coagulation testing

Who to test for heritable thrombophilia?

Patient

- Consider testing those with a strong family history of unprovoked thrombosis.
- Women planning a pregnancy who have had a VTE due to a provoking factor should be tested and considered for antenatal prophylaxis if a thrombophilia is found.

Relative of patient

- Consider testing asymptomatic relatives in selected thrombosis-prone families with high-risk thrombophilia (antithrombin, protein C or protein S deficiency). May be particularly helpful for counselling female relatives regarding COC and HRT.
- Women planning a pregnancy who have a family history of venous thrombosis should be tested if an event in a first degree relative was unprovoked or provoked by pregnancy or COC exposure.

In patients, if testing is indicated it is usually performed one month after discontinuing anticoagulation with Warfarin. We do not recommend testing in the acute phase or when anticoagulated with warfarin.

Who to test for antiphospholipid antibodies?

- Patients with unprovoked or recurrent VTE who are stopping anticoagulation.
- Ischaemic Stroke < 50 years
- Three consecutive spontaneous abortions < 10 weeks
- Foetal death > 10 weeks
- Premature birth due to (pre-)eclampsia or placental insufficiency

Samples required.

- Hereditary thrombophilia 4 citrate samples and 1 EDTA.
- Antiphospholipid antibodies 1 citrate and 1 clotted.
- Both 4 citrate samples, 1 EDTA and 1 clotted.

Platelet Function Assays (including those that form part of a non-accidental injury investigation)

These are *not routine* tests and require medical discussion *before* sample collection and testing. These need to be performed on fresh samples arriving at the Haemophilia centre (NOC site) within ideally 2 hours of collection (maximum 4 hours); as such it is essential that clinical areas contact the laboratory **before** bleeding the patient.

In routine working hours (Monday – Friday) please phone OHTC on (01865 2) 25311.

Outside of this please bleep the on-duty Haematology Specialist Registrar via switchboard (0300 3047777)

Samples referred to the laboratory for Haemostatic or Thrombotic investigations.

Samples should be sent to:

Haemophilia and Thrombosis Centre (OHTC) NOC, Windmill Rd, Headington, Oxford OX3 7HE

- Samples originating from external laboratories should be sent direct to the address above.
- Unless they can be delivered within 4 hours of collection, samples will need to be centrifuged to produce platelet poor plasma which should be separated.
- Plasma should be frozen in 2 ml freezer vials with screw cap lids and labelled with -70°C freezer proof labels. Be aware samples will be thawed at 37°C in a water bath and labels must also be resistant to this.
- Samples to be sent should packed frozen in manner that will maintain this state for the transport time. Dry ice is strongly recommended to keep the samples frozen.
- Same day or overnight direct door to door courier services are recommended to ensure sample stability.
- Samples should be accompanied with a suitable request card and covering explanation letter if there are complex clinical details. If no local SLA is in place a purchase order number should be included
- The laboratory reserves the right not to process any samples that have been transported inappropriately or insufficiently labelled.

Samples referred to the laboratory for platelet function investigations.

Samples should be sent to:
Haemophilia and Thrombosis Centre (OHTC)
NOC, Windmill Rd, Headington,
Oxford OX3 7HE

- All requests for investigations involving platelet function <u>must be</u> discussed with the laboratory before samples are taken. The laboratory may be unable to process samples of this nature if prior contact has not been made.
- Samples for platelet nucleotides must be pre-prepared before being frozen as a platelet extract on dry ice. Please contact the Haemophilia and Thrombosis Centre beforehand to discuss the preparation proceed and to receive a copy of the SOP if necessary.
- Samples for platelet function testing (chronolog, platelet aggregation etc.), must be fresh (ideally <2 hours from collection, maximum 4 hours from collection), it is the responsibility of the sending laboratory to use a transport process that will fulfil this requirement. Samples should be accompanied with a suitable request card and covering explanation letter if there are complex clinical details. If no local SLA is in place a purchase order number should be included
- The laboratory reserves the right not to process any samples that have been transported inappropriately or insufficiently labelled.

Reporting of Results

Oxford University Hospital Foundation Trust Users

All results will be sent to the Cerner Millennium EPR System

What you need before you start

A computer that has been set up to connect to the EPR either from the OUH virtual desktop, or directly from a web page short cut on your desktop. You need to ensure that your smartcard has been properly enrolled and provisioned to give you access to Trust systems and that you have an Oxnet (hospital network) account.

Login process

You will need an NHS Smartcard and passcode; it is your responsibility to obtain this and a log-in before working your first shift, (even for locum staff!).

Tap&Go

For clinicians, most of the time, you will access clinical systems via the OUH Citrix workspace virtual desktop, using your NHS smartcard to activate the proximity sensor attached to the PC, by gently tapping it with your card. This takes you to a desktop from where you can launch EPR simply by entering your passcode. You can secure your session by tapping the sensor again, and this allows you to retrieve your session at any other machine running Workspace (with a proximity sensor attached). After a pre---determined time should you not return to your session the EPR will time---out, and you will have to launch it again when you re---connect to your session

- Always secure your session before leaving the PC.
- Never share your card or passcode you would be in breach of the Data Protection Act.

