**North Glasgow Hospitals**

**Department of Haematology Service Users Handbook**







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# Introduction

The NHSGG&C Diagnostics Division, Department of Haematology, North Sector provides a comprehensive routine and specialist haematology service. This service is provided by laboratories located at Gartnavel General Hospital, Glasgow Royal Infirmary, Stobhill Ambulatory Care Hospital and the West Glasgow Ambulatory Care Hospital.

The Department complies with national and international standards assessed by UKAS (ISO 15189:2012) and regulated by the MHRA and is committed to meeting the needs and requirements of service users.

This Handbook is designed to provide information about using the Haematology and Blood Transfusion service. Within this handbook, along with contact details can be found information about specimen requirements, specimen identification, request form requirements, safety considerations, transport, reference ranges, turnaround times and other information about assays as is appropriate.

# General Information

The department currently provides services at four sites. These are Gartnavel General Hospital, Glasgow Royal Infirmary, Stobhill ACH and West Glasgow ACH

The Department provides a diagnostic laboratory service which includes:

* Core diagnostic laboratory services.
* Consultant led clinical advice and test interpretation.
* Regional specialised thrombosis and haemostasis laboratory service (Glasgow Royal Infirmary).
* A National Allogeneic Stem Cell and Regional Autologous Stem Cell processing service in association with the West of Scotland Bone Marrow Transplant Unit (Gartnavel General Hospital).
* Regional Immunophenotyping (cell marker) service for the diagnosis of haematological abnormalities and malignancies (Gartnavel General Hospital).
* Blood Transfusion Services (Glasgow Royal Infirmary and Gartnavel General Hospital).

Our Quality manual, quality policy and other information can be found on our webpage on the NHSGGC website please follow the link in section 4.2

## Regulation and Accreditation

The Haematology Department for the North Glasgow Sector of Greater Glasgow and Clyde is regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) for compliance to The Medicines for Human Use (Clinical Trials) Regulations 2004 and the Blood Safety Quality Regulations 2005 (Amendment 2007), compliance with the Human Tissues Act 2004 by the Human Tissue Authority (HTA), compliance to the JACIE standards by The Joint Accreditation Committee ISCT-Europe and EBMT. It is also accredited by the United Kingdom Accreditation service (UKAS Number 9570) to the international standard ISO15189-2022. Further information on the department’s scope of accreditation to ISO15189-2022 and accredited processes are available on the UKAS website or via the departments website. The department’s schedule of scope can be found by following the link below.

[9570-Medical-Multiple.pdf (ukas.com)](https://www.ukas.com/download-schedule/9570/Medical/)

## Complaints

Should there be cause to raise a complaint or users wish to feedback about the laboratory service a copy of the department’s feedback and complaints procedure can be found on the laboratory web page or from the Quality Manager on request. A copy of the NHSGGC complaints policy can be found on the NHSGGC website. A complaints form can be found on the department’s web page.

## Result Enquiries

Telephoning for results can be wasteful of time, both in the clinical areas and in the Haematology department, before telephoning the department service users including primary care should check for results on Clinical Portal, TrakCare or any other relevant information systems. This is the fastest and most efficient way of obtaining results. If results are not available it is most likely that the analyses are not complete. Please only contact the laboratory directly for urgent results.

All extremely abnormal results will be phoned to the requesting clinician, GP or clinical area as soon as they become available.

# Laboratory Hours

## Gartnavel General Hospital

Haematology and Haemostasis: 09:00 to 20:00 Monday to Friday

Blood Transfusion: 09:00 to 20:00 Monday to Friday

Haemato-Oncology: 09:00 to 17:00 Monday to Friday

The Blood Transfusion, Haematology and Haemostasis laboratory service is provided from Glasgow Royal Infirmary outside these hours.

## Glasgow Royal Infirmary

24 Hour service provided (core hours 08:00 to 17:00)

## Stobhill ACH

Haematology and Coagulation: 09:00 to 17:00 Monday to Friday

The laboratory service is provided from Glasgow Royal Infirmary outside these hours

## West Glasgow ACH

Haematology: 09:00 to 13:00 Wednesday **ONLY**.

This laboratory service is for the provision of the Haematology Clinic **ONLY**.

## 24 Hour Service

The 24 hour laboratory service is provided from the Glasgow Royal Infirmary Site and consists primarily of a core haematology, core Haemostasis and blood transfusion service. Specific tests can be arranged by discussion with the on-call haematologist. There is no 24 hour service on site at Gartnavel General Hospital, Stobhill ACH or the West Glasgow ACH, this service is provided from the Glasgow Royal Infirmary Site.

# Contact Details

## Postal Addresses

**Gartnavel General Hospital**

Department of Haematology or Haemato-Oncology

Gartnavel General Hospital,

Paul O’Gorman Building

21 Shelley Road

Glasgow

G12 0XB

**Glasgow Royal Infirmary**

Department of Haematology

McEwan Building

Glasgow Royal Infirmary

Castle Street

G4 0SF

**Stobhill ACH**

Haematology Laboratory

Stobhill Ambulatory Care Hospital

Stobhill

Glasgow

G21 3EW

**West Glasgow ACH**

Haematology Laboratory

West Glasgow Ambulatory Care Hospital

Yorkhill

Glasgow

G3 8SJ

## Website

## <https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/haematology-and-blood-transfusion/>

## Telephone Numbers

Please note some clinical and laboratory staff work at, or cover more than one site within the North Glasgow Sector.

### Result Enquiries

Telephoning for results can be wasteful of time, both in the clinical areas and in the Haematology department, before telephoning the department service users including primary care should check for results on Clinical Portal, TrakCare or any other relevant information systems. This is the fastest and most efficient way of obtaining results. If results are not available it is most likely that the analyses are not complete. Please only contact the laboratory directly for urgent results.

All extremely abnormal results will be phoned to the requesting clinician, GP or clinical area as soon as they become available.

### Gartnavel General Hospital Laboratory

External callers dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

Haematology and Haemostasis: 0141 301 Ext: (5)7721

Haemato-Oncology, Immunophenotyping and Stem Cell: 0141 301 Ext: (5)7708

Blood Transfusion: 0141 301 Ext: (5)7729

### Glasgow Royal Infirmary Laboratory

External callers dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

Blood Transfusion 0141 242 Ext: (2)9603

0141 242 Ext: (2)9604 0141 242 Ext: (2)9606

Haemostasis 0141 242 Ext: (2)9605

Haematology 0141 242 Ext: (2)9601

Haematology 0141 242 Ext: (2)9602

Special Haemostasis 0141 242 Ext: (2)9552

### Stobhill ACH Laboratory

External callers dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

All Laboratory Enquiries: 0141 355 Ext: (1)1469

### West Glasgow ACH Laboratory

External callers dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

All Laboratory Enquiries: 0141 211 Ext: (8)6946

#### Out of Hours Contact Numbers

**All Sites**

Out of Hours (see laboratory hours in section 3 for details) the Glasgow Royal Infirmary Laboratory can be contacted by using the appropriate extension number. Clinical advice can be obtained by contacting switchboard and asking for the duty Haematologist.

There is no 24 hour service on site at Gartnavel General Hospital, Stobhill ACH or West Glasgow ACH, this services is provided from the Glasgow Royal Infirmary site.

### Gartnavel General Hospital Clinical Staff

External callers dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

**Consultants**

Dr M Drummond 0141 301 Ext: (5)7734 email: mark.drummond@ggc.scot.nhs.uk

Secretary 0141 301 Ext: (5)7712

Dr M Leach 0141 301 Ext: (5)7736 email: mike.leach@ggc.scot.nhs.uk

Secretary 0141 301 Ext: (5)7713

 0141 301 Ext: (5)5305

Dr P McKay 0141 301 Ext: (5)7735 email: pam.mckay@ggc.scot.nhs.uk

Secretary 0141 301 Ext: (5)7711

Dr J Travers 0141 301 Ext: (5)7732 email: jennifer.travers@ggc.scot.nhs.uk

Secretary 0141 301 Ext: (5)7717

Dr C McDermott 0141 301 Ext: (5)7747 email: christopher.mcdermott@ggc.scot.nhs.uk

Secretary 0141 301 Ext: (5)7717

Dr R Soutar 0141 301 Ext: (5)7733 email: richard.soutar@ggc.scot.nhs.uk

Secretary 0141 301 Ext: (5)7715

### Glasgow Royal Infirmary Clinical Staff

Outside NHSGG&C, dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

**Consultants:**

Dr C Bagot 0141 242 Ext: (2)9594 email: catherine.bagot@ggc.scot.nhs.uk

Secretary 0141 201 Ext: (6)5306

Dr L McIlwaine 0141 242 Ext: (2)9595 email: louisa.mcilwaine@ggc.scot.nhs.uk

Secretary 0141 201 Ext: (6)5306

Dr R Rodgers 0141 242 Ext: (2)9593 email: ryan.rodgers@ggc.scot.nhs.uk

Secretary: 0141 201 Ext: (1)5305

Dr A Gibson 0141 242 Ext: (2)9554 email: alison.gibson@ggc.scot.nhs.uk

Secretary 0141 201 Ext: (1)3654

Dr M Wilson 0141 242 Ext: (2)9592 email: Matthew.wilson@ggc.scot.nhs.uk

Secretary 0141 242 Ext: (1)3654

### Registrars (Glasgow Royal Infirmary)

On Duty Registrar Page: 13733

Registrars’ Office 0141 201 Ext: (1)3641

 0141 201 Ext: (1)3655

 0141 242 Ext: (2)9590

 0141 242 Ext: (2)9591

### Registrars (Gartnavel General Hospital)

Registrars’ Office 0141 301 Ext: (5)7753

### Stobhill ACH Clinical Staff

External callers dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

**Consultant:**

Dr M Leach 0141 301 Ext: (5)7736 email: mike.leach@ggc.scot.nhs.uk

Secretary 0141 301 Ext: (5)7713

Dr L McIlwaine 0141 201 Ext: (1)3655 email: louisa.mcilwaine@ggc.scot.nhs.uk

Secretary 0141 201 Ext: (6)5306

Dr A Gibson 0141 242 Ext: (2)9554 email: alison.gibson@ggc.scot.nhs.uk

Secretary 0141 201 Ext: (1)3654

### Senior Laboratory Staff (All sites)

Outside NHSGG&C, dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

**Technical Services Manager**

Mrs Claire McKie 0141 242 Ext: (2)9529 (Glasgow Royal Infirmary)