Launching Millennium

- To launch Millennium, click on the TRUE icon in the task bar or double---click the icon on the desktop: Either will open the browser page:
- After single---clicking the Power Chart icon (the middle one of the Applications) the login window
- Your Smartcard number is entered automatically by the single sign---on system then enter your Millennium passcode (this can be set---up to be the same as your Smartcard passcode a minimum of 4 digits like a bank PIN), and press enter key or click OK.

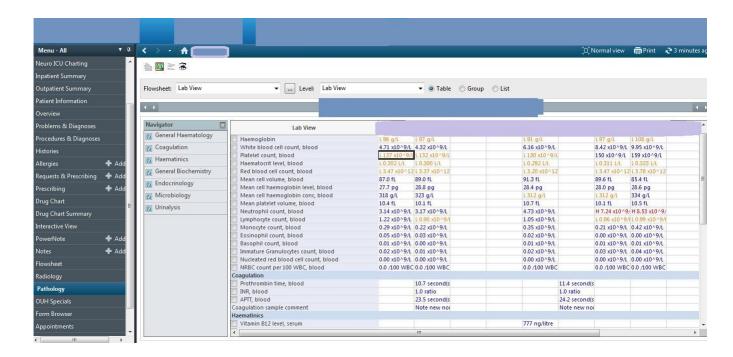
Forgotten your smartcard or it has stopped working?

- The Tap&Go infrastructure addresses a number of hardware usability and security issues that make the system easy for busy clinicians to use – faster login, fast user switching, without losing your active Millennium EPR session, secure session roaming, all using the NHS Smartcard with proximity sensor to automate the login process.
- However, if your Smartcard fails (nothing happens when you tap the sensor) or you forget it at home, then
 you can log in to your Citrix workspace e desktop by using your OUH network username and passcode
 entered into the Windows login window. This is the same process you would use if you accessed Citrix
 workspace from the web portal.

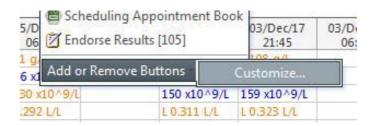
All Results should be endorsed (signed) on receipt.

- You can endorse results even if you have not requested them; you are part of a team and can sign results if you are tasked to check them.
- Endorsement ensures you have signed and if necessary, actioned a result.
- This is all about Patient Safety

- It is Trust Policy that ALL results must be endorsed.
- NB Results for FBC and Coagulation Screens will be released prior to final authorisation and may be subject to change.



Once Results reviewed click Endorse Results button.



Please remember: the Haematology laboratory does not manage EPR and is not responsible for training or the repair of equipment associated with EPR. Assistance with EPR should be directed towards OUH trust IM&T services on ext 22822.

Oxfordshire ICB GP Practices

Results are transmitted to relevant Practice IT systems after the result is authorised. Results are transmitted at 04:40, 07:50, 10:50, 12:50, 13:50, 14:50, 16:50, 17:50, 19:50 and 22:50 and would be available for collection by the practice IT after that time.

If there are any problems in receipt of results, please contact the Directorate IT team on (01865 2) 20463. Contact Details: kevin.paddon@ouh.nhs.uk

Oxford Integrated Bone Marrow Service

The integrated Bone Marrow Reports are available to colleagues in neighbouring partner hospitals by access to a secure website. If registered to access the Integrated Reports Website, please click on: http://oxfordir.oxnet.nhs.uk. NB. It only works from an NHS networked (N3) computer.

To apply for access contact Dr A Timbs mail to: Adele.Timbs@ouh.nhs.uk

RAID Anticoagulant Dosing Service

Results are posted direct to patients using First class post. Results which require a Recall test of the patient in less than 7 days will be phoned to the patient by the Nurse Specialist team.

All other users

Results will be produced hard copy and sent by second class mail.

NPEX

National Pathology Exchange, <u>The National Exchange for the UK NHS</u>. The OUH is registered and has been since 2015. We are receiving requests and samples and sending reports to a variety of users by this route, to use this route please contact Mr Kevin Paddon, <u>kevin.paddon@ouh.nhs.uk</u> initially.

Retrospective Testing

In accordance with local policies, the department stores specimens for a period of time post analysis in conditions suitable for retrospective or additional test requests. With certain analysis there is a time limit outside of which the stored sample is likely to unsuitable for processing. The following table will give information on such time limits for commonly encountered tests. For any tests that are not on this list, please contact the department for advice. Outside of the times stated on this list new samples will be required.

Test	Availability	Storage comments
FBC	All sites	Samples are suitable for processing up to 48 hours from collection. Samples however are retained by the department for 24 hours post analysis, so may not be available for use
ESR	Horton and JR sites	Samples if available are suitable for testing up to 24 hours post collection
Plasma Viscosity	JR site	Samples if available are suitable for testing up to 7 days post collection, however samples are only stored for a minimum time period so may not be available for use
Glandular Fever Screen	Horton and JR sites	Serum samples, if available, are suitable for testing up to 72 hours post collection.
		EDTA samples, if available, are suitable for testing up to 24 hours post collection.
G6PD assay	Horton site	EDTA samples if available are suitable for testing up to 5 days post collection.
Malaria RDT screen (usually performed with blood films)	Horton and JR sites	Samples are suitable for testing up to 48 hours post collection, on a suitable EDTA sample
Blood Films / Malaria Film	Horton and JR sites	Samples are suitable for testing up to 24 hours post collection, on a suitable EDTA sample
Flow Cytometry	JR site	Samples if available are suitable for testing up to 72 hours post collection, on a suitable EDTA sample
Sickle Test	Horton and JR sites	Samples if available are suitable for testing up to 4 days post collection.
Haemoglobinopathy Screen	JR & Churchill site	Samples if available are suitable for testing up to 4 days post collection.
PT / INR	All sites,	Samples are suitable for testing up to 24 hours post collection
APTT	All sites,	Samples are suitable for testing up to 8 hours post collection
Thrombin Time	All sites	Samples are suitable for testing up to 8 hours post collection
Fibrinogen	All sites	Samples are suitable for testing up to 8 hours post collection

D-Dimers	All sites	Samples are suitable for testing up to 24 hours post collection
Factor Assays	OHTC sites	Samples are suitable for testing up to 8 hours post collection, however fresh samples (<4 hours old) are strongly recommended
Platelet function testing	OHTC site	Unspun citrate samples required, these must be fresh (<4 hours old max, ideally < 2), older samples cannot be tested. Contact the OHTC before collecting samples.
Haematinic Assays (including Red Cell Folates)	Horton and JR sites	Samples if available are suitable for testing up to 72 hours post collection.
Haptoglobins	Horton site	Samples if available are suitable for testing up to 72 hours post collection.
DAT	Horton and JR sites	Samples if available are suitable for testing up to 72 hours post collection.

Sample Analysis Turnaround times

This document provides information on turnaround times for commonly encountered assays offered by the department. During routine processing, the department will endeavour to process samples to within these stated time limits. In situation of reduced staffing or unexpected analyser failure, processing times may be longer. The times stated are in-laboratory turnaround times and do not take any account of delivery of sample to department or delivery of report to final location. For any process not covered and for samples stated as urgent, we will attempt to process them as rapidly as practical, within operational constraints.

Analysis	Urgency	Turnaround (unless stated this refers to 95% of samples being processed in the given time period)
Routine Haematology	FBC: Out-patient / GP	98% <12 hours
	FBC: In-patient	3 hours
	FBC: A&E	95% < 60 minutes ⁵
	ESR	4 hours
	Routine Plasma Viscosity	72 hours
	G6PD	3 days, batches run twice a week
	Pyruvate Kinase (send away test)	7 days ⁶
	Urgent Sickle screen	2 hours
	Glandular Fever screen	24 hours
Morphology	Malaria Screen	7 hours
	Routine Blood Film	12 hours (Mon – Fri)
	Urgent blood film	4 hours (Mon – Fri)
	CSF Cytospin	2 days
Coagulation	Pre-op coagulation screen	4 hours
	Urgent coagulation screen (A&E)	95% < 1 hour ⁵
	Urgent INR (Warfarin Control)	1 hour
	Urgent APTT (Heparin control)	1 hour
	INR (GP only)	98% < 24 hours ¹

	Urgent D-Dimer (DVT screen)	1 hour
	Direct Thrombin Inhibitor screen	4 hours
	Urgent Factor deficiency investigation	5 hours
	Factor deficiency Investigation	1 week
	Von Willebrand's factor	2 weeks
	Thrombophilia Screen	3 weeks
Immunophenotyping	Leukaemia diagnosis	Formal report within 1 week
Blood Transfusion	Routine Group & Antibody Screen	24 hours ²
	Urgent Group & Antibody Screen	3 hours ²
	Routine Antenatal Serology	48 hours ³
	Routine Post Natal Rh- Negative testing	36 hours
	Urgent Crossmatch request	1 hour ²

²Turnaround times are only achievable on patients with no special transfusion requirements and a negative antibody screen.

Key Factors known to affect result quality.

Although all analytical methods used by the department are appropriately controlled by internal and external quality assurance methods, there are some factors that can affect the specific analytical methods. This document will cover the factors affecting the most common tests; information on other tests is available from the relevant sections on request.

³This excludes any samples that require further investigations.

⁴ Depending on the complexity of the investigation.

⁵ Locally agreed in laboratory TAT with ED (January 2010)

⁶ as this is a sendaway test, extra time may be needed to cover postal services and weekends.