0141 301 Ext: (5)7727 (Gartnavel General Hospital)

0141 355 Ext: (1)1469 (Stobhill ACH)

email: claire.mckie@ggc.scot.nhs.uk

 **Sector Laboratory Manager**

Ms Arlene David 0141 242 Ext: (2)9530 (Glasgow Royal Infirmary)

0141 301 Ext: (5)7727 (Gartnavel General hospital)

0141 355 Ext: (1)1469 (Stobhill ACH)

email: arlene.david@ggc.scot.nhs.uk

**Quality, Training and POCT Manager**

Mr Kevin Marriott 0141 242 Ext: (2)9597 (Glasgow Royal Infirmary)

0141 301 Ext: (5)7727 (Gartnavel General Hospital)

0141 355 Ext: (1)1469 (Stobhill ACH)

email: kevin.marriott@ggc.scot.nhs.uk

### Lead Scientific Staff Gartnavel General Hospital

Please note some laboratory staff work at, or cover more than one site within the North Glasgow Sector.

Outside NHSGG&C, dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

#### Blood Transfusion

Senior Biomedical Scientist 0141 301 Ext: (5)7727

#### Haemostasis

Senior Biomedical Scientist 0141 301 Ext: (5)7727

#### Haematology

Senior Biomedical Scientist 0141 301 Ext: (5)7727

#### Haemato-Oncology

Mrs Sharon Kelly 0141 301 Ext: (5)7707

email: sharon.kelly4@ggc.scot.nhs.uk

**Consultant Clinical Scientist**

Ms Gillian McGaffin 0141 301 Ext: (5)7709

email: gillian.mcgaffin@ggc.scot.nhs.uk

### Lead Scientific Staff Glasgow Royal Infirmary

Outside NHSGG&C, dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

#### Blood Transfusion

Ms Arlene David 0141 242 Ext: (2)9530

email: arlene.david@ggc.scot.nhs.uk

Senior Biomedical Scientist 0141 242 Ext: (2)9541

#### Haemostasis

Mrs Caroline Lawrence 0141 242 Ext: (2)9596

email: caroline.lawrence@ggc.scot.nhs.uk

#### Haematology

Senior Biomedical Scientist 0141 242 Ext: (2)9539

 0141 242 Ext: (2)9540

### Transfusion Practitioner

Outside NHSGG&C, dial full number omitting the number in brackets. Internal callers dial extension number prefixed by the number in brackets.

**Glasgow Royal Infirmary and Stobhill ACH**

Mrs Moira Caldwell 0141 242 Ext: (2)9583

email: moira.caldwell2@nhs.scot

**Gartnavel General Hospital**

Mrs Tina Watson 07789-616525

Email: tina.watson2@nhs.scot

# Urgent Samples, Advice and Result Interpretation

During normal hours, clinical and technical advice is available from scientific and clinical staff.

Out with core hour’s clinical advice is available by contacting the duty haematologist via switchboard and technical advice is available by telephone contact of laboratory staff. Please note there is no Haematology service at Stobhill ACH after 17:00. There is no Haematology service after 20:00 or Haemato-Oncology service after 17:00 at Gartnavel General Hospital, all enquiries must then be directed to the GRI laboratory or on call clinical staff.

## Urgent Samples

### Glasgow Royal Infirmary and Gartnavel General Hospital

Please contact the relevant laboratory on either site using the telephone numbers in section 4.3. Please note there is no Haematology service after 20:00 and no Haemato-Oncology service after 17:00 at Gartnavel General Hospital.

### Stobhill ACH

Please contact the Haematology laboratory on the telephone number in section 4.3.4 Please note as this is a rapid results service any sample received as routine or requiring a test not performed on the Stobhill ACH site may have already been transported to the GRI site, if advised that this has occurred please contact the GRI laboratory using the numbers in section 4.3.4 Please note there is no service at Stobhill ACH after 17:00

### West Glasgow ACH

This provides a service to the Haematology clinic only. All other samples are processed at the Queen Elizabeth University Hospital and all enquiries must be directed there.

### North East Glasgow GP’s

If a result is required by 18:00 then please contact the Glasgow Royal Infirmary Laboratory using the number in section 4.3.6

### North West Glasgow GP’s

Samples are processed at the Queen Elizabeth University Hospital please contact the laboratory there to advise of urgent samples.

Please use the following telephone number for the QEUH laboratory: 0141 354 9105

## Advice

Service Users can obtain technical advice from the laboratory including:

* Suitability of the assay
* Assays available in the laboratory.
* Significance of results
* Reference ranges

Please use the telephone numbers given in section 4.3 to contact the relevant scientific team or laboratory.

Service Users can obtain clinical advice including:

* Clinical suitability of the assay
* Treatment modality (if appropriate).
* Clinical interpretation of results

Please use the telephone numbers given in section 4.3 to contact the relevant clinical team.

### North West Glasgow GP’s

Samples for NW Glasgow primary care are processed at the Queen Elizabeth University Hospital (QEUH) however clinical advice is provided by the consultant team at Gartnavel general Hospital. To obtain clinical advice please use the contact numbers for the Gartnavel clinical team provided in section 4.3.6 for all other enquiries please contact the relevant QEUH laboratory.

# Specimen Collection

The following information in this section and its subsections, applies at all times whether taking a single sample or multiple samples from an individual.

It is the responsibility of the staff undertaking sample collection to ensure that the correct sample bottle type is selected, labelled accurately, form completed with all relevant information and transported to the laboratory in a timely and correct manner.

The sample bottles must be checked to ensure that the bottles have not exceeded their expiry date. Samples received in bottles that have expired will be rejected as the results will not be accurate.

Please note the following points relevant to collection (or venepuncture) of good quality specimens (see also sections 7.1.1, 7.1.2, 7.2.1, 7.2.3, 7.2.4, 7.3.1 5.2):

* **CONFIRM THE IDENTITY** of the patient **PRIOR** to sampling
* **NEVER** pre-label specimen tubes
* Ideally, the patient must be resting for a full five minutes before specimen collection
* Use good quality veins
* **NEVER** take blood from a drip arm
* Do not take samples for Haemostasis studies from heparinised lines
* Avoid prolonged application of the tourniquet both for patient comfort and to avoid haemolysis within the specimen.
* Samples **MUST** be filled to the fill line as marked on the bottle. This is essential for Haemostasis assays.
* Following collection, specimen bottles containing anticoagulant must be inverted several times to ensure adequate mixing.
* **Do not** decant blood from one tube to another – there are different additives and these will give erroneous results.
* Following collection, ensure specimen bottle is labelled, as detailed in Section 6.2
* Ensure Request Form is completed, as detailed in Section 6.2and that these details match those on the specimen bottle.
* Use a safe procedure at all times and dispose of sharps in sharps-boxes provided
* All specimens and request forms must be secured for transportation in the specimen compartment of an approved specimen transport bag
* Specimen tubes or request forms which are contaminated with blood will not be analysed
* Appropriate specimen containers must be used for each laboratory test.

## Specimen Type

The appropriate containers for haematological tests are available from the stores on each site they are not supplied by the department. The type and amount of anticoagulant varies depending on the investigations requested and the amount of blood required.

A colour-coded specimen container (relating to type of anticoagulant and its use for individual laboratory tests) and vacuum assisted venepuncture system (Greiner VacuetteTM) is used throughout NHS GG&C.

Wall charts and posters detailing the use of this system and the correct container for each test, are posted in most clinical areas throughout NHS GG&C, the specimen type is also detailed in sections 7.1 to 7.4. Additional guidance or information regarding the use of the Greiner VacuetteTM system may be obtained by contacting the Lead Phlebotomist.

A team of trained phlebotomists, covering all acute medical and surgical wards are available in all the North Sector Glasgow Hospitals. Public Holidays are covered by a limited service with details available from each Hospital Lead Phlebotomist.

## Sample Labelling

Sample bottles **MUST** be labelled at the patient’s side to avoid identification errors. **NEVER** place unlabelled samples in the same vicinity as others or label in a different area to the patient.

A fully completed request form must accompany a properly identified sample in all cases.

Minimal identifying particulars for Haematology and Haemostasis on **both** the request form and sample(s) (Not Blood Transfusion samples) are:

* Surname
* Forename
* CHI number
* Date of Birth

The form must also include:

* CHI number
* Gender
* Source of request i.e. ward and consultant in charge
* Brief clinical details
* Date of request
* Investigation requested
* Signature/name of requesting doctor and bleep number

Use of the Trackcare system will ensure that all of this required data will be present. Please note that due to interfacing limitations the assay requestor is not displayed in clinical portal, SCI store or IS.

Please note unlabelled or inadequately labelled samples **WILL NOT BE** accepted for analysis. In these circumstances the clinician or clinical area making the request will be notified and a fresh, suitably identified sample requested. Under **NO** circumstances will changes be allowed to any samples. **DO NOT** use addressograph labels on samples as the analysers are not compatible with these labels and they cannot be processed.

### Blood Transfusion Sample Labelling Requirements

Sample identification is of critical importance in blood transfusion. The process of ordering blood for possible transfusion involves both a request for a laboratory investigation and also for a prescribed therapeutic product.

The vast majority of major transfusion complications (although rare) are caused by clerical errors and it is therefore important to follow procedures for patient identification.

It is the responsibility of the staff undertaking sample collection to ensure that the sample bottle is labelled accurately and signed and that the form is completed with all relevant information and is transported to the laboratory in a timely and correct manner.

All samples and requests for Blood Transfusion must have the following minimum identifiers:

* Surname
* Forename
* CHI or TJ number
* Date of birth
* Gender
* Signature of person taking the sample
* Date and time of sample

The Department will **NOT** process specimens that are incorrectly or inadequately labelled. In this event, the requesting location will be contacted by telephone, and a replacement specimen requested.

Sample bottles should **NEVER** be pre-labelled or completed away from the patient’s side.

Any form of printed label **MUST NOT** be used on blood transfusion sample bottles. All blood transfusion sample bottles **MUST** be hand written and **MUST** be signed by the individual taking the sample.

### Consent

Consent for the performing of an assay is implied when the patient agrees to have a sample taken for this purpose. Those assays which require specific consent (as required under legislation), this will be discussed by a clinical member of staff during the clinical appointment/visit.

## Transportation of Samples

It is the responsibility of the staff undertaking sample collection to ensure that the sample is transported to the laboratory in a timely and correct manner.

### Portering Services

Specimens are uplifted from the various clinical units by Porters on a regular basis throughout the day. To have samples collected urgently please contact the porters.

### Vacuum Tube Specimen Delivery System

Vacuum tube systems are available for the transportation of laboratory specimens at the GGH, GRI and Stobhill sites. Please note that samples for platelet aggregation must not be sent via the tube system.

### Primary Care Specimen Collection Service

This service is co-ordinated and managed by the Facilities Managers (**NOT** by the Department of Haematology), a specimen collection service operates, up to twice a day, for the routine collection and delivery of laboratory specimens between service users in General Practice and Primary Care Health Centres to the laboratories of the Department. All enquiries relating to these services should be directed to the relevant Facilities Manager.

### Sending Specimens by Post

The Royal Mail supplies prepaid, single-use mailing containers (Safebox) that meets current legislation (UN3373) for posting laboratory specimens. Regardless of container type the following requirements apply for posted specimens:

* The primary container (specimen bottle) must be leak-proof and must not contain more than 500ml.
* There must be absorbent material, which must be present in sufficient quantity to absorb the entire content of the primary container, placed between the primary container and a secondary container.
* The secondary container must be leak-proof.
* The secondary packaging must not contain more than 4 litres (includes multiple primary containers placed into a single secondary container).
* Secondary container must be labelled with “Biological Material”, “Biohazardous Sample”, or similar, and must have the laboratory destination and return address clearly marked.

## Restricted Specimens

Patients from whom specimens **MUST NOT BE SENT** without approval of an Infectious Disease/Control Clinician:

* Specimens from patients known or suspected to have SARS.
* Specimens from patients with possible or confirmed Viral Haemorrhagic Fever.
* Any other hazard category 4 pathogens

# Assay Repertoire and Turn Around Times

The different haematological tests and bottle types (by colour) required are listed below: All turn-around times are stated for routine requests. Assays may be processed as urgent but the laboratory must be informed in advance. Assays out with our ISO15189 scope are indicated with two asterisks.

## Haematology

|  |  |  |  |
| --- | --- | --- | --- |
| **Assay** | **Bottle Required** | **Site Performed at** | **Turnaround Time** |
|  | **Urgent\*** | **In Patients** | **Outpatient/GPs** |
| Full Blood Count (FBC) | 4ml Purple | All | 1hr | 2hrs | 4hrs |
| ESR | 4ml Purple | GRI, GGH | 1hr | 2hrs | 4hrs |
| Reticulocyte Count | 4ml Purple | All | 1hr | 2hrs | 4hrs |
|  | **Turnaround Time (All areas)** |
|  Blood film | 4ml Purple | GRI,GGH | 24 hrs. |
| Bone Marrow  | 4ml Purple | GRI,GGH | 48 hrs. |
| Body Fluid Analysis\*\*† | Fluid dependent | GRI | 4hrs |
| Iron Stain\*\* | 4ml Purple | GRI,GGH | 48 hrs. |
| Glandular Fever Screen | 4ml Purple | GGH, GRI | 4 hrs. |
| Malarial Parasites | 4ml Purple | GGH, GRI | 4 hrs. |
| Sickle Cell Screen | 4ml Purple | GGH, GRI | 2 hrs. |
| Kleihauer | 4ml Purple | GRI | 4 hrs. |
| Haemoglobinopathy screen | 4ml Purple | GRI | 72 hrs. |
| Urinary Haemosiderin\*\* | 20ml urine in sterile container | GRI, GGH | 48 hrs. |

\*Samples from A&E are considered Urgent all other areas are processed as routine unless contacted to process as urgent

\*\* Assay not currently within our ISO15189 accredited scope

†Ascetic Fluid and CSF only

### Malaria Parasite Screening Request Requirements

Laboratory investigation of malaria requires a full blood count (purple tube). It is essential that the laboratory receives the sample the same day as it is taken.

A full travel history (country/countries recently visited) **MUST** be stated on the request. This can and will aid species identification.

Two investigations are performed – a rapid Malaria antigen screening test and thick and thin blood film examination for parasites. The rapid diagnostic test detects the presence of malaria only it **CANNOT** provide confirmation of species or level of parasitaemia. This can only be provided after examination of the blood films. Due to the limitations of the technology the Malaria RDT is unable to detect ***P Knowlesi.***

In all cases where malaria is confirmed, the result will be telephoned to the requesting location by a member of the Haematology medical staff.

Malaria is a parasitic disease found in tropical and subtropical regions. It is caused by protozoa of the genus Plasmodium. Five species of this protozoa cause malaria in humans, ***P.vivax, P.ovale, P.malariae, P Knowlesi*** and ***P.falciparum*.** Of these infections ***P.vivax, P.ovale*** and ***P.malariae*** can cause severe illness, but ***P.falciparum*** and ***P Knowlesi*** can cause a much more serious illness which can be fatal. ***P.falciparum*** and ***P Knowlesi*** infections must be identified urgently. A full travel history of all countries and regions is therefore essential.

Malaria must be diagnosed without delay in order to commence appropriate treatment.

### Haemoglobinopathy Screening Request Requirements

A Family Origin Questionnaire **MUST** accompany all requests for Haemoglobinopathy screening from ante-natal patients. These are not supplied by the laboratory but are generated using the PNBS system.