- Correct sample collection, storage, and transport to the laboratory: can minimize sample degradation pre
 analysis. For any analysis that requires whole (EDTA) blood, samples which contain clots are unlikely to be
 suitable for processing.
- Correct sample volume:
 - o for certain tests (e.g., Coagulation screens) this is essential as the tubes contain a liquid anticoagulant.
 - o For other tests, there will be a minimum amount of sample required for correct analysis. Samples that do not contain this will not be processed.
 - Other samples such as for ESR have significant volume requirements, so sending partially filled bottles may result in the laboratory being unable to process.
- Sample age: in general samples should be transported without delay to the laboratory post collection. However, with some tests the delay is more critical than with others. Please refer to the retrospective testing table for information on this.
- Haemoglobin: this test includes a spectrophotometric process, so excessive jaundice and lipaemia may affect the result. This can be detected in the laboratory and corrected for before releasing results.
- Platelet clumping: this is a non-specific immunological process that can lead to a falsely low platelet count.
 The current analysers used in the department check for this and the laboratory will amend results appropriately.
- Clotting tests: may be affected by the presence of anticoagulants; however, this affect will depend on the specific test and the specific anticoagulant. More information is available from the OHTC on ext 25311.
- Certain clotting tests include a spectrophotometric end point detection process. Therefore, as with Haemoglobin, the laboratory may not be able to process any samples that are excessively haemolysed or jaundiced.
- Certain clotting tests (especially platelet function analysis) cannot be transported to the department using the trust air tube system. In addition, these samples need to be as fresh as possible (less than 4 hours from collection), so please contact the OHTC on ext. 25311 before samples are taken.
- Haemoglobinopathy screens:
 - Results will be affected by the patient receiving recent blood transfusions or Bone marrow transplant. This should be discussed with the section before sending the sample as it may be prudent to defer testing for a period of time.
 - HbA2 levels: can be lowered in severe iron deficiency, clinical advice should be sought before testing.

Sickle Screening:

- Results obtained from neonates (< 6 months old) may be unreliable because of the low percentage of HbS and the high percentage of HbF.
- o Abnormally high levels of plasma protein (e.g., Myeloma) may cause false positive results.
- The kit may not reliably produce a positive result in patients who have an HbS level of less than 20%.
- Samples that have Hb less than 60 g/l are deemed grossly anaemic, and the sickle screen results may be affected due to the larger plasma: red cell ratio.
- Glandular Fever (infectious mononucleosis screen):
 - False positive result may occur in serum samples from patients with a recent infection of cytomegalovirus, leptospirosis, hepatitis A and parvovirus.
 - Some patients do not develop heterophile antibodies (<20% adults and 50% children), so will
 consistently produce a false negative result.

Malaria RDT test

- This is a screening test, as such it may not detect all very early parasite infections, so a negative result does not exclude Malaria in the presence of relevant clinical symptoms and patient history.
- o Currently no Malaria RDT test can consistently identify all cases of P. knowlesi in isolation.

 The Malaria RDT test use in the department may not be able to speciate P Falciparum cases where there is a mutation in the HRP2 gene, the test will however still be positive for plasmodium species.

G6PD assay

- This assay may be affected by a high reticulocyte count, as reticulocytes contain a high level of G6PD. It is recommended that G6PD assays are not performed if the patient is undergoing acute haemolysis.
- Neonates may have higher levels of G6PD than adults, this can be independent of the reticulocytes count.
- The gene for G6PD is on the X chromosome, female carriers should demonstrate approximately 50% normal red cell G6PD activity, however due to mosaicism, activity will vary depending on the population of red cells expressing the gene (lyonization), as such this assay cannot be used to determine heterozygous state in females.
- Blood transfusion samples: results obtained from these samples may be affected if the patient has recently received a blood transfusion or bone marrow transplant. Because of this, it is very important to ensure that the blood bank is aware of this information.

Blood Transfusion

Requests for Blood and Blood Products for Transfusion

There is a Trust "**Blood Transfusion Policies and Procedures**", a copy should be available on all wards or from on the intranet: Welcome to Blood Transfusion website

You must make yourself familiar with it if you need to request blood for transfusion.

When trained and deemed competent, doctors, nurses, phlebotomists, and medical students may take blood specimens for grouping and crossmatching. Staff who are untrained are not permitted to take blood samples for transfusion.

Particular attention must be paid to positive identification of the patient based on interrogation of the patient where possible, a wristband and the patient's hospital notes.

As a further safeguard, in addition to patient's name and other relevant information on the specimen and request card, **BloodTrack Tx** system must be used. This is an electronic system for which ensures that the patient sample is labelled correctly. It uses bar-coded wristbands in combination with a handheld computer to ensure positive patient identification and produce an on demand printed patient identification label. These labels are suitable for labelling a blood transfusion sample (NOTE: an addressograph label is not suitable). **The laboratory will not proceed with any incorrectly or inadequately labelled specimens.**

There is an expectation that samples will be accompanied by an electronic EPR request. Only in exceptional circumstances will samples be accepted with a completed signed request card.

Please note that a routine group and crossmatch will take a minimum of 3 hours. For planned transfusions including pre-planned surgical procedures, the specimen should arrive at the laboratory a full working day before the blood is required. Routine specimens received in the laboratory after 20:00 hours may not be processed until the following day in this case blood will be available by 10:00 if no atypical antibodies are present.

Patients with atypical antibodies

If you require blood for a patient with known red cell antibodies, please ensure the laboratory are given as much notice as possible. Although red cells suitable for most commonly occurring antibodies are kept in stock, for more unusual antibodies/combinations blood will need to be ordered from the NHSBT. For some combinations obtaining suitable red cells is difficult and there will be a considerable delay.

Emergency Transfusion including Massive Haemorrhage

The trust has a Massive Haemorrhage Protocol (MHP) which is available at OUH Major Haemorrhage Protocol

There is an expectation that clinical staff will be aware of how to activate the protocol and where a copy can be located.

Activation is by calling switchboard on 4444 – use the term activate the Major Haemorrhage Protocol and clearly state your site and location.

Other blood products

- 5% or 20% Human Albumin Solution
- Platelets
- Fresh Frozen Plasma

- Cryoprecipitate
- Prothrombin Complex concentrate (Octaplex)
- Prophylactic Anti-D

These are available on a named patient basis from the laboratory upon discussion with the staff on duty.

- FFP and Cryoprecipitate should only be ordered if it is to be used immediately.
- The department will not thaw out FFP and Cryoprecipitate on a "standby basis," although FFP may be available already thawed from within the laboratory.

Blood Ordering Schedule

The Trust has implemented a comprehensive system of remote blood issue in most of the theatre suites. This ensures that blood is available on request directly at the point of need for most operations. As such we no longer use a Blood Ordering schedule in its traditional sense.

Transfusion Sample Requirements

These are adult (> 7 years old) sample volume requirements, for children under 7 years old a minimum of 1.5 ml is required for group save and crossmatch. More may be required for patients requiring complex antibody investigations.

Tube Colour	Investigation
	Group and Save (Full, 4.5 ml EDTA) 2 x EDTA if patient known to have antibodies.
	Crossmatch Request (Full, 4.5 ml EDTA) 2 x EDTA if patient known to have antibodies
	Antenatal Serology: Full, 4.5 ml EDTA on mother. Other samples may need to be sent if haematology and haemoglobinopathy screening is required.
	Kleihauer test (2 ml EDTA) Routine samples on Rhesus negative mothers at delivery (2 ml EDTA on mother and baby)
	Direct Antiglobulin Test (DAT) (2 ml EDTA)
	Cold Agglutinins (Clot delivered to laboratory at 37°C in thermos flask, discuss the test with laboratory staff prior to collecting a sample)

Samples for Antenatal Testing:

Samples sent to the laboratory for antenatal testing should comply with the labelling requirements indicated above. In addition, if a patient is not yet registered with the Trust and for whom there is no NHS number available, the laboratory will accept the patients FULL address as a patient identifier (this will not be acceptable on samples for compatibility testing)

Appendix I Normal Ranges (Adult, 13 years+, apart from ESR: 17 years +)

FBC - EDTA sample required

Haemoglobin (Hb) Male: 130 - 170 g/l Haemoglobin (Hb) Female: 120 - 165 g/l Red cell count (RBC) Male: $4.5-6.2 \times 10^{12}$ /l Red cell count (RBC) Female: $3.8-5.0 \times 10^{12}$ /l

Haematocrit (Hct) Male: 0.40 - 0.50 I/I Haematocrit (Hct) Female: 0.36 - 0.46 I/I Mean Cell Volume (MCV): 83 - 101 fl Mean cell Hb (MCH): 27.0 - 32.0 pg

Mean cell Hb concentration (MCHC): 315 - 360 g/l Red Cell Distribution Width (RDW): 11.5 – 16.0% Reticulocytes percentage (RET): 0.5 - 2.5% Reticulocytes absolute (RET): 40 – 120 x10⁹/l

Ret-He: 28.7-37.6 pg

Nucleated RBC percentage (NRBC): 0 - 0.2%Nucleated RBC absolute (NRBC): $0 - 0.5 \times 10^9/l$

White cell count (WBC): 3.7-11.0 x109/l

Neutrophil count: 1.7 -7.5 x10⁹/l Lymphocyte count: 0.9 -4.0 x10⁹/l Monocyte count: 0.2 - 1.0 x10⁹/l Eosinophil count: 0.0-0.5 x10⁹/l Basophil count: 0.0-0.1 X10⁹/l

Immature Granulocytes (IG): 0 – 0.1 x10⁹/l

Platelets (Plt): 150-400 x109/l

Immature Platelet Fraction (IPF): $2.3 - 12.7 \times 10^9$ /I Mean Platelet Volume (MPV): 9.0 - 13.0 fl