## Haemostasis

|  |  |  |  |
| --- | --- | --- | --- |
| **Assay** | **Bottle Required** | **Site Performed at** | **Turnaround Time** |
|  | **Urgent\*** | **In Patients** | **Outpatient/GPs** |
| Prothrombin time | 3.5ml Blue | GRI, GGH, Stobhill | 1hr | 2hrs | 4hrs |
| APTT | 3.5ml Blue | GRI, GGH, Stobhill | 1hr | 2hrs | 4hrs |
| TCT | 3.5ml Blue | GRI, GGH, Stobhill | 1hr | 2hrs | 4hrs |
| Fibrinogen | 3.5ml Blue | GRI, GGH, Stobhill | 1hr | 2hrs | 4hrs |
| D-dimer | 3.5ml Blue | GGH,GRI | 1hr | 2hrs | 4hrs |
| INR | 3.5ml Blue | GRI, GGH, Stobhill | 1hr | 2hrs | 4hrs |
| APTT ratio | 3.5ml Blue | GRI, GGH, Stobhill | 1hr | 2hrs | 4hrs |
| PT, APTT, TCT using Mechanical clot detection method\*\* | 3.5ml Blue | GRI only | 1hr | 2hrs | 4hrs |
| Protamine Sulphate (TCT)\*\* | 3.5ml Blue | GRI, GGH | 1hr | 2hrs | 4hrs |
|  |  |  |  |
| **Assay** | **Bottle Required** | **Site Performed at** | **Turnaround Time all Areas** |
| ADAMTS13 Activity | 2 x 3.5 mL Blue | GRI | 24hrs |
| Anti Xa LMWH | 3.5ml Blue | GRI | 24 hrs |
| Anti Xa UFH | 3.5ml Blue | GRI | 24 hrs |
| Anti Xa Orgaran/danapariod | 3.5ml Blue | GRI | 24 hrs |
| Anti Xa Fondaparinux | 3.5ml Blue | GRI | 24 hrs |
| Apixaban level | 3.5ml Blue | GRI | 24 hrs |
| Rivaroxaban level | 3.5ml Blue | GRI | 24 hrs |
| Edoxaban level | 3.5ml Blue | GRI | 24 hrs |
| Dabigatran level | 3.5ml Blue | GRI | 24 hrs |
| Argatroban level | 3.5ml Blue | GRI | 24 hrs |
| Heparin Induced Thrombocytopenia (HIT) | 3.5ml Blue | GRI | By arrangement with consultant haematologist |
| Reptilase\*\* | 3.5ml Blue | GRI | By Arrangement\*\*\* |
| Factor II | 3.5ml Blue | GRI | 14 days |
| Factor V | 3.5ml Blue | GRI | 14 days |
| Factor VII | 3.5ml Blue | GRI | 14 days |
| Factor VIII | 3.5ml Blue | GRI | 7 days |
| Factor IX | 3.5ml Blue | GRI | 7 days |
| Factor IX (Refixia) | 3.5mL Blue | GRI | 7 days |
| Factor X | 3.5ml Blue | GRI | 14 days |
| **Assay** | **Bottle Required** | **Site Performed at** | **Turnaround Time all Areas** |
| Factor XI | 3.5ml Blue | GRI | 7 days |
| Factor XII | 3.5ml Blue | GRI | 7 days |
| Factor XIII | 3.5ml Blue | GRI | 14 days |
| Fibrinogen Antigen\*\* | 3.5ml Blue | GRI | 14 days |
| Chromogenic FVIII | 3.5ml Blue | GRI | 10 days |
| Emicizumab concentration\*\* | 3.5ml Blue | GRI | 7 days |
| VWF:Ag | 3.5ml Blue | GRI | 10 days |
| VWF:RCo | 3.5ml Blue | GRI | 10 days |
| VWF:CBA | 3.5ml Blue | GRI | 10 days |
| Anti Cardiolipin Antibodiesⱡ | 3.5ml Blue | GRI | 14 days |
| Antithrombin activity | 3.5ml Blue | GRI | 7 days |
| Antithrombin Ag\*\* | 3.5ml Blue | GRI | 28 days |
| Protein C activity | 3.5ml Blue | GRI | 7 days |
| Protein S (Free) Ag | 3.5ml Blue | GRI | 7 days |
| Platelet aggregation studies\*\* | Contact Lab | GRI | By Arrangement\*\*\* |
| Plasminogen | 3.5ml Blue | GRI | 42 days |
| α2 Antiplasmin | 3.5ml Blue | GRI | 42 days |
| Factor V Leiden | 3.5ml Blue | GRI | 28 days |
| ProthrombinG20210A Mutation | 3.5ml Blue | GRI | 14 days |
| CompleteThrombophilia Screen  | 4 x 3.5ml Blue | GRI | 14 days |
| Inherited Thrombophilia Screen  | 2 x 3.5ml Blue | GRI | 14 days |
| Acquired Thrombophilia Screen | 2 x 3.5ml Blue | GRI | 14 days |
| Investigation of Prolonged APTT | 2 x 3.5ml Blue | GRI | 7 days |
| Antiphospholipid Screenⱡ  | 2 x 3.5ml Blue | GRI | 14 days |
| Inhibitor to Factor VIII (Human) | 3.5ml Blue | GRI | 7 days |
| Inhibitor to Factor VIII (Porcine) | 3.5ml Blue | GRI | 7 days |
| Inhibitor to Factor VIII (Chromogenic) | 3.5ml Blue | GRI | 7 days |
| Inhibitor to FV  | 3.5ml Blue | GRI | 7 days |
| Inhibitor to FIX  | 3.5ml Blue | GRI | 7 days |

\*Samples from A&E are considered Urgent all other areas are processed as routine unless contacted to process as urgent

\*\* Assay not currently within our ISO15189 accredited scope

\*\*\*By arrangement, tests only performed after approval by Dr R.Rodgers or Dr C. Bagot. These tests are performed infrequently and therefore have no defined Turnaround Time but will take significantly longer than other available assays.

ⱡThis assay has not been validated for paediatric samples and is not currently within our ISO15189 accredited scope for those samples.

### Haemostasis Assays General Requirements

All samples **MUST** be received < 4 hours from time of venepuncture. All sample bottles must be filled correctly.

Samples for Platelet Aggregation assays **MUST** be pre-arranged with the laboratory.

Urgent requests will be processed within 24 - 48 hrs if clinically indicated and on agreement by a Consultant Haematologist.

Please note that the results of Haemostasis tests may be affected by extremely high levels of haemoglobin, bilirubin, triglycerides, heparin, or rheumatoid factor. Levels are test specific – please contact the laboratory for further guidance.

### Anticoagulation Therapy

The department offers a service for monitoring anticoagulation therapy which includes patients on Warfarin, Unfractionated Heparin, Low Molecular Weight Heparin, Fondaparinux, Danaparoid and Direct Oral Anticoagulants (DOACs). Clinical support and advice is available.

### Anti Xa Assays Special Requirements

Requests for AXa UFH must be received in the laboratory within 1 hour of venepuncture

Patients on Low Molecular Weight Heparin must have the sample taken 3.5 to 4 hrs post dose. The type of Heparin must be stated on the request.

Patients on Direct Oral Anticoagulants (DOACs) must have the sample taken 3hrs post dose. The type of DOAC must be stated on the request.

### Lupus Anticoagulant Assays Special Requirements

Samples must be received within 4 hours of the time of venepuncture.

### Anticoagulation Service

Anticoagulant clinics, for monitoring of warfarin therapy, are run by the Glasgow and Clyde Anticoagulation Service (GCAS). A Clinical Nurse Specialist led community based service.

## Haemato-oncology

The laboratory at Gartnavel General Hospital in association with the West of Scotland Regional Stem Cell Processing Service provides a comprehensive clinical Haemato-Oncology service which includes immunophenotyping.

Clinical support and advice is available.

|  |  |  |  |
| --- | --- | --- | --- |
| **Assay** | **Bottle Required** | **Site Performed at** | **Turnaround Time** |
| CD34 |  4ml Purple EDTA | GGH | 2 hrs |
| Immunophenotyping |  4ml Purple EDTA | GGH | 72 hrs |
| PNH |  4ml Purple EDTA | GGH | 24 hrs |
| Hereditary Spherocytosis (HS)\*\* |  4ml Purple EDTA | GGH | 72 hrs\* |
| Platelet Membrane Glycoproteins (PMG)\*\* |  3.5ml Blue Citrate | GGH | 72 hrs\* |

**\***Prior arrangement necessary - Please phone 57707/57708 to discuss requirements.

\*\*Assay not currently within our ISO15189 accredited scope

### Haemato-oncology sampling requirements

All peripheral blood and bone marrow samples being sent for immunophenotyping should be labelled as detailed in section 6.2. All relevant clinical information and the timing of the sample must be completed on the request form accompanying the sample. The laboratory must be made aware of all urgent samples that are being sent so they can be prioritised appropriately. Users will be notified of inappropriate requests or of samples not meeting acceptance criteria.

Samples must be sent with two representative smears which have been allowed to air dry.

Samples must be transported to the laboratory as soon as possible and kept at ambient temperature.

Specimens requiring assay for platelet membrane glycoproteins or hereditary spherocytosis must be discussed with the lab prior to sampling and must be accompanied with the following controls.

Samples for Hereditary Spherocytosis must include six age matched control samples (with normal red cell indices) to be sent with HS Assay for individuals under 16 years of age.

Two control samples in blue citrate bottles are required with to be sent with a sample for the PMG Assay.

Bodily fluids and CSF can be sent in Universal Containers (2 to 3 ml is sufficient for analysis of cell markers). Anticoagulant is not necessary for these samples. CSF samples must be transported to the laboratory immediately for analysis.

## Blood Transfusion

Blood Transfusion Maximum Surgical Blood Ordering Schedule (MSBOS), policies, guidelines and forms, both local and pan NHS GG&C, are available on the Blood Transfusion page of the Intranet.

|  |  |  |  |
| --- | --- | --- | --- |
| **Assay** | **Bottle Required** | **Site Performed at** | **Turnaround Time** |
| Group and Antibody Screen | 6ml Pink | GRI /GGH | 4 hrs |
| Cross Match | 6ml Pink | GRI/GGH | 2 hrs |
| Antibody Identification | 6ml Pink | GRI/GGH | 4 hrs |

### Routine Blood Product Orders

Blood requirements for surgery vary depending on the procedure. For procedures likely to require blood products a pre-determined number of units should be requested accordingly to the MSBOS and should be requested in good time prior to surgery.

In those cases where blood is rarely required a group and screen is recommended. A second confirmatory sample will be required to be processed before the issue of any blood products if the patient has not previously been grouped.

The Transfusion samples are stored in the laboratory for 7 days, unless they are a preoperative sample with a given date for the operation in which case the samples will be stored in the laboratory for 14 days. Samples will be stored for 72 hours only, if the patient is pregnant or has been transfused in the past three months. If blood is subsequently required it can be provided following compatibility testing or Electronic Issue. The Blood Transfusion Laboratory must be informed and a crossmatch request form must be supplied to the laboratory to confirm the request for blood products.

Blood Transfusion MSBOS, policies, guidelines and forms both local and pan NHS GG&C are available on the Blood Transfusion page of the Intranet.

### Emergency Cross Match Requests

The Blood transfusion laboratory should be telephoned in advance, and the sample transported to the laboratory immediately and not left to the routine specimen collection. It will be useful if the degree of emergency is stated. Out with laboratory core hours the on duty BMS **MUST** be contacted

### Atypical Red Cell Antibodies

Occasionally patients may have antibodies to blood group antigen systems other than ABO and Rhesus. These may have been identified on a previous occasion, in which case the patient may have been issued with an antibody card indicating the identity of the antibody/antibodies.