Plasma Viscosity at 25°C (EDTA): 1.50 - 1.72 MPa/s Glandular fever screen (Monospot) (EDTA / Clot)

Erythrocyte Sedimentation Rate (ESR) - EDTA sample required

ESR Male 17-69 years: 1-14 mm /hr ESR Male >70 years: 1-30 mm/hr ESR Female 17-69 years: 1-20 mm/hr ESR Female >70 years: 1-35 mm/hr

COAGULATION- Citrate sample required

Prothrombin time (PT): 9.0 - 12.0 sec

Activated Partial Thromboplastin Time (APTT): 20.0 - 30.0 sec

International Normalised Ratio (INR) (*Discuss with anticoagulation nurse specialist): 2.0-4.0*

Thrombin time (TT): 14.0-19.0 sec Reptilase Time: 16.0 – 22.0 sec Fibrinogen (Fib): 1.5-4.0 g/l D-Dimers: < 500μg/l FEU

Protein C: 0.70 - 1.40 IU/ml

Protein S Free (Male): 0.70 - 1.50 IU/ml Protein S Free (Female): 0.55 - 1.35 IU/ml Antithrombin (AT): 0.80 - 1.20 IU/ml

Dilute Russell's Viper Venom Tests (DRVVT) ratio: 0.80 - 1.20

Actin FSL ratio: 0.70 - 1.30

ADAMTS 13 activity: 60.6 – 130.6 IU/dl ADAMTS 13 Inhibitor: 0 – 12.0 IU/ml

Heparin levels (UFH / MWH) 0.50 - 1.00 U/ml

Von-Willebrand Factor (AG & activity & CBA): 0.50-2.00 IU/ml

Factor VIII / IX: 0.50 – 2.00 IU/ml Factor II, V, VII & XII: 0.50 – 2.00 IU/ml

Factor XI: 0.70-1.30 IU/ml Factor XIII: 0.70-1.40 IU/ml α 2-Antiplasmin : 0.80-1.30 IU/ml Plasminogen : 0.75-1.50 IU/ml

PFA: Collagen/ADP: 55 - 112 Sec

PFA: Collagen / Epinephrine: 79 - 164 Sec

Platelet Nucleotides (ATP): $25-60 \times 10^9$ /l plt Platelet Nucleotides (ADP): $20-40 \times 10^9$ /l plt Platelet Nucleotides (Ratio): 0.8 - 2.2

Chronolog Thrombin 1u/ml: 0.5 – 2.0 nmole Chronolog Collagen 2ug/ml: 0.5 – 1.7 nmole Chronolog Collagen 5ug/ml: 0.9 – 1.7 nmole

HAEMOGLOBINOPATHY (EDTA sample)

Thalassaemia screen

HbF: < 1.0% HbA2: 2.0 - 3.4%

RED CELL ENZYMES (EDTA sample)

Glucose-6 Phosphate Dehydrogenase (G6PD): 5.8-18.8 u/gHb

Pyruvate Kinase (PK) (send away test): 6.2-14.2 u/gHb

Ranges updated: 28/04/24. Ranges Reviewed 28/04/24.

Codes used in reference range list -

Although other samples may be useable, this is the preferred sample type.

EDTA – Purple topped EDTA anticoagulated tube.

Citrate – light blue topped Sodium Citrate anticoagulated tube

Clot – Yellow / Gold topped non anticoagulated clotted sample.

Reference range source

Ranges have been derived from a number of reputable sources.

- Adult Normal FBC & ESR Ranges derived from Practical Haematology; 11^h edition Dacie & Lewis 2012; checked and verified as part of new equipment implementation 2015. Amendments made to ranges with clinical oversight to reflect local population. Ranges reviewed as part of S4 harmonisation process 2022-23
- 2. Haemoglobinopathy ranges derived from Practical Haematology; 11th edition Dacie & Lewis 2012.
- 3. Coagulation and Haematinic ranges derived from manufacturers recommendations but checked and amended as part of new equipment verification 2015.
- 4. PT range amended as part of new batch change September 2018
- 5. PK range supplied by external referral laboratory.
- 6. G6PD range supplied by manufacturer of assay and verified by laboratory September 2017
- 7. Haptoglobin reviewed and updated as part of a formal verification of method in 2017, but with reference to Practical Haematology, 11th edition, Dacie & Lewis 2012.
- 8. IPF range adapted from Haematology reference intervals for established and novel parameters in healthy adults. J.M. Pekelharing et al, checked with local study in 2019.

Please note.

- Ranges for patients below the age of 13 are available on request from the quality manager (Andrew.platt@ouh.nhs.uk) or 01865 857663.
- There are no formal ranges available for the ESR test for patients <17 years, if needed clinical advice on the interpretation of results is available from HaematologyRegistrarEnquiries@nhs.net.

Due to ethical issues surrounding generation of internal ranges, reference ranges for children are derived from published sources.

- 1. Practical Haematology; 12th edition Dacie & Lewis 2017
- 2. Diagnosis in Paediatric Haematology: 1st Edition Harry N Smith 1996
- 3. Pediatric Hematology: 2nd Edition J S Lilleyman et all 1999

Appendix II, Departmental Telephone Numbers

General Enquiries	Ext	
Combined Haematology / Biochemistry office (JRH)	(01865 2) 20336	
Haematology / Coagulation (Horton)	(01295 2) 29369 / 24172	
Oxford Haemophilia & Thrombosis Centre (NOC)	(01865 2) 25311	
Blood Transfusion Laboratory (JR2 & Churchill)	(01865 2) 20339 / 20340	
Blood Transfusion (Horton)	(01295 2) 29236	
Immunophenotyping Laboratory (JRH)	(01865 5) 72827	
Medical Assistance – Monday to Friday 8:30-17:00 only		
Blood Transfusion Duty Registrar	(01865 741166) Bleep 6888	
Haemostasis Duty Registrar	(01865 741166) Bleep 5529	
Haematology Duty Registrar	(01865 741166) Bleep 1836	
Duty Registrar outside of core hours ask Switchboard to bleep duty Haematology Registrar.	JRH Switch 0300 3047777	
For <u>non-urgent</u> clinical enquiries please email	HaematologyRegistrarEnquiries@nhs.net	
For all Sickle Cell & Thalassaemia Screening Support	SCTLab.support@ouh.nhs.uk	
Service queries		
For Haemoglobinopathy screening queries please	hbopathy.screening@ouh.nhs.uk	
Staff contact details.		
Registrars (JR)*	01865 (2) 20367 or bleep 1836	
Registrars (Churchill)*	01865 (2) 35884 / 35885 or bleep 1836	
Laboratory Manager - Mr. D Smith (<u>Dan.smith@ouh.nhs.uk</u>)	01865 (2) 20337	
Quality Manager – Mr. A Platt (<u>Andrew.platt@ouh.nhs.uk</u>)	01865 (8) 57663	
Blood Bank Manager – Miss J Staves**	01865 (2) 20334	
Morphology / Flow contact – Mr Ashley Cooper**	01865 (5) 72827	
Coagulation Contact – Mr. P Baker**		
Horton lead (combined with Biochemistry) – Mrs R Kandola**	01865 (8) 57096	
Automated Haematology contact – Mr M Jacobs**	01295 (2) 29243	
Laboratory secretary	01865 (2) 21125	
	01865 (5) 72824	
Dr Pavord's Secretary	01865 (5) 72824	

^{*}For <u>non-urgent</u> clinical enquiries please use the dedicated Haematology registrar email <u>HaematologyRegistrarEnquiries@nhs.net</u>. This will be checked on a daily basis only, for urgent enquiries please phone or bleep.

^{**} These contacts should be used if there is a non-routine issue with a specific department otherwise, please use the general enquiries number or email address.

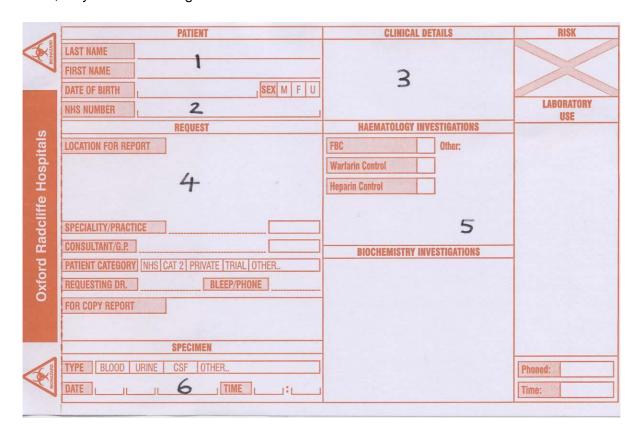
Appendix III, Examples of Haematology Request forms

Please note it is expected that the majority of requests made to the department will be made on either Cerner EPR (inpatients / outpatients) or via CliniSys ICE (GP). If available in your clinical areas the laboratory would strongly urge you to use these systems instead of using paper forms.

If using paper forms, please ensure that on each request form, the individual collecting blood, signs the form.

Haematology / Biochemistry Joint Requesting form (in use from January 2007)

This form has replaced both JR and Horton Haematology & Biochemistry forms; this form is to be used, only if EPR ordering is not available.



- 1. Please fill in the patients' full name & Date of Birth; insufficiently labelled samples or cards will not be tested. If available, it is acceptable to use addressograph labels on request forms.
- 2. Please use either NHS or Hospital number on all requests; it enables the department to merge results with previous records on the patient.
- 3. Clinical information is very important, especially for some Biochemistry requests. Please do not leave this blank.
- 4. Please include a patient location on all request cards, it will enable the laboratory to telephone the results if abnormal or if the sample is unsuitable for testing. For GP patients, please remember to give the requesting GP's name and location.
- 5. Please list the tests required, for Haematology & Biochemistry. For information on sample requirements, please refer to section in laboratory handbook. Please ensure that you have

taken sufficient blood in suitable tubes for the required tests. If the sample is urgent, please make this clear on the form.