It may be more difficult to provide compatible blood for these patients and requirements should be discussed with the Blood Transfusion Laboratory. As much advanced planning and notice as is possible of operations for such patients should be undertaken.

Failure to do so will lead to a delay in the provision of blood products.

In situations where further blood is required for a patient who has already been recently transfused a fresh sample must be sent for crossmatching.

### Transfusion Reactions

Mild transfusion reactions are not uncommon, however severe life-threatening haemolytic reactions are rare.

Transfusion reactions can be classified as:

* Haemolytic Reactions
* Non-haemolytic febrile transfusion reactions
* Urticarial and Anaphylactic reactions

Should a transfusion reaction be suspected immediately contact a Haematology Registrar or Consultant. A Transfusion reaction form must be completed and these are available on the departmental intranet page and webpage on the NHSGGC website.

### Blood Components

The following Blood components can be requested, some must be discussed with a Haematology clinician prior to requesting.

#### Red Cell Concentrate

Packs contain approximately 200mls of concentrated red cells from plasma reduced donor units or plasma depleted units. All red cell products in the UK are leucodepleted.

#### Fresh Frozen Plasma

This is normally issued after discussion with a Haematology clinician and must be given immediately on delivery to the ward/unit. First dose FFP in the context of correction of Haemostasis (for patient’s not on warfarin) can be requested without contacting a haematology clinician, provided the cause of laboratory abnormalities is understood.

#### Platelet Concentrates

This is normally issued after discussion with a Haematology clinician, there may be some delay in receiving the product as normally it is necessary to order and have it delivered from SNBTS. It **MUST NOT** be refrigerated.

#### Cryoprecipitate

This is normally issued after discussion with a haematology clinician and should be given immediately on delivery to the ward/unit.

#### Anti-D Immunoglobulin

Available in various doses and issued dependent on the stage of pregnancy or in the presence of, or possibility of, Fœtal Maternal Haemorrhage (FMH).

#### Specific Haemostasis factor concentrates

These are issued after discussion with a haematology clinician.

## Costs

Information about the costs and charges of our assay repertoire can be obtained from the Technical Services Manager on application. Their contact details can be found in section 4

# Referred Assays

The following assays are referred to laboratories within or out with NHS GG&C. All laboratories are accredited to ISO15189 unless stated.

|  |  |  |
| --- | --- | --- |
| **Assay** | **Referral Laboratory Location** | **Turnaround Time** |
| Malaria Screen Confirmation | Microbiology Glasgow Royal Infirmary | 48hrs |
| Haemoglobinopathy Confirmation | Oxford Molecular Diagnostic Laboratory | 28 days |
| Haemoglobinopathy Confirmation | Western General Hospital Edinburgh | 28 days |
| EPO receptor and VHL genetic Analysis | Belfast City Hospital, Belfast | 28 days |
| FIP1L1-PDGFRa c-KIT d816v mutation | Salisbury District Hospital, Salisbury | 28 days |
| Chromosome Breakage | Guy’s and St Thomas’ Hospital, London | 10 days |
| Fibrinogen Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Factor V Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Factor VII Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Factor VIII Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Factor IX Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Factor X Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Factor XI Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Factor V & VIII combined Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Antithrombin Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Protein C Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Protein S Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| VWF Multimers | Royal infirmary, Edinburgh | 84 days |
| VWF Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| ADAMST13 Antibodies | HSL, London | 28 days |
| Platelet Nucleotides | Royal infirmary, Edinburgh | 28 days |
| Platelet (MYH9) Genetic Analysis | Royal infirmary, Edinburgh | 42-56 days |
| Glanzmann’s Thrombasthaenia Genetics | Royal infirmary, Edinburgh | 42-56 days |
| Bernard Soulier Syndrome Genetics | Royal infirmary, Edinburgh | 42-56 days |
| X-Matching (multiple red cell antibodies) | SNBTS Gartnavel | 4 hrs\*\* |
| Red Cell Antibody Identification (multiple red cell antibodies) | SNBTS Gartnavel | 7 days |
| HLA Screening (Platelets and WBC) | SNBTS Gartnavel | 48 hrs |
| Anti IgA antibodies | SNBTS Gartnavel | 48 hrs |
| Neutrophil and Granulocyte Antibodies | NHSBT Bristol | 48 hrs |
| Anti D Quantification | SNBTS Gartnavel | 4 days |
| Fœtal Maternal Haemorrhage quantification | SNBTS Gartnavel | 48 hrs |
| Fœtal Genotyping | NHSBT Bristol | 10 days |
| Transfusion Reaction Investigations (Requested by Haematologist) | SNBTS Gartnavel | 7-14 days |

**\***Performed only by request no available turnaround time due to assay frequency.

**\*\***For very rare antibody types/combinations this may be considerably longer especially if red cell antibody identification is required as well.

# Reference Ranges

The Reference Ranges are for guidance only, and are derived from ***Dacie and Lewis Practical Haematology - 12th Edition*** unless stated. Advice, both clinical and technical is available by contacting either a member of the Haematology clinical or technical staff respectively. Some ranges differ due to age or sex. Some assays do not have a numerical reference range with the result of the assay being given in a clinical comment or as a statement of positivity or negativity. Others have a therapeutic range. For those tests that have a therapeutic range please consult the appropriate policy or contact a member of the Haematology clinical team if guidance is required. All ranges are for adults unless stated. All ranges are for both males and females unless stated.

## Haematology Reference Ranges

The Adult, Infant and Children’s Reference Ranges are sourced from, Dacie and Lewis Practical Haematology 12th Ed (2017): S M Lewis, B J Bain, I Bates, M Laffan.

The Infant and Children’s White blood cell and differential Reference Ranges are sourced from Pediatric Hematology 3rd Ed (2006): R J Arceci, I M Hann, O P Smith.

Unless stated otherwise.

### Haematology Reference Ranges for Adults

|  |  |  |
| --- | --- | --- |
| **Assay** | **Male** **Reference Range** | **Female****Reference range** |
| WBC | 4.00 – 10.00 x 109/L |
| Haemoglobin\* | 130 - 180g/L | 115 - 165g/L |
| RBC\* | 4.50 – 6.50 x 1012/L | 3.80 - 5.80 x 1012/L |
| HCT\* | 0.400 - 0.540 | 0.370 - 0.470 |
| MCV | 83 - 101fL |
| MCH | 27 - 32pg |
| MCHC | 315 -345 g/L |
| Platelets | 150 - 410 x 109/L |
| Neutrophils | 2.00 - 7.00 x 109/L |
| Lymphocytes\* | 1.1 – 5.0 x 109/L |
| Monocytes | 0.20 – 1.0 x 109/L |
| Eosinophils | 0.02 – 0.5 x 109/L |
| Basophils | 0.02 – 0.10 x 109/L |
| Reticulocytes | 50 – 100 x 109/L |
| Blood Film | Comment |
| Glandular Fever Screen | Comment |
| Malaria Parasite Screen | Comment |
| Urinary Haemosiderin | Comment |

\*Reference range by local expert review

### Haematology Reference Ranges for Children

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Assay** | **1 Year**  | **2 to 6 Years** | **6 to 12 Years** | **12 to 18 Years** |
| WBC | 6.00 – 16.00 x 109/L | 6.00 – 17.00 x 109/L | 4.50 – 13.00 x 109/L | 4.5 – 13.00 x 109/L |
| Haemoglobin | 111 - 141g/L | 110 - 140g/L | 115 - 155g/L | 115 - 155g/L |
| RBC | 3.90 – 5.10 x 1012/L | 4.00 – 5.20 x 1012/L | 4.00 – 5.20 x 1012/L | 4.00 – 5.20 x 1012/L |
| HCT | 0.300 - 0.380 | 0.340 - 0.400 | 0.350 - 0.450 | 0.350 - 0.450 |
| MCV | 72 - 84fL | 75 - 87fL | 77 - 95fL | 77 - 95fL |
| MCH | 25 - 29pg | 24 - 30pg | 25 - 33pg | 25 - 33pg |
| MCHC | 320 -360 g/L | 310 -370 g/L | 310 -370 g/L | 310 -370 g/L |
| Platelets | 200 - 550 x 109/L | 200 - 490 x 109/L | 170 - 450 x 109/L | 170 - 450 x 109/L |
| Neutrophils | 1.00 - 8.00 x 109/L | 1.50 - 8.50 x 109/L | 1.50 - 8.00 x 109/L | 1.50 - 6.00 x 109/L |
| Lymphocytes | 3.40 - 10.5 x 109/L | 1.80 - 8.40 x 109/L | 1.50 - 5.0 x 109/L | 1.0 – 4.50 x 109/L |
| Monocytes | 0.20 – 0.9 x 109/L | 0.15 – 1.30 x 109/L | 0.15 – 1.30 x 109/L | 0.15 – 1.30 x 109/L |
| Eosinophils | 0.05 – 0.9 x 109/L | 0.05 – 1.10 x 109/L | 0.05 – 1.0 x 109/L | 0.05 – 0.80 x 109/L |
| Basophils | 0.02 - 0.13 x 109/L | 0.02 - 0.12 x 109/L | 0.02 - 0.12 x 109/L | 0.02 - 0.12 x 109/L |
| Reticulocytes | 30 - 100 x 109/l | 30 - 100 x 109/L | 30 - 100 x 109/L | 30 - 100 x 109/L |
| Blood Film | Comment | Comment | Comment | Comment |
| Glandular Fever Screen | Comment | Comment | Comment | Comment |
| Malaria Parasite Screen | Comment | Comment | Comment | Comment |