6. Please fill in date and time of sample collection.

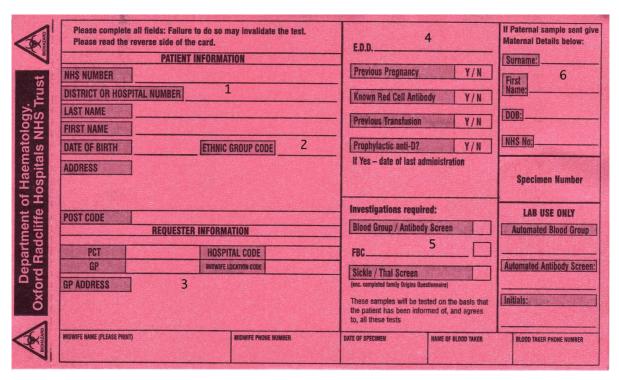
Blood Transfusion Form: This form is being used on all sites not using EPR ordering.

PATIENT	RED LABEL (enly to be used if SafeTX is unavailable	LABORATORY USE ONLY	
FIRST NAME DATE OF BIRTH 2 SEX M F	GROUP AND SAVE	SPECIMEN NUMBER(S)	
NHS NUMBER REQUEST	CROSS MATCH		
CONSULTANT LOCATION	NUMBER OF UNITS DATE REQUIRED 5	AUTOMATED BLOOD GROUP	
BLOOD GROUP AND ANTIBODY STATUS 4 CLINICAL DETAILS INCLUDING SURGICAL PROCEDURE	TIME REQUIRED	AUTOMATED ANTOBODY SCREEN	
INDICATION COD	HOSPITAL YES / NO	AUTOMATED ANTOBODY SCREEN	
		GROUP B D1 D2 Ac Bc	
NAME OF BLOOD TAKER DATE/TIME	TRANSPORT DETAILS	CHECK GROUP	
NAME OF REQUESTER BLEEP	BOX NUMBER	B D1 Abserum Ab SCREEN	
SIGNATURE 3	BOX NUMBER BOX NUMBER	SC1 SC2 SC3	
REQUESTS WITHOUT CLINICAL DETAILS OR SIGNATURE OF REQUESTING DOCTOR WILL NOT BE PROCESSED			

- 1. Patient's full name must be on the form and on the sample, not the one that the patient "likes to be known by." The correct hospital number or NHS number and date of birth must be on sample and form. If they are missing or do not match, the sample will not be processed. The use of addressograph labels on request forms (not samples) is encouraged.
- 2. If the SafeTx system is being used, there is no need to use the Red label system. Please ensure that a SafeTx label is on the request card and sample. If using the Red Label system, the red label must be on the form, sample, and patient's wristband and in the patient's notes. If the red label is missing from any of these, new samples will necessary. Incorrectly labelled forms will not be processed.
- 3. All forms must be signed, at least by the doctor requesting the transfusion: <u>no signature, no processing of sample</u>. It is important that we can work out who you are, so please write clearly!
- 4. It is essential to the blood bank that this section is filled in as completely as possible. It is of particular importance if the patient is thought to have red cell antibodies or has been transfused in another hospital.
- 5. Finally, tell us what you want when you want it and where you want it. If blood is truly required urgently then telephone the department to let us know that the sample is coming.

JR & Horton Blood bank Antenatal Request form.

As of January 2007, all antenatal (AN) samples will be processed on the JR site, please use this form for such samples.



- 1. Please ensure that you put the following information as a minimum on the form in this section:
 - a. NHS number (Hospital number is acceptable)
 - b. Full patient name.
 - c. Date of birth
- 2. Please enter the applicable ethnic code.
- 3. Please ensure that the following information is included on this form:
 - a. Midwife location code (very important) NOT the GP location code
 - b. Midwife name and contact details.
 - c. Date (and time) sample taken.
- 4. Please ensure that all the questions are answered in this section.
- 5. Please send sufficient samples for the requested tests. Current departmental policy does not allow samples to be shared for FBC and Blood grouping:
 - a. Blood Group & Antibody Screen 1x EDTA
 - b. FBC / Sickle / Thalassaemia screen 1 x EDTA
 - c. <u>Please make sure that a family origins questionnaire is included with all requests for Sickle or Thalassaemia screens.</u>
- 6. If the sample is from a partner of an antenatal patient (AN), it is very important that the AN patient details are completed in this section. The majority of partner sample request forms will be labelled with a yellow sticker.

In addition to this information, please ensure that you read the back of the request form.

Please note: Family Origins questionnaire can be completed electronically via the ICE system (request via Antenatal Haemoglobinopathy screen set) if this facility is available.