### Haematology Reference Ranges for Infants

|  |  |  |  |
| --- | --- | --- | --- |
| **Assay** | **Birth**  | **Day 3** | **Day 7** |
| WBC | 10.00 – 26.00 x 109/L | 10.00 – 26.00 x 109/L | 10.00 – 26.00 x 109/L |
| Haemoglobin | 140 - 220g/L | 150 - 210g/L | 135 - 215g/L |
| RBC | 5.00 – 7.00 x 1012/L | 4.00 – 6.60 x 1012/L | 3.90 – 6.30 x 1012/L |
| HCT | 0.450 - 0.750 | 0.450 - 0.670 | 0.420 - 0.660 |
| MCV | 100 - 120fL | 92 - 118fL | 88 - 126fL |
| MCH | 31 - 37pg | 31 - 37pg | 31 - 37pg |
| MCHC | 300 -360 g/L | 290 -370 g/L | 280 -380 g/L |
| Platelets | 100 - 450 x 109/L | 210 - 500 x 109/L | 160 - 500 x 109/L |
| Neutrophils | 2.70 - 14.40 x 109/L | 2.70 - 14.40 x 109/L | 2.70 - 14.40 x 109/L |
| Lymphocytes | 2.0 – 7.3 x 109/L | 2.0 – 7.3 x 109/L | 2.0 – 7.3 x 109/L |
| Monocytes | 0.0 – 1.9 x 109/L | 0.0 – 1.9 x 109/L | 0.0 – 1.9 x 109/L |
| Eosinophils | 0.0 – 0.85 x 109/L | 0.0 – 0.85 x 109/L | 0.0 – 0.85 x 109/L |
| Basophils | 0.0 - 0.10 x 109/L | 0.0 - 0.10 x 109/L | 0.0 - 0.10 x 109/L |
| Reticulocytes | 120 - 400 x 109/L | 50 - 350 x 109/L | 50 - 100 x 109/L |
| Blood Film | Comment | Comment | Comment |
| Malaria Parasite Screen | Comment | Comment | Comment |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Assay** | **Day 14** | **1 Month** | **2 Months** | **6 Months** |
| WBC | 6.00 – 21.00 x 109/L | 6.00 – 21.00 x 109/L | 5.00 – 15.00 x 109/L | 6.00 – 17.00 x 109/L |
| Haemoglobin | 125 - 205g/L | 115 - 165g/L | 94 - 130g/L | 111 - 141g/L |
| RBC | 3.90 – 6.20 x 1012/L | 3.00 – 5.40 x 1012/L | 3.10 – 4.30 x 1012/L | 4.10 – 5.30 x 1012/L |
| HCT | 0.310 - 0.710 | 0.330 - 0.530 | 0.280 - 0.420 | 0.300 - 0.400 |
| MCV | 86 - 124fl | 92 - 116fL | 87 - 103fL | 68 - 84fL |
| MCH | 31 - 37pg | 30 - 36pg | 27 - 33pg | 24 - 30pg |
| MCHC | 280 -380 g/L | 290 -370 g/L | 285 -355 g/L | 300 -360 g/L |
| Platelets | 170 - 550 x 109/L | 210 - 500 x 109/L | 210 - 650 x 109/L | 200 - 550 x 109/L |
| Neutrophils | 1.50 - 5.40 x 109/L | 1.50 - 5.40 x 109/L | 0.70 – 4.80 x 109/L | 1.00 - 6.00 x 109/L |
| Lymphocytes | 2.80 - 9.10 x 109/L | 2.80 - 9.10 x 109/L | 3.3 – 10.3 x 109/L | 3.30 – 11.5 x 109/L |
| Monocytes | 0.10 – 1.7 x 109/L | 0.10 – 1.7 x 109/L | 0.40 – 1.2 x 109/L | 0.20 – 1.3 x 109/L |
| Eosinophils | 0.0 – 0.85 x 109/L | 0.0 – 0.85 x 109/L | 0.05 – 0.90 x 109/L | 0.1 – 1.10 x 109/L |
| Basophils | 0.0 - 0.10 x 109/L | 0.0 - 0.10 x 109/L | 0.02 - 0.13 x 109/L | 0.02 - 0.13 x 109/L |
| Reticulocytes | 50 - 100 x 109/L | 20 - 60 x 109/L | 30 - 50 x 109/L | 40 - 100 x 109/L |
| Blood Film | Comment | Comment | Comment | Comment |
| Malaria Parasite Screen | Comment | Comment | Comment | Comment |

### ESR

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Test | 17-50 Years | 50-61 Years | 61-70 Years | >70 Years |
| ESR (male) mm/hr | ≤ 10 | ≤ 12 | ≤ 14 | ≤ 30 |
| ESR (female) mm/hr | ≤ 12 | ≤ 19 | ≤ 20 | ≤ 35 |

## Haemoglobinopathy Assays

The Reference Ranges are sourced from Haemoglobinopathy Diagnosis 2nd Ed: B J Bain

|  |  |
| --- | --- |
| **Assay** | **Adult****Reference Range** |
| HbF | <1.0% |
| HbA2 | 2.0 – 3.5% |
| Sickle Cell RDT | Comment |

## Haemato-Oncology

### Immunophenotyping

Immunophenotyping reference ranges are considered not to be appropriate and an interpretative comment is provided on the report which provides all the relevant clinical, morphological and immunophenotyping data.

CD34 absolute values are evaluated by the consultant in charge of apheresis with particular regard to the timing of mobilisation and therefore a specific reference range for CD34 counts is not applicable either.

## Haemostasis Reference Ranges

All Haemostasis reference ranges are locally derived from a pool of normal individuals.

### Routine Haemostasis Ranges

|  |  |
| --- | --- |
| **Assay** | **Adult****Reference Range** |
| Prothrombin time | 9 – 13 sec |
| APTT | 27 – 36 sec |
| TCT | 11 – 15 sec |
| Fibrinogen | 1.7 – 4.0 g/L |
| D-Dimer | <243ng/mL |
| D-Dimer for exclusion of VTE | <230ng/mL |
| INR | Therapeutic range(2.0 -4.0 Depending on Indication)  |
| APTT ratio | Therapeutic range 1.8 – 2.8 |
| Anti Xa. | Therapeutic ranges for individual anticoagulants |

### Specialised Haemostasis Assay Reference Ranges

|  |  |  |
| --- | --- | --- |
| **Assay** | **Male****Reference Range** | **Female****Reference Range** |
| Reptilase | 13 – 20 sec |
| Factor II | 97 - 141 iu/dL |
| Factor V | 66 - 167 iu/dL |
| Factor VII | 67 - 153 iu/dL |
| Factor VIII | 58 - 152 iu/dL |
| Factor IX | 81 - 157 iu/dL |
| Factor X | 79 - 155 iu/dL |
| Factor XI | 82 - 151 iu/dL |
| Factor XII | 59 - 164 iu/dL |
| Factor XIII | 70 - 140 iu/dL |
| Fibrinogen Antigen | 1.8 – 3.4 g/dL |
| Chromogenic FVIII | 50 – 200 iu/dL |
| VWF:Ag | 51 - 170 iu/dL |
| VWF:RCo | 46 – 166 iu/dL |
| VWF:CBA | 50-160 iu/dL |
| DRVVT Screen | 0.87 – 1.21 ratio |
| DRVVT Confirm | 0.81 – 1.08 ratio |
| ACL Antibody (IgG)\* | <20.0 U/mL |
| ACL Antibody (IgM)\* | <20.0 U/mL |
| Antithrombin activity | 82 - 123 iu/dL |
| Antithrombin Ag | 75 – 128 iu/dL |
| **Assay** | **Male****Reference Range** | **Female****Reference Range** |
| Protein C activity | 71 - 146 iu/dL |
| Protein S (Free) Ag | 75 - 148 iu/dL | 65 - 137 iu/dL |
| Platelet aggregation | Comment |
| Plasminogen | 80 – 133 U/dL |
| α2 Antiplasmin | 98 – 122 U/dL |
| Factor V Leiden | Comment |
| Prothrombin G20210A Mutation | Comment |
| Factor VIII Inhibitor Assay | Comment |
| ADAMTS13 Activity | 60.6 – 130.6 IU/dL |

\*Please note that references ranges for ACL Antibody (IgM/G) are not validated for paediatric samples.

## Haematinics Assays

Haematinic assays are processed by the Biochemistry department but are reported within the Haematology section of SCI store, IS and Clinical Portal. Clinical advice is available from the Haematology Clinical staff detailed in section 4.3.6. Technical advice is available from the biochemistry department.

|  |  |  |
| --- | --- | --- |
| **Assay** | **Male** | **Female** |
| B12 (active) | >25 pmol/L |
| Folate | 3 – 20 ng/L |
| Ferritin | 15 – 300 ug/L | 15 – 200 ug/L |

## Uncertainty of Measurement (UoM)

No measurement is exact. When something is measured, the outcome depends on the measuring system, the measurement procedure, the skill of the operator, the environment, and other effects. Even if the item were to be measured several times, in the same way and in the same circumstances, a different measured value would, in general be obtained each time, assuming the measuring system has sufficient resolution to distinguish between the values. This variability, for those results that are expressed numerically, has been calculated and is given in the column UoM. These values have been reviewed by the clinical staff and have been deemed not to be sufficient to affect any clinical decisions that may be taken using the results of analysis.

The uncertainty of measurement is expressed as a 95% confidence interval unless stated.

The range stated in the tables is **NOT** the assay reference range but the high and low values between which the uncertainty of measurement estimation has been established.

All uncertainty of Measurement estimations have been reviewed by a consultant clinical staff member and considered not to affect any decision required for patient care.

Uncertainty of Measurement must not be confused with error. These are defined as:

* **Uncertainty of measurement:** Quantified doubt about the result of a measurement
* **Error:** The difference between the measured value and the true value of the object being measured.

### Haematology UoM

|  |  |  |
| --- | --- | --- |
| **Assay** | **Uncertainty of Measurement +/-** | **Range** |
| **From** | **To** |
| WBC | 0.12 x10^9/L | 2.65 x10^9/L | 3.62 x10^9/L |
|  | 0.21 x10^9/L | 6.34 x10^9/L | 8.49 x10^9/L |
|  | 0.36 x10^9/L | 14.94 x10^9/L | 19.77 x10^9/L |
| Haemoglobin | 1.1 g/L | 55 g/L | 64 g/L |
|  | 1.5 g/L | 116 g/L | 130 g/L |
|  | 1.9 g/L | 152 g/L | 172 g/L |
| RBC | 0.04 x10^12/L | 2.19 x10^12/L | 2.48x10^12/L  |
|  | 0.06 x10^12/L | 4.13 x10^12/L | 4.68 x10^12/L  |
|  | 0.07 x10^12/L | 4.95 x10^12/L | 5.65 x10^12/L  |
| HCT | 0.005 | 0.155 | 0.197 |
|  | 0.009 | 0.319 | 0.406 |
|  | 0.010 | 0.418 | 0.552 |
| MCV | 1.6 fL | 70.9 fL | 81.3 fL |
|  | 1.5 fL | 77.1 fL | 90.9 fL |
|  | 1.6 fL | 82.4 fL | 93.7 fL |
| MCH | 0.5 pg | 22.5 pg | 28.8 pg |
|  | 0.4 pg | 24.8 pg | 31.2 pg |
| MCH | 0.5 pg | 27.6 pg | 33.4 pg |
| MCHC | 9.1 g/L | 280 g/L | 392 g/L |
|  | 7.3 g/L | 291 g/L | 391 g/L |
|  | 7.5 g/L | 298 g/L | 398 g/L |
| Platelets | 5 x10^9/L | 53 x10^9/L | 125 x10^9/L |
|  | 11 x10^9/L | 203 x10^9/L | 291 x10^9/L |
|  | 18 x10^9/L | 496 x10^9/L | 635 x10^9/L |
| Neutrophils | 0.06 x10^9/L | 0.86 x10^9/L  | 1.39 x10^9/L |
|  | 0.14 x10^9/L | 2.44 x10^9/L  | 3.45 x10^9/L |
|  | 0.31 x10^9/L | 6.28 x10^9/L  | 8.83 x10^9/L |
| Lymphocytes | 0.07 x10^9/L | 0.55 x10^9/L | 1.67 x10^9/L |
|  | 0.12 x10^9/L | 1.56 x10^9/L | 2.88 x10^9/L |
|  | 0.22 x10^9/L | 2.86 x10^9/L | 5.75 x10^9/L |
| Monocytes | 0.07 x10^9/L | 0.07 x10^9/L | 0.76 x10^9/L |
|  | 0.09 x10^9/L | 0.31 x10^9/L | 1.50 x10^9/L |
|  | 0.19 x10^9/L | 0.91 x10^9/L | 3.12 x10^9/L |
| Eosinophils | 0.04 x10^9/L | 0.12 x10^9/L | 0.44 x10^9/L |
|  | 0.09 x10^9/L | 0.34 x10^9/L | 1.10 x10^9/L |
|  | 0.24 x10^9/L | 0.86 x10^9/L | 2.81 x10^9/L |
| Basophils | 0.01 x10^9/L | 0.03 x10^9/L | 0.28 x10^9/L |
|  | 0.03 x10^9/L | 0.07 x10^9/L | 0.73 x10^9/L |
|  | 0.08 x10^9/L | 0.16 x10^9/L | 1.83 x10^9/L |
| Reticulocytes | 7.43 x10^9/L | 78.9 x10^9/L | 170.6 x10^9/L |
|  | 5.69 x10^9/L | 57.2 x10^9/L | 122.7 x10^9/L |
| Reticulocytes | 3.25 x10^9/L | 23.5 x10^9/L | 59.3 x10^9/L |
| ESR | 1 mm/hr | 0 mm/hr | 10 mm/hr |
|  | 1 mm/hr | 50 mm/hr | 60mm/hr |

### Manual Leucocyte Differential UoM

|  |  |  |
| --- | --- | --- |
| **Assay** | **Uncertainty of Measurement +/-** | **Range** |
| **From** | **To** |
| Neutrophils | 6.59 % | 48% | 98% |
| Lymphocytes | 6.14 % | 1% | 46% |
| Monocytes | 4.36 % | 1% | 26% |
| Eosinophils | 1.76 % | 1% | 9% |
| Basophils | 0.75 % | 0% | 1% |

### Malaria Parasite Parasitaemia UoM

|  |  |  |
| --- | --- | --- |
| **Assay** | **Uncertainty of Measurement +/-** | **Range** |
| **From** | **To** |
| Malaria Parasitaemia | 1.65% | 0.3% | 27.8% |

### Bone Marrow Myelogram

|  |  |
| --- | --- |
| **Cell Type** | **Uncertainty of Measurement +/-** |
| Myeloblasts | 1.7% |
| Proyelocytes | 1.5% |
| Myelocytes | 6.1% |
| Metamyelocytes | 6.2% |
| Neutophils | 6.5% |
| Eosinophils | 3.6% |
| Basophils | 0.8% |
| Monocytes | 3.6% |
| Erythrocytes | 4.0% |
| Lymphocytes | 5.3% |
| Plasma cells | 1.2% |

### Haemoglobinopathy UoM

|  |  |  |
| --- | --- | --- |
| **Assay** | **Uncertainty of Measurement +/-** | **Range** |
| **From** | **To** |
| HbF | 0.04 % | 1.4 % | 2.2 % |
|  | 0.10 % | 8.6 % | 9.6 % |
| HbA2 | 0.04 % | 2.1 % | 3.0 %  |
|  | 0.07 % | 5.2 % | 6.0 % |

### Routine Haemostasis UoM

|  |  |  |
| --- | --- | --- |
| **Assay** | **Uncertainty of Measurement +/-** | **Range** |
| **From** | **To** |
| Prothrombin time | 0.1 sec | 9.2 | 13.2 |
|  | 0.3 sec | 18.4 | 27.6 |
| APTT | 0.4 sec | 25.4 | 33.4 |
|  | 0.4 sec | 38.4 | 51.9 |
| TCT | 0.2 sec | 11.7 | 17.7 |
|  | 0.3 sec | 15.9 | 21.6 |
| Fibrinogen | 0.1 g/L | 1.6 | 2.6 |
|  | 0.1 g/L | 2.52 | 3.72 |
| D-Dimer | 9 ng/mL | 204 | 340 |
|  | 17 ng/mL | 466 | 698 |
| LMW Heparin | 0.03U/mL | 1.21 | 1.85 |
|  | 0.02 U/mL | 1.46 | 0.78 |
| UF Heparin | 0.01 U/mL | 1.0 | 1.4 |
|  | 0.005 U/mL | 0.3 | 0.5 |
| Apixaban | 2.2 ng/mL | 243 | 328 |
|  | 1.7 ng/mL | 55 | 85 |
| Rivaroxaban | 3.5 ng/mL | 234 | 350 |
|  | 1.7 ng/mL | 61 | 102 |
| Orgaran | 0.02 U/mL | 1.0 | 1.4 |
|  | 0.01 U/mL | 0.3 | 0.5 |
| Fondaparinox | 0.08 ug/mL | 1.0 | 1.4 |
|  | 0.04 ug/mL | 0.3 | 0.5 |
| Emicizumab | 0.8 mg/mL | 18.7 | 28.3 |
|  | 2.0 ug/mL | 55.8 | 83.8 |
| Reptilase | 0.7 sec | 13.8 | 15.8 |
|  | 0.7 sec | 14.2 | 16.2 |

### Special Haemostasis UoM

|  |  |  |
| --- | --- | --- |
| **Assay** | **Uncertainty of Measurement +/-** | **Range** |
| **From** | **To** |
| Factor II | 1.2 iu/dL | 77 | 117 |
|  | 0.4 iu/dL | 22 | 42 |
| Factor V | 2.2 iu/dL | 79 | 119 |
|  | 0.9 iu/dL | 24 | 44 |
| Factor VII | 1.3 iu/dL | 65 | 105 |
|  | 0.4 iu/dL | 19 | 39 |
| Factor VIII | 1.2 iu/dL | 77 | 117 |
|  | 0.6 iu/dL | 16 | 36 |
| Factor IX | 2.8 iu/dL | 83 | 123 |
|  | 0.8 iu/dL | 20 | 40 |
| Factor X | 1.6 iu/dL | 70 | 110 |
|  | 0.8 iu/dL | 27 | 47 |
| Factor XI | 1.6 iu/dL | 67 | 107 |
|  | 0.5 iu/dL | 21 | 41 |
| **Assay** | **Uncertainty of Measurement +/-** | **Range** |
| **From** | **To** |
| Factor XII | 3.1 U/dL | 70 | 110 |
|  | 2.6 iu/dL | 23 | 43 |
| Factor XIII | 1.5 iu/dL | 48 | 78 |
|  | 1.0 iu/dL | 13 | 33 |
| Fibrinogen Antigen | 0.1 g/L | 1.82 | 3.39 |
| Chromogenic FVIII | 5.7 iu/dL | 77 | 117 |
|  | 1.3 iu/dL | 16 | 36 |
| VWF:Ag | 1.4 iu/dL | 100 | 130 |
|  | 0.7 iu/dL | 21 | 41 |
| VWF:RCo | 0.4 iu/dL | 20 | 31 |
|  | 1.6 iu/dL | 75 | 117 |
| VWF:CBA | 0.8 iu/dL | 19 | 30 |
|  | 3.4 iu/dL | 70 | 109 |
| Lupus (APTT) | 0.3 sec | 28 | 33 |
| DRVVTs | 0.34 sec | 30 sec | 34 sec  |
| DRVVTc | 0.3 sec | 30 sec | 34 sec  |
| ACL Antibody (IgG) | 0.35 U/mL | 6 | 12 |
|  | 3.44 U/mL | 69 | 120 |
| ACL Antibody (IgM) | 0.21 U/mL | 6 | 11 |
|  | 1.26 U/mL | 52 | 120 |
| Antithrombin activity | 0.7 iu/dL | 85 | 115 |
|  | 0.6 iu/dL | 16 | 36 |
| Antithrombin Ag | 2.9 iu/dL | 85 | 115 |
|  | 1.9 iu/dL | 19 | 36 |
| Protein C activity | 0.6 iu/dL | 86 | 116 |
|  | 0.9 iu/dL | 18 | 38 |
| Protein S (Free) Ag | 0.9 iu/dL | 76 | 106 |
|  | 0.8 iu/dL | 19 | 39 |
| APC Resistance +APC | 2.9 sec | 65 | 134 |
|  | 0.4 sec | 29 | 43 |
| APC Resistance -APC | 0.6 sec | 30 | 50 |
|  | 1.4 sec | 50 | 91 |
| Plasminogen | 2.2 iu/dL | 82 | 112 |
|  | 1.6iu/dL | 19 | 39 |
| Antiplasmin | 4.7iu/dL | 85 | 115 |
|  | 1.9 | 32 | 52 |
| HIT | 0.06 | 2.4 | 3.8 |
|  | 0.03 | 0.4 | 0.7 |
| ADAMTS13 | 2.2 | 24 | 46 |
|  | 7.5 | 62 | 144 |

### Haematinics Assays UoM

Haematinics uncertainty of measurement information has been supplied by Biochemistry GRI.

|  |  |  |
| --- | --- | --- |
| **Assay** | **Uncertainty of Measurement +/-** | **Range** |
| **From** | **To** |
| B12 | 14.09 ng/L | 247 ng/L | 307 ng/L |
| B12 | 17.57 ng/L | 390 ng/L | 510 ng/L |
| Folate | 1.47 ng/L | 26.7 ng/L | 34.7 ng/L |
| Folate | 9.40 ng/L | 214.8 ng/L | 250.8 ng/L |
| Ferritin | 0.31 ug/L | 2.8 ug/L | 4.2 ug/L |
| Ferritin | 0.51 ug/L | 8.28 ug/L | 10.04 ug/L |

### Haemato-Oncology UoM

|  |  |  |
| --- | --- | --- |
| **Assay** | **Uncertainty of Measurement +/-** | **Range** |
| **From** | **To** |
| CD34 | 0.5 cells/uL | 7 cells/uL | 44 cells/uL |

### Qualitative Assays UoM

Uncertainty of measurement assessment for quantitative assays is assessed using a risk based method. Due to their composition and size they are not included in this manual. They are available on application to the quality manager.

The available assessments are:

* Factor V Leiden
* Prothrombin G20210A
* Acid Gel Haemoglobin Electrophoresis
* Cellulose Acetate Haemoglobin Electrophoresis
* Sickle Cell Solubility
* Blood Transfusion Qualitative tests
* Immunophenotyping
* Malaria RDT
* Glandular Fever RDT

## Factors That Will Affect the Accuracy of Results

The following factors will affect the accuracy of the results however their total effect on the inaccuracy of the result cannot be quantified and in some cases will lead to an inability to perform the assay. Please note that some causes of variation are common to all sample types and requests and that they cannot be controlled by the laboratory but must be controlled by the individual service users or others. It is very important to identify and minimize significant pre-assay and post-assay conditions that will affect the accuracy of the assays.

The following are lists of conditions or situations that will affect results.

### Common Factors

* Differences in patient preparation.
* Specimen collection technique.
* Transportation of sample.
* Storage time and storage temperature of sample within and out with the laboratory.
* Intra-individual variability (such as pregnancy, fasting/non-fasting, drug use, diurnal and underlying condition).
* Within individual biological variation.
* Environmental conditions within the laboratory.
	+ Temperature, humidity and dust that may affect analysers, assays and sample stability.
* Reporting.
	+ Number of significant figures

Further conditions will be more specific to a request as given below.

### Blood Transfusion

* Age of sample - only valid for 24hrs at room temperature.
* Expiry date on sample.
* Haemolysed Samples.
* Lipaemic samples.
* Clotted samples.
* Insufficient samples.
* Recent Transfusion of blood of different group.
* Haemopoetic Stem cell transplant/BMT from donor of different blood group.

### Haemostasis

* Haemostasis samples should preferably be taken before other test samples are drawn to avoid possible cross contamination of anticoagulants.
* Sodium citrate samples only must be used.
* Good venepuncture – poor venepuncture may lead to activation of the sample.
* No less than 90% fill
* No more than 110% fill.
* Blood must not be transferred from any other collection tube type to a Sodium citrate tube.
* Poor mixing of sample and anticoagulant to prevent clotting.
* High HCT’s>0.55 will require an adjustment of sodium citrate volume – contact the laboratory for advice.
* Samples must be kept at room temperature and transported to the laboratory within 1hour of collection.
	+ They must not be stored or transported on ice.
* Lipaemic samples.
* Icteric samples.
* Haemolysed samples.
* Residual Thrombin potential of factor deficient plasmas

### Haematology

* 4ml EDTA samples only
* Age of sample - only valid for 24hrs
* Expiry date on sample.
* Haemolysed Samples.
* Lipaemic samples.
* Clotted samples.
* Insufficient samples.
* Haemoglobin level (sickle solubility test)
* Red blood cell count (ESR)
* Temperature (ESR)
* Due to limitations of the technology the Malaria RDT is unable to detect ***P Knowlesi.***

### Haemato-Oncology

* Clotted Samples
* Samples greater than 48 hours old.
* Samples for PNH analysis, must be received by the lab within 48hours of sampling as cells start to lose relevant CD markers
* Better quality bone marrow samples are achieved by drawing less than 3 ml of marrow as the volume of an aspirate is inversely proportional to its purity.
* Peripheral blood may haemodilute marrow aspirates and lead to differences in cell % and immunophenotype when flow cytometry is compared with morphology or histology.
* Bone marrow samples from patients with fibrosis may yield discrepant results,
* Deposition of reticulin or lysis of fragile cell populations in bone marrow samples may not lead to the detection of the presence of lymphoma by flowcytometry.
* CSF samples may contain few malignant cells amongst a reactive infiltrate and need to be received by the laboratory as soon as possible as cells deteriorate rapidly in this fluid.

# Confidentiality

All data held within the department is done so in compliance with the NHSGGC Confidentiality and Data Protection Policy, the NHSGGC Confidentiality Policy, the NHS Code of Practice on Protecting Patient Confidentiality, The General Data Protection Regulations, The Data Protection Act 2018, The Blood Safety and Quality Regulations, The Medicines for Human Use (Clinical Trials) Regulations 2004.

# Retention of Records

Records and Specimens are also held in compliance with the RCPath guidelines on the Retention and Storage of Pathological Records and Specimens - 2015, 5thEd, The Data Protection Act 2018 and the requirements of The Medicines for Human Use (Clinical Trials) Regulations 2004 and the Human Tissues act 2004.

# References

* The Medicines for Human Use (Clinical Trials) Regulations 2004
* Blood Safety and Quality Regulations 2005 and Amendment 2007
* Data Protection Act 2018
* Human Tissues Act 2004
* ISO 15189 – 2012: Medical Laboratories, Requirements for Quality & Competence
* Rules and Guidance for Pharmaceutical Manufacturers and Distributors: MHRA, 2017
* Good Clinical Practice Guide: MHRA 2012
* M3003: The Expression of Uncertainty and Confidence in Measurement: UKAS
* Retention and Storage of Pathological Records and Specimens - RCPath, 2015, 5thEd
* Haemoglobinopathy Diagnosis 2nd Edition 2005: B.J Bain.
* Handbook of Transfusion Medicine: Fifth Edition 2014
* Dacie and Lewis Practical Haematology 12th Ed: S M Lewis, B J Bain, I Bates, M Laffan
* Blood Cells. A practical Guide 5th Edition 2015: B J Bain.
* NHSGGC: Confidentiality and Data Protection Policy
* NHSGGC: Confidentiality Policy
* NHS Code of Practice on Protecting Patient Confidentiality

# Appendix 1

## Changes from Previous Version

Update B12 reference range

Update reference to costs and charges